

24

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

*for lib HIV/AIDS  
resource file.  
for  
13/8/01*

*86/3/4/6*

# action

Issue 47  
April-June  
2000

ASIA-PACIFIC EDITION

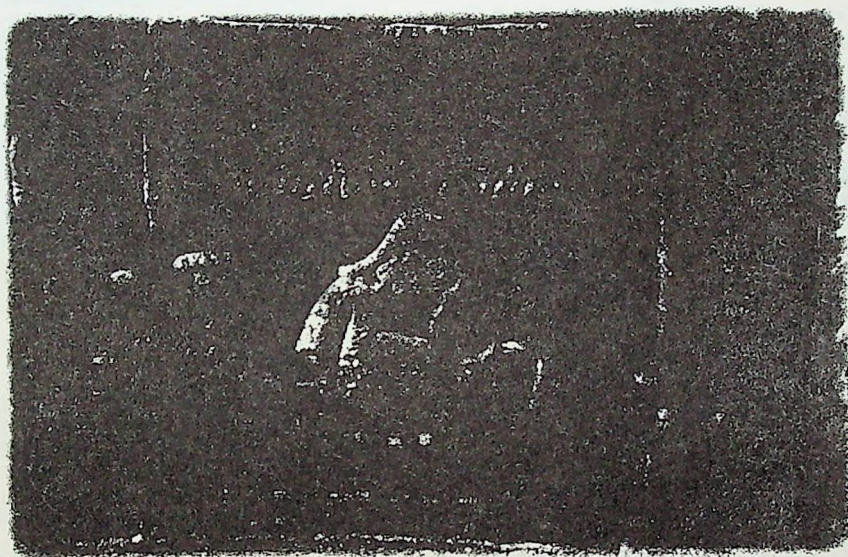
## RELIGION AND HIV/AIDS

### IN THIS ISSUE

4 Buddhist monks  
respond to HIV/AIDS

12 Buddhist monks  
respond to HIV/AIDS

24 Buddhist monks  
respond to HIV/AIDS



*This scene from the 12th century Bayon temple in Cambodia shows a woman giving birth*

**R**eligion has always been part of social life in Asia and the Pacific. The region is the birthplace of such world religions as Hinduism and Buddhism as well as many other smaller but significant religions, from Sikhism to Shinto. At the same time, the region has often been tolerant, welcoming religions from outside. Today, Asia includes the largest Islamic countries in the world — Indonesia, Bangladesh and Pakistan. Besides Islam, Christianity has also flourished in many countries in the region, to name a few, the Philippines, South Korea and the Pacific island nations.

For many Asians and Pacific islanders, religions are not just a matter of paying homage to the supernatural. They provide important ethical guidelines for living, for interpreting natural events including disasters and misfortune, and for coping with life's milestones, from birth through illness to death. They also often provide an anchor

in a time of rapid social change, with religions not just surviving but thriving amid modernisation. In fact, in several countries in the region, religious fundamentalists — Hindu, Islamic, Christian — have a growing number of followers, offering a "return to traditions" as the solution to the problems of modernisation.

HIV/AIDS poses new challenges to religions. Because its main mode of transmission is sexual, HIV/AIDS intensifies the tensions that are present around sexuality. Many religions have had ambivalent attitudes toward sexuality. Religions have always been important forms of social control, especially in the area of sexuality. But many religions, especially in the past, also respected and even celebrated the powerful forces that come with sexuality, whether for reproduction or for eroticism.

The ambivalence continues today, and often creates problems for HIV/AIDS prevention and care. The epidemic is interpreted by some people as divine

punishment for sexual transgressions, from premarital sex to homosexuality. The stigma posed by religion can be powerful. Governments and NGOs often avoid working with or supporting groups such as homosexuals or sex workers because they are seen as sinners who deserve to become infected. Some may even think of AIDS as a way of cleansing society of such "undesirables".

Even in countries where there are HIV prevention programmes to reach such sectors, the targets may themselves be socially inaccessible. Internalising what religions have said about their "sinful" behaviour, they remain marginalised, unreached by information and education campaigns.

Religious stigma works most strongly against those who are infected with HIV, who may be left to fend for themselves. Again, governments may be reluctant to respond to the needs of people with HIV because they are seen as sinners. Religious prejudices, mixed with misconceptions about HIV/AIDS, become a dangerous and volatile mixture that sends many people to their deaths.

Fortunately, there has been ferment, too, among religious institutions, as people begin to question biases and prejudices. The responses have varied. In Thailand, as we see in an article by Noemi Leis, Buddhist monks are now at the frontlines providing care and support for people living with HIV, particularly those who are very ill and who are dying. Christian missionaries and lay workers are doing similar work in many parts of Asia, again mainly providing institutional care for the sick and dying. This includes many Catholic workers who may be reluctant to promote condoms as part of preventive education, but who are at least willing to minister to the needs of patients.

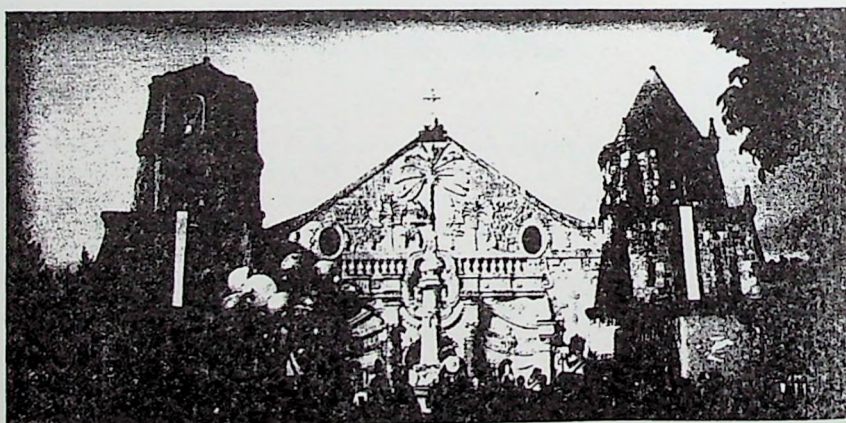
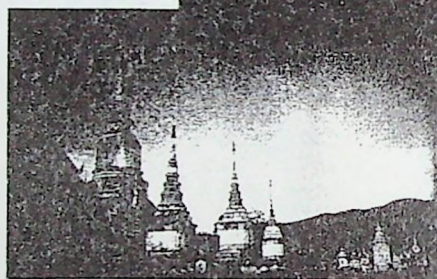
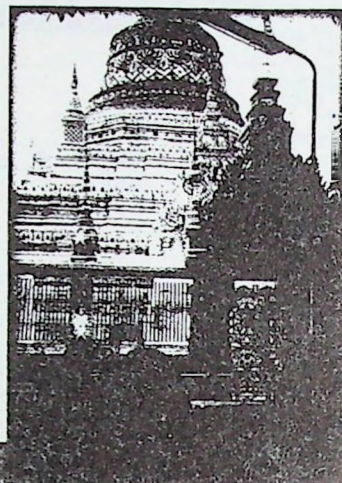
There are, too, religious thinkers who are tackling the very doctrinal bases for behaviour. The article in this issue by Masdar Mas'udi presents, in simple language, the rationale for a more secular approach in Islam toward the HIV/AIDS epidemic. He explains, for example, that condom use upholds Islam's premiere right, the right to life.

Theologians have tried to tackle other ethical dilemmas brought about by the threat of HIV/AIDS. For example, some people may object to needle exchange programmes, where drug dependants are given new clean needles. The objections come about because the programmes are seen as tacit acceptance of the use of drugs, but religious ethicists will say that the needle exchange programmes constitute a lesser evil because it saves lives.

Other religious thinkers, notably Muslim and Christian, have contributed to the fight against HIV/AIDS by questioning the role of religious doctrines in reinforcing gender inequality, and the way this inequality contributes to women's vulnerability to HIV. Religious norms that force women to be passive may become a death sentence since they are then unable to protect themselves, even if they know their husbands or partners may have HIV.

The inclusion of religious groups in HIV/AIDS work can produce many benefits, some of which are explained below:

First, many religious institutions have formidable resources that can be tapped for HIV work. These religious institutions have their



own schools, hospitals, clinics and orphanages. While some of these institutions may be reluctant to discuss sexuality issues, or to promote condoms, they can at least be mobilised to provide other services, especially for care and support.

Second, religion plays such an integral role in people's lives that an HIV/AIDS prevention programme cannot be effective unless it deals with people's religious beliefs and practices. For example, government and NGOs need to look at how religious beliefs shape the relationships between men and women. If women see the risk of HIV/AIDS as unavoidable, as part of karma, then educational programmes will not be very effective. Religious beliefs and practices also play vital roles in the care and support of people with HIV. It is important to emphasise the supportive aspects of religion.

Third, dialogues between religious institutions and groups working on HIV/AIDS can be mutually beneficial. Religions offer ethical frameworks to discuss many issues that have to be tackled in HIV/AIDS programmes. Some religious workers rightly object to programmes that only distribute condoms without encouraging people to discuss what is meant by "correct use". "Correct" is not just a matter of technical skills, but must also be based on notions of a mutual respect, and of sharing of responsibilities.

Conversely, people working in public health can bring up very practical case studies and challenges for religious leaders and thinkers to tackle. What does one do, for example, if a husband is infected and the wife is still free of HIV? Would they be asked to abstain from sex? Or would they be encouraged to use condoms, an option still not allowed among Roman Catholics?

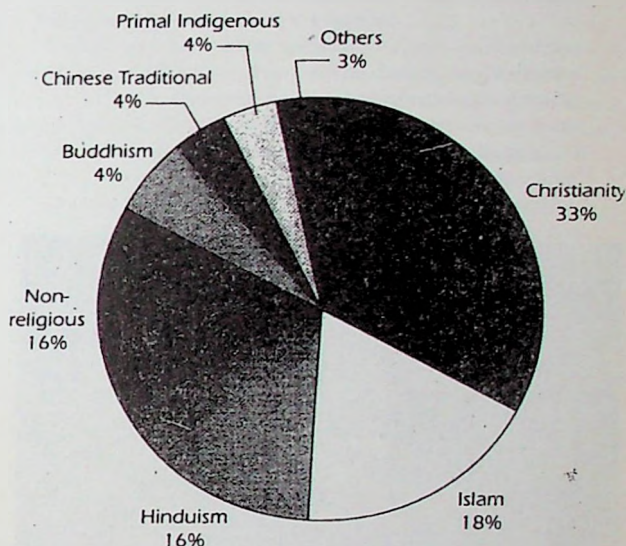
Sometimes, the implementation of HIV prevention programmes raises ethical issues that need dialogues. What happens, for example, when a Catholic physician goes around claiming that condoms do not prevent HIV/AIDS? Would that not be violating religious injunctions on speaking the truth, and on preserving life?

Dialogues open people's minds. When religious workers listen to NGOs and government workers doing HIV prevention, they begin to see the potential impact of HIV/AIDS on society, and the need for such measures as sex education. Likewise, religious workers are needed to remind medical people – often jaded by their routines – to respect human dignity and human rights.

Often, there is a fear that such dialogues will lead to compromises when in fact they can lead to new richer partnerships.

— Michael L. Tan, HAIN

## Major Religions of the World



Source: <http://www.adherents.com>

## & SOUL

Religion can influence a woman's reproductive health, whether positively or adversely. As the Women's Feature Services (WFS) puts it, "Religion is an experience so personal, yet so political, that it tends to affect many aspects of women's lives, including reproductive health."

To highlight the role of religion and to raise related issues, a series of inter-faith discussions on women, religion, and reproductive health are currently

being held in the Philippines. The multi-media programme, aptly called "Body and Soul", was developed by the WFS. The discussions present perspectives from the Catholic, Protestant and Islam religions, which are the predominant religions in the Philippines. Four multi-media discussion forums have been held, and the papers presented at each forum have been compiled and published into booklets. The discussions have focused on the following themes:

- ⊗ Frameworks on Religion and Reproductive Health
- ⊗ Condoms and Religion
- ⊗ Adolescent Sexuality
- ⊗ Population

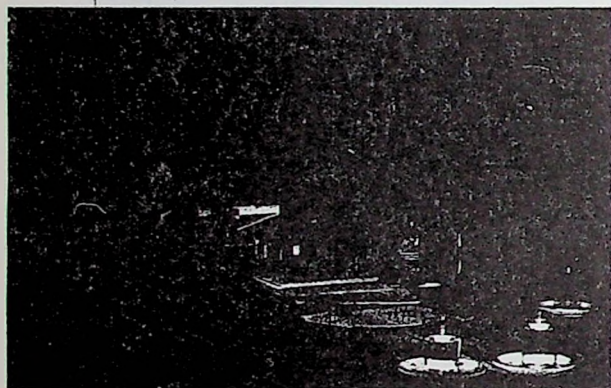
(Please see page 8 for contact details of WFS)

## Buddhist Monks:

# RESPONDING TO HIV/AIDS

The Buddhist monks have become a very important stakeholder in the fight against HIV/AIDS and are now recognised as a strong partner in HIV/AIDS work especially through their spiritual guidance.

*Monks and health workers  
planning future HIV/AIDS  
activities*



NDBLeis/HAIN



NDBLeis/HAIN

*A Buddhist temple  
in Chiang Rai, Thailand*

**T**en years ago, Mae Chan hospital in Chiang Rai, Thailand first encountered cases of HIV. It was at this time that the HIV/AIDS epidemic was rapidly spreading in Thailand, particularly in the northern area which shares borders with Cambodia and Laos.

The hospital staff, however, found it difficult to talk about HIV/AIDS with the patients. Likewise, persons with HIV/AIDS (PHAs) who were admitted to the hospital did not discuss their thoughts and feelings with the hospital staff. Instead, the patients were going to the Buddhist monks for counselling and spiritual guidance.

The health workers at the hospital then realised the monks played an important role in people's lives, and decided to explore ways they could work with the monks. Although the monks were hesitant when HIV/AIDS was first discussed, they became more open and receptive to the idea as the number of HIV cases increased, and their friends and family members became infected. Wanting to know more about a disease which was fast becoming a problem for their communities, the monks then approached the hospital staff. Gradually, the monks and health workers started to work together. Since then, the Mae Chan District Hospital and the Buddhist monks have worked together for the prevention of HIV/AIDS while providing care and support for those who are already infected.

## WORKING TOGETHER

Today, Mae Chan hospital has a meditation room where patients can read, listen to tapes of Buddhist teachings, meditate or have a one-on-one counselling session with monks. If the patient cannot walk, the monk stays at the bedside. An audiocassette tape of Buddhist teachings is aired on the hospital's sound system so that all the patients can listen.

In addition to their work in the hospital setting, the Buddhist monks also provide community support. The temples have become a venue for several activities for PHAs and their relatives. They do meditations, yoga, exercises, herbal sauna, food preparation and even income generating projects such as making herbal medicines. The monks conduct home visits as well to talk to those who are infected and affected.

Several community therapy centres have been established in Chiang Rai to provide a venue for community interaction. Community members who are not HIV positive go to the centre and provide an informal social support system for the PHAs in the community. The monks regularly visit the community therapy centre to conduct information campaigns and to provide care and support services.

The monks emphasise meditating before doing activities such as counselling or treatment. Health workers, PHAs, and their families

# THE BUDDHIST AIDS PROJECT

With its goal of linking together Buddhist communities in different countries, the Buddhist AIDS Project (BAP) maximises the use of information technology to reach a wide audience.

In the past, many of the information resources on HIV/AIDS and Buddhism have not been easy to find. BAP is working to change that situation. Through its website, BAP provides easy access to information resources.

The project aims to provide free information and referral on:

- ⊗ current HIV/AIDS information, with links to local, national and international resources
- ⊗ Buddhist teachings, practice centres and events
- ⊗ complementary alternative medicine services

The website also contains the BAP Library of Articles, which is a list of information materials on HIV/AIDS, Buddhism, spirituality, medicine, research findings, conference reports and announcements, among others.

Moreover, the BAP website serves as a virtual gathering place where many people have made themselves available for those seeking life enhancing practices that can strengthen the response to changing physical, mental, and spiritual challenges.

BAP serves persons living with HIV/AIDS, including family, friends, caregivers, as well as people who are HIV negative. The project provides information on HIV/AIDS and alternative health care to its clientele.

While focusing on the San Francisco Bay Area, BAP offers worldwide information and referral services, responding to requests through e-mail and phone. Recently, BAP has assisted community service projects in Thailand and Cambodia. They also offer study and support groups on basic Buddhist teachings and practice.

BAP is a non-profit project of the Buddhist Peace Fellowship. Established in 1987, it is now based in San Francisco, USA. BAP is run by about 30 volunteer physicians, body workers, counsellors, mediation instructors and others. BAP also welcomes interested volunteers who are willing to share their time and skills.

Contact: Steve Paskind  
Coordinator, Buddhist AIDS Project  
Tel: (415) 522-7473  
leffingeres@yahoo.com  
buddhistap@buddhistaidproject.org  
http://www.buddhistaidproject.org

are also encouraged to meditate.

In conducting educational activities, the monks use Buddhist teachings on moral conducts for human behaviour. There are five moral conducts in Buddhism:

- ⊗ Do not destroy life
- ⊗ Do not take what is not given
- ⊗ Abstain from sexual misconduct
- ⊗ Abstain from falsehood
- ⊗ Abstain from intoxicants

The monks do not prohibit condom use. However, they leave its discussion to lay educators in the hospital.

Aside from social, spiritual, and emotional support, monks also provide PHAs their basic needs such as food, clothing, soap, and others.

The monks conduct their own fundraising activities and are not dependent on the hospital for funding. The Buddhist community has traditionally supported the monks, who walk through the streets in the morning carrying bowls where people can put their donations.

There are also Buddhist festivals when people go to the temples to bring gifts for the monks. The gifts are usually money, food, clothes, and other items. These gifts are then shared with their community.

It is interesting to note that monks have also learned to write to international agencies for funding, and they have been quite successful in generating funds.

Every month, the health workers from the hospital meet with monks to provide them updates on HIV/AIDS and give information materials. During these meetings they also talk about future plans and fund raising activities.

## LESSONS LEARNED

Both the hospital workers and the monks agree that their efforts complement each other, and that they should go on working together in providing HIV/AIDS education as well as care and support services.

The participation of PHAs as well as the non-positive community is also important.

The community therapy centre provides not only social support but also lessens the impact of stigma. The PHAs have become more visible in the community without experiencing discrimination from other community members. Disclosure for PHAs about their HIV-status is thus not a very sensitive issue.

The Buddhist monks have become a very important stakeholder in the fight against HIV/AIDS and are now recognised as a strong partner in HIV/AIDS work especially through their spiritual guidance.

Explaining the Buddhist response to HIV/AIDS, Supakit, the head monk in Mae Chan district observes, "Imagine that HIV/AIDS is a glass, and you break the glass so that there are many small pieces. Each of us can pick up a piece. This is easy to do because it is only a small piece of glass that we have to pick up. We must all work together to pick up the little pieces so that we will solve the problem".

— Noemi D. Boyoneto-Leis, HAIN

Acknowledgements: The author would like to acknowledge the assistance provided by Ms. Jeap Pinituwon and Dr. Supalert Nedsuwan of Mae Chan Hospital and Monks Supakit, Sommai, Niwit, Supat Monahir, Pairov, Muangvisan from Temple Muang Klang.

# BETWEEN TWO PARADIGMS

No epidemic in the world today attracts as much attention, publication, debate and controversy as HIV/AIDS. There are many reasons for this, including HIV/AIDS being incurable and deadly. Another factor which contributes to more public attention to HIV/AIDS is that its main method of transmission is sexual. This has brought about heated debate and controversy between two paradigms: the religious and secular paradigms. The religious paradigm claims to be rooted in the sacred texts while the secular paradigm is rooted in the realities of the world.

Within the framework of the religious paradigm, particularly the more conservative ones, human beings have no other way to differentiate the good (*al-hasan*) from the evil (*al-qabih*), except through divine revelation. Using this perspective, advocates of the religious paradigm view the HIV/AIDS epidemic as a blessing in disguise. This looks at HIV/AIDS as a curse and punishment from God for humanity's disobedience. Using this line of argument, religious conservatives condemn

the use of condoms because this is seen as justifying illicit sexual relations, i.e., disobedience to God. Some religious conservatives even go to the extent of saying there should be no room for compassion for those affected by the virus because they are sinners. According to conservatives, the only way to prevent HIV/AIDS is to return to the demands of religion and faith.

Those advocating a secular paradigm say that "good" is defined as something useful for humanity and "truth" is something that can be proven empirically. This saying explicitly recognises the necessity of looking at the material bases of one's faith. If so, the religious people should not look at the human life only from the formal religious perspective, but from the reality of material life. As the Prophet Muhammad says, "*Kaada al-faqr an yakuna kufran: poverty can bring about somebody to disbelieve.*"

Responding to conservatives, secularists say that no one can positively prove that HIV/AIDS is a curse sent by God to punish human beings for disobeying God's will. Secularists ask how one can justify isolation or "excommunication" of those in great suffering.

Is it not those who are ill who need, even more, God's love?

On the argument that HIV/AIDS is caused by sin, secularists point out that transmission can also occur within the *halal* (lawful) sexual relationship between a husband and wife. Moreover, HIV transmission also occurs through blood transfusions and from a mother to child.

Secularists point out that according to Islamic teaching, there are five human rights: the right to life, the right to believe, the right to have knowledge, the right to have property and the right to have clan

identity (*nasab*). Of these five rights, the right to life is the most important. For the secularists then, condom use upholds this premier right to life.

In the context of a married couple where one of them has been infected with HIV, can one allow sexual relations to occur without any protection? Does that not mean we are putting them in danger, with fatal consequences? Or must couples with one infected with HIV be separated forever?

Ced/HAIN

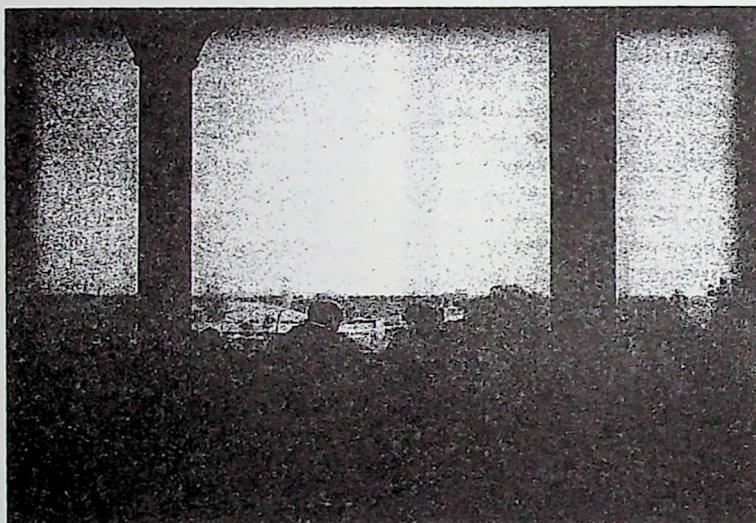
We have seen many cases of women working in brothels who become infected with HIV. Would it not be moral to offer the use of condoms to protect themselves, their client, and their family? We understand that *zina* (illicit sexual relations) is a religious sin, particularly for those already married. But is not *zina* without protection (i.e., without the use of condoms) an even greater sin because it allows a deadly virus to be transmitted?

These critical questions are difficult to answer by the *ulama* holding the very formalistic and conservative religious paradigm. A moral and ethical perspective concept built on the authority of doctrine without being based on empirical reality tends to become empty words.

On the other hand, modern humanity must also be aware of the dangers of a morality without a transcendental dimension because there is the risk of losing one's orientation. An exchange of views, where each side is open to the insights of the other, is clearly needed if we are to work out a program of understanding and action.

— Masdar F. Mas'udi

Director of The Indonesian Society for Pesantren and Community Development, Jakarta, Indonesia



# Religious Leaders Speak Out on HIV/AIDS

"... the magnitude of AIDS epidemic problem in the ASEAN region is increasing significantly. The increase has to be controlled in time, otherwise, religious, social and economic development in the region will be hindered and disparities within and between ASEAN Member Countries will increase accordingly,

... every individual has the right to have an appropriate and right information on HIV/AIDS. Without having the information nobody will be able to prevent HIV infection,

... all Muslim Leaders in all ASEAN Member Countries have to be properly trained to use the IEC instruments and methods. The well-trained Muslim leaders will then play their important role in HIV/AIDS campaign in their respective community.

— The Jakarta Declaration of Islamic Religious Leaders  
December 1998

"To Tibetan physicians, AIDS is really something new, and the immediate cause is negative: sexual liberty... such a major illness or major negative event also has a karmic cause, no doubt. But I think AIDS also has a positive aspect. It has helped to promote some kind of self-discipline."

— The Dalai Lama, 1994

"Perhaps the AIDS crisis is God's way of challenging us to care for one another, to support the dying and to appreciate the gift of life. AIDS need not be merely a crisis: it could also be a God-given opportunity for moral and spiritual growth, a time to review our assumption about sin and morality. The modern epidemic of AIDS calls for a pastoral response."

— Bishops of Southern Africa  
June 1990

"God loves you all, without distinction, without limit. He loves those of you who are elderly, who feel the burden of the years. He loves those of you who are sick, those who are suffering from AIDS. He loves the relatives and friends of the sick and those who care for them. He loves us all with an unconditional and everlasting love."

— Pope John Paul II, California  
September 1997

"For us, an encounter with people infected with HIV/AIDS should be a moment of grace - and opportunity for us to be Christ's compassionate presence to them as well as to experience His presence in them."

— Bishops' Conference  
of the Philippines, 1993

## Tree of Hope

Located in New South Wales, Australia the Tree of Hope is a centre for HIV-positive women and men, and their partners, family, friends, and care-givers. The Centre offers Personal Care - composed of emotional, spiritual and social support. Upon request, the Catholic nuns who operate the Centre visit persons with HIV/AIDS (RHAs) and their loved ones at home or in the hospital. The centre is open from Mondays to Fridays during the daytime, and the answering machine is left on during the hours that the Centre is unattended.

## Sisters in Islam

Sisters in Islam (SIS) is a group of professional Muslim women committed to promoting the rights of women within the religious framework. To attain its objectives, SIS embarks on activities in four programme areas:

- ⊗ Research and interpretation of textual sources of Islam
- ⊗ Advocacy for policy and law reform
- ⊗ Awareness raising and public education
- ⊗ Strategic planning and policy formulation

(Please see page 8 for contact details of SIS)

**AIDS and Muslim Communities: Opening Up** by S Ali. Summary of an international meeting in Karachi to explore the relationship of Muslim religious and political concepts with HIV transmission, medical care, and human rights. AIDS/STD Health Promotion Exchange 1996(2):13-6. Available from HAIN.

**AIDS and the Muslim Communities—A Personal View/AIDS and the Muslim Communities—Challenging the Myths.** Leaflets in English, Gujarati, Urdu, Arabic, Farsi, Gengali and Turkish available from The Naz Project, Palinswick House, 241 King St., London W6 9LP, UK.

**Body & Soul: a Multimedia Discussion on Women, Religion & Reproductive Health, 2000.** A collection of papers presented in several interfaith dialogues related to reproductive health. Four booklets are available on different themes, namely: Frameworks on Religion and Reproductive Health; Adolescent Sexuality; Population; and Condoms and Religion. For orders, write to Women's Feature Service (WFS), Philippines, 313-E Katipunan Ave., Quezon City, Philippines. wfs@pacific.net.ph

**Catholic Ethicists on HIV/AIDS Prevention, 2000.** James Keenan (editor). A collection of essays and case studies discussing HIV/AIDS prevention from a Catholic perspective, drawing on theology, philosophy and ethics. It includes a good selection of 26 case studies, based on real-life situations from different countries—developed and developing—with a discussion of options. Available for US\$24.95 (Paperback) from Continuum International Publishing Group, Inc., 370 Lexington Ave., New York, NY 10017, USA; or £15.99 from Continuum International Publishing Group Ltd., Wellington House, 125 Strand, London WC2R0BB. Or visit their website: <http://www.continuum-books.com>

**The Church Responds to HIV/AIDS: a Caritas Internationalis Dossier, 1996.** A selection of statements on HIV/AIDS by Catholic Church leaders such as Pope John Paul II, bishops' conferences and other church groups. The booklet presents the stand of the Church based on its teachings and as shown by pronouncements of Church officials. Available for £1.50 from CAFOD, Romero Close, Stockwell Road, London SW9 9TY, UK. ISBN 1 871 549 639

**Friends for Life** by R Manning. Describes a Buddhist monk's initiatives in establishing Friends for Life, a hospice for PHAs in the outskirts of Chiang Mai, Thailand. AIDS Action Asia Pacific edition Jul-Sep 1995 (28):11 Available from HAIN.

**A Guide to HIV/AIDS Pastoral Counselling.** Explains the process of HIV/AIDS counselling, provides basic information for pastors on the topic and features case studies. Available in English, French, Spanish, Portuguese at US\$10, surface mail. Free to developing countries from CMC-Churches' Action for Health, World Council of Churches, P.O. Box 2100, 1211 Geneva 2, Switzerland. dgs@wcc-coe.org

**Handle with Care: a Handbook for Care Teams Serving People with AIDS** by RH Sunderland and EE Shelp. A step-by-step guide for congregations that wish to organise care teams to serve people with HIV/AIDS. Contact Foundation for Interfaith Research and Ministry, PO Box 205528, Houston, Texas, USA.

**Islam, Reproductive Health and Women's Rights.** Zainah Anwar and Rashidah Abdullah (editors). 2000 A collection of papers presented at a recent conference on Islam and reproductive health. The papers were prepared by theologians, academicians and NGO workers. They discuss Islamic teachings—drawing from the Quran and hadith—and its relationship to reproductive health and rights, on issues ranging from HIV prevention to gender relations. Available for US\$20 (RM40) plus postage cost which is 25% of the total order for surface mail and 100% of total order for airmail. Write to SIS Forum (Malaysia) Berhad, Sisters in Islam, JKR No. 851, Jalan Dewan Bahasa, 50640 Kuala Lumpur, Malaysia. Tel: (603) 242 6121/248 3705. Fax: (603) 248 3601. Write to sis@sisforum.org.my or visit <http://www.sistersinislam.org.my>

**The Jakarta Declaration** is the result of the First HIV/AIDS ASEAN Regional Workshop of Islamic Religious Leaders held November 30-December 3, 1998. The Declaration sets forth the rationale for the involvement of Muslims in the regional response to HIV/AIDS. It also includes a Plan of Action which presents objectives, activities, and recommendations identified at the workshop. Posted on SEA-AIDS—Message 1707. Copies available from HAIN.

**Knowledge, Attitudes, and Behavior: Cambodia's Monks, Nuns Fill Gap for AIDS Patients, 1997.** Describes the HIV/AIDS situation in Cambodia and how the religious community such as the Buddhist monks and nuns help PHAs by providing care and support. Available from HAIN.

**Learning About AIDS: a Manual for Pastors and Teachers.** Available in English and French, US\$2. Free to developing countries from Churches' Action for Health, World Council of Churches, P.O. Box 2100, 1211 Geneva 2, Switzerland.

**Religion, Ethnicity and Sex Education: Exploring the Issues.** A briefing pack, presents seven religious perspectives on sexuality, sex education and gender. £15.50 Order from Book Sales, National Children's Bureau, 8 Wakley St., London EC1V 7QE, UK

**Spiritual Aspects of Health Care by D Stoter.** A reference for health workers on how to respond when grief and anger make communication very difficult. Guides the health worker in meeting the spiritual and religious needs of patients. Available from Mosby, Times Mirror International Publishers Ltd., Lynton Hse., 7-12 Tavistock Square, London WC1H 9LB, UK. ISBN 0 7234 1955 8

## AIDS action

AIDS Action is published quarterly in seven regional editions in English, French, Portuguese and Spanish. It has a worldwide circulation of 179,000.

The original edition of AIDS Action is produced and distributed by Healthlink in London.

**AIDS Action Asia-Pacific edition staff**  
**Editor** Michael L. Tan  
**Managing editor** Mercedes B. Apilado  
**Editorial Assistants** Joyce P. Valbuena, Noemi D. Bayoneta-Leis  
**Layout** Dennis C. Cortez  
**Circulation** Antonieta Llacuna  
**Board of Advisers**  
 Dr Roy Chan (Singapore)  
 Mr Jagjit Singh (Malaysia)  
 Dr Mohammad Tufail (Pakistan)  
 Ms Caluh Wandita (Indonesia)  
 Dr S. Sundararaman (India)  
 Dr Kangmai Liu (China)

**International edition**  
**Commissioning Editor** Sian Long  
**Editor** Christine Kalume  
**Copy Editor** Celia Till  
**Design and Production** Ingrid Emsden

**Publishing partners**  
 ABIA (Brazil)  
 Colectivo Sol (Mexico)  
 ENDA (Senegal)  
 HAIN (The Philippines)  
 SANASO Secretariat (Zimbabwe)  
 Consultants based at University Eduardo Mondlane (Mozambique)

The Asia-Pacific edition of AIDS Action is supported by The Ford Foundation, CAFOD, and Christian Aid

**SUBSCRIPTION DETAILS**  
 If you would like to be put on the mailing list to receive AIDS Action, please write to:  
 HAIN  
 No. 9 Cabanatuan Road, Philam Homes 1104  
 Quezon City, Philippines  
 Tel. (632) 927-6760  
 Fax: (632) 929-8805  
 E-mail: [hain@mail.info.com.ph](mailto:hain@mail.info.com.ph)  
 Website: <http://www.hain.org>

**Annual subscription charges**  
 Free Readers in developing countries  
 US\$20 Individuals elsewhere  
 US\$40 Institutions elsewhere

**REPRODUCING ARTICLES**  
 Healthlink and HAIN encourage the reproduction or translation of articles in this newsletter for non-profit-making and educational uses. Please clearly credit AIDS Action/Healthlink/HAIN as the source and, if possible, send us a copy of the reprinted articles

Healthlink (formerly Appropriate Health Resources & Technologies Action Group or AHRTAG) is a UK-based international development agency which supports the goal of health for all by promoting primary health care. Registered charity (UK) no. 274260

HAIN (Health Action Information Network) is a Philippine NGO involved in research and information on health and development issues. Registered with Securities and Exchange Commission 127593

Opinions expressed in this newsletter do not necessarily represent those of HAIN or Healthlink. The mention of specific companies or of certain manufacturers' products does not imply preference to others of a similar nature. A person's HIV status or sexual orientation should not be assumed based on her or his article or photograph.

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



# Missionsärztliches Institut Würzburg

## Medical Mission Institute

Missionsärztliches Institut, Postfach, D- 97067 Würzburg, Germany

TO ALL RECIPIENTS OF OUR

LITERATURE PACKAGE

05. June 2001

Dear friends and colleagues,

Once again it is time to send you a new information and literature package – we do hope that it arrives in good order and that it will be of much use to you and to many others who receive copies from you.

Since the silence about AIDS was broken at last year's Durban Conference, the HIV situation in the resource poor countries of the world and possibilities of action have been the focus of a number of national and international conferences. By the time this package will reach you, the Special Session of the General Assembly of the United Nations will probably have taken place already – we enclose a declaration by the UN Secretary which was circulated in anticipation of this important meeting (item No 16). An African summit on HIV/AIDS, tuberculosis and other infectious diseases took place recently in Abuja, the capital of Nigeria, where also Kofi Annan addressed the participants (items 14 and 15). It is good to know that heads of governments take vital health issues seriously – it remains to be seen how much of it will be converted into action.

An UNAIDS publication informs about the reasons for the success of HIV prevention interventions in Senegal, Thailand and Uganda (Nr 1). Two articles deal with new communication strategies to better convey prevention messages (Nr 12 and 13). The prevention of mother-to-child transmission of HIV remains an important issue (Nr. 2 and 3). Care and support for the affected need our attention; the question of how and when and under what conditions antiretroviral treatment can be introduced in resource poor countries gains momentum (Nr. 4,5 and 6). Three papers (Nr. 18, 19 and 20) deal with TB related issues. There are a number of other interesting articles on further HIV/AIDS related issues and other important health matters which may evoke new ideas and initiatives on your side.

Before you start reading the 22 papers, we ask you to do some other 'home-work'. We are all painfully aware, that HIV/AIDS plays an increasing role at the workplace, also at the Catholic workplace. Please read the letter "Study on HIV/AIDS and the Catholic Workplace" carefully and be kind enough to complete the attached questionnaire!

☐ **Managing Director/Secretariat**

Salvatorstr. 7; D-97074 Würzburg, Germany  
Tel.: ++49-931-791-2900, Fax: ++49-931-791-2801  
e-mail: mi.gf@mail.uni-wuerzburg.de

Units:

☐ **Tropical Medicine and Control of Epidemics**

Hermann-Schell-Str. 7, 97074 Würzburg, Germany  
Tel.: ++49-931-80485-23, Fax: ++49-931-80485-30,  
e-mail: mi.tropmed@mail.uni-wuerzburg.de

☒ **Health Services and HIV/AIDS**

Salvatorstr. 22; D-97074 Würzburg, Germany  
Tel.: ++49-931-80485-0, Fax: ++49-931-80485-25  
e-mail: mi.health@mail.uni-wuerzburg.de

☐ **Appropriate Technology in the Health Sector**

Hermann-Schell-Str. 7, D-97074 Würzburg, Germany  
Tel.: ++49-931-80485-15, Fax: ++49-931-80485-20  
e-mail: mi.appro@mail.uni-wuerzburg.de

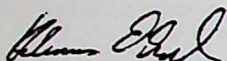
☐ **Cooperation in Need and Disaster**

Salvatorstr. 22; D-97074 Würzburg, Germany  
Tel.: ++49-931-80485-17, Fax: ++49-7841- 441  
e-mail: mi.cinad@mail.uni-wuerzburg.de

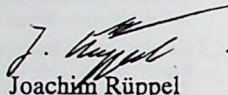
Finally we want to draw the attention of all those of you who have computer facilities equipped with CD-ROM to the possibility of participating in the Human Information Project. The goal of this non-for-profit project is to provide the South with a complete basic library of +- 3.000 essential books at the lowest cost possible, namely for 30 US\$ or less. For details please inquire from:  
Humanity Information Project, Humaninfo.orgNGO – HumanityCD bvba  
Oosterveldlaan 196- B-2610 Antwerpen – Belgium Tel 32-3-448.05.54, Fax 32-3-449.75.74  
E-mail: [mloots@humaninfo.org](mailto:mloots@humaninfo.org) - <http://www.humaninfo.org>

We wish you enough time to be able to study all the documents sent and the chance to implement what you find meaningful and suitable for your particular situation! – Please always remember that we expect you to be a multiplier for the information sent to you and that the latter will finally reach a number of persons and institutions engaged in HIV/AIDS work!

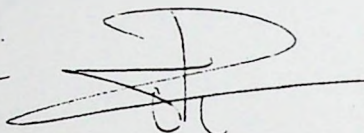
With kind regards and best wishes for your work



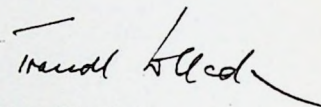
Klemens Ochel



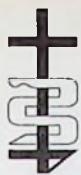
Joachim Rüppel



Piet Reijer



Traudl Solleder



# Missionsärztliches Institut Würzburg

## Medical Mission Institute

☒ Health Services and HIV/AIDS  
Salvatorstr. 22; D-97074 Würzburg, Germany  
Tel.: ++49-931-80485-0, Fax.: ++49-931-80485-25  
e-mail: mi.health@mail.uni-wuerzburg.de

TO ALL RECIPIENTS OF OUR  
LITERATURE PACKAGE

06. June 2001

Study:

### **HIV/AIDS and the Catholic Workplace**

Dear friends and colleagues,

"The Body of Christ is affected by AIDS". This was the eye-catching text on a badge carried by a Ugandan Bishop during the International AIDS Conference in Berlin in 1993. We met at our booth. Right from the beginning we had a topic to discuss. The statement on the badge is not only an acknowledgement of a reality, but also a prophetic statement on the response.

While the HIV/AIDS epidemic developed in the 90ies, the Church has had difficulties to acknowledge that people of Christian faith, engaged lay people, as well as priests and members of religious congregations are getting infected with the virus. In official statements Church leaders have generally given priority to the creation of a positive pastoral environment. In many homilies and letters responsible persons of the Church have been asking for respect, solidarity and charity for those infected and affected. However it seemed hard for the Church to acknowledge the reality, that it has a problem like other parts of the society. Church members living with HIV suffered from a special stigmatisation. Repeatedly they became victims of hasty judgements, unfounded prejudices and discrimination. The parts of the civil society without link to the Church looked very attentively to the consistency of the messages of a non-judgemental, non-discriminatory approach and the assurance of basic rights and solidarity within the Church.

This whole issue was brought up at the last meeting of the Working Group on HIV/AIDS of Caritas and CIDSE organisations (AFNG) in January in London. The organisations of the North had to admit that they knew very little about concrete policies and approaches of their partners in developing and rapidly developing countries in respect to HIV/AIDS. The Medical Mission Institute volunteered to add a questionnaire to their mailing of information materials in order to invite partners to share with them and the CI/CIDSE network their experiences. Taking into account the diversity of the correspondents, we are aware that this study is not representative and scientific. The aim is to better approach the problem and to identify examples and lessons learned which can be shared within the network. The questions touch on policies and guidelines of the Church as an institution and employer. The questionnaire tries to look at HIV/AIDS in the catholic workplace. It addresses specifically the assurance of basic rights, possible approaches to fighting stigma and discrimination, measures taken to prevent HIV infection and the provision of psychological, social, medical and pastoral care, treatment and support for infected and affected people.

We are very well aware that this study touches delicate and sensible issues. Therefore we would like to assure you the confidentiality you will request. However we would welcome your open collaboration, because we think it is important to improve the cooperation between CI/CIDSE partners. We intend to present the results of this study at the next AFNG meeting in October 2001 and provide you with a feedback. Therefore we ask you to respond till August this year. Feel free to send your answers back to us by a way most convenient to you. Thank you very much for you collaboration.

Yours sincerely

Klemens Ochel

# QUESTIONNAIRE

## General Information

Country: \_\_\_\_\_

Diocese: \_\_\_\_\_

Collaborating CI/CIDSE

Partner(s) in the North: \_\_\_\_\_

### Information on the HIV Epidemic in your region:

- ☐ Very high prevalence area for HIV (HIV prevalence > 10 % adult population)
- ☐ High prevalence area for HIV (HIV prevalence > 5 % adult population)
- ☐ Medium prevalence area for HIV (HIV prevalence between 1 to 5 % adult population)
- ☐ Low prevalence area for HIV (HIV prevalence less than 1 % of the adult population)

### Legal Situation in regard to HIV/AIDS

Do government laws assure basic human rights for people living with HIV

e.g. assurance of confidentiality

☐ yes ☐ no

prohibition of testing without informed consent

☐ yes ☐ no

prohibition of discrimination in the labour market

☐ yes ☐ no

exemption of fees in public health services for HIV/AIDS

as chronic disease

☐ yes ☐ no

If yes, can you give a short description of these laws?

---

---

## HIV/AIDS in the Catholic workplace

### Level of work

Are you working on national level

☐ yes ☐ no

... on diocesan level

☐ yes ☐ no

... in a health service

☐ yes ☐ no

... in another project or programme

☐ yes ☐ no

### HIV/AIDS at the workplace

Did you discuss the issue of HIV/AIDS at your workplace

☐ yes ☐ no

Do you have written guidelines and policies, how to deal with persons affected and infected with HIV/AIDS (PLHIV) at your workplace.

☐ yes ☐ no

If yes, would you share it with us. Please send us a copy!

Do you think that basic rights of PLHIV are assured

☐ yes ☐ no

Are there any specific preventive activities in respect to HIV/AIDS for the staff e.g. education?

☐ yes

☐ no

Are you aware of any mandatory testing procedures e.g. for employment at a Catholic workplace or for entering religious life

☐ yes

☐ no

☐ yes

☐ no

Does the Church provide counselling services for the 'worried well' employees, PLWHIV

☐ yes

☐ no

☐ yes

☐ no

if yes, where are they established?

---

Is stigmatisation and discrimination of PLHIV in your setting a problem?

☐ yes

☐ no

Are there specific actions to fight the stigma and avoid discrimination of PLHIV in your setting?

☐ yes

☐ no

Are there services and benefits for PLHIV, once they are in need?

☐ yes

☐ no

If yes, could you please specify

---

---

---

Do links to other social, pastoral and medical services exist?

☐ yes

☐ no

Specify.

---

---

Are there any services offered to the family and other affected persons?

☐ yes

☐ no

Specify.

---

---

Are there any services offered to face the needs of HIV/AIDS orphans?

☐ yes

☐ no

Specify.

---

---

Has the issue of HIV/AIDS at the catholic workplace been discussed at the level of the Bishop conference of your country?

☐ yes

☐ no

If yes, could you share any statement on the issue!

Specify.

---

---

Do you have any general comments about the problem of HIV/AIDS at the catholic workplace. Could you share with us your expectations and make suggestions how CI/CIDSE organisations in the North could be of help to improve the situation?

---

---

---

---

---

---

---

Thank you very much for answering!

Please send the questionnaire back to:

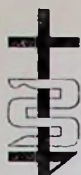
**Medical Missions Institute**

**Unit Health Services and HIV/AIDS**

Salvatorstr. 22; D-97074 Würzburg, Germany

Tel.: ++49-931-80485-0, Fax.: ++49-931-80485-25

e-mail: [mi.health@mail.uni-wuerzburg.de](mailto:mi.health@mail.uni-wuerzburg.de)



# Missionsärztliches Institut Würzburg

## Medical Mission Institute

☒ Health Services and HIV/AIDS  
Salvatorstr. 22, D-97074 Würzburg, Germany  
Tel.: ++49-931-80485-0, Fax: ++49-931-80485-25  
e-mail: mi.health@mail.uni-wuerzburg.de

### TABLE OF CONTENTS

- 1 UNAIDS: HIV prevention needs and successes: a tale of three countries. An update on HIV prevention success in Senegal, Thailand and Uganda. Best Practice Collection. 2001. 17 pp.
- 2 Healthlink: HIV and motherhood. 2000. 19 pp.
- 3 WHO/ UNAIDS/ UNFPA/UNICEF: New data on the prevention of mother-to-child transmission of HIV and their policy implications. Conclusions. 2001. 11pp.
- 4 WHO/UNAIDS: Key elements in HIV/AIDS care and support. 2000. 31 pp.
- 5 UNAIDS: AIDS: Palliative care. Best Practice Collection. Technical Update. 2000. 16 pp.
- 6 WHO, Initiative on HIV/AIDS and Sexually transmitted infections: Safe and effective use of antiretroviral treatments in adults with particular references to resource limited settings. 2000. 25 pp.
- 7 UNAIDS: National AIDS programmes. A guide to monitoring and evaluation. Part 1-2. 2000. 23 pp.
- 8 World Health Organization (WHO): Rejection of hypothesis associating an experimental polio vaccine with the origin of HIV. Weekly Epidemiological Record, 2000, No.48 pp.406-407
- 9 Kahn, P.: Vaccines at Durban: a closer look. IAVI Report. Vol. 5 (2000) no.5 pp.5-7,19.
- 10 Aghaji, A.E.: Catholic ethicists on HIV/AIDS prevention. Book review. 2000. 2 pp.
- 11 Hoppenbrouwer, J.: Mother-to-child transmission of HIV. 2001. 37 pp.
- 12 Airhihenbuwa, C.O., B. Makinwa, and R. Orbregon: Toward a new communication framework for HIV/AIDS. Journal of Health Communication. Vol.5 (2000) Suppl., pp.101-111.
- 13 Diop, W.: From government policy to community-based communication strategies in Africa: Lessons from Senegal and Uganda. Journal of Health Communication, Vol.5 (2000) Suppl., pp.113-117.
- 14 Annan, K.: Speech at the "African summit on HIV/AIDS, tuberculosis and other infectious diseases, Abuja, 26 April 2001. 4 pp.
- 15 African Summit on HIV/AIDS and other related Infectious Diseases, Abuja, Nigeria, 24-27 April 2001: Abuja declaration on HIV/AIDS, tuberculosis and other related infectious diseases. 2001. 7 pp.
- 16 United Nations General Assembly: Special Session of the General Assembly on HIV/AIDS. Report of the Secretary-General. 2001. 30 pp.
- 17 Laing, R., H.V. Hogerzeil, and D. Ross-Degnan: Ten recommendations to improve use of medicines in developing countries. Health Policy and Planning, Vol. 16 (2001) No.1, pp.13-20.
- 18 Girardi, E., M.C. Raviglione, G. Antonucci, et al.: Impact of the HIV-epidemic on the spread of other diseases: the case of tuberculosis. AIDS, Vol.14 (2000) Suppl.3, pp.S47-S56.

- 19 Hawken, M.P., D.W. Muhindi, J.M. Chakaya, et al.: **Under-diagnosis of smear-positive pulmonary tuberculosis in Nairobi, Kenya.** International Journal of Tuberculosis and Lung Disease, Vol.5 (2001) No.3, pp.360-363.
- 20 Granich, R., N. J.Binkin, W.R. Jarvis, et al.: **Guidelines for the prevention of tuberuclosis in health care facilities in resourcelimited settings. Contents and executive summary.** Geneva, 2000. pp.1-8.
- 21 Haddad, S., P. Fournier, N. Machouf, et al.: **What does quality mean to lay people ? Community perceptions of primary health care services in Guinea.** Social Science & Medicine. Vol.47 (1998) No.3, pp.381-394.
- 22 Jakob, B.: **Participating in God's salvation activities in the world.** DIFAM Study Document, No.3, 2001, pp.74-97.
- 23 Ihezue, C.H., and A. Likita: **Blood transfusion: the case for preoperative haemodilution in adults.** Africa Health, 2000, May, pp.5-6.
- 24 Healtlink and HAIN: **Religion and HIV/AIDS.** AIDS Action, Asia-Pacific edition, 2000, No.47. 8 pp.

**1**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

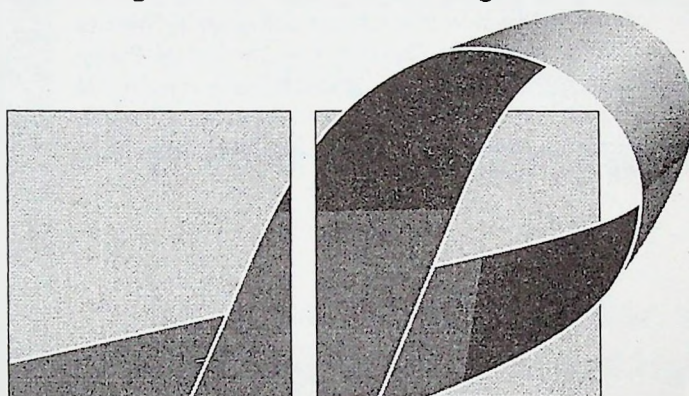
**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

# HIV Prevention Needs and Successes: *a tale of three countries*

*An update on HIV prevention success  
in Senegal, Thailand and Uganda*



Joint United Nations Programme on HIV/AIDS  
**UNAIDS**  
UNICEF • UNDP • UNFPA • UNDP  
UNESCO • WHO • WORLD BANK

UNAIDS Best Practice Collection  
**KEY MATERIAL**

A revised version of a speech delivered by Werasit Sittitrai, Associate Director, Department of Policy, Strategy and Research, UNAIDS, to a meeting of the Office of AIDS Research Advisory Council, National Institutes of Health, Bethesda, MD, USA, 28 April 1999

---

UNAIDS/01.15E (English original, April 2001)  
ISBN 92-9173-055-6

---

---

© Joint United Nations Programme on HIV/AIDS (UNAIDS) 2001.

All rights reserved. This document, which is not a formal publication of UNAIDS, may be freely reviewed, quoted, reproduced or translated, in part or in full, provided the source is acknowledged.

The document may not be sold or used in conjunction with commercial purposes without prior written approval from UNAIDS (Contact: UNAIDS Information Centre).

The views expressed in documents by named authors are solely the responsibility of those authors.

The designations employed and the presentation of the material in this work do not imply the expression of any opinion whatsoever on the part of UNAIDS concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers and boundaries.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by UNAIDS in preference to others of a similar nature that are not mentioned.

Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

---

UNAIDS - 20 avenue Appia - 1211 Geneva 27 - Switzerland  
Telephone: (+41 22) 791 46 51 - Fax: (+41 22) 791 41 87  
e-mail: [unaids@unaids.org](mailto:unaids@unaids.org) - Internet: <http://www.unaids.org>

# HIV Prevention Needs and Successes: a tale of three countries

An update on HIV prevention success  
in Senegal, Thailand and Uganda



Joint United Nations Programme on HIV/AIDS  
**UNAIDS**  
UNEP • UNDP • UNFPA • UNICEF  
UNESCO • WHO • WORLD BANK

Geneva, Switzerland  
April 2001

# Table of Contents

Introduction .....	v
Uganda .....	1
Fig. 1: HIV prevalence among pregnant women. <i>Selected sentinel sites, Uganda, 1990-1996</i> .....	1
Fig. 2: HIV prevalence by age group, Nsambya .....	2
Fig. 3: Percentage sexually experienced by current age (15-24 years old) in 1989 and 1995 .....	2
Fig. 4: Percentage of sexually active men and women who have ever used a condom. <i>Urban Uganda, 1989 and 1995</i> .....	3
Senegal .....	5
Fig. 5: HIV seroprevalence trends in different populations in Dakar, Senegal, 1989-1997 .....	6
Fig. 6: Median age at first sex for women in six African countries, 1997 .....	6
Fig. 7: Condom use with casual partners, reported by men, Dakar, 1997 .....	7
Fig. 8: Condom distribution in Senegal by the National AIDS Programme, family planning services, and the condom social marketing programme, 1988-1997 .....	7
Fig. 9: Frequency of STIs among women in Dakar, Senegal, 1991-1996 .....	8
Thailand .....	9
Fig.10: Substantial and sustained risk reduction in urban males visiting sex workers 1990-1997 .....	11
Fig.11: Risk reduction continues .....	12
Fig.12a: Risk reduction still continues .....	12
Fig.12b: HIV prevalence in northern Thai military conscripts, 1991-1998 .....	13
Fig.13: Comparison of increase in condom use with decline in reported male STIs on a national scale, Thailand 1989 to 1994 .....	13
Fig.14: Trend in HIV prevalence in 21-year-old Thai military conscripts .....	14
Fig.15: Reduction in male, female, and total STIs reported at government clinics between 1985 and 1996 .....	14
Fig.16: Percentage distribution of frequency of STD checks of SWs by sector of employment - 1997 .....	15
Fig.17: Increase in condom use with recent clients as reported by sex workers at direct sex establishments, 1989-1997 .....	16
Fig.18: Percentage distribution of reported regularity of condom use with <i>casual</i> customers by type of SE-1997 .....	16
Fig.19: Percentage distribution of reported regularity of condom use with <i>regular</i> customers by type of SE-1997 .....	17
Fig.20: Percentage of men using condoms every time by type of partner in the past 12 months - 1997 .....	17
Fig.21: Percentage distribution of risk status related to condom use by sex workers who know somebody who has AIDS - 1997 .....	18
Fig.22: HIV Infection in Thailand, Baseline Scenario .....	18
Summary.....	19

## Introduction

---

In recent years we have learned a number of things about HIV prevention around the world.

In industrialized countries where success has been achieved, HIV prevention efforts need to be sustained among the general public and strengthened among such groups as ethnic minorities.

HIV prevention is necessary even in the presence of advanced antiretroviral therapies. The cost of the drugs, the limited access to these therapies (and to drugs for opportunistic infections in general), and the development of drug resistance remain important issues, even in the wealthiest countries. In many areas, prevention programmes and information need to be strengthened as many people mistakenly view antiretroviral therapies as a cure and therefore continue to engage in risky behaviour.

Success is not limited to industrialized countries. In developing countries, prevention activities aimed at changing behaviour and associated social norms can and do work, not only on a large scale but also at national level. Examples of changes include increase in condom use, reduction in visits to sex workers, postponement of first sex and reduction in the sharing of injecting equipment among drug users.

To demonstrate this, data and experiences from three countries with differing cultures and different levels of the epidemic are reported here. Uganda was hard hit throughout the 1980s, and has had almost two million cumulative deaths to date. Senegal, on the other hand, has not been seriously affected by the epidemic. In Thailand, the epidemic became prominent only at the end of the 1980s but spread rapidly once it took hold. These are three different situations, but behavioural change and some containment of the epidemic were achieved in all three.

What are some essential features of effective programmes which are shared by the three countries? In each one, national AIDS programmes share a package of common features that UNAIDS regards as "best practice", namely:

- strong political commitment at the highest level to dealing with the epidemic (this ensures policies and funding to address the epidemic);
- multisectoral approaches to prevention and care and, at government level, involvement by multiple ministries;
- multilevel responses (at national, provincial, district and community levels);
- effective monitoring of the epidemic and risk behaviours, and dissemination of the findings both to improve policies and programmes and to sustain awareness;
- a combination of efforts aimed at the general population and focused on groups at high risk, at the same time;
- implementation on a large scale;
- integrated prevention and care.

## Uganda

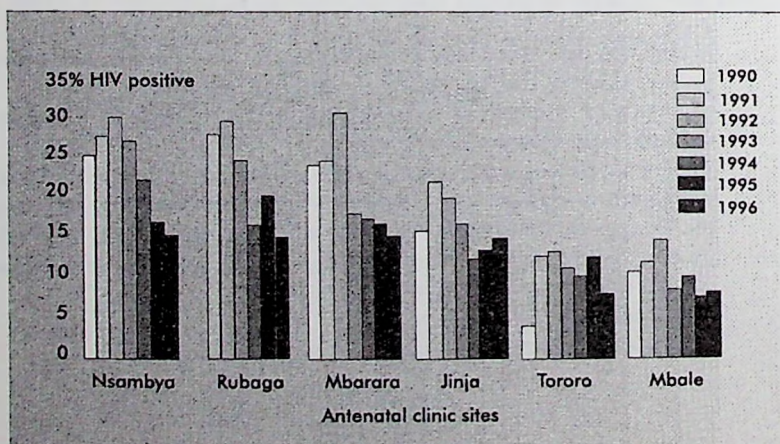
Uganda is one of the world's poorer countries and one of the most severely affected by the epidemic. Uganda has 21 million people, with less than 14% living in cities. The gross national product per capita is equivalent to about US\$ 240. Total prevalence among adults is over 8%.

Fortunately, Uganda is also one of the African countries where the HIV epidemic was recognized relatively early and so prevention efforts were started on a national level.<sup>1</sup>

- In 1986, the President publicly acknowledged the country's HIV/AIDS problem and made a commitment to mobilizing efforts against it. A national budget for the AIDS programme was established early in the epidemic.
- The country adopted a multisectoral approach. The Uganda AIDS Commission was set up in the President's office, and HIV/AIDS control programmes were established in several government ministries, including the Ministry of Health.
- Persons at different levels of society were involved, such as political, community and religious leaders. The Islamic Medical Association of Uganda has supported community education on HIV/AIDS throughout the country, including the distribution of condoms.<sup>2</sup> Radio messages on HIV/AIDS were broadcast very widely.
- Condom social marketing services, backed by USAID, were implemented countrywide.
- HIV voluntary counselling and testing was made available extensively and outside the formal health-care service.

In Uganda the best option for tracking the epidemic was sentinel surveillance among pregnant women, with samples of blood taken routinely at antenatal clinics. Surveillance started in 1989 at six sites in major cities and has since covered the whole country. The results are shown in Fig.1.

Fig. 1: HIV prevalence among pregnant women. *Selected sentinel sites, Uganda, 1990-1996*



<sup>1</sup> For more detailed information, see *A measure of success in Uganda: the value of monitoring both HIV prevalence and sexual behaviour*, Case Study UNAIDS/98.8, Geneva, May 1998.

<sup>2</sup> For further information, see *AIDS education through Imams: a spiritually motivated community effort in Uganda*, Case Study UNAIDS/98.33, Geneva, October 1998.

All these urban sentinel sites showed a significant decline in HIV infection during the first half of the 1990s. In some cases, the percentage of mothers testing HIV-positive almost halved.

This evidence is strengthened when the analysis is focused on the youngest women—those aged 15–19 years. This limits distortions caused by ageing and by infertility, and will actually be much closer to the incidence among the young.

**Fig. 2: HIV prevalence by age group, Nsambya**

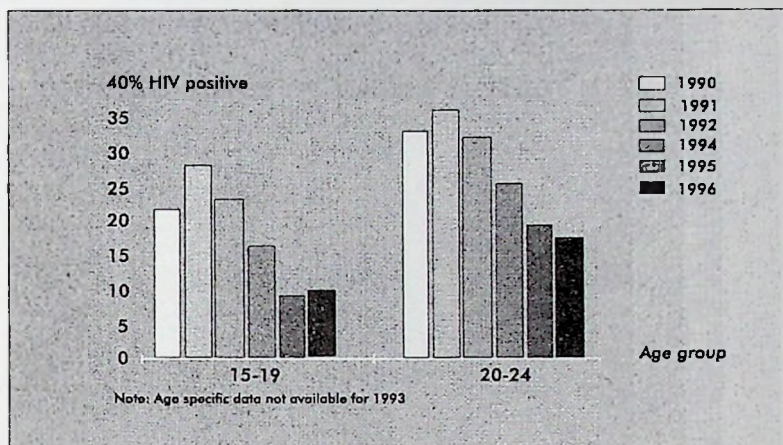
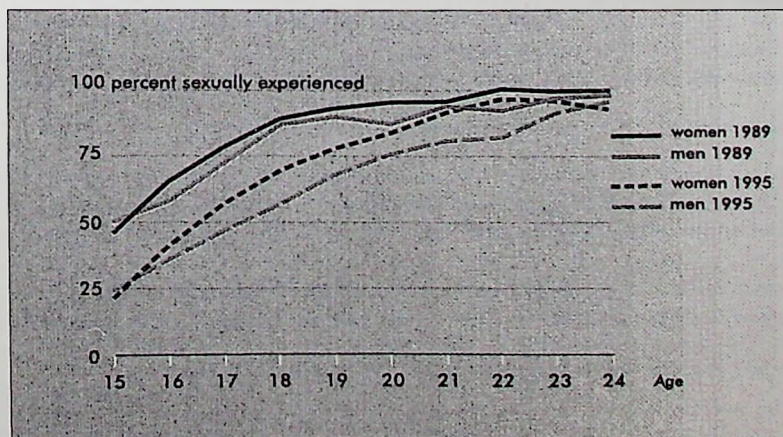


Fig. 2 focuses on Nsambya, a hospital in Kampala. Prevalence among pregnant women aged 15–19 dropped from 22% in 1990 to 10% in 1996, after reaching a peak of 28% in 1991. The steady drop for the youngest women suggests a real fall not just in HIV prevalence but also in incidence.

Uganda conducted two large population-based surveys in 1989 and 1995 that permit comparisons. Both surveys covered two urban areas—Kampala and Jinja—where HIV surveillance was carried out over this period.

Very encouraging data arose from questions about behavioural change among young people in 1995 when compared with their predecessors of the same age in 1989.

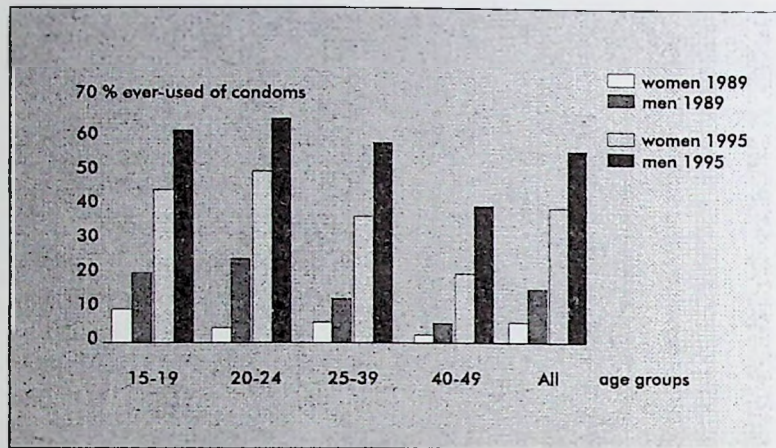
**Fig. 3: Percentage sexually experienced by current age (15–24 years old) in 1989 and 1995**



The first finding related to delayed age of first sexual experience, as shown in Fig. 3.

The clearest difference between 1989 and 1995 can be seen at the left of the figure. For the youngest, the 15-year-olds, the proportion of boys or girls reporting that they had never had sex rose from around 20% to around 50%. Overall, age of sexual initiation shifted upward.

**Fig. 4: Percentage of sexually active men and women who have ever used a condom. Urban Uganda, 1989 and 1995**



The second finding related to the increase in condom use (Fig. 4).

Between 1989 and 1995, the percentage of sexually active men and women who reported using condoms increased significantly. If the numbers are merged, the proportion of men who said that they had ever used a condom rose from 15% to 55%. Among women, the total rose from 6% to 39%.

This steep increase in condom use occurred in all age groups.

In addition to these two large surveys, there have been numerous quantitative and qualitative investigations into behavioural change in recent years, although on a smaller scale.

In rural areas, the number of new infections is still high even among the younger age groups. Obviously, a review of strategies and implementation for rural areas is needed. However, even with this troubling situation a great deal has clearly been accomplished.

Uganda's experience can be summed up as follows:

- First, sentinel surveillance indicates that the prevalence, and probably the incidence, of HIV infection has fallen among pregnant women in urban areas. Other studies show falling prevalence for other groups, although not as strongly as this one.
- Second, surveys of sexual behaviour suggest that increasing condom use and/or a delay in starting sexual activity play a key role in the decline of incidence.

## Senegal

---

Much has been written about the need to intervene early to stop the spread of HIV before it gets a grip on a population. Obviously, however, if a country intervenes early and HIV infection rates stay low, it is difficult to say that the low rates were definitely the consequence of the intervention.

Nevertheless, Senegal's HIV prevention programme has been extensive and contains the elements of an effective programme. There is good evidence that Senegal has maintained one of the lowest rates of infection in sub-Saharan Africa by changing the behaviour of many of its citizens.<sup>3</sup>

Like Uganda, Senegal is not a rich country. It has 9 million people, with 44% living in towns. Per capita income is below US\$ 600 a year. Total HIV prevalence among adults is estimated at about 1.8%.

Senegal has long emphasized prevention and primary health care. Reproductive health and child health are well-established priorities. In addition, registered sex workers are required to have regular health checks, and are treated for any curable sexually transmitted infections (STIs) that are found.

What was the response in Senegal?

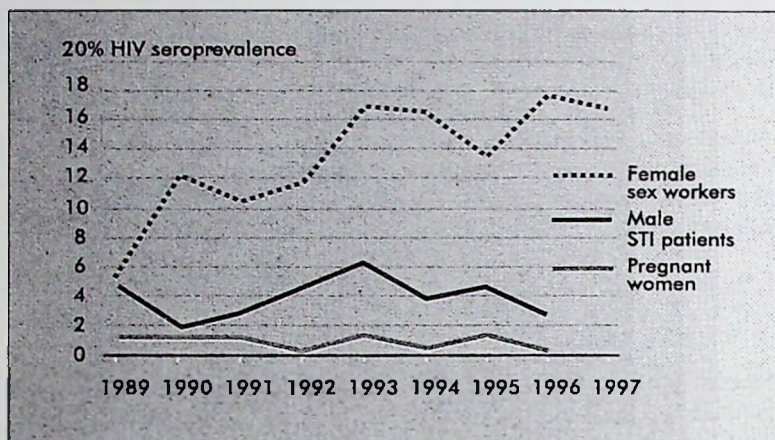
- As in Uganda, politicians in Senegal were quick to move against the epidemic once the first cases appeared in the second half of the 1980s.
- Since 93% of Senegalese are Muslims, the government made efforts to involve religious leaders. HIV/AIDS became a regular topic in Friday sermons in mosques, and senior religious figures talked about it on television and radio.
- Many other levels of Senegalese society joined in. By 1995, 200 NGOs were active in the response, as were women's groups with about half a million members.
- HIV prevention was included when sex education was introduced in schools. Parallel efforts reached out to young people who are not in school.
- HIV voluntary and confidential counselling and testing were made available.
- Programmes were immediately put in place to support sex workers to persuade their clients to use condoms.
- STIs moved up the list of health priorities. Senegal was one of the first countries in Africa to establish a national STI control programme that integrated STI care into regular primary health services.

---

<sup>3</sup> For more detailed information, see *Acting early to prevent AIDS: the case of Senegal*. UNAIDS Key Material, June 1999.

Those were the actions. What happened in epidemiological terms?

**Fig. 5: HIV seroprevalence trends in different populations in Dakar, Senegal, 1989–1997**



Again, sentinel surveillance was the best option for monitoring the disease, but with more groups than in Uganda. In Fig. 5, the bottom line shows that HIV prevalence among pregnant women was just over 1.4% at the end of 1996, with no significant trend over time.

The next line represents male STI patients. Their HIV infection rates are higher, but remained under 6%.

Female sex workers are probably at highest risk. The top line shows their HIV prevalence levels rising significantly after 1989. Since 1993, however, especially in the capital Dakar, they have remained stable at around 17%.

Some changes in behaviours resemble the changes seen in Uganda.

**Fig. 6: Median age at first sex for women in six African countries, 1997**

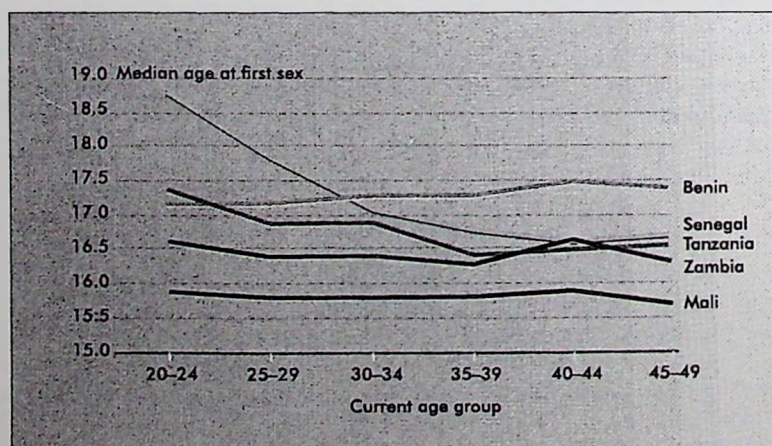
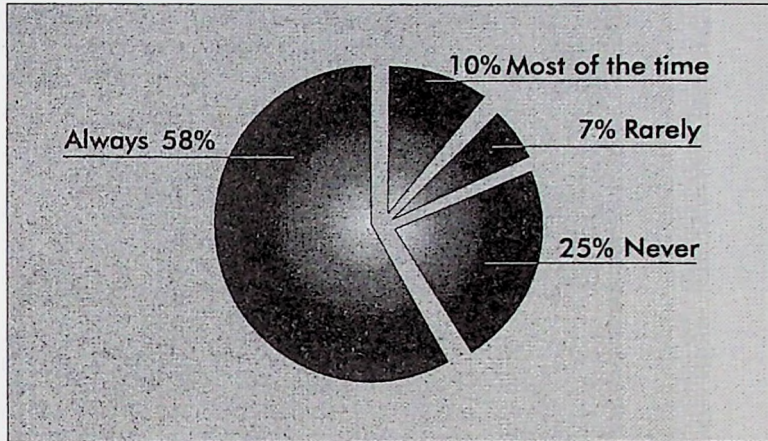


Fig. 6 tracks age at first sexual experience for women in five African countries. The line that falls most steeply is that representing women in Senegal. In 1997, most

Senegalese women in their early 20s did not have sex until they were almost 19 or older. For their mother's generation—the women who were between 40 and 49 in 1997—the median age was closer to 16.

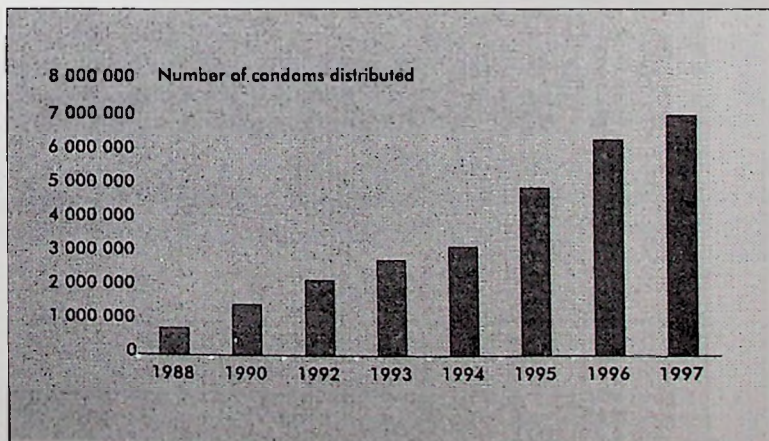
What about condom use? From virtually zero before the HIV/AIDS epidemic, consistent condom use with casual partners in Senegal rose to 68% among men having casual sex in 1997 (Fig. 7).

Fig. 7: Condom use with casual partners, reported by men, Dakar, 1997



The national HIV/AIDS programme has overcome the checks posed by some traditional religious teachings. The programme achieved a dramatic rise in condom sales and distribution.

Fig. 8: Condom distribution in Senegal by the National AIDS Programme, family planning services, and the condom social marketing programme, 1988–1997



Annual condom distribution rose from 800,000 in 1988 to 7 million in 1997 (Fig. 8). Most were distributed free but some were sold at a social marketing price.

It is unlikely that this rise would have happened without the education and condom promotion campaigns to which men were exposed.

**Fig. 9: Rates of STIs among women in Dakar, Senegal, 1991-1996**

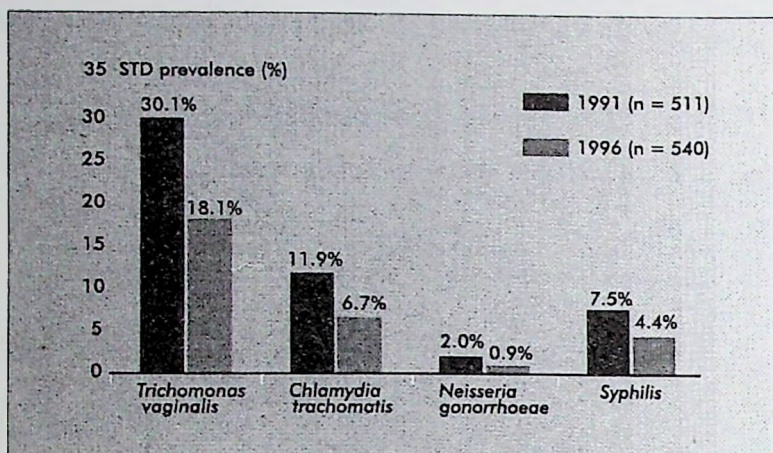


Fig. 9 is from a study of STIs among pregnant women in 1991 and 1996. It shows big falls in infection rates for all STIs measured, especially trichomoniasis, from 30% down to 18%.

This shows that HIV infection has remained low in Senegal since the start of the epidemic and shows no signs of an upwards trend. But why?

Three major factors can be identified, namely:

- People are choosing to have their first sexual experience at a later age (there is also evidence that extramarital sex is relatively limited).
- Condom use during extramarital sex, and especially during commercial sex, is high.
- STI control programmes are apparently quite effective.

The first two factors are strongly linked to the country's HIV/AIDS prevention efforts. And the change in social norms, which is evident in delayed sexual activity, is probably being reinforced by the AIDS prevention programme.

Clearly, much in the social structure and health services of Senegal before AIDS favoured a successful response. In addition, strong political commitment and the implementation of effective prevention activities helped keep Senegal's rates of HIV infection among the lowest in sub-Saharan Africa.

## Thailand

---

Few countries show the link between behaviour and HIV infection as clearly as Thailand.<sup>4</sup> Overall, behavioural changes have reduced the number of new HIV infections each year from almost 143,000 in 1991 to 29,000 in 2000.<sup>5</sup>

Thailand has a little over 60 million people, about 20% of whom live in cities. The gross national product per capita is equivalent to about US\$ 2700. HIV prevalence among adults is estimated at about 1.9%, with higher prevalence in certain geographical areas and among certain groups. Thailand's HIV prevalence is lower than that of Uganda, but it means a similar number of people living with HIV/AIDS.

Until the end of 1987, ad hoc testing in men having sex with men, in female sex workers and in injecting drug users (IDUs) revealed few HIV infections. Then in 1988, rapid growth of HIV infections among IDUs first gave the Thai authorities a clue that a problem was emerging. The prevention programme in the 1980s focused on knowledge and fear; it was sporadic, lacked continuity and was aimed only at the so-called "high risk" groups.

After the rise in prevalence among IDUs, Thailand quickly set up a national sentinel system. In the first round of testing in June 1989, high infection levels were detected among sex workers in the country's northern provinces. By June 1990, HIV prevalence among brothel-based sex workers had risen to 15% nationwide. Prevalence was also growing rapidly among young men.

In addition to the research for monitoring the epidemic, Thailand has conducted three rounds of a national survey on sexual risk behaviours using a similar methodology (in 1990 funded by WHO/GPA; in 1993 funded by the office of the Prime Minister; and in 1997 funded by Ministry of Public Health and UNAIDS). The preliminary results of the first national survey were presented rapidly to policy-makers, community leaders and the mass media. The level of risk behaviours among groups of the Thai population was strikingly high and made Thai society open its eyes to the HIV situation. This helped reinforce a push for multisectoral, intensive and extensive prevention efforts.

In 1991, some key government officials, politicians, academics and AIDS activists managed to increase government commitment. The strategies of the 1980s were replaced by a new approach—the so-called intensive and extensive prevention programme for rapid nationwide implementation using combined actions by the mass media and the community. Some of the guiding principles for the programme's implementation, again based on the lessons learned during the 1980s, were that:

- Focusing on populations with high risk behaviour, such as sex workers and injecting

---

<sup>4</sup> For more information, see *Relationships of HIV and STD declines in Thailand to behavioural change: a synthesis of existing studies*, Key Material, UNAIDS/98.2, 1998. See also *Collecting lower HIV infection rates with changes in sexual behaviour in Thailand: data collection and comparison*, Case Study, UNAIDS/98.15, June 1998, and *The success of the 100% Condom Promotion Programme in Thailand: evaluation of the 100% Condom Promotion Programme and the validation of the decline in trends for selected STDs*, Institute for Population & Social Research, Mahidol University, Thailand (funded by the Thai Ministry of Public Health and UNAIDS, February 2000).

<sup>5</sup> *Projections for HIV/AIDS in Thailand: 2000-2020*. The Thai Working Group on HIV/AIDS Projection. Bangkok, June 2000.

drug users (IDUs), is important but not enough—the general population and young people are also critical. Emphasis was placed on the risk behaviour and vulnerability of young people as well as on the more specific risk behaviour of particular groups.

- It is necessary to reach the population both extensively (on a broad level) and intensively (through many channels at the same time).
- Knowledge and awareness are important but are not sufficient; life skills training (e.g. decision-making and negotiation), condom promotion and long-term approaches such as changing social norms are also necessary.
- Socioeconomic interventions were introduced to reduce vulnerability to HIV infection; for example, increasing the opportunity for girls to continue their schooling and to receive vocational training so that they are less likely to become sex workers.<sup>6</sup>
- Rapid implementation aimed at extensive coverage in a short time, with intensive efforts between 1991 and 1993, created both a programmatic momentum that was carried on by subsequent Thai administrations and a societal momentum by which all regions of the country felt they had a part to play.

The effective nationwide prevention programme, which began in 1991, included several elements:

- The Prime Minister chaired the National AIDS Programme.
- The Office of the Prime Minister took an active role in policy discussion, led the national public education effort using government-run mass media (that is, public, not private), and took part in monitoring.
- The Parliament established a sub-committee on AIDS.
- The National Economic and Social Development Board worked closely with the Ministry of Public Health to integrate the National AIDS Plan into the five-year National Development Plan.
- The government AIDS budget increased drastically during the following years.
- Each key ministry had its own AIDS plan and budget as well as a person as the AIDS focal point.
- All provincial governors led the AIDS programme in their respective provinces through the provincial development planning system.
- The business community, people living with HIV/AIDS, religious leaders and other community leaders became very involved in contributing to policy dialogue, resource mobilization and the local implementation of activities.
- In Thailand, 1991 was the turning point on human rights protection for people living with HIV/AIDS. HIV was removed from the list of diseases that required notification to the health authority. The ban on entry to Thailand of people with HIV/AIDS was lifted. A set of national policy guidelines to protect the rights of people living with HIV/AIDS was issued.<sup>7</sup>

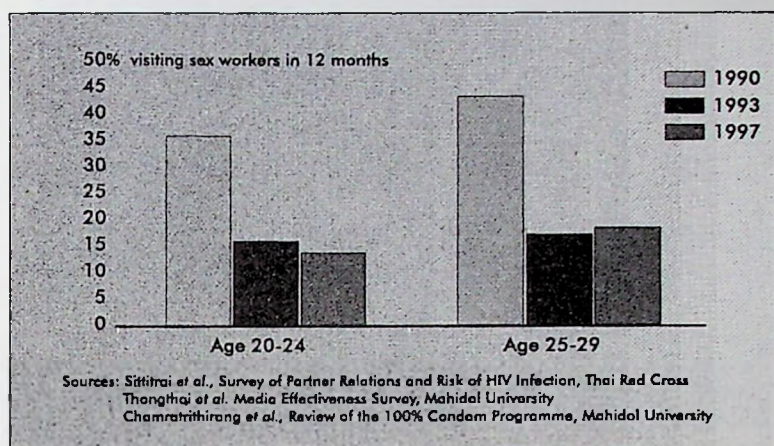
One of the most striking effects of the national programme was shown in the number of visits to sex workers. This is the behaviour most closely associated with HIV infection in Thai studies.

<sup>6</sup> For further information, see the Case Study UNAIDS/99.34E, *Reducing girls' vulnerability to HIV/AIDS: The Thai approach, June 1999*.

<sup>7</sup> Jon Ungphakorn and Werasil Sittitrai. *The Thai response to the HIV/AIDS epidemic, AIDS 1994*, 8 (Supplement), pp./S155-S163.

Fig. 10 shows the figures for urban men aged 20–24 and 25–29 who visited sex workers. The proportion of the younger group who said they had visited a sex worker in the past year fell to about 17% in 1993 from over 35% in 1990. It fell even

**Fig. 10: Substantial and sustained risk reduction in urban males visiting sex workers 1990-1997**



more sharply among those aged 25-29. Men aged 15–49 visiting sex workers dropped from approximately 19% in 1990 to 9% in 1993.<sup>8</sup> The proportion has changed little since 1993, but the lower levels have been sustained according to the 1997 survey.

An effect of this nationwide intensive and extensive prevention programme can be seen in the drastic reduction in the number of Thai men having commercial sex not only in Bangkok but also in all other regions.

Sustained increase in condom use is a major indicator of success in the Thai prevention effort. Between 1990 and 1993, data from national surveys show a sharp increase in consistent condom use among men who visited sex workers. This increase occurred in Bangkok and in all four regions of the country.

<sup>8</sup> Thai Working Group on HIV/AIDS Projection. *Projections for HIV/AIDS in Thailand: 2000-2020*. Bangkok, June 2000.

Another study in Bangkok (Fig. 11) shows that the percentage of males visiting sex workers declined according to the data of 1993, 1994 and 1996 among all three groups (STI clinic attendees, service workers and students).

Fig. 11: Risk reduction continues

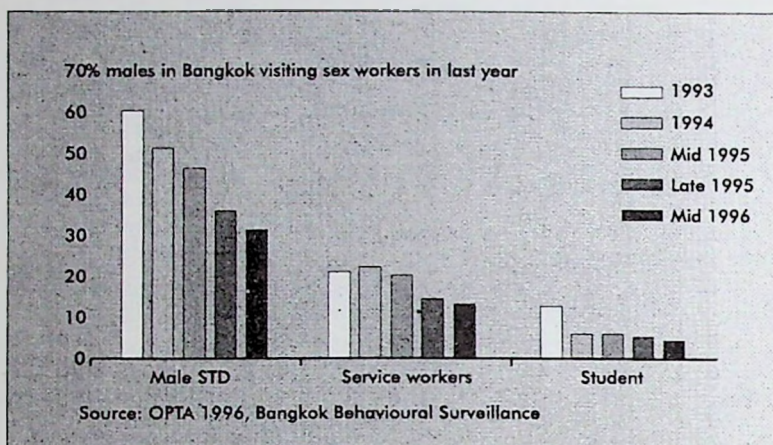
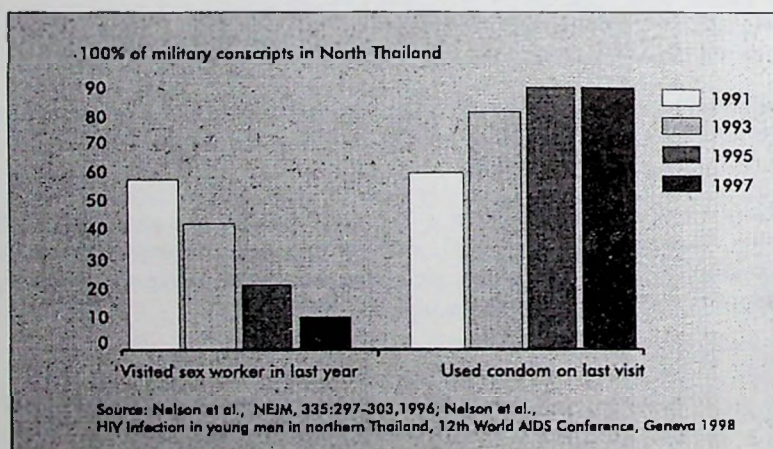
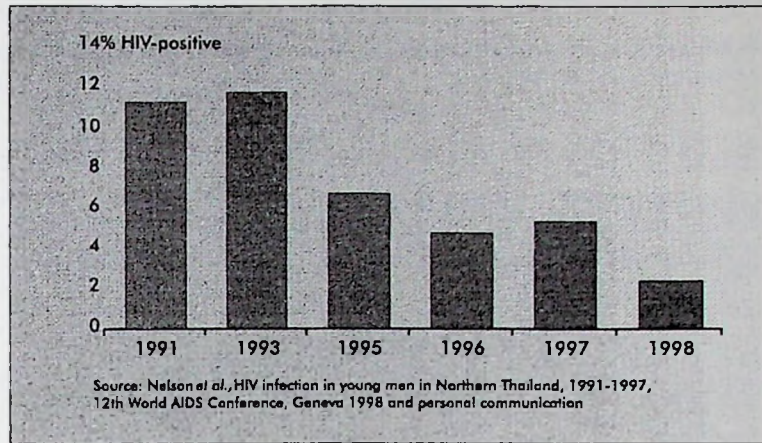


Fig. 12a: Risk reduction still continues



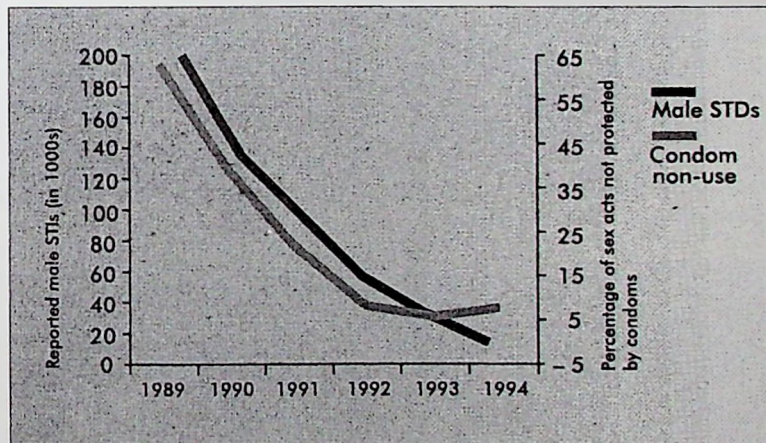
How does behavioural change correlate with the prevalence of HIV and STIs? Between 1991 and 1998, researchers found among military conscripts of northern Thailand a reduction in visits to sex workers, lifetime history of visiting sex workers, and HIV prevalence, while at the same time condom use with sex workers increased dramatically ( Fig. 12a and 12b).

Fig. 12b: HIV prevalence in northern Thai military conscripts, 1991–1998



How do we link the epidemiological patterns with these behavioural changes? The patterns of other STIs are independently related both to commercial sex and to HIV infection. Logic suggests that condom use would be associated with lower rates of STIs. That logic is borne out in Thailand (Fig. 13).

Fig. 13: Comparison of increase in condom use with decline in reported male STIs on a national scale, Thailand 1989 to 1994



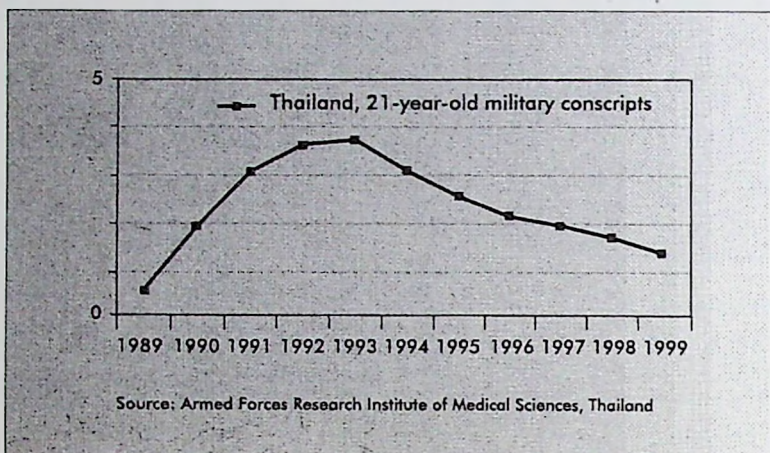
At the time of the study shown in Fig. 13, the intensive and extensive prevention programme had been in effect nationally for six years. During that time, reported STI rates in the country fell by over 90%, as did condom "non-use", which tends to change in step with STI prevalence.

Major prevention packages were implemented side by side and each one reinforced the achievement of the other. These were intensive media campaigns, peer education, workplace AIDS programmes, life-skills training for young people, non-discrimination campaigns, and the famous 100% condom programme in all commercial sex establishments

(which was accompanied by the distribution of free condoms and the campaign for condom use among the general male population).

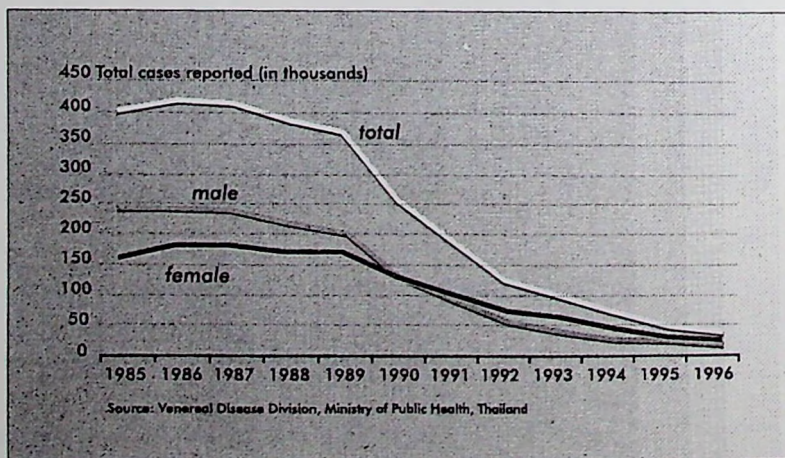
In this context, what happened to HIV prevalence on a national scale? Evidence shows that it declined substantially.

**Fig. 14: Trend in HIV prevalence in 21-year-old Thai military conscripts**



When military conscripts from all regions of Thailand were tested in 1999, a considerably lower proportion of 21-year-old conscripts were found to be infected than in the peak years of 1992–93 (Fig. 14). This indicates that very significant changes in behaviour among young Thais have continued. A recent study shows that HIV prevalence among 21-year-old conscripts had fallen to 1% by 1999 from a peak of 3.5% in 1992.<sup>9</sup>

**Fig. 15: Reduction in male, female, and total STIs reported at government clinics between 1985 and 1996**



<sup>9</sup> The Armed Forces Research Institute of Medical Sciences

As in Senegal, the number of reported cases of new STIs may be an indicator of recent sexual risk behaviour.

Thai government clinic data here suggest strongly that unprotected sex with high-risk partners continues to decline (Fig. 15). In 1985, about 400,000 people were diagnosed with STIs, with men much more represented. The numbers began to fall sharply around the time that the national AIDS strategy got under way. By 1996, the total was under 50,000.<sup>10</sup> An independent evaluation review in 1997 confirmed this decline through data from population and drugstore surveys on self-reporting of STIs and sales of antibiotics. The 1997 survey also showed that over 70% of sex workers in a range of establishments (brothels, hotels, bars, massage parlours, restaurants) had STI checks at least once a week (Fig. 16). STIs among sex workers were roughly at 25% in 1989 and fell steadily to 1.6% in 1999.<sup>11</sup>

**Fig. 16: Percentage distribution of frequency of STI checks of sex workers by sector of employment – 1997**

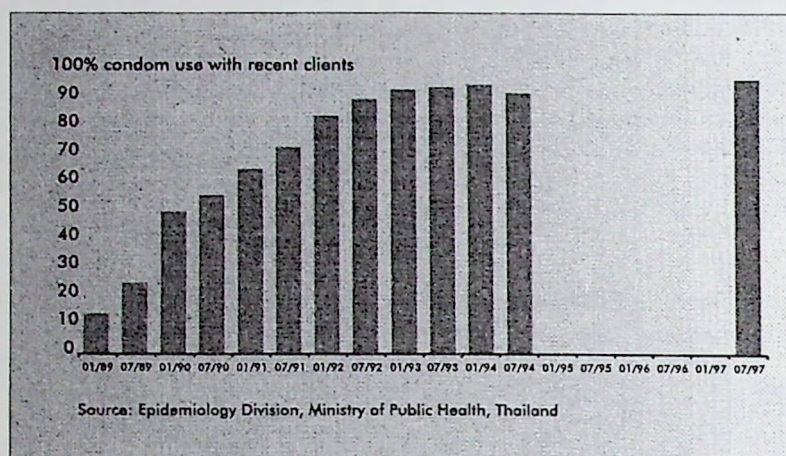
Frequency of STI checks	SEX INDUSTRY SECTOR				
	brothel	hotel	bar/karaoke	massage parlour	restaurant and other
More than 1 week	0.0	8.3	0.0	22.6	1.6
Once a week	73.3	66.7	75.9	54.8	82.5
2-3 times a month	18.3	0.0	17.2	0.0	12.7
Once a month	8.3	16.7	6.9	6.5	3.2
Less than 1 month	0.0	8.3	0.0	12.9	0.0
Not sure	0.0	0.0	0.0	3.2	0.0
TOTAL (N)*	100% (60)	100% (12)	100% (29)	100% (31)	100% (63)

\* N: number of sex establishments  
Source: Institute for Population and Social Research, Thailand, 1997

<sup>10</sup> In Thailand, STI prevalence data are available only for people who seek treatment at government clinics. There is a sizeable private sector client base that is not included in these figures.

<sup>11</sup> Thai Working Group on HIV/AIDS Projection. *Projections for HIV/AIDS in Thailand: 2000-2020*. Bangkok, June 2000.

Fig. 17: Increase in condom use with recent clients as reported by sex workers at direct sex establishments, 1989–1997 (data from 1995 to early 1997 are not available)



The 1997 survey shows that consistent condom use among sex workers increased from over 50% in 1990 to almost 90% in 1996 (Figs. 17, 18, 19).

Fig. 18: Percentage distribution of reported regularity of condom use with *casual* customers by type of SE—1997

Type of sex establishment	REGULARITY OF USE				
	never used	almost never used	sometimes used	almost always used	always used
Brothel	0.0	0.3	1.9	1.1	96.7
Hotel	0.0	0.0	1.4	2.8	95.8
Bar/Karaoke	0.0	0.0	2.2	2.2	95.7
Massage parlour	0.0	0.0	0.3	0.3	99.4
Restaurant/other	0.2	0.0	1.2	2.2	96.5

Source: Institute for Population and Social Research, Mahidol University, Thailand, 1997

The news is not uniformly good, however. Condom use appears to be lower among men from rural areas, and among men with limited formal education. National behavioural surveillance in the provinces revealed that only half the men reporting commercial sex said they had always used a condom. As in the case of Uganda, different or more intensive strategies appear to be necessary for rural populations.

The 100% condom programme was remarkably successful in expanding condom use between sex workers and clients. Other complementary programmes aimed at young people and the general population also increased condom use in non-commercial sexual relationships. This is especially important because of a shift in sexual behaviour away from commercial sex towards more casual sex.

Fig. 19: Percentage distribution of reported regularity of condom use with **regular** customers by type of sex establishment—1997

Type of sex establishment	REGULARITY OF USE				
	never used	almost never used	sometimes used	almost always used	always used
Brothel	0.7	0.3	4.5	2.1	92.4
Hotel	3.7	0.0	5.6	5.6	85.2
Bar/Karaoke	1.4	0.0	4.6	4.1	89.9
Massage parlour	0.3	0.2	0.5	1.0	97.9
Restaurant/other	1.2	1.0	3.8	5.7	88.4

Source: Institute for Population and Social Research, Mahidol University, Thailand, 1997

The figures for condom use with minor wives (that is, mistresses), girl-friends and friends are between 40% and 60% according to the 1997 survey (Fig. 20). The figures were much lower in the 1990 survey. That represents a major change in behaviour between 1990 and 1997. There is a misconception that if people know someone who has AIDS this will increase their level of consistent condom use. This does not, however, seem to be the case in many African countries where HIV prevalence is very high and condom use remains low. Successes in increasing condom use seem rather to be the result of intensive intervention programmes.

Fig. 20: Percentage of men using condoms every time by type of partner in the past 12 months – 1997

Partner	Percentage of use every time*
Wife	11.5
Minor wife (mistress)	66.7
Fiancée	37.9
Girl friend	40.3
Friend	66.2
Other woman	78.4
Direct regular sex worker	89.0
Indirect regular sex worker	84.6
Direct temporary sex worker	94.3
Indirect temporary sex worker	93.9
Male	57.1
Male sex worker	2 of 3

Source: Institute for Population and Social Research, Thailand, 1997

\* compared with all those who ever used condoms

In Thailand, condom use during commercial sex increased rapidly between 1991 and 1993, during the first two years of the extensive and intensive prevention programme. These increases in condom use occurred uniformly across the country, both in regions where there were many people living with AIDS, such as the upper north, and in regions where there were few, such as the north-east. Thus, during that time, most people did not know anyone with AIDS but condom use increased anyway.

**2**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

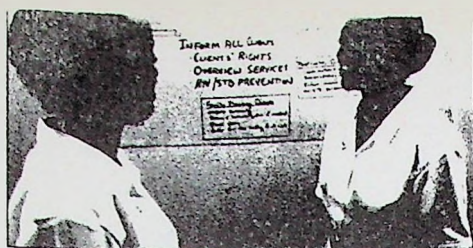
**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



**healthlink**  
WORLDWIDE

# HIV and safe motherhood



## Acknowledgements

This publication was compiled by Jilly Rosser (midwifery consultant) and edited by Helen Cressey, Healthlink Worldwide, AIDS and Sexual Health Programme. The section on infant feeding does not reflect the views of Jilly Rosser in some key areas. It has been copy-edited by Coral Jepson and Christine Kalume and designed by Ingrid Emsden.

Cover photographs by Danielle Baron/JHU/CCP Photoshare and Maggie Murray/Format.

Healthlink Worldwide would like to thank the following organisations and individuals for their contribution towards this publication: Rachel Baggaley, Honorary Research Fellow, London School of Hygiene and Tropical Medicine, UK; Marge Berer, Reproductive Health Matters, UK; Marilen Danguilan, UNICEF, USA; Lynde Francis, International Community of Women Living with HIV/AIDS, Zimbabwe; Petra ten Hoope-Bender, International Confederation of Midwives, The Netherlands; Mavis Kirkham, Professor of Midwifery, University of Sheffield, UK; Mette Kjaerby, Healthlink Worldwide, UK; Siân Long, Healthlink Worldwide, UK; Dr Hermione Lyall, Department of Infectious Diseases, St Mary's Hospital, London, UK; Dr Justin Mandala, UNAIDS, Switzerland; Dr James McIntyre, University of Witwatersrand, South Africa; Dr Kevin O'Reilly, World Health Organisation, Switzerland; Gabrielle Palmer, UNICEF, USA; Dr Brian Pazvakavambwa, UNAIDS, Switzerland; Naomi Rutenberg, HORIZONS, USA; Koenrad Vanormelingen, UNICEF, USA.

Production and distribution of this publication has been possible thanks to the financial support of The Ruben and Elisabeth Rausing Trust, UK; HIVOS, The Netherlands; the Swedish International Development Agency (SIDA), and UNICEF, USA.

### *HIV and safe motherhood*

Published by Healthlink Worldwide, Cityside, 40 Adler Street, London E1 1EE, UK.  
© Healthlink Worldwide 2000

Keywords: HIV prevention / safe motherhood / HIV infection / transmission – maternal / HIV testing / infant feeding / breastfeeding

Any part of this publication may be reproduced without permission for educational and non-profit use if the source is acknowledged.

Printed by Russell Press Ltd.

ISBN 0 907320 47 3

# CONTENTS

Definitions ii

Introduction 1

- Section 1 Before parenthood 3**  
Avoiding infection 3  
Reproductive rights and choices 3  
Improving access to contraception 3  
Abortion 3  
Getting pregnant 3
- Section 2 HIV in pregnancy 4**  
Mother-to-child transmission 4  
Keeping all mothers healthy 4  
Caring for women who know they are HIV positive 5
- Section 3 Voluntary counselling and testing for HIV 6**  
Counselling 6  
Testing for HIV 7
- Section 4 Care during labour and delivery 9**  
General care during labour 9  
Elective caesarean section 9  
Antiretroviral therapy 9
- Section 5 Infant feeding and HIV 11**  
International guidelines 11  
Deciding whether to breastfeed 11  
Essential information for HIV-positive women 11  
Alternatives to breastfeeding 12  
Exclusive breastfeeding 12  
Stopping breastfeeding early 13
- Section 6 What else can health workers do? 14**  
No need to feel helpless 14  
Becoming more at ease with sexuality 14  
Safe working practices 15  
Making the most of limited resources 17
- Section 7 Resources 18**

# DEFINITIONS

**AIDS** stands for Acquired Immune Deficiency Syndrome. HIV destroys the body's immune system, leaving the body open to infections that it cannot fight in the normal way. When this happens, a person has AIDS.

**Amniocentesis** is a test for genetic abnormalities done in hospital. A needle is passed through the abdomen of a pregnant woman and into her uterus, to take a sample of the amniotic fluid surrounding the baby.

**Antibodies** are produced by the body's immune system in response to an outside organism that causes disease, such as a virus or bacteria. Antibodies are specific to the particular virus or bacteria.

**Antiretrovirals (ARV)** are drugs that fight the HIV virus.

**Artificial feeding** means feeding a baby on breastmilk substitutes. These can be any food or drink which is used as a replacement for breastmilk, whether or not it is suitable. Examples are infant formula, cow's milk and goat's milk.

**Asymptomatic** is when a person has HIV infection, but is well and has no signs or symptoms of HIV-related illness.

**CD4 count** is a blood test that measures the number of CD4 cells in a cubic millimetre of blood. CD4 cells help to protect the body from getting infections. The CD4 count roughly reflects the state of a person's immune system. The CD4 count in a healthy, HIV-negative adult is usually 600-1200 CD4 cells per cubic millimetre of blood. HIV attacks and destroys CD4 cells, so the CD4 count of people with HIV usually falls over time. If the CD4 count drops below 200 cells per cubic millimetre of blood, there is a high risk of serious infection.

**Combination therapy** is drug treatment with two or more different ARV drugs.

**ELISA** stands for enzyme-linked immunosorbent assay. This is one of the blood tests done to find out if somebody is HIV positive.

**Exclusive breastfeeding** is when a baby is given nothing except breastmilk – no water, no juice, no other food or drink. Exceptions are medicines and vitamins.

**HIV** stands for Human Immunodeficiency Virus. It is the virus which causes AIDS. There are two types of HIV: HIV-1 and HIV-2. This paper is only about HIV-1, because HIV-2 does not usually pass from mother to child.

**HIV-positive** is when somebody has become infected with the HIV virus. The virus multiplies rapidly in the blood, and antibodies are produced. A person is then said to be HIV positive. Although she may have no signs of illness, she can still infect others.

**MTCT** stands for mother-to-child transmission, and means the same as vertical transmission.

**Monotherapy** is drug treatment with only one ARV drug (not a combination).

**Opportunistic infections** are the infections which people with HIV/AIDS get because their immune systems are damaged. These are infections which the person's body would normally be able to fight, like thrush, or which are only common among people with HIV/AIDS, like pneumonia caused by pneumocystis carinii.

**Perinatal transmission** is any transmission from mother to child which happens during pregnancy or delivery or up to one week after birth.

**Prophylaxis** is the prevention of, or protection against disease. For instance, if women are routinely given antimalarial tablets in pregnancy to prevent, rather than treat, malaria, it is called malaria prophylaxis.

**Rapid assay testing** is a test for HIV using a kit which clinic staff can be trained to use. It gives an immediate result on a blood test to show whether a person is HIV positive, without the need for a laboratory. Some rapid assay tests need refrigeration.

**Resistance** to an ARV means that the HIV in a person's body has changed so that the drug no longer works against it.

**Symptomatic HIV** is when a person with HIV has started to become ill with HIV-related illness.

**Sexually transmitted infections (STIs)** are infections which can be passed from person to person by sexual contact. HIV is an STI, so are gonorrhoea, syphilis, chlamydia trachomatis, herpes simplex, trichomoniasis, cytomegalovirus (CMV) and hepatitis B.

**Unprotected sex** means having sexual intercourse without a condom. It also refers to other sexual activities where there is a risk of HIV transmission (oral sex, anal sex).

**Vertical transmission** is when the HIV virus passes from an HIV positive mother to her baby. This can happen during pregnancy, during labour and delivery, or during breastfeeding.

**Viral load** is one of the tests done on the blood of an HIV-positive person. It measures the amount of HIV in the blood. If a person is HIV positive, a viral load more than 100,000 is considered to be high, and less than 10,000 is considered to be low. An **undetectable viral load** means that there is not enough HIV in the blood for it to be measured with the usual tests.

**Window period** is the time between a person becoming infected with HIV and a blood test showing a positive result. Because the blood tests look for antibodies to HIV, rather than the virus itself, it can be up to three months before the tests show a positive result. During the window period people can transmit the HIV virus to other people.

# INTRODUCTION

The health and wellbeing of women everywhere is of great importance in its own right. It is also key to the health and wellbeing of their families, communities and societies. But every year, over half a million women in developing countries die in pregnancy and childbirth. The Safe Motherhood Initiative was started in 1987 to improve maternity services and to protect the health of mothers and their infants.

HIV presents an enormous challenge to safe motherhood. In 1998, it was estimated that approximately two million HIV-positive women worldwide would give birth. In several major towns in eastern and southern Africa, more than a quarter of pregnant women are now HIV positive.

Women with HIV are more likely to have complications during pregnancy and delivery, or abortion. They are also more vulnerable to anaemia, malaria, pneumonia, urinary infections, and tuberculosis (TB). For women with symptomatic HIV, pregnancy can also speed up the progress of their illness to AIDS. In South Africa, about one in eight maternal deaths are directly due to HIV, and it is a factor in other maternal deaths, for instance from bleeding.

It is estimated that in Africa and Asia, more than two million children each year will lose their mother or both parents to AIDS. These children can be at especially high risk of poverty, neglect and early death. When grandparents or older children are left to look after orphans, they often lack the support or resources to meet basic needs.

HIV can also pass from mother to child during pregnancy, labour and delivery, or through breastfeeding. It is not known exactly what proportion of babies born to HIV-positive mothers will be infected

themselves, but without any kind of intervention, it is estimated that between 15 and 45 out of every 100 would be infected. Around 570,000 children aged 14 or younger (most of them in sub-Saharan Africa) became HIV positive in 1999, almost all from mother-to-child transmission.

The prospects for infected children are not good. Children who are HIV positive are over 20 times more likely to die before the age of five than non-infected children. A study in Rwanda found that, even with frequent medical treatment, over a quarter of the children with HIV in the study died before they were two years old, and over half died before their fifth birthday.

Good HIV prevention and care is an essential part of safe motherhood. Maternity services could play a crucial role by improving care for pregnant women with HIV and AIDS, and helping to reduce the spread of HIV and AIDS before, during and after pregnancy. Fewer resources will be needed if programmes work together.

This briefing paper is for health workers in sub-Saharan Africa who care for mothers during and after pregnancy and delivery. It will also be useful for health planners, and anyone working with young people and with women and men, providing information, advice or counselling on reproductive health and parenthood.

The paper provides information on the issues raised for Safe Motherhood by the high prevalence of HIV in the region. It suggests actions that can improve care and advice for all women, including those who are HIV positive, as well as ways to reduce the risk of mother-to-child transmission for those women who know they are HIV positive.

# 1

## BEFORE PARENTHOOD

Young people, women and men, need advice about HIV and about pregnancy long before they consider becoming parents.

### Avoiding infection

Health workers can play an important role in educating people about HIV/AIDS and how they can protect themselves against infection. This may involve working with teachers, youth groups, women's groups and others, to help people to understand HIV better and find ways to encourage and support behaviour change. Improving women's status in society is also crucial – only then will women be able to negotiate with their partners for safer sex.

### Reproductive rights and choices

All women, regardless of their HIV status, should have the right to choose whether and when to have children and how many they would like to have. A woman who knows she is HIV positive needs information about the HIV-related risks of pregnancy for herself and her baby and how they can be reduced. But she must still be free to make her own decision about whether or not to have children, and should be supported in her choice.

### Improving access to contraception

In an ideal world, every pregnancy would be a wanted pregnancy. All women and men should have access to safe and reliable contraceptives, which include barrier methods, such as condoms. Condoms prevent sexually transmitted infections (STIs), including HIV, as well as unwanted pregnancy.

Where women choose other ways to prevent pregnancy, they should still be encouraged to use condoms as well, to protect against HIV and other STIs. Couples should also be advised to use condoms to avoid infection throughout pregnancy, breastfeeding and afterwards. Even when both partners are HIV positive, they should still use condoms to avoid other STIs and the possibility of re-infection with HIV.

Many women find it difficult to negotiate male condom use with their partners and more female-controlled methods, such as the female condom, are needed. The female condom is already available in many parts of Africa, but often women find it expensive to buy and difficult to use. Female condoms



Role play helps young people develop their skills in negotiating and is a good starting point for talking about HIV prevention.

need to be made more affordable and accessible with better information on how to use them.

### Abortion

HIV status should never be used as a reason for forcing a woman to have an abortion. In many parts of Africa abortion is illegal. In places where it is available, an HIV-positive woman may decide to end her pregnancy. If she does, she should be supported in her decision. Any decision must be made freely, without pressure from health workers or family members.

### Getting pregnant

Getting pregnant involves a risk of transmitting HIV if either partner has been exposed to infection. Couples trying to conceive can minimise the risk of transmission by only having unprotected intercourse (without a condom) during the few days each month when the woman is most likely to be fertile.

Research is being done to develop vaginal microbicides (chemical substances that can be used in the vagina to reduce transmission of STIs including HIV). It is hoped that some microbicides will prevent pregnancy by killing sperm, and also kill sexually transmitted infections such as HIV. It is also hoped that other microbicides will be developed which will kill HIV and other STIs without killing sperm, so that couples can become pregnant without risking HIV infection. However, it is likely to be five to ten years before any microbicides are on the market.

## 2 HIV IN PREGNANCY

It is estimated that at the end of 1999, over 12 million women in sub-Saharan Africa between the ages of 15 and 49 were living with HIV. As more and more women become HIV positive, the number of pregnant women with HIV also increases. In some areas, the proportion of pregnant women who are HIV positive is very high. For instance, information collected in a number of antenatal clinics in major urban centres in Botswana, Rwanda and Malawi between 1996 and 1998, found that more than 30 in every 100 pregnant women were HIV positive.

### Mother-to-child transmission

In developing countries, between one in three and one in four babies born to HIV-positive women are born with HIV themselves. Some of these babies become infected during pregnancy, but most become infected during the birth itself.

There appears to be a greater risk of HIV transmission during pregnancy and childbirth if the mother has a high viral load, or if her immune status is poor. Her viral load will be higher if she:

- has become HIV positive just before or during her pregnancy
- is continuing to be exposed to the HIV virus through unprotected sex in pregnancy
- has symptomatic HIV.

A woman's immune status may be linked to a high viral load and can be assessed by taking a CD4 count. The lower the CD4 count, the lower her immune status.

Poor diet, having another STI such as gonorrhoea, chlamydia or syphilis or having other infections such as malaria also appear to increase the risk of transmission from an HIV-positive mother to her baby. In general, the better the health of the mother, the less likely she is to transmit HIV to her baby.

### Keeping all mothers healthy

All women need care and advice to help them remain healthy during their pregnancy.

**Protect women from HIV** The only completely reliable way to stop mother-to-child transmission of HIV is to prevent all girls and women becoming HIV positive.

**Involve fathers** Talking to the male partner about HIV and parent-to-child transmission, and explaining to him what he can do to keep the pregnancy safe, can encourage him to practise safer sex and protect the health of his baby.



Women with HIV need information and support to help them make the best choices for themselves and their babies.

**Promote safer sex** Even after becoming pregnant, women should continue to practise safer sex (use a condom) unless they are absolutely certain that their partner is not HIV positive. Continuing to use condoms will also prevent STIs. Keeping to one sexual partner makes sex safer.

**Test for, and treat, all infections** An essential part of care for all pregnant women is to look for, ask about and treat, any infections the woman may have, especially STIs, tuberculosis (TB) and malaria.

**Prevent malaria** In areas where malaria is common, malaria prophylaxis is an important part of antenatal care. It is even more important for women who are HIV positive, because an infection can increase the risk of transmission (see below). Pregnant women should take whichever antimalarial drug is recommended in their area, and sleep under an insecticide-treated bed net where possible.

**Promote a well-balanced diet** Eating a good diet, including all the necessary vitamins and minerals, is important for all pregnant women, but especially those who are HIV positive. It is difficult for many women to decide what they eat – poverty, custom or their status may mean they have few choices. Education about which local foods are most nutritious and the importance of pregnant women being well fed, needs to be ongoing. In many parts of sub-Saharan Africa, traditional foods are often more nutritious and cheaper than popular western diets.

**Encourage rest** For many pregnant women, particularly where hard physical tasks are part of their daily routine, getting enough rest can be difficult. Supporting women to look after themselves during their pregnancy, including resting whenever they can, is important.

**Discourage smoking and the use of alcohol and other drugs** Smoking cigarettes, drinking alcohol and the use of some drugs and herbal remedies can harm the unborn child. HIV-positive women need to be especially careful, because anything that damages their health can lower their CD4 count.

**Avoid invasive medical procedures** Because of the risk of HIV and other infections being passed to the baby, procedures such as amniocentesis should be avoided unless they are really necessary (see Section 4, page 10).

**Avoid blood transfusions** Blood transfusions are still a source of HIV infection in some parts of Africa and should be avoided unless they are absolutely essential.

**Provide voluntary counselling and testing for HIV** (see Section 3, page 7) Many women do not know their HIV status and may wish to find out during pregnancy. Knowing their status can help women to make decisions that reduce the risk of transmitting HIV to their baby. Confidentiality is essential if women are to be encouraged to take up services offered and avoid the risks of their status becoming public.

## Caring for women who know they are HIV positive

For women who know they are HIV positive, additional care may be available.

**Antiretroviral therapy** (see box) Most women in sub-Saharan Africa do not have access to long-term combination ARV treatment for their own health or the necessary support services to ensure its correct use. If an HIV-positive woman is on combination therapy, she should continue to take it during pregnancy after talking to her doctor about any changes which might be needed.

**Treatment of HIV-related infections** Even if combination ARV therapy is not available for women, many women do have access to treatments for HIV-related infections such as TB and Herpes zoster. There are also plenty of locally available, relatively cheap and effective treatments for symptoms of opportunistic infections, such as diarrhoea, weight loss and skin infections.

Health workers need to be aware of what treatments women in their community are using – including traditional treatments – so that they can promote ones which are effective and warn women against false and dangerous treatments.

Providing a safe, supportive environment in which to raise concerns and fears is an important part of care, and can also help HIV-positive women stay healthy.

## TYPES OF ANTIRETROVIRAL THERAPY

Antiretrovirals (ARVs) are drugs that fight the HIV virus. ARV therapy can help people with HIV stay healthy.

### Combination therapy

ARVs are usually given in combination, because different ARVs fight HIV in different ways and are therefore more effective when used together. This is known as combination therapy. (See Resources for where to find more information on ARVs).

### Reducing mother-to-child transmission

Short courses of treatment (using a single drug, known as monotherapy) can be given to women in the late stage of pregnancy and/or during labour and delivery, in order to reduce the risk of passing HIV to the baby. Sometimes drugs are also given to the baby in the first week of life. This short course treatment will not be of any benefit to the mother's own health, but will not harm it either. (See Section 4, pages 10 and 11 for more information).

### Post exposure prophylaxis for healthworkers

ARV drugs can also be used for post-exposure treatment of health workers, in the event of an accidental needle-stick or other injury (see Section 6, page 18).



Giacomo Prozzati/Planos Pictures

Subsidised pharmacies are one way to improve access to antiretroviral drugs.

# 3 VOLUNTARY COUNSELLING AND TESTING FOR HIV

The majority of women in sub-Saharan Africa do not know their HIV status. But if they are to make appropriate choices about how to prevent their children from becoming infected, they need to have access to affordable confidential and voluntary counselling and testing. Counselling and testing should be offered to both the woman and her partner. Both parents are responsible for preventing HIV transmission to their children, not just the mother. Women, however, should never be pressured to include their partner in counselling and testing if they do not wish it.

## Counselling

HIV counselling is a confidential and supportive dialogue between a person and a trained counsellor. It should focus on both the physical and emotional wellbeing of the person, and help them to make the decisions that are right for them. Counselling is not the same as giving advice or telling people what they should do. The counsellor's role is to listen to the individual concerns, raise issues that need to be considered, and provide information, emotional support and appropriate referral. Counsellors should avoid judging the person or their partner.

Counselling must be confidential – the person must be confident that the counsellor will not talk to anybody else about what they have discussed together. But this does not mean that counselling must only be between one individual and the counsellor. It may sometimes be better to counsel people together with their sexual partner. In societies where decisions about health and welfare are taken by the family, shared counselling with other family members can be helpful. Confidentiality is just as important in this situation.

The counsellor may be a health worker such as a midwife or a nurse, or may be a layperson. Peer counsellors – such as people who are themselves HIV positive – can be very valuable and health workers should welcome their help and involvement. Whoever takes on this role needs to be specially trained and to be a good listener. Counselling should be more about listening than about talking.

## Pre-test counselling

Anyone thinking about having an HIV test should always have pre-test counselling. This is not only to ensure that the man or woman gives their informed consent to the test, but so that they have the chance to consider the impact that a positive result will have on their life and the life of their family. If, after counselling, the person decides not to have a test, the



Pre-test counselling of couples, such as here in Zambia, can help the couple discuss important issues together.

counsellor has no reason to pressurise them. The following guidelines may be helpful:

- Be in a private area for counselling, where you will not be disturbed or overheard.
- Assure the person that everything said is confidential and that you will not talk to anyone else about it. (You could have a poster on your wall making this clear and showing your commitment).
- Talk through the reasons for HIV testing – theirs and yours. Look at both the benefits and the disadvantages.
- Ask questions in a sensitive way to find out about current and previous risk behaviour. Remember that they may not know about their partner's risk behaviour.
- Offer information about HIV and AIDS.
- Offer information about the HIV antibody test, including information about the 'window period' of infection (this is the time between becoming infected and a blood test showing positive results).
- Go through the implications of a positive test result for the person and their family.
- Discuss the person's possible responses to a positive test result. They can think about who they would tell and where they might get support.
- Be aware of what the person's concerns are and let these guide the discussion. For example, if a woman is being counselled and already has children, her major concern may be what will happen to them if she is HIV positive.
- Go through the implications of a negative test result.
- Provide information about how the test is done, how long before the results will be ready, and how they should find out the results.
- Give enough time for them to think about whether or not they want to have the test.
- If they decide to have the test, obtain informed consent.

## Post-test counselling

Counselling after an HIV test is essential, whether or not the result is positive. Always meet with the person to give the result as soon as possible after the test.

### If the result is negative

- Deal with the feelings arising from a negative result and explain about the 'window period'.
- Discuss ways to prevent HIV infection through safer sex and the importance of remaining negative for the rest of the pregnancy, during breastfeeding, and afterwards.

### If the result is positive

- Tell the person as clearly and gently as possible. Deal with their immediate feelings and explain the need for a supplementary test to confirm the result. Give them time to understand and discuss the result.
- Provide information in a way that they can understand, give emotional support and help them to discuss how they will cope.
- Discuss how the person plans to spend the next few hours and days.
- Identify what support they have.
- Discuss who they want to tell about the result. Find out if they intend to tell their partner, help them to decide whether or not to tell them and, if appropriate, how to tell them.
- Go through the ways they can take care of their own health and let them know about any available treatment.
- For a pregnant woman, go through the ways to reduce the risk of transmitting HIV to her baby during pregnancy, labour and after the birth.
- Discuss how she will feed the baby and the importance, if she breastfeeds, of exclusive breastfeeding.
- Identify what difficulties or problems the person foresees and discuss how to deal with them.
- Encourage them to ask questions.
- Refer the person, where possible, to a community-support organisation and for follow-up care and counselling.
- Encourage them to return for another session when they have had time to take in some of the information they have just heard. If appropriate, some information could be written down as the person is unlikely to be able to remember everything that was said.

## Testing for HIV

### What is an HIV test?

Testing for HIV is done on a blood sample. Most tests look for antibodies to the virus in the blood. Antibodies are produced by the body as it tries to fight the HIV virus. If no antibodies are found, the person is antibody negative (also called seronegative or HIV negative). If antibodies are found, the person is antibody positive

(also called seropositive or HIV positive).

The test result may be negative if the person has been infected only recently. It can take up to three months from the time of infection for antibodies to be produced. This is known as the window period. Anyone who might have become infected in the last three months should take a second test three months after the first test.

Until recently, the most commonly used antibody test was the ELISA (enzyme-linked immunosorbent assay). ELISA testing needs skilled technical staff, equipment in good order, and a steady power supply. Now, simple or rapid assay tests are used more widely. These are quicker and easier to use than ELISA tests, and can be used for on-the-spot testing. They do not need highly trained staff or expensive laboratory equipment, although some do need refrigeration.

It is better to use a combination of tests to be sure of the results. The price of ELISA and other screening tests range from about US\$0.45 to \$2. Using a combination of rapid tests cost about US\$5 per person.

### Deciding whether to be tested

Most women living in the developing world do not have a choice about whether to be tested for HIV, because the test is not available to them. It is thought that only one in twenty women in the developing world have been tested and know their status.

For those women who do have a choice, deciding whether to have a test should be done very carefully. The health worker should not try to persuade the woman to have the test – it should be a decision which she takes freely. Because of the fear and misunderstanding that surrounds HIV and AIDS, there is a lot of stigma towards HIV-positive people.

There are benefits and risks of testing, and these will vary for each woman. Some of the possible benefits of



Testing blood samples for HIV.



Pregnancy is the time when couples may want to think about being tested for HIV.

a pregnant woman knowing she is HIV positive are that she can:

- take the measures available to her to keep herself healthy for as long as possible
- decide, in countries where abortion is available, whether to continue the pregnancy
- take appropriate steps to reduce the risk of transmitting HIV to her baby
- tell her sexual partner(s) that she is HIV positive, so that they can be tested too.

Some of the possible risks of knowing that she is HIV positive are:

- her family may blame her for bringing HIV into the family and may react violently or make her leave her home
- she may be stigmatised and looked down on by her neighbours and by health workers (if her HIV status is known about)
- she may become anxious and depressed.

Even where HIV tests are available to all pregnant women, many choose not to have the test. And after having the test done, some women will not return to find out the result.

*'My partner died six years ago. Before he died we talked, and he agreed, on my suggestion, to have an HIV test. We both took the test and were both diagnosed positive. Hell broke loose, but we got counselling and accepted the situation. I have since faced problems as a human being and as a health*

*worker. Ill health may lead to me losing my job, which is a major worry. I see patients suffering and it is an indication of what I may face in the future. I always think about what people may say about me. However, knowing about HIV and AIDS does help me practise positive living.'*

*Health worker, Uganda*

### Being tested without consent

In some places, women find out they are HIV positive through routine testing during antenatal visits, without having been given adequate pre-test counselling and without their consent. This should be avoided if at all possible, but if a healthworker is meeting a woman for the first time after she has already been tested, she will need a particularly sensitive approach when being told her results.

*'My first husband died of what I suspect was AIDS. I think I must have the virus too, especially when I know that we were having sex right throughout even in the month he died. I don't want to be told I've got it – even though I suspect it. It would break my heart to know for certain I would go through all that suffering like my husband.'*

*29 year old woman, Zambia*

### Testing babies

When babies are born they have their mother's antibodies in their blood. So if their mother is HIV positive, the baby's blood will often be positive too, until the baby is about 18 months old. If they do not have the virus, the mother's antibodies go away by this time. So antibody tests cannot tell if babies are themselves infected with HIV until the age of about 18 months. If an earlier test is negative, however, it does mean that the child is not infected.

There are tests which can give an accurate result earlier (such as PCR tests) but these are expensive and not usually available in developing countries.

### Where to be tested?

Counselling and testing can be offered as part of an antenatal service or as a separate service. There are advantages in both types. Using the antenatal services may be more convenient for women and so increase the uptake of testing. But in a separate service there will often be links to ongoing support services for people living with HIV and AIDS. This will mean that continuing care for HIV-positive women may be available. If a woman is tested elsewhere and is found to be positive she should be encouraged to share the information with the antenatal services in order to ensure that she is given appropriate care and advice.

# 4 CARE DURING LABOUR AND DELIVERY

All women, whether they are HIV positive or not, should be offered good care and support through their labour and delivery. For women who are known to be HIV positive however, there may be additional types of care or treatment available which can help to reduce the risk of mother-to-child HIV transmission. Health workers have no reason to be afraid of looking after HIV-positive women. Universal precautions for infection control should be used for all deliveries, whatever the woman's HIV status, and if used properly, will minimise the risk of HIV infection for the health worker during the delivery (see Section 6, page 17).

Many women do not know their HIV status, so the following advice on care during labour and delivery should be followed for all women. However, interventions specifically for HIV-positive women, such as ARV therapy (where it is available), will only be possible where women can find out their status and have access to confidential voluntary counselling and testing (see Section 3, pages 7-9).

## General care during labour

**Keep the skin intact** Avoid, as far as possible, all practices that break the baby's skin or increase the baby's contact with the mother's blood, for example, episiotomy and fetal scalp electrodes (for listening to the baby's heart beat).

**Keep the membranes intact** The risk of HIV being transmitted to the baby increases after the membranes have been ruptured ('waters broken') for more than four hours. It follows that it is better if the health worker does not rupture the membranes ('break the waters') unless there is a very good reason for doing so, as this opens up a route for HIV and other infections to reach the baby.

It is already known that it is better not to do more vaginal examinations during labour than absolutely necessary, and this is even more important when the membranes have ruptured, as it increases the risk of infection to the mother and baby. The risk of transmitting infections may be reduced by washing the vagina (see box).

## Elective caesarean section

If the baby is delivering by elective caesarean section (a planned caesarean delivery which is done before

labour begins), the risk of HIV transmission is reduced by half. In resource-rich settings, elective caesarean section is becoming a routine part of care for HIV-positive women.

However, the situation is very different in many parts of sub-Saharan Africa. In resource-poor settings, the risks of serious complications after a caesarean delivery may outweigh the potential benefits. This is particularly true for HIV-positive women who are more vulnerable to other infections and whose wounds may be slow to heal. All women who have a caesarean delivery should be given antibiotics to prevent infection, whether they are HIV-positive or not.

## Antiretroviral therapy (ARV)

Antiretroviral therapy (ARV) is one of the most effective ways of reducing the risk of mother to-child transmission, but it is also the most expensive. The drugs work by reducing the viral load in the mother, making it less likely that she will pass on HIV to her baby.

Several different regimens for short courses of ARV drug treatment to reduce mother-to-child transmission during pregnancy and delivery have been studied, and these are summarised in the table on page 11. Further research is needed to find out whether longer treatment of infants following delivery can prevent transmission, whether mothers breastfeed and not.

Decisions on the appropriate drugs to use will be made by health planners and policy makers according to which is the most affordable and cost-effective option. The most recent research does suggest, however, that single-dose nevirapine given to the woman at the onset of labour and then to the baby, may offer the most affordable option for many countries. For example, in order to treat all HIV-positive pregnant women in Uganda, the costs for nevirapine would be US\$640,000 per year while for zidovudine the cost would be US\$21,450,000.

### WASHING THE VAGINA

Known as 'vaginal lavage', this technique consists of cleaning inside the vagina with a disinfectant such as chlorhexidine hydrochloride shortly before the baby is born (when the woman begins to push). Research shows that vaginal lavage reduces the risk of HIV transmission to the baby when the membranes have been ruptured for more than four hours, but not in other cases. It also seems to reduce other types of infection in the baby. More research is being done on this at the moment.

# Summary of short-course antiretroviral treatments for prevention of mother-to-child transmission

NAME BY WHICH STUDY IS KNOWN	STUDY LOCATION	DRUGS USED	TREATMENT REGIMEN			PERCENTAGE TRANSMISSION FROM MOTHER TO CHILD		PERCENTAGE REDUCTION IN MOTHER-TO-CHILD TRANSMISSION
			From 36 weeks	During labour	1 week post partum	Active group (receiving treatment)	Placebo group (not receiving treatment)	
NOT BREASTFED								
CDC Thailand	Thailand	Zidovudine (ZDV)	300mg 2 x daily	300mg every hour	None	9.4%	18.9%	50%
BREASTFED								
CDC Abidjan <sup>1</sup>	Côte D'Ivoire	Zidovudine	300mg 2 x daily	300mg every 3 hours	None None	15.7% 21.5%	24.9% 30.6%	37% (3 months) 24% (18 months)
ANRS Abidjan <sup>2</sup>	Côte D'Ivoire and Burkina Faso	Zidovudine	300mg 2 x daily	600mg at onset of labour	300mg 2 x daily for mother only	16.8% 22.8%	25.1% 30.1%	38% (3 months) 30% (15 months)
PETRA A	South Africa, Tanzania and Uganda	Zidovudine and Lamivudine (3TC)	300mg ZDV and 150mg3TC 2 x daily	300mg ZDV every 3 hours and 150mg 3TC every 12 hours	ZDV and 3TC every 12 hours for mother and baby	7.8%	16.5%	53% (6 weeks)
PETRA B	South Africa, Tanzania and Uganda	Zidovudine and Lamivudine	None	As above	As above	10.2%	16.5%	38% (6 weeks)
NVP HIVNET Uganda	Uganda	Nevirapine (NVP)	None	Single dose 200mg of NVP at onset of labour	None for mother but single dose of NVP 2mg/kg for baby at 2-3 days old	11.9% 13.1%	21.3% 25.1%	44% (6-8 weeks) 48% (14-16 weeks)

1 Wiktor et al., Lancet 1999; 353: 781-5, with update on follow up data from presentations at Montreal MTCT Conference

2 Dabis et al, Lancet 1999; 353: 786-92, with update on follow up data from presentations at Montreal MTCT Conference

# 5

## INFANT FEEDING AND HIV

For anyone working with mothers and infants, it has been distressing to learn that HIV can be transmitted through breastmilk, because the promotion and support of breastfeeding has been so important in reducing the number of infant deaths from diarrhoeal and respiratory infections and from malnutrition. The situation has left many unsure about what they should be doing and saying about breastfeeding in places where HIV prevalence is high.

It is estimated that out of every 100 children breastfed by HIV-positive mothers, 14 (or one in seven) will become HIV positive through breastfeeding. If mothers are newly infected while breastfeeding, the infection rate from breastfeeding is even higher – 29 in every 100 children, or more than one quarter of the children will become HIV positive. A recent study showed that the number of infants who get HIV from their mothers could be reduced by 40 per cent if HIV-infected women avoided breastfeeding.

### International guidelines

In 1997, the WHO, UNAIDS and UNICEF made a new policy about HIV and infant feeding. It says that where adequate alternatives are available and the risks associated with artificial feeding can be minimised, HIV-positive women should be advised not to breastfeed because of the risk that infants can become infected through breastfeeding.

In many of the larger towns and cities across sub-Saharan Africa, at least amongst the more affluent and well-educated families, HIV-positive women can get access to breastmilk substitutes and can ensure that feeds are prepared safely. But for many women, there will be no safe and economic alternative to breastfeeding. The risk to the infant of early death because of not breastfeeding in such circumstances is likely to be greater than the risk of HIV transmission.

### Deciding whether to breastfeed

Women everywhere have the right to be given the information they need to make an informed decision about whether or not to breastfeed, according to their individual circumstances.

### Getting tested

Many women do not know their status. Voluntary testing and counselling services should be made more widely available to enable women to make an informed decision about the best feeding option for them and their baby.

Women who know that they are HIV negative can



Women who choose to breastfeed need support to ensure their baby is properly attached.

breastfeed their baby with confidence (or near confidence, see page 2 for information on the window period), provided they take care not to become infected while they are breastfeeding.

### What increases the risk of HIV through breastfeeding?

The risk of HIV transmission through breastmilk is higher when a woman:

- › becomes infected with the virus during pregnancy or while breastfeeding
- › shows signs of HIV-related illness (AIDS) – this is because she has a high viral load, and because her CD4 count will be low.

Breast problems such as cracked nipples or breast infection (mastitis) may also increase the risk, but further research is needed to confirm this.

### Essential information for HIV-positive women

For HIV-positive women, it is essential that they are given all the information they need to make an informed decision about infant feeding.



HIV-positive women need ongoing support with decisions about infant feeding.

- There is a one in seven risk of an HIV-positive woman passing the virus to her baby through breastmilk.
- Children who are HIV positive are much more likely to die before the age of five than non-infected children and may suffer from frequent illness during their childhood.
- Mixed feeding (giving other foods or drinks as well as breastmilk) seems to have the highest risk of HIV transmission. If a woman chooses to breastfeed she should breastfeed **exclusively** for at least the first three months, which means giving no other drinks or food (see box, page 14).
- Breastfeeding protects babies against infections other than HIV, and is nutritionally the best and most hygienic form of infant feeding. In countries where malnutrition and infectious diseases are the main cause of infant deaths, infants who are not breastfed are more likely than breastfed babies to die from diseases such as diarrhoea and acute respiratory infections.
- Breastmilk alternatives – formula or animal milk – can be very expensive. For example, in Zimbabwe, the monthly cost of formula milk for a baby would be around Zimbabwe \$250-300, about the same as the monthly minimum wage.
- Safe and hygienic preparation of breastmilk alternatives requires access to adequate supplies of clean water and fuel, and knowledge about how to mix feeds correctly. Health workers have an important role in ensuring that women have good information and support to help them to prepare feeds safely.
- Cup feeding, rather than bottle feeding of breastmilk substitutes, is recommended to reduce the risk of contamination.
- Exclusive breastfeeding protects against pregnancy. If a woman decides not to breastfeed, she needs to have access to safe and reliable contraception.
- Not breastfeeding may signal to others that a mother has HIV, and she may wish to keep her status confidential. The public disclosure of a woman's status

can put her, and her family, at risk of social exclusion or even violence.

Once a woman has made a decision about which method of infant feeding is best for herself and her baby, she should be given support and advice so that she can do this as safely as possible. (See 'Alternatives to breastfeeding' and 'Care and advice to breastfeeding women').

## Alternatives to breastfeeding

- Commercial infant formula provides the best mix of nutrients for infants who cannot have breastmilk. But it is expensive if bought commercially, and is not an option for many mothers at the moment. Feeding an infant for six months requires on average 40 x 500g tins (44 x 450g tins) of formula. There are efforts being made to reduce the price of commercially prepared infant formula and to make it more widely available. This would mean that HIV-positive women who decide not to breastfeed would be able to give their babies a safe and nutritionally adequate alternative to breastmilk, whatever their economic circumstances.
- Home-prepared formula – made with fresh animal milk, dried whole milk or unsweetened evaporated milk. These milks must be modified to make them suitable for infants. For example, to prepare fresh cow's milk: mix 100mls milk with 50mls of water and two level teaspoons of sugar, and boil. Micronutrient supplements should also be given, because animal milks contain insufficient iron and zinc, and sometimes vitamin A and folic acid.
- Expressed breastmilk – this must be boiled (to kill the virus) and then cooled immediately by putting it in cold water or a refrigerator.
- Breastmilk banks – in some areas donated breastmilk is used for short periods, for example, to feed sick and low birth weight babies in hospital. Donors should be tested for HIV and the donated milk pasteurised before use.
- Breastmilk from another woman who can breastfeed (known as a wet nurse) and who already knows that she does not have HIV. This is often the grandmother. Women who act as wet-nurses, must be given information about how to practise safer sex, to make sure they remain HIV negative while breastfeeding the infant.

## Exclusive breastfeeding

For women who decide that breastfeeding is still the best option for them, it is important that they **exclusively breastfeed**, for at least the first three months. This means giving nothing at all to the baby from the moment he or she is born except breastmilk – no water, no tea, no formula, no honey, no juice, no porridge and no dummies.

Recent observations from a study in Durban, South Africa, found that mixed feeding, where infants were breastfed but were also given other drinks or food in their first three months, carried the highest risk of HIV transmission through breastmilk. These results have not been confirmed by other studies and more research is urgently required.

It is not clear exactly why mixed feeding puts the baby at higher risk of becoming infected with HIV, but it may be because anything except breastmilk can damage the lining of the baby's stomach and intestines. Once the baby's intestines have been damaged, then the natural protection against all infections, including HIV, is lost.

### When women cannot breastfeed exclusively

Mothers cannot always breastfeed exclusively. These mothers face difficult decisions about how to feed their babies, whether they are HIV positive or not. Each must do their best according to their own circumstances, depending on what food is available, who is caring for the baby, how old the baby is, and so on. For women who are not HIV positive, the best advice is for them to carry on breastfeeding the baby as much as they can; during the night, before going to work, after coming back from work, on days off. During work hours breastmilk will need to be substituted with the most nutritional, cleanest food and drink possible.

For women who know they are HIV positive and have decided to breastfeed, going back to work means that they cannot exclusively breastfeed their babies. Their babies may then be at a higher risk of becoming HIV infected through mixed feeding.

### Stopping breastfeeding early

There is much discussion about when, and how, to wean the babies of HIV-positive mothers. HIV can be transmitted through breastmilk at any time – even when the baby is over six months old. Some people think that it might be best to wean the baby from the breast at six months of age. This is because the main

### CARE AND ADVICE TO BREASTFEEDING WOMEN

The care and advice to give HIV-positive women who decide to breastfeed is the same as to other breastfeeding women:

- 1 Breastfeed within the first hour of birth, so that the baby gets the full benefit of colostrum with all its anti-infective properties. HIV is present in higher concentrations in colostrum, but there is no evidence to show an increased risk of transmission.
- 2 Give nothing but breastmilk for the first four to six months of life. Breastmilk will meet all the babies' needs for nutrition up to the age of six months and protects against infections.
- 3 Make sure the baby is 'attached' properly when breastfeeding. This means that the baby has got enough of the breast in its mouth for feeding not to hurt. Good attachment prevents cracked and sore nipples.
- 4 Use a condom when having sex. For women who are already HIV positive, this may help to prevent reinfection with HIV or infection with another STI and thus keep down the viral load and reduce the risk of HIV transmission.
- 5 Seek treatment for infections, particularly malaria, TB, other chest infections and STIs. This will help to keep the mother healthy and able to breastfeed and, in HIV-positive women, may help to keep the CD4 count up.

benefits of breastfeeding are in the earliest months and the baby can cope better with other foods after six months.

More research is needed to find out more about the importance of breastfeeding to the health of babies after they reach six months, and the time at which the risk of HIV transmission through breastmilk is greatest. It is also important to look at how acceptable early weaning is to mothers and babies.

# 6

## WHAT ELSE CAN HEALTH WORKERS DO?

Health workers can do many things to improve the services they offer, and reduce the spread of HIV among women and their families. This may involve providing information and services or improving their own skills in dealing with the sensitive issues of HIV and sexual health.

### No need to feel helpless

If you work in a health service with very little money to spend, it is easy to feel helpless in the face of HIV and AIDS. Even if you cannot provide ARV therapy for the HIV-positive pregnant women in your area, there is still plenty you can do:

- Make sure all young men and women are well informed about HIV and how to keep themselves safe. This may include getting involved in schools or with youth groups and organisations.

- Make condoms available as widely and as cheaply as possible and promote their use through bars, clinics, markets, grocery shops, truck stops and so on. They are still the best way of preventing HIV spreading.

- Improve access to confidential voluntary HIV counselling and testing services for women and their partners.

- Encourage women with HIV to form support groups. Positive women can gain a lot of mutual support and strength from such groups and they can also be powerful agents for change.

- Make links with organisations and groups that are already active in your country. As well as government health services, you can look for support and resources from AIDS organisations, churches and mission hospitals, community-based groups, and many non-governmental organisations (NGOs).



Market places are a good place to promote condoms.

- Strengthen maternity services. Make good-quality antenatal care accessible to more women, particularly the poor and those in rural areas. This could involve running mobile clinics, training traditional birth attendants, making stronger links with the nearest hospital and using their laboratory facilities for testing blood and other specimens.

- Update your own practice by getting together with colleagues who also work in maternity care to look together at the areas of practice which need to change.

- Improve services for STIs and encourage people to practise safer sex.

- Make sure all women are well informed about the risks and benefits of different feeding options for their infants. Where women choose to breastfeed, encourage them to do so exclusively for the first six months of life. Find out what women in your area do, and what they believe, about supplementing breastmilk. Try to find ways to overcome the common fears that a baby will go hungry or thirsty if he or she does not receive other drinks or foods.

### Becoming more at ease with HIV and sexuality

You cannot work in the field of HIV and AIDS without coming face-to-face with sexuality and very intimate areas of people's lives. These are things which you would not normally talk to people about. They may make you feel ashamed, embarrassed or angry and you may not know which words to use. Here are some activities to help you become more comfortable discussing these difficult topics.

#### ACTIVITY 1

#### GIVING THINGS A NAME

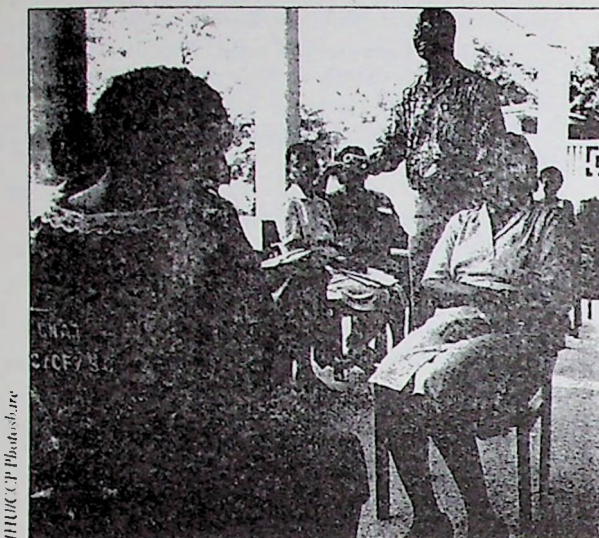
You can do this exercise alone, but it is better in a group. You might prefer to do it in single sex groups, but everyone will learn more if it is a mixed group.

Think of all the words you need for your work with HIV and AIDS which can be difficult or embarrassing. Write up all the 'proper' words for the group to see – you might have words like: sexual intercourse, masturbation, condoms, penis, testicles, kissing, sex worker, anal intercourse, oral sex, breasts, sperm, vagina, homosexual.

Now, ask the group to think of other names which might be used for these things. Write them up for everyone to see.

Discuss where, or how, these words would be used and by whom – friends of the same sex, health workers, boyfriend or girlfriend, husbands or wives, children and so on.

Decide which words health workers should use in their work to make sure that they are clearly understood without causing offence.



Role playing helps health workers practice how to handle concerns about HIV more confidently.

## ACTIVITY 2 ROLE PLAYING

It makes it easier to deal with an embarrassing or difficult situation if you have thought it through ahead of time. One of the best ways of doing this is by role playing a situation with a group of your colleagues. Here are some examples:

a) Michael, aged 26, is HIV positive. He tells a health worker he has a new girl friend, Angela, who is now pregnant by him. She does not know he is HIV positive. Try acting this out with a health worker and Michael and then with different combinations, for example, Michael and Angela, the health worker and Angela, all three together. *What can the health worker say and do? What works and what doesn't work?*

b) Maria is pregnant and has had an HIV test. Now the health worker has received the result – Maria is HIV positive. *How does the health worker tell Maria? What words should the health worker use? What information should be given? How can the health worker find out Maria's concerns?*

c) Nasiba comes to talk to the health worker. She is an educated woman with two young children. Her husband is expected home soon from the city where he has been away working. Last time he came home Nasiba was frightened that he might have become HIV positive and tried to talk to him about using a condom. He became angry and violent and refused to even discuss it. Now Nasiba is even more afraid; what would become of her children if she became HIV positive? Nasiba asks the health worker for advice.

Try acting this out with just Nasiba and her husband, with the health worker and Maria, and with all three of them together. *What can the health worker say and do? What works and what doesn't work?*

## ACTIVITY 3

### ACCEPTABLE BEHAVIOUR

This exercise can be used for small groups where the members trust each other and can agree to keep the exercise confidential. The facilitator should make sure that the exercise is used to challenge stigma and discrimination and not to reinforce negative stereotypes about people living with HIV and AIDS.

Prepare separate pieces of paper with words describing different kinds of sexual behaviour such as unprotected vaginal sex, vaginal sex with a condom, oral sex with a woman, oral sex with a man, group sex, sex with a prostitute, anal sex, sex outside marriage, sex between two men, sex between two women, a man forcing his wife to have sex with him.

Ask the group to sit around a table. Mark one end of the table 'Very Acceptable' and the other end 'Not at all acceptable'.

Each person then selects a piece of paper and places it in a position on the table according to how she or he feels about the activity named. The participants should be asked to say what thoughts and feelings made them decide to place the paper at that point. You could also ask people to discuss how some of their attitudes would affect their work and their relationships with HIV-positive people.

## Safe working practices

Although the risk of health workers becoming HIV positive through their work is very low, all health workers who care for people with HIV and AIDS need to protect themselves.

Midwives, birth attendants, obstetricians and anybody else attending births are at higher risk than other health workers, because of the large amount of blood present during and after delivery. As well as being exposed to HIV, they are also exposed to other serious infectious diseases such as hepatitis B and C, and TB. Health workers need to know what the risks are and how to minimise them.

Like anyone else, health workers can also be at risk from their own or their partner's sexual behaviour. This is likely to put them at much greater risk than their work with HIV-positive patients, yet is often the most difficult to accept.

### Risks at work

HIV can be transmitted from one person to another in blood and other body fluids such as, amniotic fluid (the waters that surround a baby when inside the mother), vaginal and cervical secretions, and breastmilk. HIV cannot be transmitted in saliva, sweat, tears, vomit, urine or faeces, unless blood is visibly present.

- Splashes of HIV-infected blood or body fluid on unbroken skin, presents a **very low risk** of HIV transmission.

- HIV-infected blood or body fluid on cuts or grazes, or in the eye, presents a possible risk if a lot of blood or fluid is in contact with the cut, graze or eye for a significant length of time.
- Needlestick injuries involving HIV-infected blood, where the skin is pierced by a sharp instrument such as a needle or scalpel, present a higher risk, especially if the injury is caused by a hollow needle.

## Preventing accidents

Accidents normally happen during emergencies, when health workers are working quickly. Poor working conditions, such as bad lighting or long working hours, also make accidents more likely. Both individual health workers and managers have responsibility for preventing accidents at work.

## Health workers

Use universal precautions (see box).

- ✓ Handle sharps carefully, especially in emergencies.
- ✓ Use gloves to prevent contact with blood and other body fluids. If necessary, re-use gloves after rinsing in water (not alcohol or disinfectant) and leaving to dry, out of direct sunlight.
- ✓ Only give injections or take samples for laboratory tests when it is really necessary.
- ✓ Avoid episiotomies (cutting the opening to the vagina during labour).

Health workers working in people's homes need to take special care. Poor housing often means that they have to work in dark and crowded rooms. Home deliveries may be particularly difficult. Health workers will have to think ahead about how they and other family members will stay safe in an environment where there may not be a clean water supply or an easy way of disposing of needles. How will the blood of the delivery be cleared up? Who will dispose of the placenta and how? The best answers to these questions will depend on the circumstances, but preparation is needed.

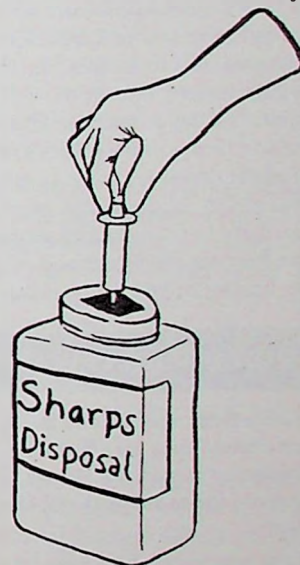
Health workers also need to explain to family members how to protect themselves – make sure that the person washing any clothes from the delivery or disposing of the placenta knows how to do it safely.

## Managers

- ✓ Judge where the greatest risk is: injecting rooms, operating theatres, delivery rooms, laboratories, clean-up departments and mortuaries, and make sure that infection control procedures are followed.
- ✓ Use resources rationally. For example, if supplies of gloves are limited, keep them for activities with the greatest risk of exposure, such as delivery.
- ✓ Make staff safety a priority. If health workers believe that infection at work is unavoidable, they may take unnecessary risks. Some health units have set up infection control committees to reduce the number of accidents.

## UNIVERSAL PRECAUTIONS FOR LABOUR AND DELIVERY

- Cover open cuts, sores or dermatitis with a waterproof dressing.
- Wear gloves whenever there is a risk of contact with blood and body fluids, including when caring for women after delivery, if you may come in contact with lochia (the bloody vaginal discharge which is passed for the first few days after delivery).
- If your skin does come in contact with blood or other body fluids, wash with soap and water straight away.
- Wear glasses or goggles and a mask if there is a risk of blood or amniotic fluid being splashed and always during a caesarean section. Wear a waterproof apron for delivery.
- Always wash hands before and after contact with the woman and after removing gloves.
- Take care to prevent injuries when handling sharps. Handle them as little as possible and use a needle holder when suturing. Do not recap used needles. Do not remove needles from syringes by hand. Do not bend or break them by hand. Hollow needles are the most risky.
- Place used sharps in a puncture-resistant container with a lid (sharps boxes). Keep these as close to the place of use as possible. Sharps boxes can be made from large drug tins, or buckets with a lid.
- During a Caesarean section: wear eye goggles, use double gloves, pass sharps using a receiver rather than hand-to-hand, use needle holders and avoid using the fingers in needle placement.
- Avoid using suction on newborns unless really necessary. If essential, use wall suction if available. The De Lee type of suction apparatus (in which the suction is provided by the health worker's mouth) puts health workers at risk.
- Dispose of solid waste such as blood soaked dressings safely.
- Handle newborn babies with gloves until they have been washed.
- Advise women how to handle and dispose of sanitary pads and rags safely.



- ✓ Remember the needs of cleaners, porters and other auxilliary staff and provide them with the protection and information they need too.
- ✓ Encourage staff to report all exposure incidents and try to make sure that they are treated in a non-judgemental and supportive way.

### After an accident

Even if they are careful, health workers can be vulnerable to an accident at some time in their work which may put them at risk of infection. All health workers need to know what to do after an accident and where to go for help. It may be useful to have this information on a poster on the wall of the clinic or ward (see box).

Health workers who have possibly been exposed to HIV need time to think about the implications of having an HIV test. They need access to trained, confidential counselling and support in making decisions.

### Post-exposure prophylaxis

Antiretroviral treatment after exposure to HIV can reduce the risk of infection. After a needlestick injury with HIV-infected blood, zidovudine alone reduces the risk of HIV transmission from an average of 3 in 1,000 injuries to less than 1 in 1,000. Combination therapy with zidovudine and lamivudine is recommended for deeper injuries and lacerations but is obviously more expensive. It is recommended that all health facilities, particularly those offering ARV treatment to patients, should make drugs available to staff for this purpose. The availability of the drugs, even if they are never used, is likely to make health workers feel safer in their work and reduce the likelihood of substandard care for patients known to be HIV positive.

#### ACTION AFTER AN ACCIDENT

- 1 If body fluids have been spilled, clean them up immediately using soap and water, or a chemical disinfectant if available. Bleach, isopropyl alcohol, povidone iodine and soap will all work to stop the HIV virus.
- 2 If the eyes or skin have been splashed with blood or body fluid, wash them as soon as possible with water (for eyes) and soap (for skin). Do not scrub skin or use disinfectant chemicals as this may cause cuts or grazes.
- 3 If the skin has been cut or pricked, let the wound bleed for two minutes. Then clean with alcohol disinfectant if available (which will burn) for 3-4 minutes. Try to judge the risk of transmission. Unless quite a lot of blood is involved, such as with a hollow needle, there is no need to do any more.
- 4 Report the accident to the manager, so that steps can be taken to avoid similar exposures in the future.

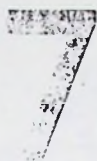
## Making the most of limited resources

People working in the field of HIV in pregnancy will need to make decisions about the best use of the available resources. The following exercise can help health planners, policy makers, health care providers, community leaders, pregnant women and their partners and people living with HIV, plan effective activities.

### ACTIVITY

## HIV INTERVENTIONS

- 1 Get people together in small informal groups and ask them to list, on separate pieces of paper, all the interventions which they believe will reduce the number of pregnant women with HIV within their community or country. These might include:
  - HIV education in schools
  - accessibility and promotion of condoms
  - education activities which focus on men
  - improved status of women
  - health services which diagnose and treat STIs
  - availability of ARV therapy.
- 2 Ask each small group to rank the interventions in order of effectiveness, that is, putting the most effective intervention at the top and the least at the bottom. Each group will then present their list to the larger group.
- 3 In the large group discuss the lists of each group and discuss which of the interventions would be easiest to achieve and which would be the most difficult. The group should also try to identify:
  - particular barriers and how these might be overcome
  - resources required and where they might come from.
- 4 Repeat the whole exercise looking at the interventions which would reduce the risk of mother-to-child transmission of HIV. This time the interventions might include:
  - ARV therapy for pregnant women known to be HIV positive
  - increased availability of voluntary counselling and testing
  - HIV education in schools
  - better information for women on the risks and benefits of breastfeeding
  - accessibility and promotion of condoms.
- 5 Finally, ask participants to agree:
  - What are the priority interventions?
  - What can be done now within existing resources?
  - Who will do it?
  - By when?



## RESOURCES

### BOOKS AND MANUALS

#### Background materials

*A positive woman's survival kit* is written by and for women living with HIV and AIDS. It includes a set of fact sheets on specific subjects such as STIs and reducing mother-to-child transmission. Price: free to readers in developing countries, £7/US\$10.50 elsewhere. Available in English, French and Spanish from: ICW, 2C Leroy House, 468 Essex Road, London N1 3QP. Fax: +44 20 7704 8070. E-mail: info@icw.org

*HIV/AIDS in Southern Africa – The threat to development* highlights the need to integrate HIV prevention with wider development activities. Price: £2.50. Available from: CIIR, Unit 3, Canonbury Yard, 190a New North Road, Islington, London N1 7BJ, England, UK. Fax: +44 20 7359 0017. E-mail: CIIR@CIIR.org

*Clinical Tuberculosis* is a practical, comprehensive and up-to-date guide to the diagnosis of all forms of TB, in both adults and children. Price: £3.50. Available from: TALC, PO Box 49, St Albans, Herts, AL1 4AX, UK. Fax: +44 1727 8453869. E-mail: talcuk@binternet.com

#### Counselling and testing

*Care counselling model: a handbook* designed primarily for HIV/AIDS counsellors working in the field, this book covers pre-test counselling, post-test counselling and ways to mobilise the community. Includes useful exercises to make counsellors aware of new techniques for dealing with clients. Price: free. Available from: SAfAIDS, 17 Beveridge Road, PO Box A509 Avondale, Harare, Zimbabwe. Fax: +263 4 336195. E-mail: info@safaid.org.zw

*Counselling and voluntary HIV testing for pregnant women in high HIV prevalence countries: guidance for service providers* provides an overview of the magnitude of mother-to-child transmission. It looks at both the content of counselling and voluntary testing during pregnancy and the operational issues in setting up and maintaining a service. Price: free. Available from: UNAIDS, CH-1211, Geneva 27, Switzerland. Fax: +44 7914 187. E-mail: unaids@unaids.org. Internet: www.unaids.org

*HIV testing: a practical approach* contains information on HIV testing and counselling services for use in developing countries. Price: free to readers in developing countries, £7.50/US\$15 elsewhere. Available from: Healthlink Worldwide.

#### Infant feeding

*HIV and infant feeding*, a set of three manuals comprising: guidelines for decision-makers, a guide for health care managers and supervisors, and a review of HIV transmission through breastfeeding (WHO/FRH/NUT/CHD). Price: US\$8.30 developing countries, US\$14 elsewhere. Available in developing countries from any UNICEF office or from WHO, CH-1211, Geneva 27, Switzerland. Fax: +41 22 7910746. E-mail: publications@who.int

*Frequently asked questions on: Breastfeeding and AIDS*, a short but useful fact sheet. Price: free. Available from: AED, 1255 23<sup>rd</sup> Street NW, Washington DC, USA. E-mail: linkages@aed.org

#### Safe motherhood

*Care in normal birth: a practical guide* looks at common practices used during labour. It recommends interventions which can support normal birth and points out those which are harmful and should be discontinued (WHO/RHT/MSM/98.3). Price: free. Available from: RHR Documentation Centre, WHO, CH-1211, Geneva 27, Switzerland. E-mail: lambert.s@who.ch. Internet: www.who.int/rht  
*Note: practical guides are also available on postpartum care of mother and newborn; detecting pre-eclampsia; basic newborn resuscitation and preventing prolonged labour (the partograph)*

*Safe Motherhood Initiatives: critical issues*, analyses the successes and failures of safe motherhood initiatives and offers a wide range of perspectives on making pregnancy, childbirth and abortion safer in the future. Price: £8/US\$14 for students/those in developing countries, £24/US\$40 for others. Available from: Blackwell Science Ltd, Osney Mead, Oxford OX2 0EL, UK. Tel: +44 1865 206206. Fax: +44 1865 721205. E-mail: jnl.orders@blacksci.co.uk. Internet: www.blackwell-science.com/rhm

*HIV in pregnancy: a review* is a technical overview of the issues, not written specifically for the developing world. Price: free. Available from: WHO (see above)

#### NEWSLETTERS

Relevant back issues of *Child Health Dialogue* (CHD) and *AIDS Action* (AA) are:

CHD8 Safe motherhood (1997)

CHD12 HIV and children (1998)

CHD14 Reducing mother-to-child HIV transmission (special supplement, 1999)

CHD18 Strengthening safe motherhood (2000)

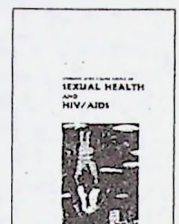
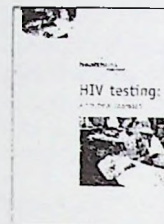
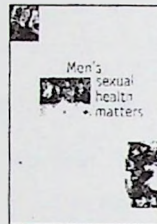
AA38 HIV and its impact on health workers (1997)

AA43 Improving access to care (1999)

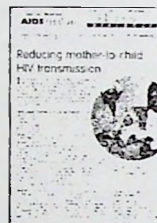
Please write to Healthlink Worldwide stating which issues you require.

# Other free and low cost practical publications from Healthlink Worldwide

## AIDS and Sexual Health



## Child Health



## Disability



## Health Policy



For further details and to receive a copy of Healthlink Worldwide's Publications List, please contact:

Healthlink Worldwide (HIVSAFEM)

Cityside

40 Adler Street

London E1 1EE, UK

Telephone +44 20 7539 1570

Fax +44 20 7539 1580

E-mail [info@healthlink.org.uk](mailto:info@healthlink.org.uk)

or visit our website at [www.healthlink.org.uk](http://www.healthlink.org.uk)

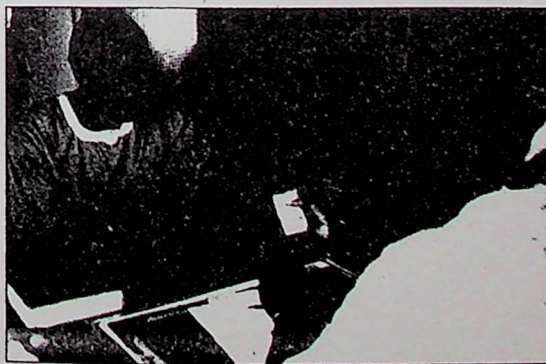


*HIV and safe motherhood* is aimed at all those working in health, family planning and women's organisations in sub-Saharan Africa. It provides practical information to strengthen communication with women who are vulnerable to and affected by HIV, to help them keep themselves and their infants healthy. It calls for efforts to prevent HIV transmission among women and infants to be approached within the context of wider Safe Motherhood initiatives.



Healthlink Worldwide  
Cityside  
40 Adler Street  
London E1 1EE, UK

Telephone +44 20 7539 1570  
Fax +44 20 7539 1580  
E-mail [info@healthlink.org.uk](mailto:info@healthlink.org.uk)  
<http://www.healthlink.org.uk>



**3**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

## **New Data on the Prevention of Mother-to-Child Transmission of HIV and their Policy Implications**

### **Conclusions and recommendations**

WHO Technical Consultation on Behalf of the  
UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on  
Mother-to-Child Transmission of HIV

Geneva, 11-13 October 2000

Approved: 15 January 2001

## Contents

Introduction .....	1
Objectives.....	3
Participants.....	4
Background information .....	4
Conclusions and recommendations on the use of antiretrovirals.....	5
Short term efficacy of ARV prophylactic regimens .....	5
Long-term efficacy of ARV prophylactic regimens .....	5
Safety of ARV prophylactic regimens .....	5
Selection of resistant viral populations .....	6
Women who received a sub-optimal antepartum regimen.....	7
Scaling-up MTCT-prevention programmes and choice of ARV regimen.....	7
Conclusions and recommendations regarding infant feeding .....	7
Risks of breastfeeding and replacement feeding:.....	7
Cessation of breastfeeding .....	8
Infant feeding counselling.....	9
Breast health.....	10
Maternal health.....	10
Identified needs for research .....	12
References .....	15
Abbreviations .....	19
Participants .....	20

## Introduction

Mother-to-child transmission (MTCT) of HIV is the most significant source of HIV infection in children below the age of 10 years. The strategy recommended by the United Nations agencies to prevent mother-to-child transmission of HIV includes: (1) the primary prevention of HIV infection among parents to be, (2) the prevention of unwanted pregnancies in HIV-infected women, and (3) the prevention of HIV transmission from HIV-infected women to their infants. While the best ways to prevent HIV infection in infants remain primary prevention of HIV infection and reduction of unwanted pregnancies among women who are infected with HIV, many HIV-infected women become pregnant. In 1994 a long and complex regimen of the antiretroviral drug Zidovudine (ZDV) taken 5 times daily from the 14<sup>th</sup> week of pregnancy and intravenously during labour was shown to reduce the risk of transmission from mother to child by two-thirds, from 26% to 8%. This regimen had little practical value in developing countries and more appropriate short course ZDV regimens starting later in pregnancy were evaluated and also shown to be effective. Other interventions shown to prevent transmission of HIV include elective caesarean section and the avoidance of breastfeeding. While these interventions have become standard practice in developed countries, they are not always practical or safe in resource-limited settings.

Following release of results in 1998 that a short course ZDV regimen starting from 36 weeks of pregnancy reduced the rate of transmission of HIV by 50%, a comprehensive strategy for MTCT-prevention was developed.<sup>a</sup> Considerable experience has been obtained with pilot intervention projects, many initiated by UNICEF under the umbrella of the UN Inter-Agency Task Team (IATT) on Mother-to-Child Transmission (MTCT). The entry point to the interventions is voluntary counselling and testing (VCT) for HIV, followed by ZDV from 36 weeks and during labour to mothers who are HIV-infected, and counselling on infant feeding options. More recent clinical trials have shown that other short-course ARV regimens using ZDV, the combination ZDV + Lamivudine (3TC), and Nevirapine are also effective in reducing the risk of transmission.

MTCT-prevention interventions should not stand in isolation, but be integrated where possible into existing health care infrastructures and reproductive health services. Moreover, the interventions should be seen as part of a wider response to HIV/AIDS, which includes expanding access to care and support for HIV-infected mothers and their families, including treatment of opportunistic infections and accelerating access to HIV treatment.

While the efficacy of ARV regimens in reducing the risk of HIV transmission is important, other issues need to be considered about the use of ARVs in MTCT-prevention interventions:

- *Practicality and effectiveness.* The selection process for enrolment and individual monitoring in clinical trials produce ideal conditions for women to access, and adhere to the treatment under study. These ideal conditions are seldom achieved once the treatment is expanded to a wider population in implementation

---

<sup>a</sup> WHO Weekly Epidemiological Record, 1998: 73, 313-320

programmes and the actual reduction in the rate of mother-to-child transmission achieved (effectiveness) is likely to be less than that observed in clinical trials (efficacy). The effectiveness of antiretroviral regimens that are the more practical and simpler to administer should be close to their efficacy observed from clinical trials while the effectiveness of regimens complex and difficult to administer may be considerably less.

- *Safety:* For the women and infants who are offered antiretroviral prophylaxis, the risks of exposure to one or more drugs must be balanced by the benefit of preventing transmission of a fatal infection in the infant. In randomized controlled trials the incidence of adverse events can be compared between the treated and untreated groups, providing good comparative data on safety. However, observational studies and long-term monitoring of exposed mothers and infants are an important additional source of information that better reflects the actual conditions under which the ARV regimens are used.
- *Drug Resistance.* Drug resistance has been reported in some women exposed to short course antiretroviral regimens used for MTCT-prevention. The implications of such resistance are uncertain and need to be considered in the context of increasing access to ARV treatment for patients in developing countries.

There is continued concern that up to 20% of infants born to HIV-infected mothers may acquire HIV through breastfeeding, depending on duration and other risk factors. Replacement feeding<sup>b</sup> is the only way to completely avoid post-natal HIV transmission; however, this may not be possible in many locations in the developing world. Despite the risk of HIV transmission, breastfeeding provides appropriate nutrition, passively conveys protection against some micro-organisms including respiratory and gastrointestinal pathogens, and is more economical. Exclusive breastfeeding<sup>c</sup> provides the infant's complete nutritional needs up to the age of four to six months, and delays the return of fertility playing an important role in birth spacing. To protect breastfeeding from commercial influences, the World Health Assembly adopted the International Code of Marketing of Breastmilk Substitutes, now implemented world wide. UNICEF and WHO launched the Baby Friendly Hospital Initiative to improve maternity services so that they protect, promote, and support breastfeeding.

Breastfeeding remains the best source of nutrition for the great majority of infants and should continue to be promoted and supported among mothers who are not known to be HIV-infected. Implementation of the Code of Marketing in national legislation and regulations provides protection to all women and their infants, whether or not they are breastfed.

---

<sup>b</sup> *Replacement Feeding* is defined as the process of feeding a child, who is not receiving any breast milk, with a diet that provides all the nutrients the child needs.

<sup>c</sup> *Exclusive Breastfeeding* is defined as giving an infant no other food or drink, not even water, apart from breast milk (including expressed breast milk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.

New information on MTCT-prevention has emerged since WHO issued guidance on the choices of ARV regimens<sup>d</sup> and the risks of HIV transmission through breastmilk.<sup>e</sup> Important new research data related to the long-term efficacy and safety of different ARV regimens, to the dynamics and clinical implications of viral resistance, and to the role of infant feeding practices were published or presented at the 13<sup>th</sup> International AIDS Conference in Durban, South Africa in July 2000. In addition, considerable experience has accumulated over the past two years from pilot implementation of MTCT-prevention programs in resource-limited settings. In particular, programme managers have identified problems implementing current recommendations on HIV and infant feeding and have asked for clarification.

On behalf of the Inter-Agency Task Team on MTCT, WHO's Department of Reproductive Health and Research, in collaboration with the HIV/STI Initiative and the Department of Child and Adolescent Health, convened a Technical Consultation on new data on the prevention of MTCT and their policy implications. The objective was to review recent scientific data and update current recommendations on the provision of ARVs and infant feeding counselling. The Technical Consultation focused on these two components, although it was recognized that many other components are important for a comprehensive package for MTCT-prevention.

### *Objectives*

The specific objectives of the meeting were:

1. To review the most recent scientific data on the use of ARV regimens to prevent MTCT, including issues of efficacy, safety, drug resistance and factors affecting optimal choices of ARV regimens in different settings;
2. To consider developments and likely time frame for access to and use of antiretroviral drugs for the treatment of HIV infection in resource-limited settings and the likely impact that MTCT-prevention programmes may have on the effectiveness of such treatments;
3. To review evidence on risks and benefits for mother and infant of breastfeeding, including exclusive breastfeeding, and of replacement feeding, and consider issues

---

<sup>d</sup> Available on UNAIDS Web site <http://www.unaids.org/publications/documents/mtct/index.html>

- WHO/UNAIDS recommendations on the safe and effective use of short-course ZDV for prevention of mother-to-child transmission of HIV (*WHO Weekly Epidemiological Record* 1998, 73, 313-320).
- Technical Working Group Meeting to Review New Research Findings for the Prevention of Mother-to-Child Transmission of HIV. Geneva, 10-11 August 1999.
- Use of Nevirapine to Reduce Mother-to-Child Transmission of HIV (MTCT). WHO Review of Reported Drug Resistance. Geneva 24 March 2000.

<sup>e</sup> Available on UNAIDS Web site <http://www.unaids.org/publications/documents/mtct/index.html>

- HIV and Infant Feeding: A Policy Statement Developed Collaboratively by UNAIDS, UNICEF and WHO. May 1997.
- HIV and Infant Feeding: a Guide for Health-Care Managers and Supervisors, Guidelines for Decision-Makers and Review of HIV Transmission through Breastfeeding. Jointly issued by UNICEF, UNAIDS and WHO. June 1998.
- HIV and Infant Feeding: WHO, UNICEF, UNAIDS Statement on Current Status of WHO/UNAIDS/UNICEF Policy Guidelines. 4 September 1999.

in conveying complex information on risks and benefits of different feeding options to mothers and enabling informed choice;

4. To review, and revise if necessary, existing UN agency policies on choices of ARV regimens and infant feeding guidelines and counselling in MTCT-prevention programs in resource-limited settings;
5. List outstanding research questions on the prevention of MTCT using ARV regimens or through infant feeding.

### *Participants*

Participants included expert scientists and programme managers from the African region (11), Asia (2), Latin America (1), The Caribbean (1), Europe (4) and the USA (2), HIV-infected mothers (2), collaborating agency scientists (6), representatives from non-governmental organizations implementing MTCT-prevention programs (6) and UN agencies (UNAIDS, UNFPA, UNICEF, WHO). The full list of participants is given at the end of the report.

### *Background information*

Background papers that were prepared for the consultation, presented in plenary sessions and discussed in the sub-groups, included:

- Munjanja S. Antiretroviral regimens for the prevention of MTCT: the programmatic implications.
- Farley TMM, Buyse D, Gaillard P, Perriens J. Efficacy of antiretroviral regimens for prevention of MTCT and some programmatic issues.
- Mofenson L, Munderi P. Safety of antiretroviral prophylaxis of perinatal transmission on HIV-infected pregnant women and their infants.
- Nájera R. MTCT and antiretroviral drug resistance.
- Fowler MG, Newell ML. Breastfeeding, HIV transmission and options in resource poor settings.

These papers are available on the WHO and UNAIDS web sites<sup>f</sup> together with a summary of information presented during the discussion.

The conclusions and recommendations from this meeting are given below. They will be reconsidered as new information becomes available.

---

<sup>f</sup> Available on WHO Department of Reproductive Health and Research web site:  
<http://www.who.int/reproductive-health/>  
and on UNAIDS web site: <http://www.unaids.org/publications/documents/mtct/index.html>

## Conclusions and recommendations on the use of antiretrovirals

### *Short term efficacy of ARV prophylactic regimens*

Several antiretroviral regimens evaluated in randomized controlled clinical trials showed short-term efficacy, as determined by infant infection status at 6-8 weeks.<sup>1-8</sup> This reflects the reduction of *in utero*, intrapartum and early postpartum transmission.

- The drugs used in the effective antiretroviral prophylaxis regimens evaluated included zidovudine (ZDV) alone, ZDV + Lamivudine (3TC), and Nevirapine.
- All regimens include an intrapartum component, with varying durations of antepartum and/or postpartum treatment (see table).
- The most complex effective regimen includes antepartum/intrapartum/postpartum ZDV, while the simplest effective regimen includes single dose intrapartum/postpartum Nevirapine.
- The mechanisms by which these regimens provide protection against mother to child HIV transmission include decrease of viral replication in the mother and/or prophylaxis of the infant during and after exposure to virus.

### *Long-term efficacy of ARV prophylactic regimens*

Short-course ZDV, ZDV + 3TC, and Nevirapine have been evaluated in breastfeeding populations. Long-term efficacy as measured by infant infection status through 12 to 24 months has been demonstrated for short-course ZDV and Nevirapine regimens,<sup>9,10</sup> showing that the early reduction in HIV transmission persists despite continued exposure to HIV during breastfeeding. Analysis of long-term efficacy of the ZDV + 3TC regimens is in progress.<sup>5</sup>

### *Safety of ARV prophylactic regimens*

Short-term safety and tolerance of the effective antiretroviral prophylactic regimens has been demonstrated in all the controlled clinical trials,<sup>1-4,6-8,10-12</sup> while collection of long-term safety data is ongoing.

- In the controlled clinical trials, the effective antiretroviral prophylaxis regimens have not been associated with an excess of severe adverse events (including mortality) compared with the control arms in HIV-infected women or their children.<sup>1-4,10,13,14</sup>
- Normal growth, neurologic development, and immunologic parameters have been demonstrated in industrialized countries in uninfected children with in utero/neonatal exposure to ZDV compared to those without such exposure.<sup>15</sup>
- HIV-related disease progression in mothers does not appear to be altered by receipt of prophylactic antiretroviral regimens.<sup>16</sup>
- There have not been significant differences in HIV disease progression or mortality in children who became infected despite receipt of prophylaxis

compared with infants who became infected in the control arms in the clinical trials.<sup>17,18</sup>

- In the randomized, controlled clinical trials the only adverse effect attributable to drug exposure was mild transient anaemia in infants receiving ZDV-containing regimens.<sup>1-4,7,11,13,17</sup>
- Mitochondrial dysfunction has been reported to occur in a small number of infants in France exposed in utero or neonatally to nucleoside reverse transcriptase inhibitor (ZDV or ZDV/3TC),<sup>19</sup> but no similar findings were reported following an extensive review of deaths in a cohort of 16,000 infants in the USA,<sup>20</sup> nor in the PETRA study.<sup>21</sup> However, neither of these studies did specific laboratory assessment for mitochondrial dysfunction. Non-nucleoside reverse transcriptase inhibitor drugs, like Nevirapine, do not inhibit mitochondrial DNA polymerase and therefore should not be associated with such toxicity.<sup>22</sup>

*Conclusion:* The WHO Technical Consultation concluded that benefit of these drugs in reducing mother-to-child HIV transmission greatly outweighs any potential adverse effects of drug exposure.

#### *Selection of resistant viral populations*

Selection for pre-existing resistant viral populations or development of new mutations may occur with all antiretroviral drugs or drug regimens that do not fully suppress viral replication. However, this is more likely to rapidly occur with drugs in which a single mutation is associated with development of drug resistance; such drugs include 3TC (with and without concomitant ZDV treatment) and Nevirapine.<sup>22-24</sup> Virus containing drug resistant mutations decreases in amount once antiretroviral drug prophylaxis is discontinued, and wild type virus dominates.<sup>25</sup> However, the mutant virus may remain present in an individual at very low levels.

- This could decrease antiviral effectiveness of future treatment with antiretroviral regimens that contain the same drug, or drugs within the same class, as that used for prophylaxis.
- It is unknown if such low-level drug resistance would affect the efficacy of the antiretroviral prophylaxis regimen if used in a subsequent pregnancy.
- There is currently no evidence that drug-resistant viruses are more transmissible than non-resistant viruses.
- There are currently no data to indicate that drug-resistant viruses are more virulent than non-resistant viruses.

*Conclusion:* The WHO Technical Consultation concluded that the benefit of decreasing mother-to-child HIV transmission with these antiretroviral drug prophylaxis regimens greatly outweighs concerns related to development of drug resistance.

### ***Women who receive a sub-optimal antepartum regimen***

For antiretroviral prophylaxis regimens that include an antepartum component, the minimum duration of antepartum treatment necessary for protection is not defined. However, it is likely that a major mechanism for effective antepartum prophylaxis is reduction in maternal viral load, which is likely to require at least one to two weeks of treatment.<sup>4,6</sup>

**Recommendation:** For women receiving prophylactic regimens that include an antepartum component and who have received less than two weeks of ZDV antepartum treatment, prophylaxis with six weeks ZDV to the infant, intrapartum/postpartum ZDV + 3TC, or the two-dose Nevirapine regimen may be considered.<sup>5-8</sup>

### ***Scaling-up MTCT-prevention programmes and choice of ARV regimen***

Since the last WHO Technical Consultations on prevention of mother-to-child HIV transmission with antiretroviral prophylaxis, important new data have become available related to long-term efficacy and safety of these regimens. Additionally, longitudinal assessment has demonstrated that antiretroviral resistant virus detected at 6 weeks postpartum was no longer detectable when reassessed at 12 months postpartum. Furthermore, the presence of detectable resistant virus was not associated with either increased mother-to-child HIV transmission or increased mortality in infants who became infected despite prophylaxis.<sup>25</sup>

**Conclusion:** The WHO Technical Consultation concluded that implementation of any of the antiretroviral prophylaxis regimens shown to be effective in randomized clinical trials (ZDV, ZDV + 3TC, or Nevirapine regimens) can be recommended for general implementation. There is currently no justification to restrict use of any of these regimens to pilot project or research settings.

**Recommendation:** The local choice for the antiretroviral prophylactic regimen to include in the standard package of care should be determined by issues of feasibility, efficacy and cost. Considerations that contribute to decisions regarding the composition of the standard prophylactic package include: proportion of women attending antenatal care; time of initiation of antenatal care; frequency of antenatal visits; type of HIV voluntary counselling and testing available; logistics and acceptability of antiretroviral prophylaxis administration; and cost of drugs.

**Recommendation:** The prevention of mother-to-child HIV transmission should be part of the minimum standard package of care for women who are known to be HIV infected and their infants.

## **Conclusions and recommendations regarding infant feeding**

### ***Risks of breastfeeding and replacement feeding:***

The benefits of breastfeeding are greatest in the first six months of life (optimal nutrition, reduced morbidity and mortality due to infections other than HIV, and delayed return of fertility).<sup>26-34</sup>

Exclusive breastfeeding during the first 4-6 months of life carries greater benefits than mixed feeding with respect to morbidity and mortality from infectious diseases other than HIV.<sup>27,29,35,36</sup>

Although breastfeeding no longer provides all nutritional requirements after six months, breastfeeding continues to offer protection against serious infections and to provide significant nutrition to the infant (half or more of nutritional requirements in the second six months of life, and up to one third in the second year).<sup>37</sup>

Replacement feeding carries an increased risk of morbidity and mortality associated with malnutrition and associated with infectious disease other than HIV. This is especially high in the first 6 months of life and decreases thereafter. The risk and feasibility of replacement feeding are affected by the local environment and the individual woman's situation.<sup>38-41</sup>

Breastfeeding is associated with a significant additional risk of HIV transmission from mother to child as compared to non-breastfeeding. This risk depends on clinical factors and may vary according to pattern and duration of breastfeeding. In untreated women who continue breastfeeding after the first year, the absolute risk of transmission through breastfeeding is 10-20%.<sup>42-45</sup>

The risk of MTCT of HIV through breastfeeding appears to be greatest during the first months of infant life but persists as long as breastfeeding continues. Half of the breastfeeding-related infections may occur after 6 months with continued breastfeeding into the second year of life.<sup>9,44,45</sup>

There is evidence from one study that exclusive breastfeeding in the first 3 months of life may carry a lower risk of HIV transmission than mixed feeding.<sup>46</sup>

#### *Recommendations:*

- When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended.
- Otherwise, exclusive breastfeeding is recommended during the first months of life.
- To minimize HIV transmission risk, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition).
- When HIV-infected mothers choose not to breastfeed from birth or stop breastfeeding later, they should be provided with specific guidance and support for at least the first 2 years of the child's life to ensure adequate replacement feeding. Programmes should strive to improve conditions that will make replacement feeding safer for HIV-infected mothers and families.

#### *Cessation of breastfeeding*

There are concerns about the possible increased risk of HIV transmission with mixed feeding during the transition period between exclusive breastfeeding and complete cessation of breastfeeding. Indirect evidence on the risk of HIV transmission through

mixed feeding, suggests that keeping the period of transition as short as possible may reduce the risk.

Shortening this transition period however may have negative nutritional consequences for the infant, psychological consequences for the infant and the mother, and expose the mother to the risk of breast pathology which may increase the risk of HIV transmission if cessation of breastfeeding is not abrupt.

The best duration for this transition is not known and may vary according to the age of the infant and/or the environment.

*Recommendation:* HIV-infected mothers who breastfeed should be provided with specific guidance and support when they cease breastfeeding to avoid harmful nutritional and psychological consequences and to maintain breast health.

### *Infant feeding counselling*

Infant feeding counselling has been shown to be more effective than simple advice for promoting exclusive breastfeeding in a general setting.<sup>47-50</sup> Good counselling may also assist HIV-infected women to select and adhere to safer infant feeding options, such as exclusive breastfeeding or complete avoidance of breastfeeding, which may be uncommon in their environment. Effective counselling may reduce some of the breast health problems which may increase the risk of transmission.

Many women find that receiving information on a range of infant feeding options is not sufficient to enable them to choose and they seek specific guidance. Skilled counselling can provide this guidance to help HIV-infected women make a choice that is appropriate for their situation to which they are more likely to adhere. The options discussed during counselling need to be selected according to local feasibility and acceptability.

The level of understanding of infant feeding in the context of MTCT in the general population is very limited, thus complicating efforts to counsel women effectively.

The number of people trained in infant feeding counselling is few relative to the need and expected demand for this information and support.

### *Recommendations:*

- All HIV-infected mothers should receive counselling, which includes provision of general information about the risks and benefits of various infant feeding options, and specific guidance in selecting the option most likely to be suitable for their situation. Whatever a mother decides, she should be supported in her choice.
- Assessments should be conducted locally to identify the range of feeding options that are acceptable, feasible, affordable, sustainable and safe in a particular context.
- Information and education on mother-to-child transmission of HIV should be urgently directed to the general public, affected communities and families.

DIS-325

06893

001

- Adequate numbers of people who can counsel HIV-infected women on infant feeding should be trained, deployed, supervised and supported. Such support should include updated training as new information and recommendations emerge.

### ***Breast health***

There is some evidence that breast conditions including mastitis, breast abscess, and nipple fissure may increase the risk of HIV transmission through breastfeeding, but the extent of this association is not well quantified.<sup>51-53</sup>

*Recommendation:* HIV-infected women who breastfeed should be assisted to ensure that they use a good breastfeeding technique to prevent these conditions, which should be treated promptly if they occur.

### ***Maternal health***

In one trial, the risk of dying in the first 2 years after delivery was greater among HIV-infected women who were randomized to breastfeeding than among those who were randomized to formula feeding.<sup>54</sup> This result has yet to be confirmed by other research.

Women who do not breastfeed or stop breastfeeding early are at greater risk of becoming pregnant.

*Recommendation:* HIV-infected women should have access to information, follow-up clinical care and support, including family planning services and nutritional support. Family planning services are particularly important for HIV-infected women who are not breastfeeding.

## Regimens of proven efficacy (randomized controlled clinical trials)

Study	Drug	Antepartum			Intrapartum	Postpartum/postnatal	
		14-28 wks	28-36 wks	>36 wks	Labour	1 wk PP	1-6 wks PP
ACTG 076	ZDV						Infant
Harvard Thai	ZDV						Infant
Harvard Thai	ZDV					Infant	
Harvard Thai	ZDV						Infant
Harvard Thai	ZDV					Infant	
DITRAME	ZDV					Mother	
CDC	ZDV						
PETRA Arm A	ZDV + 3TC					Mother and Infant	
PETRA Arm B	ZDV + 3TC					Mother and Infant	
HIVNET/SAINT	NVP					Infant	

4

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



**The World Health Organization**



**Draft Working Document**

**KEY ELEMENTS IN  
HIV/AIDS CARE AND SUPPORT**

**WHO/UNAIDS**

**8 September 2000**

## CONTENTS

1. Introduction
2. Care Needs
3. Principles and Values
4. Key Interventions for Care and Support
5. Structural Elements for Service Delivery
6. Prioritisation

**Appendix: List of Abbreviations**

AFRO:	Regional Office for Africa
AIDS:	Acquired immuno-deficiency syndrome
ARV:	Antiretroviral
CBO:	Community based organisation
DOT:	Directly observed therapy
GIPA:	Greater involvement of people living with AIDS.
HAART:	Highly active antiretroviral therapy
HIV:	Human immuno-deficiency virus
MTCT:	Mother-to-child transmission
NGO:	Non-governmental organisation
OI:	Opportunistic infection
PAHO:	Pan American Health Organization
PLHA:	People living with HIV/AIDS
SEARO:	South East Regional Office
STI:	Sexually transmitted infection
TB:	Tuberculosis
UNAIDS:	Joint United Nations Programme on HIV/AIDS
VCT:	Voluntary counselling and testing
WHO:	World Health Organization

## **1. INTRODUCTION**

### **Purpose**

A lot of publications have been produced on care for people living with HIV/AIDS. This document attempts to bring key issues on HIV/AIDS care in one practical and concise publication. It is intended to provide guidance to all partners in the provision of HIV care and support in resource-constrained settings. The purpose of this document is to identify the key elements and interventions in provision of care and support for PLHA and affected communities. Each element of care is discussed and references for more information on how this element should be implemented are provided as much as possible. These references will be interactive for those documents having an electronic file available in WHO or in UNAIDS Secretariat websites. These references are practical publications useful for the implementation of the key elements of HIV/AIDS care. This document also covers structural elements for service delivery. Finally, it discusses prioritization of the various elements of HIV/AIDS care: these two sections are helpful in the process of prioritization and implementation of HIV/AIDS care interventions listed in this document.

### **Target audience**

The intended audience of this document is policy makers in health care (e.g., senior officials in government ministries, directors of health and medical services, district health officers, National AIDS Control Programme managers) and related sectors such as education, transport and finance. It is also directed to implementers of health policies or care providers (physicians and other clinicians, including nurses, social workers and counsellors), people living with and affected by HIV/AIDS, non-governmental organisations, multi/bilateral aid agencies, UN agencies and other partners working in provision of HIV/AIDS care and support.

### **Link to other documents**

Following the resolution adopted by the WHO Executive Board in January 2000 and by the World Health Assembly in May 2000, WHO is developing a Global Health Sector Strategy

for improving health systems response to HIV/AIDS and Sexually Transmitted Infections<sup>1</sup>. This strategy has been developed within the framework of the UNAIDS Global HIV/AIDS Strategy<sup>2</sup>. The present paper represents a contribution toward the discussion surrounding the development of these global strategies, from a care and support perspective, and each country will need to adapt these key elements in HIV/AIDS care and support to its own realities.

## 2. CARE NEEDS

### 2.1. Epidemiology and background

At the end of 1999, there were 33.6 million people living with HIV/AIDS. More than 95% of them live in developing countries. The epidemic is continuing to spread globally, with 5.4 million newly infected people in 1999. The cumulative number of deaths due to HIV/AIDS is 18.8 million. 2.8 million deaths due to HIV/AIDS occurred in 1999. HIV/AIDS is the leading cause of death in sub-Saharan Africa where two-thirds of all PLHA are found<sup>3</sup>.

Worldwide, the main burden of disease in PLHA arises from a limited number of common infections - and their complications - to which PLHA are particularly susceptible, namely tuberculosis, pneumonia, diarrhoea and candida infection of the mouth and throat.

Tuberculosis is worldwide the single biggest killer of PLHA.

Appreciation and understanding of the care and support needs of PLHA are essential in order to develop relevant and adequate care responses. Studies have revealed that needs of PLHA go beyond clinical care and treatment. PLHA's needs also include, for the most part, social support to alleviate the socio-economic impact of HIV (e.g. basic needs for food, school fees and shelter), psychological support to cope with the implications of having a life-threatening condition, PLHA's right to protection in employment, to confidentiality, to medical care and access to new treatments, counselling, emotional, protection against discrimination and stigma, social support for their orphans left behind after the patients die, etc.

<sup>1</sup> Global Health Sector Strategy for Responding to HIV/AIDS, WHO, 2000 (draft)

<sup>2</sup> Global HIV/AIDS Strategy Framework, UNAIDS, 2000 (preliminary draft for discussion)

<sup>3</sup> Report on the global HIV/AIDS epidemic, UNAIDS, June 2000

### 2.1.1. The need to strengthen responses

Health systems face increasing challenges in providing care and support for PLHA. When one looks at the impact of HIV/AIDS on the health care system, several observations can be noted: for instance, HIV/AIDS lays additional burdens on the already over-stretched health services and reduces the capacity of health systems to adequately respond to other health challenges. Demand for health services increases due to the increasing numbers of individuals who become ill as a result of HIV infection. This results in increased workload and congestion of health facilities. Hospital bed occupancy rates have increased with over 55% of beds occupied by PLHA in several most affected countries. In addition to demand for hospital beds, consumption of medical supplies and drugs has increased.

HIV infection has given rise to a concurrent epidemic of tuberculosis, which requires additional efforts and resources to address.

The output of health workers in some high prevalence countries can be substantially reduced by HIV/AIDS because of illness and death among health workers; need to care or attend funerals for family members or relatives; burn-out due to overwork; and the fear of perceived risk of occupational transmission of HIV infection.

Some clinical conditions become much more difficult to diagnose and to treat when associated with HIV/AIDS. This and the chronic nature of HIV/AIDS disease translate into increased cost of care to both the service and the users.

Difficulties experienced in resource-constrained settings include:

- low priority for financial support to the health sector nationally and internationally (very small proportion of health budget in most affected countries)
- insufficient remuneration and support for care professionals
- serious managerial weaknesses in health sector at all levels
- irregular and inadequate supplies of drugs, reagents, and equipment,
- lack of investment in buildings infrastructure.
- local production of drugs and other commodities insufficient given the weakness of local pharmaceutical manufacturers and markets and patent protection

Insufficient response to PLHA needs may also be explained by the following factors:

- Within the national and health budgets, HIV care has low priority.
- Sometimes, health reforms and globalisation do not allow for a strong emphasis on HIV care.
- Loss of staff due to burn-out.
- Shortage of relevant HIV information and HIV training opportunities,
- Essential drug lists and drugs procurement not adapted to needs of PLHA.
- Loss of staff due to high HIV-related mortality and morbidity among staff,
- Increasing demand while resources are decreasing.

All these factors lead to inadequate provision of care not only to PLHA but also to other patients.

## 2.2. Objectives

The **goals** of providing a care and support for PLHA are to:

- reduce HIV-related mortality and morbidity,
- improve the quality of life for PLHA, and
- improve the survival of PLHA.

**Specific objectives** are:

- to strengthen HIV prevention ,
- to expand greater involvement of PLHA (GIPA),
- to reduce the impact of HIV on the TB and HIV-related diseases,
- to mitigate the socio-economic and psychologic impact of HIV on individuals, families, communities, countries and society at large, and
- to improve HIV care for vulnerable populations such as young people, pregnant mothers, drug users and orphans, whose access to care is limited.

## 2.3. Rationale for Care and Support

- The consensus about the importance of care highlighted the fact that health care is a **human right**.
- Access to care and support also **contributes to the prevention of HIV infection**. Care provision offers an opportunity to discuss with the client and significant others how they might prevent further spread of the infection, and support them in their choices to do so, e.g. by availing access to interventions that reduce mother to child transmission of HIV, enabling them to increase their safety as a sexual partners through safe sex and condom use, and through use of antiretroviral therapy.
- Care and support for PLHA **decreases the spread of infectious diseases** that are common among HIV-infected people, in particular TB and STIs by early diagnosis and treatment of these conditions.
- By caring openly and compassionately for HIV infected people, their care-givers alleviate the fear of their community for HIV infection, and **alleviate stigma and discrimination**.
- **Social and economic benefits** of care and support for PLHA arise from recognising that when PLHA live longer and healthier, the loss of income for themselves and their families is postponed, and the future of their dependents will be better. And, the economy will benefit through the better performance of its workforce.
- **Care and support for PLHA builds confidence and hope in clients**: if the quality of life of PLHA improves as a result of care and support, **hope** will be instilled to the benefit of the individual and the family, and as a result to the society at large.
- Care and support for PLHA **supports the Greater Involvement of People living with HIV/AIDS (GIPA) in the fight against the epidemic**. Beyond opening the possibility of involving PLHA in policy and decision making, and target action against the epidemic with more precision, GIPA enables the personalization of HIV infection in

provision of health care, prevention, peer counselling, community care and HIV/AIDS advocacy. This makes non-infected people, institutions and policy makers realize that HIV is also their problem, and motivates them to do something about it.

### 3. PRINCIPLES AND VALUES

To meet the physical, emotional, social and economic needs of PLHA, care and support should be governed by the following principles and values:

- **Respect** for human rights, ethics, confidentiality, informed consent, privacy, and individual dignity. Human rights and ethical practices apply equally to PLHA as to other individuals. Fighting discrimination, enhancing respect of individual autonomy and human dignity, and pursuing informed consent are all relevant to HIV care and support.
- **Equity:** affordable care of acceptable quality should be provided to all people regardless of gender, age, race, ethnicity, sexual identity, income and place of residence. More attention should be given to those groups of the population that have more problems to access care: widows and orphans, pregnant women, children, the elderly, the uneducated and the poor.
- **Quality of care:** care should be of good quality. Interventions and services have maximum benefit if they are of good quality. There ought to be continuous improvement in quality of the services. Quality can be measured in terms of the nature of services provided and in the specific interventions. Measures of quality of services include indicators such as waiting time, attitude of health workers and the type of facilities available. Indicators of specific interventions include compliance with recognized standards in administering the interventions. Quality of services is a strong indicator of how responsive the services are to the expectations of the people.
- **Efficiency and effectiveness:** care should be provided at reasonable societal costs. Resources invested should be result-oriented and there should be corresponding concrete quantifiable results. Efficiency considerations fuel the need to coordinate and integrate health systems so as to ensure the continuity of service delivery among different providers and different levels of care.
- **Accessibility and availability:** all levels of the health system should make care accessible to as many people as possible. The provision of care appropriate to the

resources available and levels of HIV prevalence need to be decided through local consensus building that involves the whole community. This requires regular review with all stakeholders.

- **Sustainability:** initiatives in provision of care and support will remain meaningful – and other principles of care and support will only be viable - where they are embedded in a sustainable programme of provision. This requires taking into account human, logistic and financial resource requirements.

## 4. KEY INTERVENTIONS FOR HIV/AIDS CARE AND SUPPORT

There exist several cost-effective HIV/AIDS care interventions for which evidence has been documented. Key activities for HIV/AIDS care and support are presented below in Table 1 and are grouped according to their complexity and cost. It should be noted that HIV testing of transfusion blood, the promotion of universal precautions, and health policy activities, such as the regulation of care delivery and the drugs supply, should be undertaken everywhere, and are thus also essential health sector activities.

Table 1 : Care and Support activities, according to need, complexity and cost	
Essential activities	<ul style="list-style-type: none"> <li>• HIV voluntary counselling and testing</li> <li>• Psychosocial support for PLHA and their families</li> </ul>
	<ul style="list-style-type: none"> <li>• Palliative care and treatment for common OIs : pneumonia, oral thrush, vaginal candidiasis and pulmonary TB (DOTS)</li> <li>• Nutritional care</li> <li>• STI care and family planning services</li> <li>• Cotrimoxazole prophylaxis among HIV-infected people</li> <li>• Recognition and facilitation of community activities that mitigate the impact of HIV infection (including legal structures against stigma and discrimination)</li> </ul>
Care and support activities of intermediate complexity and/or cost	<b>ALL THE ABOVE PLUS</b> <ul style="list-style-type: none"> <li>• Active case finding (and treatment) for TB, including for smear negative and disseminated TB, among HIV-infected people</li> <li>• Preventive therapy for TB among HIV-infected people</li> <li>• Systemic antifungals for systemic mycosis (such as cryptococcosis)</li> <li>• Treatment of HIV-associated malignancies : Kaposi's sarcoma, lymphoma and cervical cancer</li> <li>• Treatment of extensive herpes</li> <li>• Prevention of mother to child transmission of HIV</li> <li>• Post exposure prophylaxis of occupational exposure to HIV and for rape</li> <li>• Funding of community efforts that reduce the impact of HIV infection</li> </ul>
Care and support activities of high complexity and/or cost	<b>ALL THE ABOVE PLUS</b> <ul style="list-style-type: none"> <li>• Triple antiretroviral therapy</li> <li>• Diagnosis and treatment of opportunistic infections that are difficult to diagnose and/or expensive to treat, such as atypical mycobacterial infections, cytomegalovirus infection, multiresistant TB, toxoplasmosis, etc</li> <li>• Advanced treatment of HIV related malignancies</li> <li>• Specific public services that reduce the economic and social impacts of HIV infection</li> </ul>

It is a widespread belief that the majority of health care needs of PLHA can be addressed by ensuring access to medications, in particular antiretroviral therapy. However, this idea falls

short of effectively meeting their complete range of medical, emotional, social and economic needs. PLHA require comprehensive care and support, not just medicines.

For a care and support package for HIV to be comprehensive, it should include elements of voluntary counselling and testing for HIV infection, psychosocial support, home and community-based care, and clinical management (including medical, nursing and counselling care). Many of the activities in each of these areas straddle the divide between care and support, and prevention. This is one of the reasons why care and support to PLHA contribute to prevention. Major elements of care and support of PLHA are described below. Taken as a whole, each contributes to the development of an **enabling environment** which is essential for ensuring adequate levels of care, support, and prevention.

#### 4. 1. Voluntary Counselling and Testing for HIV infection (VCT)

Voluntary counselling and testing (VCT) for HIV infection is an entry point for HIV/AIDS care and prevention. It has several benefits as figure 1 below show. It is therefore important that *voluntary counselling and testing* for HIV infection be made available on a much larger scale than today.

It needs to be emphasised that availability of testing alone is not enough: testing should be voluntary and confidential, and it should be accompanied by counselling. Counselling is important to prepare clients to come to terms of their HIV status: this includes dealing with fear, guilt, stigma, discrimination, care for a chronic condition, the possibility of early death, and to give them an understanding of what they can and should do about HIV infection, should they be HIV-infected. It is also important to help people devise or strengthen ways of staying HIV negative, if they test HIV negative<sup>4</sup>.

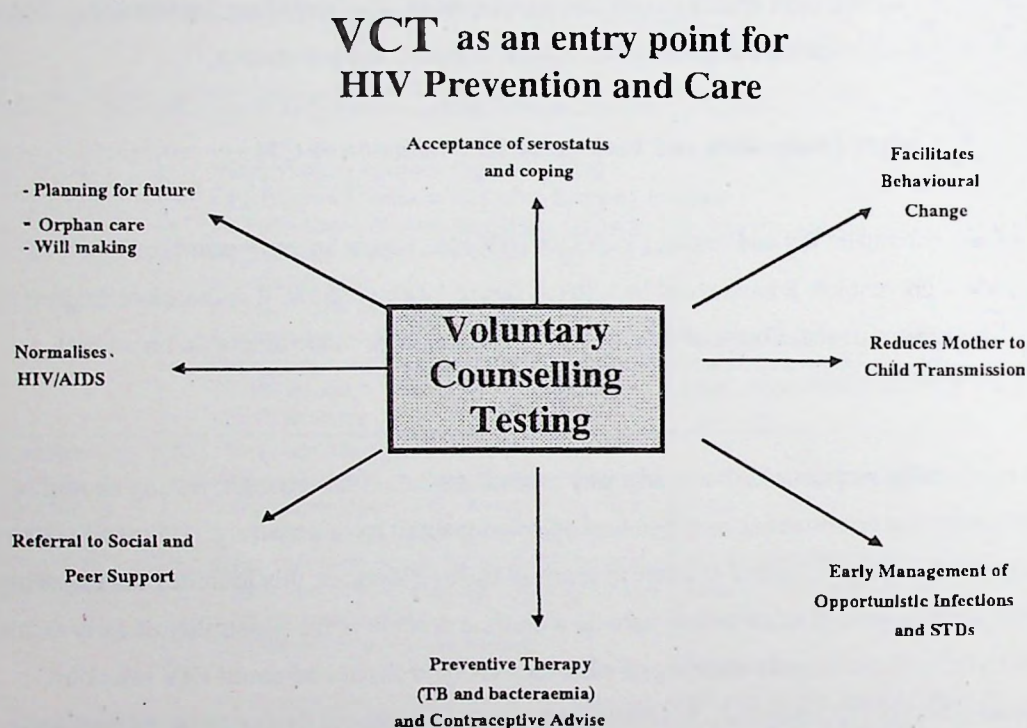
In order to be effective, the implementation of VCT services requires many key elements, including community awareness, education and mobilization to ensure those wishing to be tested understand what the test process is and where testing may be undertaken, and to ensure that those who are tested and found infected are not discriminated against and supported with their infection, the training of people (health, educational and other staff and volunteers) in minimum standards of counselling and psychological recognition, acute

---

<sup>4</sup> Voluntary Counselling and Testing Technical Update (UNAIDS, 2000)

management and onward referral (and therefore the development of networks of services and resources for taking up onward referrals from counselling); the provision or development of support groups for those affected; the provision of physical facilities suitable for having private, confidential discussions, and monitoring and support for those doing the complex task of counselling<sup>5, 6</sup>.

**Figure 1: VCT is an entry point for HIV prevention and care**



<sup>5</sup> Voluntary counselling and testing for HIV infection in antenatal care: an implementation guide, WHO, 1999.

<sup>6</sup> Tools for Evaluating Voluntery Counselling and Testing, (UNAIDS, 2000)

## 4.2 Psychosocial support

A key element in care and support is the provision of psychosocial support. Counselling, spiritual support, support to enable disclosure and risk reduction strategies, medication adherence, and end of life and bereavement support are all part of psychological support. This should be part of the care package at all levels. At its most basic level, this requires the establishment and support of peer-support groups for those found positive, and those affected by HIV. Many good examples of such services – which act as a focus for education, training, and provision of material, basic economic, spiritual and psychosocial support – currently exist in many countries. Those most affected often create such groups through a need for solidarity in the face of broader public stigma and discrimination. The greater involvement of people affected by HIV/AIDS (GIPA) is a vehicle for generation of psychosocial support in communities, and needs to be incorporated and encouraged in designs for care and support.

## 4.3. Home and community-based care

Home and community-based care means any form of care given to PLHA in their own home and community. It can be care activities that PLHA might do to take care of themselves or the care given by their relatives, friends or health workers within their homes and communities. HIV/AIDS being a chronic condition, it is essential to recognize that PLHA do not always require to be hospitalized and care within their families might be more appropriate at some stage of their disease. Discharging PLHA back to their communities at an early stage or not admitting the person in the first place can be more appropriate provided that the individual's needs can be addressed outside the institution<sup>7</sup>. There will be times that person will need to consult the health professionals for follow up but most of the time, PLHA are well taken care in their homes, their families and communities. Home and community care is thus an essential element of comprehensive care for PLHA in a continuum of care from health institutions to homes and vice versa. For those facing a future of uncertainty and who are fearful of possible consequences of having their status disclosed to others because of stigma and discrimination associated with HIV/AIDS<sup>8,9</sup>, and for those living far from care and treatment facilities, or without the means to obtain transport to medical and psychosocial support services, provision of care in the home and community

<sup>7</sup> Sexual Health and Health Care: Care and Support for people with HIV/AIDS in resources poor settings, DFD, 1998

<sup>8</sup> VCT Outcomes, UNAIDS, 2000

<sup>9</sup> Opening up the HIV/AIDS Epidemic, UNAIDS, 2000

based care is critically important. Such provision requires community-level organisation, training and support to ensure services are being appropriately implemented and used<sup>10</sup>. Nursing care and support to nursing activities in home-based care and elsewhere must be encouraged<sup>11</sup>.

#### 4.4. Medical management

##### 4.4.1. Diagnosis and treatment of HIV-related diseases

Worldwide, the main burden of disease in PLHA arises from a limited number of common infections – and their complications – to which PLHA are particularly susceptible, namely tuberculosis (TB), pneumonia, diarrhoea, and candida infection of the mouth and throat<sup>12</sup>. Diagnosis of these infections is usually possible at health centres and district hospitals, and they are generally amenable to successful treatment with cheap, affordable and effective antibiotics<sup>13, 14</sup>. Strengthening of the general health services is crucial to ensuring that PLHA have access to care for common HIV-related diseases.

TB is worldwide the single biggest killer of PLHA, yet a course of TB treatment costs as little as US\$20. In addition to strengthening national TB programmes and harnessing community contributions to ensure that every PLHA with TB has access to effective TB care, increased collaboration is necessary between TB and HIV programmes to provide a coherent response to the dual TB/HIV epidemic<sup>15, 16, 17</sup>.

In addition to these common HIV-related diseases, there is a variety of HIV-related infections and cancers for which treatments are more expensive and, in many parts of the world, not widely available. These HIV-related infections include toxoplasmosis, cryptococcosis, pneumocystis carinii pneumonia, herpes simplex virus, cytomegalovirus and atypical mycobacteria. HIV-related cancers include Kaposi's sarcoma and lymphoma.

<sup>10</sup> AIDS Home Care handbook, WHO/GPA, 1993

<sup>11</sup> Nursing Fact sheets in HIV/AIDS, WHO/UNAIDS, 2000

<sup>12</sup> Technical Update on Opportunistic Infections (UNAIDS \_\_\_\_\_)

<sup>13</sup> Guidelines on Treatment of Opportunistic Infections (WHO/EDM \_\_\_\_\_)

<sup>14</sup> WHO model prescribing information on essential drugs used in the treatment of HIV infection and STDs)

<sup>15</sup> TB/HIV: A Clinical Manual (WHO/TB/96.200)

<sup>16</sup> Treatment of Tuberculosis: Guidelines for National Programmes, 2<sup>nd</sup> Edn, 1997. (WHO/TB/97.220)

<sup>17</sup> TB and HIV: The Dual Epidemic. (UNAIDS PoV \_\_\_\_\_).

#### 4.4.2. Ensure adequate nutritional advice to PLHA

As denutrition is an important feature of advanced HIV infection, it is important to prevent it. This requires nutritional assessment, nutritional counselling and education that includes food safety, and, if possible, the development of a plan of action to prevent weight and muscle mass loss. With some drugs dietary changes are also needed to prevent side effects and specific symptoms. In some cases provision of nutritional supplements, and the use of anabolic steroids may be useful to prevent or treat wasting. More information on HIV infection and nutrition is found in the UN Secretariat Committee on Nutrition Newsletter, 1998<sup>18</sup>.

#### 4.4.3. Palliative care

Palliative care not only includes the management of physical symptoms, such as pain, cough, skin rashes, fever, diarrhoea, but also dealing with depression, suicidal thoughts, and other psychological problems. It also comprises spiritual support, and bereavement counselling, and is inclusive of the client and his environment. It often requires a multidisciplinary approach.

More on palliative care can be found in the UNAIDS Technical Update on Palliative Care<sup>19</sup>.

#### 4.4.4. Prevention of HIV-related diseases.

Fortunately, affordable and effective drugs are available to prevent many of the common HIV-related diseases responsible for the main burden of illness and death in high HIV prevalence countries. Isoniazid is effective in preventing reactivation of latent TB<sup>20</sup> and cotrimoxazole is effective in protecting against many of the common pathogens (such as pneumococcus and salmonella) responsible for pneumonia and diarrhoea and their complications<sup>21</sup>. The challenge remains to find ways of dramatically increasing access of PLHA to preventive treatments.

#### 4.4.5 Antiretroviral treatment

While antiretroviral therapy is expensive, it should be recognized that it also represents the present gold standard for the treatment of HIV infection. Regardless of whether

<sup>18</sup> UN Secretariat Committee on Nutrition Newsletter, 1998, Volume...

<sup>19</sup> UNAIDS Technical Update on Palliative care, ....

<sup>20</sup> Preventive therapy against tuberculosis in people living with HIV. Policy Statement. Weekly Epidemiological Record 1999; 74: 385-400

<sup>21</sup> Provisional recommendations on the use of cotrimoxazole in Africa.

governments can afford to subsidize their availability to the general public, there is the need to regulate their use to protect their future usefulness. Also, rather than refusing to deal with these drugs for fear of having to fund them, governments should consider regulating their use and facilitating access to them by supporting human resource development and treatment monitoring infrastructures for antiretroviral therapy, so as to build capacity in the health system to safely and effectively use these drugs<sup>22, 23</sup>. In countries where resources are more plentiful, there is in addition a strong case to subsidise their use.

#### **4.4.6 Family planning**

Family planning is important for PLHA as part of an adjustment strategy that aims to guarantee or improve a future of their family, including their spouses and children. Limiting family size might also enable them to have saved enough to contribute to the cost of their treatment, where such treatment needs to be totally or partly privately funded. It also has a role in the prevention of mother to child transmission<sup>24</sup>.

#### **4.4.7. Promotion of safe sex and condom use to clients in HIV care and support programmes**

In the care of HIV infected people the focus is often on drugs, results of viral load tests and CD4 counts, and possible toxicity of the treatments received. Contacts with health services should be used to support preventive behaviour and to promote safe sex or condom use. When doctors perform poorly in this area, the services should be organized in such a manner that HIV-infected people get referred to counsellors or services that avail these services to them<sup>25, 26, 27</sup>.

#### **4.4.8. Diagnosis and treatment of STIs**

Diagnosis and treatment of STIs are important not only to prevent HIV but also to prevent complications from STIs. STIs increase HIV transmission, with a factor of 2 to 40. When an STI is treated, this enhancement of HIV transmission disappears. In addition to considerations about the cost-effectiveness of STI intervention, the potential to prevent HIV infection explains why WHO and UNAIDS vigorously promote STI control.

<sup>22</sup> Guidance Modules on antiretroviral Treatment , WHO and UNAIDS, 1998

<sup>23</sup> Safe and effective use of antiretroviral in resource-constrained settings, WHO/UNAIDS, 2000.

<sup>24</sup> RELEVANT FAMILY PLANNING REFERENCES

<sup>25</sup> RELEVANT REFERENCES ON MALE AND FEMALE CONDOM USE

<sup>26</sup> Sex and Youth: contextual factors affecting risk for HIV/AIDS, UNAIDS, 1999

<sup>27</sup> RELEVANT REFERENCES ON ADOLESCENT HEALTH AND HIV/AIDS

Where STI control is insufficient, it would make sense to strengthen it first in services where known HIV infected people consult. Indeed, targeting PLHA with enhanced STI treatment services has significant benefit beyond that individual: chances of HIV transmission to sexual partners are reduced. Practical information on STI control can be found in various publications<sup>28, 29, 30, 31, 32</sup>.

#### 4.4.9. Intervention to reduce mother to child transmission of HIV

1.2 million children under the age of 15 years are infected with HIV now, and a cumulative total of 3.6 million children have already died of AIDS since the beginning of the epidemic. Mother to child transmission (MTCT) is responsible for more than 90% of these infections. Strategies to reduce mother to child transmission of HIV infection include primary prevention of HIV infection among women, family planning, antiretroviral therapy, restricted use of invasive obstetric procedures during vaginal delivery, and replacement feeding for the infant.

In the field, pilot programmes on prevention of MTCT are being undertaken. Their monitoring and evaluation will provide many lessons in taking the MTCT experiences to a larger scale. So far, it is known that MTCT prevention has to face many challenges: the weakness of antenatal care infrastructures and services in many developing countries, lack of awareness of HIV transmission and personal HIV infection in many pregnant women, reluctance to engage in VCT for HIV, relatively weak compliance in taking ARV and dilemmas in maintaining infant feeding options.

The UNAIDS technical update on mother to child transmission of HIV provides an overview and strategic guidance for the implementation of interventions to prevent mother to child transmission of HIV<sup>33</sup>.

---

<sup>28</sup> Consultation on STD interventions for preventing HIV: what is the evidence?, WHO/UNAIDS, Geneva 2000

<sup>29</sup> Management of sexually transmitted diseases, WHO/GPA 1994

<sup>30</sup> Guidelines for Sexually Transmitted infections Surveillance, WHO/UNAIDS, 1999.

<sup>31</sup> The public health approach to STD control, UNAIDS Technical Update, 1998.

<sup>32</sup> Sexually transmitted diseases: policies and principles for prevention and care, WHO/UNAIDS, 1997.

<sup>33</sup> CITE REFERENCE

#### 4.4.10. Post exposure prophylaxis of HIV infection for occupational exposure to HIV and for rape victims

Interventions to reduce HIV transmission in the health care setting include the use of universal precautions when handling potentially infected material, e.g. wound care and surgical procedures, and ensuring the safety of blood and blood products. While the use of universal precautions is clearly more cost-effective than that of antiretroviral therapy after an occupational exposure to HIV (or possible exposure to HIV through rape), post-exposure prophylaxis of HIV infection is also among the interventions to be considered here<sup>34</sup>.

#### 4.5. Behavioral issues in HIV/AIDS care and support

- **Avoid stigma and discriminatory attitudes:** Improving access to HIV/AIDS care and support requires conducive behaviour. Health professionals, relatives and friends should avoid stigma or discrimination against PLHA: stigma and discrimination constitute obstacles to care service development and use, and may jeopardise access to care, openness, adherence to treatment and the whole quality of care.
- **Management of drug addicted people and vulnerable groups:** when present, drug addiction can greatly complicate the clinical management of HIV infection. Continued IV drug use might also put others at risk of becoming infected, in particular when needles are shared or when drug users resort to sex work to finance their habit. For both the individual client and society it is therefore important that care and support services take into account the management of drug addiction in HIV infected clients. Care provision should be an opportunity to explain and recommend to the clients, particularly vulnerable groups (e.g. youth, sex workers, mobile and migrant groups, intravenous drug users, men having sex with men) cost-effective HIV prevention methods that could be used to protect themselves and their entourage.
- **Social and legal support:** community involvement and household assistance to mitigate the impact of HIV/AIDS are examples of social support. Providing food support, volunteers for daily duties, orphan support, PLHA peer support, welfare services, and legal support are also part of social support and should be part of a comprehensive care and support package.

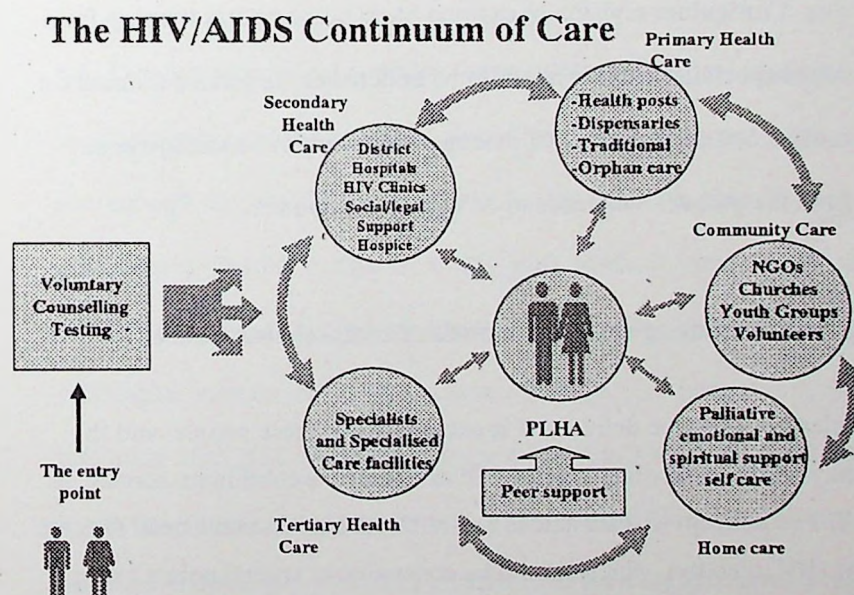
<sup>34</sup> 'Title of relevant publication on universal precautions, WHO, 1993'  
'The safe and effective use of antiretrovirals in resource constrained settings'.

## STRUCTURAL ELEMENTS FOR SERVICE DELIVERY

### 5.1. Identification of actors of comprehensive care and support for PLHA

The provision of comprehensive HIV care and support requires the inputs of many people, ranging from family members to nurses and doctors, and from community workers to psychologists. These people can be grouped according to their affinity with, and access to training in, different care and support activities. There will be people involved more in clinical care, usually the formal health sector where health professionals offer relief of symptoms and diagnosis and treatment of specific diseases and psychosocial problems, and those more obviously involved in social support provided by community based organisations, counsellors or support groups, and social sector organisations.

**Figure 2: Care and support continuum**



## **5.2 Human resource development.**

The response to HIV/AIDS requires additional skills and approaches that may not have been characteristic of the health system. This includes not only skills for effective clinical management of PLHA but also counselling and psycho-social support skills. These skills are now essential for the response and need to be developed because of the particular PLHA care requirements. There is need to develop human resource management strategies that take into account the impact of the epidemic on the health system as discussed earlier: basic training as well as continuing education will be necessary to produce qualified health personnel in sufficient numbers to cope with the epidemics.

## **5.3 Guidelines and training.**

National guidelines need to be updated or developed on all essential and enhanced elements of comprehensive care. Curriculum revision of existing basic health cadres training from nursing aides to medical specialist training needs to be undertaken. In service training on new interventions such as counselling or ARV management needs to be strengthened. Existing guidance from the global level needs to be widely distributed.

## **5.4. Strengthening the links among various channels of comprehensive care**

To improve the efficiency of service delivery, it is necessary that these people, and the services in which they work, collaborate together, so as to create a continuum service, as depicted in Figure 2. The concept of care across a continuum expresses the need for care through all stages of HIV infection, which should be accessible at several points along a continuum from VCT services, health services (primary health care (PHC), secondary and tertiary health care) and social services to community-based support and home care<sup>35, 36, 37</sup>,

<sup>35</sup> HIV/AIDS care and support for persons living with HIV/AIDS, USAID discussion paper, 1999

<sup>36</sup> Model of care for patients with HIV/AIDS, Osborne, van Praag and Jakson.

<sup>37</sup> The international Newsletter on AIDS prevention and care. AIDS Action. January – March 1999.

<sup>38, 39</sup>. An important feature of the concept is the explicit recognition that community based activities play a vital role, not only for HIV care and support, but also for HIV prevention, and a formal recognition of the links between care and prevention. Depending on the needs of the patients, they are provided care at PHC level, or secondary or tertiary level of health services. The health services may refer the patients to the community-based care organisations that in their turn refer the patients to health care services when necessary. Thus, the system needs to strengthen the referral system between different levels of health services and between health services and community based care.

### 5.5 Infrastructure development

Health care services should be established where necessary. VCT services and laboratories need to be established and adequately staffed and equipped. Where advanced ARV treatment is given, there is need for basic facilities to monitor the side effects (toxicity) of the drugs and to measure the efficacy of the treatment by CD cell counts and viral loads.

**5.6. Drugs and medical supplies** (commodities, condoms, reagents, needles and syringes, surgical equipment and supplies, gloves, etc.): having human resources and infrastructure is not enough to provide good quality health care. Another important ingredient that the government should secure is drugs and medical supplies. Most people living with HIV/AIDS have very limited access to essential medicines. Essential medicines for HIV/AIDS include established essential drugs (for pneumonia, TB, diarrhoea, candida, palliative care, STI treatment), drugs to prevent mother-to-child transmission, and newer high-cost drugs (for opportunistic infections, HIV-related cancers, and highly active antiretroviral therapy – HAART). In order to increase access to drugs and medical supplies, four strategies are suggested<sup>40</sup>:

<sup>38</sup> HIV/AIDS care in Uganda, MOH, March 2000.

<sup>39</sup> Enhancing care initiative, Harvard School of Public Health, 1999 Report.

<sup>40</sup> The UN strategy for increasing access to HIV-related drugs, IIT on access to drugs, 2000.

1. **Rational selection and use** - Drugs of choice are identified for specific priority indications based on best evidence on local morbidity patterns and drug efficacy, safety, quality, and cost-effectiveness.
2. **Affordable prices** – “Best prices” for governments, NGOs and people living with AIDS will be sought through better price information, negotiation, competition, and reduction of duties, taxes, and distribution costs.
3. **Sustainable financing** – There will be strong advocacy for reallocation of government resources to HIV/AIDS care (taking ‘from outside health sector, not from HIV prevention or other priority health problems) and expansion of external financing.
4. **Reliable health care services** – Effective use of new HIV-related drugs and prevention of resistance depends on the ability of health care services to diagnose HIV infection, to diagnose associated illnesses and adequately to monitor treatment

**5.7. Financing :** advocacy programmes to get resources mobilised at national and international levels for care should be developed. Financing of health systems for effective response to HIV/AIDS must achieve two things. First there must be an overall increase in the amount of funds available in health systems. This is because the magnitude of the HIV/AIDS problem requires a lot more resources to deal with than what is available in most countries. HIV/AIDS increases the cost of providing health care. The second goal must be to implement measures that offer protection to people living with HIV/AIDS and their families from financial ruin or reduced access to health services as a result of increased cost of health care.

**5.8 Reorganisation of service delivery and partnership:** the above-mentioned inputs need to be well planned, equitably distributed and effectively implemented. Supervision, monitoring and evaluation of the services should be ensured. Comprehensive care for PLHA

should be accessible at all levels along a continuum ranging from formal health and social services to community based services and home care. Partnerships between communities and institutions within a catchment area should be developed in such a way that an effective referral system between VCT services, basic hospitals and health centres, and home care services is strengthened. Hospitals, NGOs, and CBOs should ensure complementarity and discharge planning across the continuum. In view of the large number of actors (stakeholders and partners), there is a need for synergy through effective collaboration among different actors or centres on the continuum of care. There is also a need to harmonise the inputs of different partners so that efforts are complementary and relevant to priority PLHA care and support needs. This synergy is essential for improving the effectiveness of different levels and actors within the continuum of care.

#### 5.9. Other factors to take into account in the reorganisation:

- Essential care delivery needs not only trained staff but also a **conducive working environment**. This would include: space, privacy and staff time for VCT in general health services and for particular groups such as young people, antenatal services; operational procedures for patient care, for referrals to home care or enhanced care to ensure a care continuum and for universal precautions, and monitoring of coping capacity and adherence to standards to be put in place.
- **Care for the carers**, including activities to prevent burn-out of staff and access to post exposure prophylaxis at the institutional level, VCT services for health staff, antiretroviral treatment and institutional policies for HIV infected staff.
- **Universal precautions and safe blood supplies**. Institutional policies for infectious disease control should be developed or updated. These include institutional procedures for the rational prescription of blood transfusions. Order and distribution procedures for HIV test kits, gloves, blood collection equipment and sterilisation facilities.

### **5.10. Facilitating community mobilisation and action**

Health services have been traditionally perceived as possessing the knowledge, expertise and means to make people healthy. However, this has often led to complete dependency of people on health services and diminished the autonomy of individuals to safeguard their health. Therefore, when health systems experience difficulties or fail to perform well, health outcomes decline significantly. Therefore the people's responsiveness is as important as the services. Individuals and their behaviour -- sexual relationships, eating habits, substance abuse, or drug compliance -- determine the effectiveness of the intervention.

Health systems ought to aim at empowering individuals and communities to identify health challenges and take measures to promote and protect their health and prevent disease. One way of empowering individuals and communities is by providing appropriate, practical and timely information. The participation of communities and affected individuals is considered essential for a responsive campaign. The more the users participate the more the services may be made more responsive to the expectations of the people. Broader participation also ensures that there is a multiplicity of efforts and skills that are needed for the scale and complexity of the epidemic. Partnerships need to be developed between health services and communities through mutual influences and support.

**5.11. Policy development and legislation:** several relevant policies and regulations need to be formulated: e.g., HIV testing policies for diagnostic and clinical purposes at national and institutional level, including professional codes need to be reassessed to ensure confidentiality and disclosure policies of HIV testing and result provision, prevention of discrimination and stigma against PLHA in health settings; formalization of counselling as a duty or occupation; formulation of HIV care policies and national standards of essential and

comprehensive HIV care; policies on collaboration between private and public sector and with NGO/CBOs to ensure care provision and referrals across a continuum from institution to home. National drug policies and essential drug lists should be updated to reflect the needs for HIV care. Regulation and standardization of use of relevant HIV treatments (e.g. antiretroviral treatments at accredited sites, for MTCT and post exposure prophylaxis, preventive therapies. Policies to protect the rights of people living with HIV/AIDS need to be developed, promoted and implemented.

### **5.12. Monitoring and evaluation**

HIV/AIDS comprehensive care programs must include a monitoring and evaluation component to refine, adapt and strengthen existing and new services and should be budgeted for and implemented in all HIV/AIDS comprehensive care programs. Services will only be effective if they are consistently evaluated to measure effectiveness, efficiency, quality, usage and acceptability in the community. Programs should seek to collect, analyse and use data that reflect the extent to which quality care is provided at all levels of the health system, and to identify any problems and potential gaps requiring remedial actions, including participatory assessments and evaluation involving communities.

This implies developing indicators and measurement tools appropriate to compare the quality, extent and coverage of care services at each level with needs, demands and set standards and norms. It also implies that monitoring and evaluation systems must be designed to respond to questions that are relevant for decision-making purposes. More information on HIV/AIDS monitoring and evaluation can be found in the guide to monitoring and evaluation of national AIDS Programme<sup>41</sup>.

---

<sup>41</sup> National AIDS Programmes: A guide to monitoring and evaluation, UNAIDS, WHO, MEASURE, etc. 2000.

## 6. PRIORITISATION

As resources are never sufficient to satisfy the needs of all, resource allocation is a key activity in public decision making, also in HIV care. WHO and UNAIDS advocate that in care and support resources be allocated taking into account the principles of respect, equity, quality of services, efficiency and effectiveness, accessibility and availability, and sustainability so as to make services available and accessible to as many people as possible. In order to protect the rights of the poor, it is also important to define what services should be considered as first priority and which services of intermediate or high complexity and cost could be considered when more resources are available. Table 1 attempts to do this.

As Table 1 shows, there are three levels of HIV/AIDS care and support interventions on the basis of their complexity and cost. Ideally, all components should be provided within the health system. According to resources available in a setting, the focus might be on the provision of essential (basic) care interventions (Type 1 settings) or on the provision of intermediate cost/complexity care interventions (Type 2 settings) or on the provision of more advanced and highly complex care interventions (Type 3 settings). One might think about a gradual dynamic progress with the ultimate goal of obtaining the standard of care in type 3 settings accessible and available to all PLHA. But in real life of most countries, it is seen that both essential and more complex and costly elements of HIV/AIDS care and support co-exist. For instance antiretroviral drugs (ARVs) are found in most countries, but only for very limited number of patients and in a few clinics in resource-constrained settings. Whenever more resources (human, technical and financial) are available, HIV/AIDS care and support can be scaled up to increase coverage and/or additional elements of care can be considered. The process of enhancing HIV care and support is seen not to be a static "process" but an evolving, dynamic process in which new HIV care elements can be added or integrated depending on the amount of human and financial resources available. Each country may consider a different set of enhanced care elements, that could change over time and place depending on socioeconomic conditions.

While different health sector activities differ in their complexity and cost, it is clear that essential (basic) and complex and high cost services co-exist in all health systems. When essential services don't cover the majority of their target population some would argue that these essential services must be improved before one can even think of public funding or

other public support for more complex and high cost services. It is suggested that the strategic planning approach be used, with the objective to make progress where possible, by choosing from Annex 1 the activities which could be implemented in effective and sustainable way. The process of making the choice and the formulation of a strategic plan<sup>42</sup> to enhance care and support should involve all stakeholders in HIV care, including NGOs and PLHA groups. The outcome of the exercise should be a community consensus about the future content of the local care and support package, about how service delivery will be optimised, and about how different components will be financed.

WHO/PAHO has also developed a model of prioritisation of care options in relation to resource availability. The advantage of this model is that it covers not only the health sector but also the community and home based care activities<sup>43</sup>. WHO/SEARO has developed a concept of care which suggests a step-by-step approach in the implementation of HIV/AIDS care activities<sup>44</sup>.

---

<sup>42</sup> Guide to strategic planning process for a national response to HIV/AIDS, UNAIDS, 1999.

<sup>43</sup> Building Blocks: Guidelines for providing comprehensive care to persons living with HIV/AIDS in the Americas, WHO/PAHO, 1999.

<sup>44</sup> Planning and implementing HIV/AIDS care programmes: a step-by-step approach, December 1998

### Annex 1: Comprehensive HIV/AIDS Care and Support activities by level of service delivery.

Level of Health System

<b>COMMUNITY LEVEL</b>	<ul style="list-style-type: none"> <li>• Day care centers</li> <li>• Financial support</li> <li>• Legal representation</li> <li>• Management of drug banks</li> <li>• Provision of sterile needles</li> <li>• Hospice care</li> <li>• Bereavement and funeral support</li> </ul>
	<ul style="list-style-type: none"> <li>• Emotional support and counselling</li> <li>• Community information, education, communication (IEC) and participation</li> <li>• Personal accompaniment</li> <li>• Support groups</li> <li>• Nutritional assessment, counseling and food safety</li> <li>• Food kitchens and programs</li> <li>• Multidisciplinary health practices</li> <li>• Condoms and bleach</li> <li>• Access to family planning methods</li> <li>• Advocacy</li> <li>• Assistance to orphaned children</li> </ul>
<b>HOME CARE LEVEL</b>	<ul style="list-style-type: none"> <li>• Formal sharing of experience and networking</li> <li>• Adherence to medications and complementary measures</li> </ul>
	<ul style="list-style-type: none"> <li>• Universal precautions</li> <li>• Safer sex activities, including family planning</li> <li>• Personal and environmental hygiene practices</li> <li>• Nutrition and food safety measures</li> <li>• Knowledge about when and where to seek additional support</li> </ul>

## Annex 1: Comprehensive HIV/AIDS Care and Support activities by level of service delivery (cont'd)

Level of Health System

<b>TERTIARY LEVEL</b>	<ul style="list-style-type: none"> <li>• Use of steroids and other hormones</li> <li>• Elective surgery</li> <li>• Management of anxiety and depression</li> <li>• ARVs for HAART</li> <li>• Antitumoral treatments</li> <li>• Management of chronic pain</li> <li>• Management of anal and procto-colonic syndromes</li> <li>• Parenteral nutrition</li> <li>• Post-exposure prophylaxis (PEP) among health providers</li> </ul>
	<ul style="list-style-type: none"> <li>• Treatment of toxoplasmosis, PCP and other relevant OIs</li> <li>• Management of complex manifestations of HIV</li> </ul>
	<ul style="list-style-type: none"> <li>• ARVs for HAART</li> </ul>
<b>SECONDARY LEVEL</b>	<ul style="list-style-type: none"> <li>• Screening, prophylaxis and treatment of toxoplasmosis and PCP</li> <li>• Nutritional interventions, including anabolic steroids</li> <li>• ARVs for selected patients</li> <li>• Management of sexual functions</li> </ul>
	<ul style="list-style-type: none"> <li>• Counseling for secondary prevention</li> <li>• Screening, prophylaxis and treatment of TB</li> <li>• Prophylaxis of PCP</li> <li>• Confirmatory diagnosis of HIV infection and related conditions</li> <li>• ARVs to prevent MTCT</li> <li>• Breast milk substitutes/alternatives to breast-feeding</li> <li>• Vaccination against tetanus and HBV</li> <li>• Access to safe blood and derivatives*</li> </ul>
<b>PRIMARY LEVEL</b>	<ul style="list-style-type: none"> <li>• Clinical and laboratory monitoring of progression of disease</li> <li>Flu vaccination</li> <li>• Prophylaxis/treatment of TB, toxoplasmosis and PCP</li> <li>• Management of HIV-related diseases</li> <li>• Nutritional supplements (vitamins, micronutrients)</li> <li>• Sensitivity-based management of STI</li> <li>• ARVs to prevent MTCT</li> <li>• Breast milk substitutes/alternatives to breast-feeding</li> <li>• Vaccination against HBV</li> </ul>
	<ul style="list-style-type: none"> <li>• Voluntary and confidential counseling and testing</li> <li>• Management of pain, malaise and fever</li> <li>• Education on personal and environmental hygiene, universal precautions, safer sex and family planning</li> <li>• Nutritional assessment, counseling and food safety</li> <li>• Syndromic management of STIs</li> <li>• Clinical diagnosis of HIV-related diseases</li> <li>• Vaccination against tetanus</li> </ul>

\* In countries where transfusional services are available at the primary level, this component should be available at the primary level.

**5**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

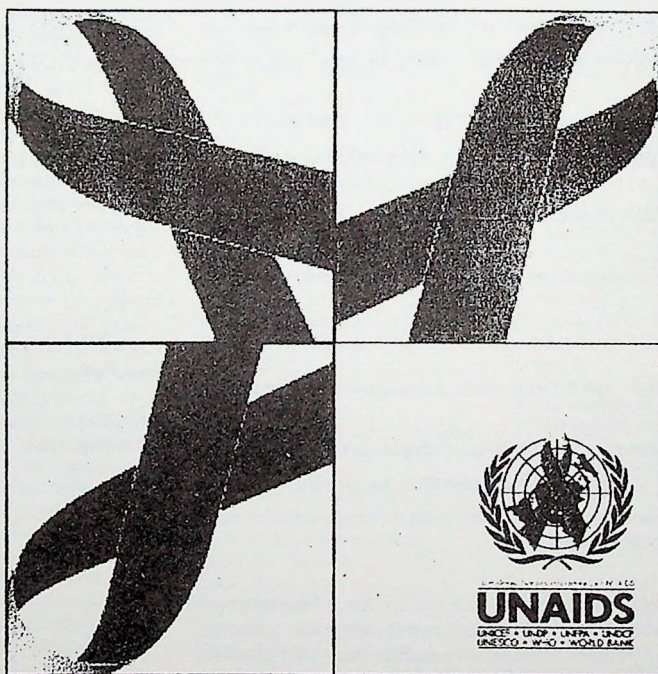
**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

II. 10.5.5. 1. 7

## AIDS: Palliative Care

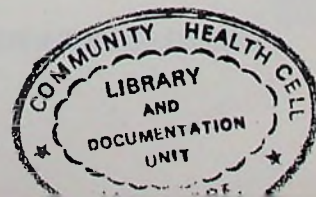


**UNAIDS**  
**Technical update**

**October 2000**

UNAIDS Best Practice Collection

DIS-325  
06893 001



# At a Glance

***Palliative care aims to achieve the best quality of life for patients (and their families) suffering from life-threatening and incurable illness, including HIV/AIDS. Crucial elements are the relief of all pain—physical, psychological, spiritual and social and enabling and supporting caregivers to work through their own emotions and grief.***

Palliative care has relieved the intense, broad suffering of people living with HIV/AIDS but the latter brings a number of challenges to its philosophy and practice including:

- The complex disease process with its unpredictable course and wide range of complications, which means that palliative care has to balance acute treatment with the control of chronic symptoms;
- Complex treatments which can overstretch health services;
- The stigmatization and discrimination faced by most people living with HIV/AIDS;
- Complex family issues, such as infection of both partners;
- Role reversal in families, such as young children looking after their parents;
- Burdens on health care workers.

A wide range of palliative care is needed for people living with HIV/AIDS, including:

- Pain relief;
- Treatment of other symptoms such as nausea, weakness and fatigue;
- Psychological support for psychological problems;
- Spiritual support and help with preparation for death;
- Support for families and carers—help with nursing, infection control and psychological support.

To ensure that effective palliative care is provided for all people living with HIV/AIDS, governments must tackle the misconceptions that palliative care is only for people approaching death. They also need to:

- improve the training of health and community workers, and general health education, including tackling stigmatization;
- make good palliative care widely available in hospital, hospices and in the community for people living at home;
- provide access to the necessary drugs;
- provide support for carers, counsellors and health care workers;
- recognize the special needs of children.

## UNAIDS Best Practice materials

The Joint United Nations Programme on HIV/AIDS (UNAIDS) publishes materials on subjects of relevance to HIV infection and AIDS, the causes and consequences of the epidemic, and best practices in AIDS prevention, care and support. A Best Practice Collection on any one subject typically includes a short publication for journalists and community leaders (Point of View); a technical summary of the issues, challenges and solutions (Technical Update); case studies from around the world (Best Practice Case Studies); a set of presentation graphics; and a listing of Key Materials (reports, articles, books, audiovisuals, etc.) on the subject. These documents are updated as necessary.

Technical Updates and Points of View are published in English, French, Russian and Spanish. Single copies of Best Practice materials are available free from UNAIDS Information Centres. To find the closest one, visit the UNAIDS website (<http://www.unaids.org>), contact UNAIDS by e-mail ([unaids@unaids.org](mailto:unaids@unaids.org)), or telephone (+41 22 791 4651), or write to the UNAIDS Information Centre, 20 Avenue Appia, 1211 Geneva 27, Switzerland.

AIDS Palliative Care. UNAIDS Technical update. English original, October 2000.

I. UNAIDS II. Series

1. Palliative Care
2. Medical/Nursing Staff
3. Voluntary Workers

UNAIDS, Geneva WC 503

### What is palliative care?

Palliative care is a philosophy of care which combines a range of therapies with the aim of achieving the best quality of life for patients (and their families) who are suffering from life-threatening and ultimately incurable illness. Central to this philosophy is the belief that everyone has a right to be treated, and to die, with dignity, and that the relief of pain – physical, emotional, spiritual, and social is a human right and essential to this process.

This philosophy of care developed out of the treatment of patients dying in hospital, usually from cancer. It led to the establishment of the hospice movement, and palliative care is now provided for patients living with many life-threatening diseases, including HIV/AIDS.

Palliative care ideally combines the professionalism of an interdisciplinary team, including the patient and family. It is provided in hospitals, hospices and the community when patients are living at home. This care should be available throughout a patient's illness and during the period of bereavement. An integral part of palliative care is providing the opportunity and support for caregivers to work through their own emotions and grief, which inevitably arise from their work.

Carers work hard to remain sensitive to patients' personal, cultural and religious values, beliefs and practices, and to ensure effective communication with patients, their families and others involved in their care.

### Palliative care for people with HIV/AIDS

Experience shows that palliative care can relieve the intense,

broad suffering of people living with HIV/AIDS. However, HIV/AIDS has challenged the ideas of palliative care because of its specific dimensions:

#### ■ The complex disease process.

The course of HIV/AIDS is highly variable and unpredictable, with a wide range of potential complications, rates of progression, and survival. Some patients remain free of serious symptoms for a long time; others experience alternating periods of increasing dependency with episodes of acute illness, or suffer frequent non-life threatening complications throughout their infection. So palliative care for HIV/AIDS is – unlike that for other illnesses – a balance between acute treatment and attending to the control of chronic symptoms and conditions. Patients also vary in their emotional response to the infection; this again complicates the planning and delivery of palliative care.

#### ■ Complex treatments.

A wide range of treatments for HIV/AIDS patients is now available. Antiretroviral drugs (ARV) have been shown to be highly effective in controlling the progress of HIV disease, but their high cost means they are not readily available to most patients in developing countries. Patients may experience many treatable opportunistic infections and other symptoms, which puts stress on health delivery systems as well as creating compliance problems when the treatments produce unpleasant side-effects. As HIV/AIDS patients are living longer, they may become more dependent on health care workers, and this can create psychologi-

cal problems for both patients and carers.

#### ■ Stigmatization and discrimination.

People living with HIV/AIDS face a very specific set of psychosocial problems. Many patients have to live with stigmatization and discrimination, even in high-prevalence countries where HIV affects nearly every member of the population. People are reluctant to be open about their HIV status, thus increasing their feeling of isolation, and carers may be wary of disclosing the positive status of a sick relative. In communities where HIV is less common, people with HIV are often from marginalized or minority groups, such as drug users, men who have sex with men, or sex workers. They may have less well established support networks, and face added discrimination if they are suspected of being seropositive.

#### ■ Complex family issues.

HIV/AIDS has a major effect on families, especially in areas of high prevalence and where most patients are young and economically active. Both partners in a relationship may be infected. Or often the partner of someone with HIV may be unsure if he or she is infected, and thus the illness of one partner raises worries about infection in the other as well as anger with the infected partner. If a child is infected, the mother, and often the father, will usually be infected. Siblings may also be infected. Financial problems increase as the breadwinner becomes ill and children will often not be able to continue, or even start, schooling.

## Background

- **Role reversal in families.**  
HIV care often involves older people looking after their younger, previously productive children, without the financial contribution from those children. This has resulted in harsh economic and social consequences. When people become unwell with HIV disease, and are unable to continue working to support their family, they may return to their parents to be cared for during the last stages of their illness. Old people are being left to care for their grandchildren. In other homes, children have become the main carer for their parents or their sick siblings. Child carers need special emotional and practical support.
- **The burden on health care workers.**  
Caregivers working with HIV/AIDS patients face causes of stress unique to this condition. So many patients are young and health workers caring for people with late-stage HIV disease face the death of all their patients. Eventually, workers may become withdrawn and fatigued by multiple losses and the complex care needs of patients. In developing countries, these stresses are exacerbated by the lack of resources, in turn creating feelings of hopelessness because workers feel they have so little to offer patients in terms of treatment. In palliative care, the mental health of health care workers is vital if they are to remain empathic and effective in the direction and delivery of care.

### The range of care needed for the patient

#### Treatment of symptoms

**PREVALENCE OF SYMPTOMS: Multi-centre French National Study (314 people)**<sup>1</sup>

Symptom	Prevalence
Pain	52%
Tiredness	50%
Anxiety	40%
Sleep disturbance	37%
Mouth sore	33%
Sadness	32%
Weight loss	31%
Nausea	28%
Fever	27%
Cough	27%
Depression	24%
Diarrhoea	24%
Skin problem	24%
Pruritus	23%
Respiratory problem	22%
Vomiting	20%

<sup>1</sup> Larue F, Brasseur L, Musseaut P, Demeulemeester R, Bonifassi L, Bez G. Pain and symptoms during HIV disease. A French national study. *J Palliative Care* 1994; 10(2):95

The medical management of people with AIDS is a balance between acute treatment and trying to control symptoms. Most people living with HIV/AIDS suffer from many symptoms, including pain. These symptoms can occur at the same time, can affect one or more body system(s)/function(s) and can lead to other symptoms, including anxiety and depression. As people reach the end of their illness, it may be inappropriate to continue investigations and treatments that will have little long-term benefit and merely add to the distress of the patient. However, some of the HIV associated illnesses and opportunistic infections (OIs) are easy to treat – for example, tuberculosis – and should be treated. Early and accurate

diagnosis of OIs is important at any stage of HIV disease. Wherever possible, the person with HIV should decide about his/her treatment and be informed of the options; educating the patient is an essential tenet of palliative care. He/she should be helped to understand the limits of any treatment, and its outcome.

#### 1. Pain

Pain relief is paramount for people living with HIV/AIDS. Pain is what the patient says hurts. It is always subjective, never what others, such as caregivers, think it ought to be. Every patient should be helped to lead as pain-free a life as possible. Health workers should not withhold pain relief because they worry that a

## Background

patient will become addicted to pain killers. Pain medication should be reviewed frequently and increased when necessary. Pain should be controlled in a way that keeps the patient as alert and active as possible.

Pain relief should begin with a straightforward explanation of the causes of pain. Many pains are best treated with a combination of drug and non-drug measures.

Unlike cancer, pain for AIDS patients is not permanent, but temporary and associated with infections. So if the infections are treated energetically, the pain reduces and less pain control is needed. But there is often more than one source of pain and each needs to be diagnosed and treated.

It is important to remember that emotional pain, the fear of dying, for example, or the pain of guilt, the meaninglessness of life, can be as real and hurt just as much as physiologically inspired pain. The psychological and spiritual suffering of AIDS patients can be unusually severe.

Physical pain can lead to anxiety and/or depression, which in turn can lower a person's pain threshold. If there is a conspiracy of silence in the family concerning the patient's disease, he or she may feel even more isolated and this can lead to more pain and fears about the pain worsening. The problem of uncontrolled pain can create anger from the patient and the family, and anger and/or feelings of inadequacy among carers.

Very anxious or depressed patients may need an appropriate psychotropic drug in addition to analgesia, otherwise the pain may remain intractable. Psychotropic drugs, however, are not analgesics and should not be

used instead of analgesics.

A relatively inexpensive yet effective method of pain relief exists for the majority of people with pain. The keys to this method are:

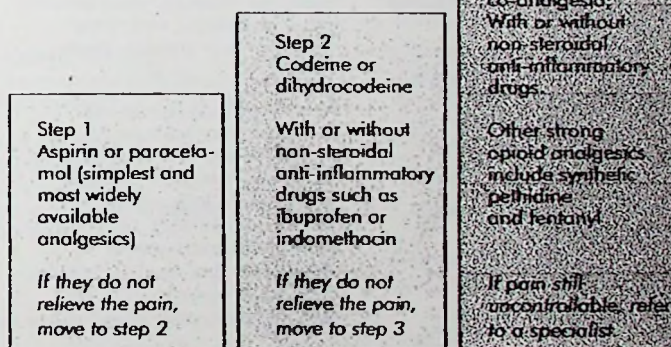
- **"By mouth"**. If possible analgesia should be given by mouth.
- **"By the clock"**. Analgesics should be given at fixed time intervals. The dose should be titrated against the patient's pain and the next dose should be given before the previous one has fully worn off. In this way, it is possible to relieve pain continuously.

Recently, pain guidelines have recognized that pain suffered by people with HIV disease is very like that of cancer pain. For this reason, carers should rapidly advance to step 3 medications. When opiate analgesia is given, nausea and constipation commonly occur and it will be necessary to treat these at the same time.

## 2. Diarrhoea and constipation

Initial management should include the diagnosis and treatment of underlying infection. If no cause can be found and there is no blood in the stools or

### The analgesia ladder



Adapted from *Cancer pain relief*, second edition, WHO, 1996 and *Docteurs sans frontières*, 1998

- **"By the ladder"**. The sequential use of analgesic drugs is shown in the figure:
- **"For the individual"**. The choice and dosages of analgesics will vary widely from individual to individual and must be tailored accordingly. Keeping a pain score is useful for adjusting the dose of pain medications.

constant fever, diarrhoea should be treated with oral agents such as loperamide (up to 16 mg per day in divided doses) or codeine (15–60 mg every 4 hours). People with diarrhoea should take plenty of fluids or use oral rehydration solutions to avoid dehydration. If the person has diarrhoea immediately after eating, the initial problem could be lactose intolerance or pancreatic

## Background

insufficiency. A review of the diet and an attempt to temporarily eliminate milk products or fat may be helpful. A stool with the consistency of thick soup may be caused by the mechanical obstruction by a hard stool or a tumour, and might be treated with an enema rather than something to decrease motility.

Constipation may result from prolonged bed rest, profound cachexia (weakness through considerable weight loss), a poor diet, or opioid use. Treatment includes dietary advice, increased fluid intake and the use of stool softeners and laxatives.

### 3. Nausea, vomiting, anorexia and weight loss

Nausea and vomiting can be caused by drug therapy, central nervous system infections or space occupying lesions, gastro-intestinal infections, or blockage of the gastric outlet or proximal duodenum by intra-abdominal tumours (most commonly a lymphoma or Kaposi's sarcoma).

Prochlorperazine (5–10 mg 2–3 times daily) is useful for mild nausea. Metoclopramide (10 mg every 4–8 hours) or ginger is useful for nausea caused by gastro-intestinal disturbance. However, it may cause *neurological side effects* in people who are cachexic. It should not be used in intestinal obstruction. When nausea is caused by central nervous system disorders, low doses of antidopaminergic drugs such as haloperidol may be useful.

If oral and oesophageal infection is present, antifungal treatment may improve dysphagia (problems with, or painful, swallowing) considerably.

### Summary of treatment for oral and oesophageal infections

Gingivitis	oral hygiene metronidazole 400 mg twice daily for 5 days. betadine mouth wash
Oral candidiasis	topical or systemic antifungals (e.g. nystatin oral suspension 2–4 times daily, miconazole oral gel (2–4 times daily) or amphotericin lozenges (10 mg 2–4 times daily)
Oesophageal candidiasis or severe oral candidiasis	systemic antifungals (e.g. ketoconazole 200 mg twice a day for 10–14 days) or fluconazole 200 mg for 3 days
Mouth ulcers	1% gentian violet prednisolone 10 mg daily for 5 days

Nutritional support with multivitamin and micronutrient supplementation may be useful, with, if possible, advice from a dietician. Making meals smaller, more appetizing and more frequent may improve dietary intake.

People with advanced HIV infection may have profound weight loss with loss of muscle bulk: the so-called "wasting syndrome". Although dietary advice, antiemetics, appetite stimulants, treatment of diarrhoea, and anabolic steroids may be of some benefit, this usually has a poor prognosis.

### 4. Cough and shortness of breath

In developing and many middle-income countries, tuberculosis (TB) is commonly associated with HIV infection. As TB can occur at any stage during HIV infection, it should always be actively sought for and treated in people with HIV disease. Any cough that persists for longer than three weeks after treatment with a standard antibiotic should be thoroughly investigated for TB (including by chest X-ray where available because many patients with HIV-associated TB have negative

sputum smears). Other causes of cough that should be considered are *Pneumocystis carinii* pneumonia (PCP) and bacterial and fungal pneumonias. Non-infectious causes of cough include pulmonary Kaposi's sarcoma, lymphoma and interstitial pneumonitis.

As well as treating the underlying infections, use should be made of antitussive agents (cough suppressants).

Morphine or codeine can also be used to decrease the sense of breathlessness. People who are very short of breath despite treatment may find breathing easier if they are sitting upright. *Physiotherapy* is usually helpful to clear secretions and improve air-entry.

Benzodiazepines should be used to relieve the associated anxiety. During a patient's last days of life, scopolamine 0.3–0.6 mg *subcutaneously* every 4–8 hours or glycopyrrolate 0.1–0.4 mg intramuscularly every 4–6 hours will be useful in reducing the quantity of secretions when the person is too weak to cough.

Oxygen may prolong death rather than improve quality of life, and may not be appropriate.

## Background

It is important in such cases to provide support and information for those people at the bedside, particularly if this laboured breathing is perceived as distressing to the patient.

### 5. Malaise, weakness and fatigue

Fatigue, lack of energy and malaise are common symptoms reported by people with HIV disease. Fatigue is reported as being a distressing symptom by 40-50% of people with advanced HIV disease. There are often many reasons for fatigue, but it may be associated with:

- anaemia
- direct HIV effects on the central nervous and neuromuscular systems
- malnutrition and "wasting" syndrome
- secondary infections and tumours
- adverse effects from drug therapy
- chronic pain
- insomnia
- depression.

Where possible, any underlying problem should be treated. Often no specific cause is found but physiotherapy and rehabilitative exercise may be helpful. Changes in work and household duties may enable people with fatigue to cope better and have an improved quality of life.

### 6. Fever

Fever is often the sign of secondary infections, and every effort should be made to find and treat the underlying cause. For symptomatic treatment, paracetamol (500-1000 mg every 4-6 hours) or aspirin (600 mg every 4 hours) is usually effective. Paracetamol and aspirin can be alternated every 2

hours if necessary. Ensuring adequate fluid intake is important and sponging the person with a wet towel can also bring some relief.

### 7. Skin problems

About 90% of people with HIV have skin problems. It is important to recognize the underlying cause, as some of these are treatable with cheap and simple medicines. Successful treatment will improve a person's quality of life because skin problems often cause emotional

distress and the avoidance of social interaction. Some people fear stigma or rejection if their lesions are unsightly and may need counselling and reassurance. Scabies is often atypical and should always be considered if significant itching pruritus is present, regardless of the nature of the rash. This will often require at least three courses of treatment as well as antipruritic agents such as antihistamines and/or topical steroids after the treatment is washed off. Opioids may be needed to treat severe itching.

**Common skin problems associated with HIV disease**

Skin problem	First-line treatment
Bacterial infections (boils, abscesses etc.) violet	Antibiotic treatment (e.g. erythromycin or flucloxacillin) and topical gentian violet  Abscesses should be drained, cleaned and dressed before antibiotic treatment
Fungal infections tinea corporis, folliculitis, candidiasis	Topical antifungals if mild, systemic antifungals in severe cases
Viral infections herpes simplex herpes zoster molluscum contagiosum papillomavirus (warts)	Early herpes zoster can be treated with aciclovir 800 mg 5 times daily (if available) or topical gentian violet and most importantly pain relief. If warts/molluscum are uncomfortable they can be treated with topical podophyllin or a silver nitrate stick.
Scabies	Topical treatment with lindane, benzyl benzoate or permethrin (treat contacts as well).
Pressure sores	Prevent by keeping skin clean and dry and turning a bed-bound person every 2-4 hours. Treat by cleaning with salt solution (should taste no more salty than tears) daily and covering with a clean dressing.
Wounds or ulcers	Clean with salt solution and keep covered with a clean dressing. Infected wounds can be treated with antibiotics: smell and infection can be controlled by metronidazole powder or gel.
Drug-induced eruptions	Supportive care with oral antihistamines and 1% hydrocortisone cream.

## Background

### 8. Brain Impairment

*HIV associated brain impairment* (often called HIV dementia) is an important illness of advanced HIV disease. Up to 15% of people with advanced HIV disease will develop some degree of brain impairment and a further 15–20% may develop some degree of motor or cognitive impairment. HIV associated brain impairment is characterised by abnormalities in motor and cognitive function consisting of psychomotor slowing with behavioural disturbance. Early symptoms include apathy, poor concentration, mood swings and memory disturbance. Later symptoms may include disinhibited behaviour, agitation and poor sleep. Global dementia, paralysis and incontinence can occur in the final stages. It is important to differentiate mild brain impairment from a depressive illness, as the latter is treatable with antidepressants.

Antiretroviral drugs are helpful in treating HIV dementia. Where these are not available, the outlook is poor, as the brain impairment is irreversible and progressive. At the early stages, counselling may be helpful. Environmental clues to improve memory such as family pictures, calendars and clocks may be useful. Most importantly, family members and friends should receive support and counselling so that they understand the illness and are aware of the prognosis. Delirium or agitation of late-stage dementia may respond to neuroleptic drugs, such as haloperidol (1–5 mg 6–8 hourly) or chlorpromazine (25–50 mg 6–8 hourly). Low doses should be used initially because of the increased risk of extrapyramidal side effects in people with HIV-related brain impairment. For brain impaired

patients who live on their own, day-to-day activities can be a major problem, especially as some people may have few physical symptoms or problems but still need 24-hour supervised care. Hospices or palliative care units, if available, may be required to give medium-term care. If these are not available, regular support and supervision from a home care team is important to support the carer and patient.

#### Counselling and social support

##### *Psychological problems*

People living with HIV/AIDS frequently experience emotional and psychiatric problems. But their quality of life can be considerably improved when health workers, family members and carers understand these problems, and support the patient experiencing them.

Depression is common. If mild and clearly associated with factors in the patient's life, it may be helped by counselling alone. If it does not respond quickly to psychological support, or symptoms are severe, treatment with antidepressant drugs should be started promptly. Tricyclic antidepressant drugs (such as amitriptyline, imipramine or trimipramine) will usually be the first line therapy. In physically ill patients, antidepressant drugs should be started slowly, to minimize side-effects (such as dry mouth, sedation and postural hypotension). Once the depression improves, antidepressants should be continued for a further 4–6 months to avoid relapse. When antidepressants are stopped the dose should be reduced gradually, monitoring for signs of relapse.

People living with HIV/AIDS may consider suicide. This may result

from depression or be a rational choice. Such tendencies can usually be helped with emotional support from health care workers, including the reassurance that these feelings of hopelessness are common with any chronic illness and tend to be short-lived. Some people with advanced disease, with severe symptoms, or those who have also watched family and loved ones die from HIV disease, state that they wish to end their lives. Family and spiritual support as well as counselling may be particularly important in these circumstances.

Anxiety is also a common symptom in people with advanced HIV infection, expressed in physical as well as psychological symptoms. Tachycardia, palpitations, shortness of breath and panic attacks may occur. Emotional support and behavioural interventions such as relaxation therapy are the first line of management. Benzodiazepines (such as diazepam 2 mg 6–8 hourly as required) may be helpful for short-term severe anxiety, and beta-blockers (e.g. propranolol 10 mg 4–6 hourly as required) may be used for palpitations.

#### Forms of psychological support

##### *1. VCT (voluntary counselling and testing)*

In many developing countries a diagnosis of HIV infection or AIDS is made by a health care worker when the patient already has advanced HIV infection. If HIV testing is available it should confirm the diagnosis. Whether HIV testing is carried out or not, it is important to share the presumed or confirmed diagnosis with the patient. Carers and families often believe that it is kinder to shield the patient from

the diagnosis of HIV infection and that talking about HIV will make him/her more depressed. However, most people with symptomatic HIV infection will have given it much thought and sharing their worries and fears can be of great comfort. They may wish to discuss whether they should disclose their HIV status to other family members and friends, if they have not already done so. Carers can listen, be non-judgmental and offer love and support, especially if the patient feels isolated or fears rejection.

### 2. Spiritual support

Even if they have not been actively involved with a church or religious group, many people find great comfort from priests or other spiritual leaders during chronic illness. Others, however, may feel pressurized into talking about spiritual issues by loved ones, when they would prefer not to. Carers should acknowledge the patient's spiritual needs, or lack of them, and arrange for support and visits from a priest, pastor or other spiritual person, when appropriate.

### 3. Preparing for death

It is often believed that it is not appropriate to talk about the fact that someone is going to die, and that mentioning death will in some way hasten it. However, for those who wish to discuss death, open discussion, ideally from early diagnosis, can help dying persons to feel that their concerns are heard, that their wishes are followed, and that they are not alone. Sometimes it is easier for patients to express their feelings and concerns with a counsellor rather than their family, especially initially. Support groups can provide great comfort and relief; many patients are helped by talking to other people who are terminally ill.

Most people want to know that they will be remembered. Encouraging friends and family to share stories or memories of the individual's life makes the person feel loved and cared for.

People who are nearing death are frequently afraid of dying in great pain. Health workers should be able to reassure patients that pain relief will be carried out up to the point of death. Another great worry is what will happen to patients' dependants after they die. Where possible, plans should be made for dependants and partners. Although it can be distressing to discuss these issues, making plans can reduce anxiety. Making a will can prevent family conflict and ensure that partners and children are not left destitute. This is particularly important where "property grabbing"<sup>1</sup> is common.

Practical issues to be discussed before death

- custody of children
- family support
- making a will
- funeral costs
- future school fees.

Emotional issues to be discussed before death

- resolve old quarrels
- tell patient and family members or friends that they are loved
- share hopes for the future, especially for children who are left behind
- say goodbye to carers and providers.

### Support for families and carers

For family members, partners and friends, looking after someone with HIV infection can be very daunting. In high-prevalence areas carers may be looking after several family members who are sick with HIV infection. Carers need technical assistance with nursing and infection control, and emotional support. They need educating in the limits and outcomes of particular treatments, and advice and support so as to avoid burnout.

#### 1. Nursing

Nursing people with late-stage HIV can be time consuming and tiring. If the patient is not fully mobile or bed bound he/she will need constant attention, such as:

- turning to prevent bedsores
- helping to the toilet or latrine, or to use a bed pan
- washing and keeping cool by sponging with a damp towel
- if the patient is incontinent of urine or faeces, washing both patient and bedclothes
- preparing food and drinks and helping to feed the patient
- providing company when the patient is feeling lonely, anxious or scared
- helping with drug taking
- cleaning and dressing sores and ulcers.

Many of these nursing tasks will be new to the family or community carer. They will therefore need help and support from a nurse, or knowledgeable health worker, who can explain about drug taking schedules and simple nursing techniques, such as how to dress ulcers. This will

<sup>1</sup> "Property grabbing" occurs in some countries in sub-Saharan Africa. It is the practice of relatives of the deceased to seize his/her property at death. This often results in women and orphans being left destitute following a death.

## Background

give them confidence and make them feel less isolated. Written or illustrated material explaining drug taking schedules can be useful as these may be complicated, and some medicines have adverse effects, drug interactions or must be taken with particular foods.

Coping with HIV related brain impairment could be particularly difficult and distressing for friends and relatives, especially when the patient behaves aggressively or without normal inhibitions. Health care workers need to take time to explain what is happening when cognitive and behavioural problems develop, and to support carers in this situation.

### 2. Infection control

There are many myths about HIV and its transmission. Carers often worry about being infected themselves with HIV by the person they are looking after. Health workers should help carers explore these anxieties and, whilst giving them practical information on how to avoid infection, reassure them that the risk of catching HIV whilst caring for someone is minimal.

**Carers should be aware of and understand the following:**

- The risk of HIV infection to carers and household contacts is *extremely low*.
- There is no risk from casual household contact such as sharing eating utensils, and gloves do not need to be worn when touching and lifting someone with HIV.
- Gloves, when available, should be worn for cleaning wounds and clearing up blood or body fluids. When gloves are not available, covering the hands with plastic bags is a helpful alternative.

- Spillage of blood, faeces, urine or vomit should be cleaned up using household bleach.
- Cutlery, bed linen, etc. should be washed with normal washing products.

### 3. Psychological support

When carers, such as partners or children, are uncertain about their own HIV status, health workers can help them address their worries and offer a referral to voluntary counselling and testing (VCT).

Other problems, such as a shift in *family dynamics when the elderly parent or young child becomes the carer*, can make carers feel isolated. They may be reluctant to talk about these issues for fear of being judged as inadequate. Health workers can try to reassure them that their concerns are normal, or put them in touch with other carers. Sharing their experiences, for example, through support groups, can be very helpful to both parties.

The need to offer counselling to partners and families following the death of a family member or friend is often overlooked, particularly in developing countries. Bereavement counselling can help the bereaved person to discuss and reflect on the changes brought about by loss, to mourn appropriately and to look to the future. Partners and parents of a child who dies may have unresolved fears about HIV infection for themselves, or other family members, and can be helped to come to decisions about HIV testing.

The process of grieving may last many months or even years. However, for some people a single counselling session may be sufficient to clarify their thoughts and feelings, and to reassure them that they are coping as best

they can under the circumstances. This is particularly true for people who have other emotional supports, such as family, friends and church or other spiritual support. Other people may need several sessions. Some people never completely come to terms with a loss, particularly that of a child.

In high-prevalence developing countries, grieving may be made worse by multiple losses of friends and relatives through HIV infection. People who have recently suffered multiple losses may be afraid that they are 'going crazy' or losing their mind. Reassurance that such feelings are a normal part of grieving is important. Some traditional beliefs and practices may be helpful, but others, such as "property grabbing", may add to difficulties.

### 4. Helping the carers to care

Carers may become exhausted if they have been looking after a sick person for a long time, or if they have had many other friends or family members die recently. If they are tired or distressed, they cannot give their sick relative or friend the care they need. If respite care is available, it may be appropriate for the patient to spend short times there. If this is not available, other family members, friend or volunteers can be encouraged to share the care so that the main carer can get adequate rest. Health workers should reassure carers that they are bound to be tired and give them 'permission' to 'have a break' or take more rest.

*Day respite care for children with symptomatic HIV disease* may be offered. This not only gives respite to the children, but also to the carers who are often themselves sick or elderly.

Structured home-based care programmes, where available,

## Challenges

can provide good support for carers as well as patients. Health workers can share the burden of care, as well as providing treatment, advice and support. They also encourage acceptance of HIV/AIDS patients by communities, and help dispel myths and stigmatization.

Many patients first seek help and support from traditional or complementary medical practitioners. These practitioners may offer symptomatic treatment with herbal or other remedies, or pain relief through therapies such as acupuncture. Patients and carers may also be offered counselling and support. Health workers should discuss treatment and care plans with other practitioners involved in a patient's care, and should ensure that any complementary therapy is useful and not too costly. They can protect patients and carers from exploitation by unscrupulous charlatans.

### Challenges:

#### Perceptions and recognition of palliative care

Palliative care has developed considerably since its early days when most patients treated were terminally ill and approaching death. But still many people living with HIV/AIDS shy away from the notion of palliative care because they link it with death and many of them don't want to admit they are dying. Policy-makers, planners and health workers have to tackle this misconception in order to ensure patients with HIV/AIDS receive palliative care.

Many developing and middle-income countries have limited health resources, including drug budgets, and palliative care,

particularly medicines used for symptomatic relief, is not always seen as a priority. Governments must appreciate that for humanitarian reasons alone, palliative care—reducing the pain and suffering of those who are chronically ill or dying—should be a priority.

Although HIV has added enormously to the health care burden in many of the poorest countries, many of the drugs and services which can benefit people with HIV are readily available, listed as WHO/UNAIDS essential drugs, and are cheap. If, however, additional resources are not provided to care for the increasing numbers of people with HIV, and to train carers and health workers, many people will die in pain, isolation and distress, and their carers, including many orphaned children, will be left feeling unsupported and helpless.

In some low-prevalence countries, people living with HIV/AIDS are even more isolated because HIV is perceived as a problem of marginalized groups such as injecting drug users, refugees and men who have sex with men. Health services need to structure health care and support to meet the needs of these particular groups, including tackling their isolation and stigmatization.

There are other sound development reasons for ensuring that people living with HIV/AIDS receive treatment to ensure a decent quality of life. Many people who are ill with HIV are intermittently ill and with access to appropriate medicines they have much to contribute to their families and communities. As people with HIV are often young adults, many have young children who need their parents to be with them for as long as possible.

In order to provide effective palliative care, governments and planners may need to transform health services through improved training, by making care available in a wide range of settings and by ensuring a sustained supply of appropriate drugs and medicines.

#### Organizing training

Even in settings where HIV is a major health problem, most communication about HIV infection has dealt with HIV transmission and prevention, with little emphasis on how to care for people with HIV. Nor do the majority of health professionals know how to holistically assess and control pain.

Palliative care training should be provided for health care workers in hospitals and in the community, for teachers, religious and community leaders; they in turn can teach community health workers, community volunteers and families caring for people living with HIV/AIDS.

General HIV education in the community can be very beneficial in reducing stigma, by helping to change negative attitudes towards people with HIV and their families, and giving factual information about caring for people living with HIV/AIDS.

#### Making good palliative care services available

In areas of high HIV prevalence the number of people with symptomatic disease requiring medical and psychological support increases as the epidemic matures. For example, in Zambia, which has a population of about 8.5 million, one in five adults are infected and an estimated 90 000 become unwell with HIV each year. In some hospitals in sub-Saharan Africa, 50–70% of adult medical beds

## Challenges

are occupied by people with HIV-related illnesses. This has put an impossible burden on already very over-stretched and under-funded health services. Wards and outpatient clinics become overcrowded and medical staff feel demoralized and impotent as they have little treatment to offer. In response to this crisis, two main approaches have been taken in developing countries. First, alternatives to traditional inpatient and outpatient hospital services were sought. Secondly, there has been a development and expansion of services, including home care services, provided by nongovernmental organizations (NGOs).

### 1. Home care

Many successful models of home care have been developed in different settings. Those that are *community-based*, rather than developed as outreach from hospitals, tend to be cheaper to run and provide a wider coverage. Using volunteers has not only been successful in keeping costs lower, but has also enabled communities to work together in supporting each other, raising awareness and promoting tolerance and acceptance.

### 2. Residential hospice care

Residential hospices have been set up in many industrialized countries to help care for people with terminal HIV disease. Hospice care is particularly helpful for people who live alone or who have poor symptom control or symptoms that are difficult to manage, such as those associated with severe brain impairment. Hospice care is also useful for providing respite care, when carers need a break or when patients are being stabilized on new drug regimes. In developing countries there are a few examples of hospices, often run by religious groups. In high-

HIV-prevalence developing countries, inpatient hospice care is too expensive to provide for the large numbers of people requiring palliative or terminal care.

### 3. Day centres

In some countries day care facilities for people living with HIV/AIDS may be available. These enable patients to remain at home whilst allowing carers time off during the day. Patients can receive palliative care at the day centre, counselling and emotional support, cooked meals, services for their children and, in some cases, schemes for income-generation.

Each of the models of care has advantages and disadvantages and patients may benefit from different care at different stages in their illness.

### 4. Access to analgesics and palliative care drugs

There are often strict legal controls on analgesics such as codeine and other opiates. Because of fears about their misuse, in many countries they can only be prescribed by doctors. In settings where the majority of palliative care is delivered by nursing staff or community carers, and there are few doctors, access to analgesics can be problematic. A balance is needed between increasing access to adequate pain relief for people with HIV and the careful supervision and record keeping of prescription of opiate analgesics.

In some settings cannabis has been found to be helpful in symptom control (particularly for the relief of nausea and improvement of appetite) for people with HIV. However, their use is often restricted by strict legislation. Some PLHA groups argue for these drugs to be made more widely available.

### 5. Providing support for carers, counsellors and health care workers

Health services need to address the specific causes of stress for people who care for HIV/AIDS patients. Support groups for carers enable them to share their particular anxieties and concerns, such as coping with multiple deaths or coming to terms with the person's sexual orientation. Caring for people with HIV at the end of their life is emotionally draining and can be depressing. To avoid burnout adequate support for carers, counsellors and health care workers should be available.

In many cultures, parents find it difficult to discuss painful issues with their children. As a result, children are unprepared for the death of their parents, unable to protect themselves from HIV infection in the future and often unable to trust adults. Children with HIV or whose parents or siblings have HIV disease may need culture and age-specific counselling and their parents or carers need support and guidance in talking to children about sensitive and distressing issues.

### 6. The special needs of children with HIV

Most children with HIV disease in developing countries have little access to medical care, and palliative care or rehabilitation is seldom offered. Assumptions such as 'because the child does not verbalize his or her problems he/she has none', or that 'addressing issues around death and dying will cause more harm than good' are now being challenged. The importance of communicating with children and involving them in decision-making is now being recognised by parents and health workers.

What is currently being done to overcome these challenges?

### Examples of current projects initiatives in palliative care.

#### **The Catholic Diocese in Ndola, Zambia**

In the late 1980s Zambia developed the new strategy of "home based" care to cope with the increasing number of people with symptomatic HIV disease. This strategy was not confined to medical treatment and nursing care, but took a more comprehensive approach to the needs of individuals, families and communities. However, many of the early projects had limited coverage and were relatively expensive to operate. In 1991 the Catholic Diocese in Ndola, in the Zambian copperbelt, established a comprehensive home care programme for people with HIV disease, which aimed to provide much higher coverage at less expense. The key to its success is the role of the 500 volunteers who offer counselling, social and emotional support, and basic medical and nursing care for people with HIV disease and their families. They also provide links between the local health centres and the community, allowing people with HIV to receive care in their homes rather than as inpatients. HIV education to the communities has helped to change attitudes to PLHA increasing acceptance and tolerance and reducing stigma.

#### **The AIDS Support Organisation (TASO), Uganda**

TASO in Uganda was founded in 1987 as a self-help support group, and it is an example of what can be done when people living with HIV/AIDS and their families identify their own needs and spearhead the process of defining the nature of services to meet those needs. TASO began by offering counselling and

outpatient clinical care of opportunistic infections to people living with or affected by HIV/AIDS. Soon it became evident that when TASO clients became bed-bound, they were often not receiving good-quality care due to stigma in homes and communities, and the lack of care skills in the homes. TASO started a campaign of AIDS awareness aimed at changing attitudes in communities. At the same time TASO began training and supervision programmes for families and community members in basic home care. People living with or affected by HIV became the driving force of this campaign, sharing their personal experience and advocating "positive living". Family level income-generation activities were started and linked to church and other community-based organizations. TASO also runs training programmes for counsellors, community carers and community-owned resource persons.

#### **The Mildmay Mission Hospital, London, United Kingdom**

Mildmay is a Christian foundation and was the first to set up inpatient and day palliative care services in Europe. It is funded mainly through contracts with the National Health Service together with by donations and grants. It is situated in central London and aims to care for people with HIV without regard to race, religion, culture or lifestyle.

People with HIV may be admitted for rehabilitation, respite or terminal care, or for support while changing drug regimens. The use of the hospice has changed since the use of ARVs became routine for people with HIV in the United Kingdom. Many more patients are now seen for rehabilitation or respite care than for terminal care. Associated

services include counselling, referral for hospital outpatient care such as gynaecology and dermatology, social support and support for children. Mildmay has a family care unit and a unit for people with brain impairment, with separate day care centres for children and adults. People who use the centre include men who have sex with men, injecting drug users, and people from Africa now living in London. Mildmay has found that close links with churches and religious groups in the community have helped to raise awareness about HIV and enabled people living with HIV/AIDS to obtain ongoing spiritual support once they are back in their homes.

#### **The Mildmay Centre for AIDS palliative care and international study centre, Kampala, Uganda.**

The Mildmay Centre in Uganda was developed as a joint project between the Ugandan Ministry of Health (AIDS control programme), the United Kingdom Department for International Development and Mildmay International, who have a contract to manage the centre for ten years. It was opened to patients in 1998.

The Mildmay Centre was designed to provide specialist outpatient palliative care and rehabilitation for people living with HIV/AIDS, and to serve as a demonstration model for cost-effective care in resource-limited settings. It also provides day and residential training programmes in all aspects of HIV care for health workers, volunteers and carers.

## Responses

The emphasis is on rehabilitation and the promotion of independence wherever possible. It has a patient-focused team with support from:

- Medical and nursing staff
- Physiotherapists
- Occupational therapist
- Nutritionist
- Counsellors
- Spiritual care
- On-site laboratory services
- On-site pharmacy.

At the Mildmay Children's Centre in Kampala, children with HIV have free access to the same range of services as at the adult centre. The services are child-friendly, with therapeutic play and counselling. The aim is to meet not only their physical needs but also their emotional needs as many children seen are severely traumatized. Day respite care for orphans with advanced HIV disease is also provided.

### **Calmette Hospital, Cambodia**

The Calmette hospital and a Phnom-Penh military hospital have implemented an innovative treatment and training programme to fight AIDS in the community through education, and to provide a comprehensive response to the medical and psychosocial care needs of the patients it serves. It is now estimated that 200 000 Cambodians are HIV-positive, of whom 30 000 have progressed to AIDS, with an impact that is also growing on military and police forces. Working with Doctors without Borders, the programme has developed a capacity to provide both care, including inpatient and outpatient services, and training for health care providers. As a result, trained physicians have established a pain clinic and provide pain management in these two

hospitals. The current project was based on the premise that a response is required which addresses medical and psychosocial needs simultaneously. Treatment focuses particular attention on pain management and responding to symptoms. Psychological and social supports are provided to infants who are orphans. Another primary objective of the project is to provide education and training for clinicians, pharmacists, and family members. Within communities, families and neighbourhoods receive health education and HIV prevention. The system of care has expanded to include ambulatory and home care for patients living with AIDS and cancer.

### **Sahara Michael's Care Home, India**

Sahara Michael's Care Home, a nongovernmental organization in India, is pioneering a continuum of care that addresses aspects of HIV/AIDS care lacking in the health service, concentrating on areas that include treatment, training, human rights advocacy, and the development of networks and partnerships. The Care Home, a 16-bed facility, evolved in response to changing disease patterns for HIV/AIDS and the need for care giving of a greater intensity and longer periods. The programme has been serving areas of high need, in resource-constrained settings, since 1978. Funded by the Catholic Relief Organisation, the model of care initiated in 1997 for people living with HIV/AIDS is now being utilized by HIV/AIDS communities throughout India.

The model of care includes care giving, counselling, a nutrition programme, cost viable treatment strategies, crisis care, and training for self and family care provided by a team of

professionals and non-professionals. The professional team consists of a consulting physician and nurses. The care staff includes 17 men and women who perform a variety of tasks ranging from autoclaving, cooking and driving to hospital visits. In the next year, the team will be developing an outpatient department for HIV-positive people, counselling which embraces issues that go beyond HIV status, and a systematic training programme for the intricacies of HIV/AIDS care.

The Care Home has a spiritual undercurrent to its programmes and a team with a service-like devotion to care giving. This has fostered an acceptance of HIV/AIDS in local communities and encouraged people everywhere to offer materials and support.

### **The Positive and Living Squad (PALS) and Kara Counselling and Training Trust (KCTT), Zambia**

KCTT and the PALS are closely linked Zambian NGOs, working to provide care and support services for people living with HIV/AIDS. The PALS are a group of people living openly with HIV. They organize a wide range of HIV prevention activities, but also have an important role in supporting other people with HIV when they become sick and families when a loved one dies. For people who are unwell with HIV, having support and understanding from someone who is also infected with HIV is often very helpful. It can lessen the feeling of isolation and help families to see that their problems are not unique. During the time of someone's last illness and death the PALS often provide practical and material help, including helping with funeral arrangements and helping make plans for dependants. The PALS

also have an important advocacy role and are active in fighting discrimination and promoting the rights of widows and dependants.

Among the activities provided by KCTT is a training programme for home care volunteers. Lay volunteers are taught about basic nursing and listening and counselling skills. KCTT also has a day centre where people with HIV can meet and learn skills from an income generation scheme, counselling services and close links with community based care teams. They also provide TB screening and preventive therapy for people with HIV and family counselling for families affected by HIV.

As palliative and supportive care needs are often overlooked, they must be emphasized in national strategic plans. There is also need for coordination with donors to ensure that palliative care is seen as a priority, and resource mobilization is essential to strengthen these efforts.

## Selected Key Materials

Blinkhoff P, Bukanga E, Syamalevwe B, Williams G. (1999) *Under the Mupundu Tree. Volunteers in home care for people with HIV/AIDS and TB in Zambia's copperbelt*. Strategies for Hope series No. 14. ActionAid.

Doyle D, Hanks G, MacDonald N. (eds.) (1998) *Oxford textbook of palliative medicine*. Second edition. Oxford University Press.

Fernis FD, Flannery JS, McNeal HB, Morissette MR, Cameron R, Bally GA (eds.) (1995) *A comprehensive guide for the care of persons with HIV disease. Module 4: Palliative care*. Mount Sinai Hospital/Casey House Hospice.

Oleske J, Czarniecki L (1999) Continuum of palliative care: Lessons from caring for children infected with HIV-1. *The Lancet* 354: 1287-90.

Osborne C, van Praag E (1997) Models of care for people with HIV/AIDS. *AIDS* 11 (suppl. B): S135-S141.

Sims R, Moss V (1995) *Palliative care for people living with AIDS*. Second edition. Arnold, London, United Kingdom.

Welch J, and Newbury J. (1990) *Looking after people with late HIV disease*. Lisa Sainsbury Foundation. Pattern Press, United Kingdom.

WHO (1993). *AIDS home care handbook*. WHO/GPA/IDS/HCS/93.2.

WHO (1996). *Cancer pain relief*. Second edition. ISBN 92 4 154482 1.

WHO (1998). *Cancer pain relief and palliative care in children*. ISBN 92 4 154512 7.

WHO (1998). *Symptom relief in terminal illness*. ISBN 92 4 1545070.

WHO (1999). *Drugs used in HIV-related infections. WHO model prescribing information*. WHO/DMP/DSI/99.2.

© Joint United Nations Programme on HIV/AIDS (UNAIDS) 2000. All rights reserved. This publication may be freely reviewed, quoted, reproduced or translated, in part or in full, provided the source is acknowledged. It may not be sold or used in conjunction with commercial purposes without prior written approval from UNAIDS (contact: UNAIDS Information Centre, Geneva-see page 2). The views expressed in documents by named authors are solely the responsibility of those authors. The designations employed and the presentation of the material in this work do not imply the expression of any opinion whatsoever on the part of UNAIDS concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers and boundaries. The mention of specific companies or of certain manufacturers' products do not imply that they are endorsed or recommended by UNAIDS in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

**6**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



safe and effective

# **use of antiretroviral treatments in adults**

**with particular references to resource limited settings**



## TABLE OF CONTENT

<b>1</b>	<b>Introduction</b>	<b>3</b>
<b>2</b>	<b>Section one</b>	<b>4</b>
2.1	BACKGROUND	4
2.2	CHARACTERISTICS OF AVAILABLE ANTIRETROVIRAL DRUGS	5
2.3	INITIATION OF THERAPY	6
2.3.1	Choice of regimen	7
2.4	MONITORING	9
2.4.1	TREATMENT FAILURE	9
2.4.2	HIV RESISTANCE TO ANTIRETROVIRAL DRUGS	10
2.4.3	FUTURE APPROACHES TO THERAPY	11
<b>3</b>	<b>SECTION TWO SOME EXPERIENCES WITH ART IN RESOURCE LIMITED SETTINGS</b>	<b>12</b>
3.1	ART COVERAGE	12
3.2	CONTEXT: PUBLIC OR PRIVATE SECTOR, DONOR SUPPORTED AND RESEARCH PROJECTS	12
3.3	QUALITY OF CARE AND OUTCOMES	13
3.4	LABORATORY MONITORING SERVICES	13
3.5	Surveillance for Drug Resistance	13
3.6	SUPPLY AND DISTRIBUTION OF THE DRUGS	13
3.7	Initiation of treatment	14
3.8	CHOICE OF THERAPEUTIC REGIMEN	14
<b>4</b>	<b>SECTION THREE GUIDE TO ART IN RESOURCE LIMITED SETTINGS</b>	<b>14</b>
4.1	WHAT SHOULD BE IN PLACE BEFORE INITIATING ART PROGRAMMES *	14
4.1.1	COUNSELLING FOR ART	15
4.1.2	FINANCIAL CONSIDERATIONS	15
4.1.3	DRUG INFORMATION	16
4.1.4	EMOTIONAL SUPPORT AND DIFFICULT DECISIONS	16
4.1.5	CONFIDENTIALITY AND SHARING HIV STATUS*	17
4.1.6	ADHERENCE TECHNIQUES	17
4.1.7	CLINICAL EVALUATION BEFORE INITIATION OF ART	17
4.1.8	HIV-RNA TESTING	18
4.2	INITIATION OF THERAPY	19
4.2.1	WHOM TO TREAT	19
4.2.2	CHOICE OF THE REGIMEN	19
4.3	MONITORING ANTIRETROVIRAL THERAPY *	20
4.3.1	Monitoring adherence to ART	20
4.3.2	Monitoring tolerance to ART	21
4.3.3	Monitoring the efficacy of ART	22
4.4	CONSIDERATIONS OF DRUG INTERACTIONS	22
4.4.1	ANTIRETROVIRAL DRUGS AND THE TREATMENT OF TUBERCULOSIS	23
4.4.2	INTERACTIONS WITH DRUGS COMMONLY USED FOR THE PREVENTION AND TREATMENT OF OIs	24
4.5	FURTHER RESEARCH NEEDS	24
4.6	INFORMATION AND TRAINING NEEDS	25

## **1 INTRODUCTION**

In April 1997, WHO and UNAIDS held an Informal Consultation on the Implications of Antiretroviral Treatments for HIV/AIDS, with the objective of providing policy guidance on major issues relating to the use and provision of antiretroviral drugs.

As a follow up activity to this consultation, a set of nine Guidance Modules on several aspects of antiretroviral treatments was produced. 2 Guidance Module number 4, entitled Safe and Effective use of Antiretroviral Therapies, provided guidance primarily to clinicians, counsellors, and managers of clinical services. Policy makers, people living with HIV/AIDS (PLHA) and decision-makers in national referral and district hospitals as well as training institutions have also found this guidance module very helpful. The module reflected the published standards of care and the consensus of participants at the time of the consultative meeting in 1997.

Treatment guidelines need to be regularly updated to take into account evolution in knowledge and experiences from different healthcare settings. There is today a much better understanding of the biological basis for antiretroviral therapy (ART) and clinical research has provided consistent data on its effectiveness. The adherence difficulties and adverse effects associated with some of the antiretroviral drug combinations are better understood and regimens that are easier to take are being developed.

There is also an increasing body of knowledge on the therapeutic implications of antiretroviral drug resistance. A variety of international treatment guidelines have been developed to keep clinical practice as much as possible in pace with the data emerging from basic and clinical research. Clinical guidance for the use of ART must take into account the profile of patients seeking care as well as the capacities of the healthcare setting in which this care is being delivered. Low and middle-income countries have requested recommendations for the provision and monitoring of ART that are more directly relevant to their resource limited settings than the published International Guidelines. In response to this requirement, WHO in collaboration with UNAIDS and the International Aids Society (IAS) organised a technical consultative meeting, in February 2000. This consultation brought together experts in HIV/AIDS care and HIV clinical research from industrialised countries and developing countries, to analyse available scientific evidence and discuss contextual issues relating to the safe and effective use of antiretroviral therapies in resource limited settings. This guide is a result of the discussions and recommendations of the February 2000 consultation.

In section one, the principles behind current use of antiretroviral drugs for the treatment of HIV-1 infection are outlined. This section refers to existing international recommendations. Several factors that relate to the profile of patients seeking HIV care in resource limited countries may influence the choice and the outcome of antiretroviral therapy:

- the vast majority of patients are currently treatment naive because antiretroviral drugs are usually not available through the public sector and are poorly introduced into private markets.
- most patients have advanced stage HIV disease at the time treatment is initiated because in the absence of wide spread counselling and testing, diagnosis is often delayed.
- patients in resource poor countries are more likely to have co-existing morbidity such as anaemia, malnutrition as well as tuberculosis and other medical conditions, which may act in concert to affect the choice of therapy and the considerations on the potential spectrum of drug interactions and drug toxicity.
- the majority of patients are in a low-income bracket and because antiretroviral drugs are not usually provided free of charge, financial constraints are a common cause of treatment interruptions and of further delay in initiating therapy.

Within many resource limited countries there are "sites of excellence" where small scale ART programmes have been implemented. Nevertheless, inadequacy of healthcare services in terms of

# TABLE OF CONTENT

<b>1</b>	<b>Introduction</b>	<b>3</b>
<b>2</b>	<b>Section one</b>	<b>4</b>
2.1	BACKGROUND	4
2.2	CHARACTERISTICS OF AVAILABLE ANTIRETROVIRAL DRUGS	5
2.3	INITIATION OF THERAPY	6
2.3.1	Choice of regimen	7
2.4	MONITORING	9
2.4.1	TREATMENT FAILURE	9
2.4.2	HIV RESISTANCE TO ANTIRETROVIRAL DRUGS	10
2.4.3	FUTURE APPROACHES TO THERAPY	11
<b>3</b>	<b>SECTION TWO SOME EXPERIENCES WITH ART IN RESOURCE LIMITED SETTINGS</b>	<b>12</b>
3.1	ART COVERAGE	12
3.2	CONTEXT: PUBLIC OR PRIVATE SECTOR, DONOR SUPPORTED AND RESEARCH PROJECTS	12
3.3	QUALITY OF CARE AND OUTCOMES	13
3.4	LABORATORY MONITORING SERVICES	13
3.5	Surveillance for Drug Resistance	13
3.6	SUPPLY AND DISTRIBUTION OF THE DRUGS	13
3.7	Initiation of treatment	14
3.8	CHOICE OF THERAPEUTIC REGIMEN	14
<b>4</b>	<b>SECTION THREE GUIDE TO ART IN RESOURCE LIMITED SETTINGS</b>	<b>14</b>
4.1	WHAT SHOULD BE IN PLACE BEFORE INITIATING ART PROGRAMMES *	14
4.1.1	COUNSELLING FOR ART	15
4.1.2	FINANCIAL CONSIDERATIONS	15
4.1.3	DRUG INFORMATION	16
4.1.4	EMOTIONAL SUPPORT AND DIFFICULT DECISIONS	16
4.1.5	CONFIDENTIALITY AND SHARING HIV STATUS*	17
4.1.6	ADHERENCE TECHNIQUES	17
4.1.7	CLINICAL EVALUATION BEFORE INITIATION OF ART	17
4.1.8	HIV-RNA TESTING	18
4.2	INITIATION OF THERAPY	19
4.2.1	WHOM TO TREAT	19
4.2.2	CHOICE OF THE REGIMEN	19
4.3	MONITORING ANTIRETROVIRAL THERAPY *	20
4.3.1	Monitoring adherence to ART	20
4.3.2	Monitoring tolerance to ART	21
4.3.3	Monitoring the efficacy of ART	22
4.4	CONSIDERATIONS OF DRUG INTERACTIONS	22
4.4.1	ANTIRETROVIRAL DRUGS AND THE TREATMENT OF TUBERCULOSIS	23
4.4.2	INTERACTIONS WITH DRUGS COMMONLY USED FOR THE PREVENTION AND TREATMENT OF OIs	24
4.5	FURTHER RESEARCH NEEDS	24
4.6	INFORMATION AND TRAINING NEEDS	25

## **1 INTRODUCTION**

In April 1997, WHO and UNAIDS held an Informal Consultation on the Implications of Antiretroviral Treatments for HIV/AIDS, with the objective of providing policy guidance on major issues relating to the use and provision of antiretroviral drugs.

As a follow up activity to this consultation, a set of nine Guidance Modules on several aspects of antiretroviral treatments was produced. 2 Guidance Module number 4, entitled Safe and Effective use of Antiretroviral Therapies, provided guidance primarily to clinicians, counsellors, and managers of clinical services. Policy makers, people living with HIV/AIDS (PLHA) and decision-makers in national referral and district hospitals as well as training institutions have also found this guidance module very helpful. The module reflected the published standards of care and the consensus of participants at the time of the consultative meeting in 1997.

Treatment guidelines need to be regularly updated to take into account evolution in knowledge and experiences from different healthcare settings. There is today a much better understanding of the biological basis for antiretroviral therapy (ART) and clinical research has provided consistent data on its effectiveness. The adherence difficulties and adverse effects associated with some of the antiretroviral drug combinations are better understood and regimens that are easier to take are being developed.

There is also an increasing body of knowledge on the therapeutic implications of antiretroviral drug resistance. A variety of international treatment guidelines have been developed to keep clinical practice as much as possible in pace with the data emerging from basic and clinical research. Clinical guidance for the use of ART must take into account the profile of patients seeking care as well as the capacities of the healthcare setting in which this care is being delivered. Low and middle-income countries have requested recommendations for the provision and monitoring of ART that are more directly relevant to their resource limited settings than the published International Guidelines. In response to this requirement, WHO in collaboration with UNAIDS and the International Aids Society (IAS) organised a technical consultative meeting, in February 2000. This consultation brought together experts in HIV/AIDS care and HIV clinical research from industrialised countries and developing countries, to analyse available scientific evidence and discuss contextual issues relating to the safe and effective use of antiretroviral therapies in resource limited settings. This guide is a result of the discussions and recommendations of the February 2000 consultation.

In section one, the principles behind current use of antiretroviral drugs for the treatment of HIV-1 infection are outlined. This section refers to existing international recommendations. Several factors that relate to the profile of patients seeking HIV care in resource limited countries may influence the choice and the outcome of antiretroviral therapy:

- the vast majority of patients are currently treatment naive because antiretroviral drugs are usually not available through the public sector and are poorly introduced into private markets.
- most patients have advanced stage HIV disease at the time treatment is initiated because in the absence of wide spread counselling and testing, diagnosis is often delayed.
- patients in resource poor countries are more likely to have co-existing morbidity such as anaemia, malnutrition as well as tuberculosis and other medical conditions, which may act in concert to affect the choice of therapy and the considerations on the potential spectrum of drug interactions and drug toxicity.
- the majority of patients are in a low-income bracket and because antiretroviral drugs are not usually provided free of charge, financial constraints are a common cause of treatment interruptions and of further delay in initiating therapy.

Within many resource limited countries there are "sites of excellence" where small scale ART programmes have been implemented. Nevertheless, inadequacy of healthcare services in terms of

consistency of supplies and quality assurance of laboratory support as well as a scarcity of trained clinicians, are characteristic of most resource limited settings. Experiences with the use of ART in these settings, however, continue to accumulate and there are important lessons to be drawn from them.

In section two of this guide, some national ART programmes and some pilot initiatives from six low and middle income countries are described. In section three, discussions and recommendations on the use of antiretroviral drugs in resource limited settings, for the treatment of HIV-1 infection, are presented. The participation of patients in decision-making processes is crucial to the outcome of any treatment programme. People living with HIV/AIDS (PLHA), from resource limited countries participated in this consultation and their contributions on adherence issues and on the psychosocial support needs of patients form an important element of the contents of this guide.

## **2 SECTION ONE**

### **2.1 BACKGROUND**

Data published over the last two years in Europe and North America, from clinical trials and observational cohorts, provide convincing evidence of the beneficial impact of combination antiretroviral therapy on the morbidity and premature mortality from HIV infection. This benefit is mainly due to a reversal of the progressive immune deficiency that is characteristic of HIV infection and to effective restoration of the immune system's reactivity to HIV induced opportunistic infections (OIs).

The course of many OIs has been altered by widespread use of effective ART. Previously untreatable OIs like cryptosporidiosis and AIDS defining illnesses like Kaposi's sarcoma may resolve without specific treatment and the clinical progression of complicated OIs like cytomegalovirus and atypical mycobacterial infections may be halted and/or reversed. As an extension of the benefits of effective ART, criteria for the discontinuation of chemoprophylaxis against pneumocystis carinii pneumonia, which in the past was a lifelong intervention, have been introduced into current practice guidelines. In time, HIV infection may therefore be considered as a chronic disease manageable over the course many years. The approach to antiretroviral therapy and the design of therapeutic regimens has been influenced by the following key findings from studies on the pathogenesis of HIV infection:

- demonstration that a continuous high-level of replication of HIV is present from the early stages of infection (at least  $10^{10}$  particles are produced and destroyed each day)
- demonstration that a specific immune response to HIV occurs in HIV infected subjects during "primary" infection but begins to decline after the first months of infection.

The strength of this primary immune response may be predictive of subsequent concentrations of HIV in the body as measured by the plasma HIV-RNA or "viral load".

- demonstration that the measured concentration of plasma viral load is predictive of the subsequent risk of disease progression and death.
- proof that combination antiretroviral therapy is not only able to consistently suppress HIV replication, but also able to induce a significant delay in progression to AIDS; this survival benefit is particularly marked in previously untreated patients.
- elucidation of the molecular, functional and clinical impact of resistance to antiretroviral drugs.

Since ongoing replication of HIV drives the disease process, causing progressive immunological damage, an ideal target of antiretroviral treatment is to obtain timely and sustained suppression of viral replication. Many ART regimens that achieve this target to some degree have already become available. Reliable techniques for quantifying HIV in plasma, measured as the amount of HIV-RNA or

the “viral load” are also available and have allowed clinical researchers to compare the relative antiviral potency of various antiretroviral drug regimens, while providing a rational tool for monitoring the efficacy of ART in clinical practice. Measurement of the numbers of CD4+ cells in the blood are a reliable indicator of the extent of immunological damage caused by HIV infection and provide further rationale for clinical decisions on antiretroviral therapy.

While the progress so far has been impressive, there is a growing appreciation of some of the difficulties associated with ART and much work still remains to be done. Difficulties with adherence to treatment, long-term toxicity and cross-resistance among antiretroviral drugs have become major drawbacks of current ART strategies. Even with the most potent antiretroviral drug regimens available today, there exists a proportion of patients who fail to have complete and durable virologic responses to therapy for a myriad of reasons. These shortcomings of the current regimens are particularly evident in patients whose baseline levels of plasma “viral load” are high, who have had extensive prior treatment and in whom the stage of disease is advanced.

## 2.2 CHARACTERISTICS OF AVAILABLE ANTIRETROVIRAL DRUGS

Currently available antiretroviral drugs belong to two major classes:

1. Reverse Transcriptase Inhibitors (RTIs)
2. Protease Inhibitors (PIs).

Reverse Transcriptase Inhibitors are further divided into 2 groups:

- 1.1 Nucleoside Reverse Transcriptase Inhibitors (NRTIs)
- 1.2 Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs).

In most industrialised countries a range of antiretroviral agents have been approved, licensed and registered for the treatment of HIV. At present, they include:

<i>six NRTIs</i>	<i>three NNRTIs</i>	<i>five PIs</i>
<ul style="list-style-type: none"> <li>• zidovudine (AZT, ZDV)</li> <li>• didanosine (ddI)</li> <li>• zalcitabine (ddC)</li> <li>• stavudine (d4T)</li> <li>• lamivudine (3TC)</li> <li>• abacavir (ABC)</li> </ul>	<ul style="list-style-type: none"> <li>• nevirapine (NVP)</li> <li>• efavirenz (EFV)</li> <li>• delavirdine (DLV)</li> </ul>	<ul style="list-style-type: none"> <li>• saquinavir (SQV)</li> <li>• ritonavir (RTV)</li> <li>• indinavir (IDV)</li> <li>• nelfinavir (NFV)</li> <li>• amprenavir (APV)</li> </ul>

All these drugs act by blocking the action of enzymes that are important for replication and functioning of HIV. Once HIV invades a macrophage or T-lymphocyte, the enzyme HIV reverse transcriptase initiates copying of the viral genetic code (RNA) into the genetic code of the infected host cells (DNA). After this, HIV genetic material is integrated into the host's DNA. This is followed by multiplication, creating several billion new copies of HIV per day. The enzyme protease contributes to viral reproduction by enabling the assembly and release of viable particles of HIV from infected cells.

For optimal efficacy, antiretroviral drugs, usually from different classes, must be used in combination. A similar approach to therapy is already established practice in the treatment of other important long-term diseases such as cancers, tuberculosis and leprosy. Several combination regimens with demonstrated effectiveness in achieving durable suppression of HIV replication are available. All available antiretroviral drugs have class-specific adverse effects, which are summarised below. For more details on drug specific adverse effects, see Annex II.

### **Nucleoside Reverse Transcriptase Inhibitors**

(NRTIs) may cause fatty change in the liver, which is reversible upon stopping the medications, or lactic acidosis, a metabolic complication that is potentially fatal if unrecognised. These two adverse effects are due to toxicity of the NRTIs on cellular mitochondria. Changes in body fat distribution as well as derangements in the metabolism of fats, which are described below, have also been associated with the prolonged use of NRTI containing regimens.

### **Protease Inhibitors**

(PIs) have been associated with body fat redistribution which manifests physically as thinning of the arms, legs and face and/or deposition of fat in the abdominal and shoulder regions. A further effect of this class of drugs on the metabolism of fat may result in raised levels of serum cholesterol and serum triglycerides, in insulin resistance and rarely in increased blood sugar levels. The overall cumulative incidence of these metabolic disturbances may be 30% to 60% after 1 to 2 years of treatment, increasing with duration of therapy. All drugs in this class may cause bleeding episodes in patients with hemophilia.

### **Non-Nucleoside Reverse Transcriptase Inhibitors**

All NNRTIs may cause a skin rash. These rashes are generally mild and self-limited, though severe forms similar to a Stevens-Johnson syndrome have been reported. NNRTIs may also cause elevation of serum aminotransferases and rare cases of fatal hepatitis have been reported.

## **2.3 INITIATION OF THERAPY**

Earlier hopes that HIV could be eradicated from an infected individual were based on the erroneous assumption that complete suppression of viral replication could be achieved using currently available therapies. It is now known that low-level replication of HIV occurs at concentrations of plasma "viral load" below the limits of detection by the most sensitive assays in use. The decay half-life of resting memory CD4+ lymphocytes which harbour latent HIV in 'sanctuary sites' in the body, is at least 6 months and as long as 44 months. It is therefore estimated that eradication of HIV with ART alone would take at least a decade and so the goal of treatment must now be redirected towards the long-term management of a chronic infection.

The ultimate aim of antiretroviral treatment must be maximal suppression of HIV replication because the major short-term risk of any continuing viral replication in the presence of antiretroviral drugs, is the emergence of drug resistance. The success of ART is determined more by the patient's compliance with and adherence to the prescribed regimen than by the specific drug combination used. Decisions about when to start therapy and what regimens to use are crucial because future treatment options may be severely compromised by an initial regimen that is inadequately adhered to or insufficiently potent. Physicians and patients together need to weigh the advantages and disadvantages of starting antiretroviral therapy and make individualised informed decisions.

Arguments in favour of early initiation of antiretroviral treatment include:

- HIV infection almost invariably causes progressive immune damage
- disruption of the immune system and the building of viral reservoirs are early events the natural history of untreated HIV infection includes selection for more diverse and more virulent strains of HIV

There is, however, an increasing tendency to defer initiation of ART until immune deficiency becomes measurable and the risk of disease progression becomes relevant because:

- the risk of disease progression is low until substantial CD4+ cell loss has occurred
- immune recovery is impressive even when therapy is delayed
- many patients only achieve incomplete or transient control of viral replication, resulting in selection for resistant strains of HIV
- any regimen has toxicity and cost.

According to current published international guidelines, the following broad criteria guide the selection of patients for initiation of therapy:

- all patients with symptomatic HIV infection, regardless of CD4+ count and "viral load" levels
- all patients with CD4+ counts below 350/mm<sup>3</sup>
- all patients with a high viral load (i.e. above 30,000 copies/ml by RT - PCR \*)

Current guidelines recommend that treatment be considered for patients in the intermediate range, i.e. plasma viral load between 10, 000 and 30,000 copies/ml (RT-PCR) and CD4+ cell counts between 350/mm<sup>3</sup> and 500/mm<sup>3</sup>. Treatment of asymptomatic patients, with CD4+ cell counts above 500 mm<sup>3</sup> is generally deferred as long as the probability of significant immune system damage and of clinical progression of HIV infection remains low.

### 2.3.1 Choice of regimen

Several regimens with acceptable antiviral potency are available, particularly for patients being treated for the first time. These regimens are composed of three to four drugs. Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) generally form the backbone of most of these combinations. The choice of specific NRTI is based on convenience, adverse effects and patient preference.

Possible NRTI combinations (not in preferred order)

- zidovudine + didanosine, zalcitabine, or lamivudine
- stavudine + didanosine or lamivudine

Zidovudine and Stavudine should not be used together because of their antagonistic effect on each other. Similarly, Didanosine and Zalcitabine may lead to additive neurotoxicity and should not be combined.

### Combination regimens containing a Protease Inhibitor

PI-containing regimens, (2 NRTIs + 1 PI), have been the first choice for initiating ART since 1997 and there is sufficient data on their effectiveness over the last two to three years. Protease Inhibitor regimens have proven potency and are effective in patients at all levels of plasma "viral load." However, there are important disadvantages that limit the acceptability of PI containing regimens:

- complexity of the regimens makes adherence difficult
- cross-resistance between different PIs may limit future use if initial therapy fails
- there is growing concern over the long-term toxicity of PIs, particularly the fat redistribution and the metabolic abnormalities whose effect on cardiovascular morbidity and mortality remains uncertain.

---

\* \* The different techniques used for measuring viral load; reverse transcriptase polymerase chain reaction (RT-PCR), branched chain DNA (bDNA) and nucleic- acid sequence based amplification (NASBA), produce different results that are consistent within the technique, but different between techniques. The values of viral load referred to in this document are those of RT-PCR.

Combinations of 2 PIs are increasingly being used instead of a single PI because they have pharmacokinetic advantages and possibly increase the PI regimen's potency while potentially improving adherence to therapy. Addition of a reduced dose of Ritonavir, to Saquinavir, Indinavir or Amprenavir improves the pharmacokinetic profiles, may reduce pill burden, lower the dose frequency, lower cost, and obviate the need for administration of PIs on an empty stomach. The long-term benefit and toxicity of dual PI combinations remains to be fully characterised.

### Combination regimens without a Protease inhibitor

Combination regimens without a Protease Inhibitor Combinations between NNRTIs and NRTIs have recently gained popularity. There is convincing evidence from controlled clinical trials that in treatment-naïve patients, NNRTI regimens offer a suitable alternative to PI-containing combinations in terms of antiviral potency. Besides the advantage of deferring the introduction of PIs, NNRTI containing regimens may also allow for a lower pill burden and for improved adherence. The main disadvantage of NNRTIs is the ease and rapidity with which resistance develops to the individual drugs in this class if they are used in the context of a regimen that is not maximally suppressive and the very strong likelihood that cross class resistance will follow. Data on the long-term clinical efficacy of NNRTI containing regimens remains limited.

The use of three NRTIs to "spare" both PIs and NNRTIs has recently been proposed. Most data refer to the combination of abacavir, zidovudine and lamivudine which has shown durable antiviral activity (after 48 weeks of treatment), equivalent to that of a "standard" 2NRTI + 1PI regimen (zidovudine/lamivudine/indinavir), in treatment naïve patients. This combination, however, seems to have reduced potency in patients with high baseline plasma viral loads. The main attraction of a 3NRTI regimen is deferral of the use of PIs, while also sparing the NNRTI and placing only a single class of antiretroviral drugs "at risk" for the development of resistance. Once again, the long-term efficacy and toxicity of multinucleoside regimens remains unknown and there is concern over the potential possibility of selecting for multinucleoside-resistant variants of HIV.

There is no data at present demonstrating superiority of any one of the above acceptably potent initial regimens over the others and recommendations for a specific initial regimen or for a specific combination of individual drugs cannot be made. The choice of a particular regimen remains individualised with consideration given to the strength of supportive data, the tolerability of the regimen, the potential for adverse effects, likely drug-drug interactions, convenience and likelihood of adherence and the potential for alternative treatment options should an initial combination fail.

Table 1. Summary of currently available initial ART regimens\*

Advantages	Disadvantages
<b>2 NRTIs + 1PI</b>	
<ul style="list-style-type: none"> <li>• Solid clinical data</li> <li>• Longest experience for viral suppression</li> </ul>	<ul style="list-style-type: none"> <li>• Complexity and high pill burden</li> <li>• May compromise future PI regimens</li> <li>• Concerns on long-term toxicity</li> </ul>
<b>2 NRTIs + 2PIs</b>	
<ul style="list-style-type: none"> <li>• High potency</li> <li>• Low pill burden</li> </ul>	<ul style="list-style-type: none"> <li>• High pill burden with some regimens</li> <li>• Long-term toxicities unknown</li> </ul>
<b>2 NRTIs + 1 NNRTI</b>	
<ul style="list-style-type: none"> <li>• Low pill burden</li> <li>• Equal potency to PI regimens</li> </ul>	<ul style="list-style-type: none"> <li>• Limited long-term data</li> <li>• Compromises future NNRTI regimens</li> </ul>

3 NRTIs	
<ul style="list-style-type: none"> <li>• Defers 2 classes (PI, NNRTI)</li> <li>• Low pill burden</li> </ul>	<ul style="list-style-type: none"> <li>• Lower potency in patients with high baseline viral load</li> <li>• Limited long-term data</li> <li>• May compromise future NRTI regimens</li> <li>• Potential convergence of mitochondrial toxicity</li> </ul>

\* Source: Carpenter et al. JAMA, January 19, 2000; 283 (3); 384.

## 2.4 MONITORING

Response to ART is monitored clinically and biologically. The most important biological measurements are the concentration of HIV – RNA in plasma (the “viral load”) and CD4+ cell counts. These measurements correlate with clinical outcome. The desirable “virologic” endpoint is a plasma viral load that is “below the limits of detection”, by the most sensitive assay being used, within 3 to 4 months of starting treatment and the achievement of a minimum decline from the baseline viral load of 1.5-2.0log by the end of the first month of treatment. In patients with higher baseline plasma viral loads (e.g. above 100,000 copies/ml by RT-PCR) maximal suppression of viral replication may take a longer time. When optimal response to therapy is achieved, the median CD4+ cell rise is 100 – 200 cells within the first year. The CD4+ cell response may lag behind the “virologic” response in timing and at times the two responses may even be discordant.

The optimal frequency of viral load monitoring is unknown. In general, plasma viral load is checked within 1 month of initiating therapy and two-monthly thereafter until the virologic goal of therapy, i.e. viral load below the limits of detection, is achieved. Following this, plasma viral load may be checked every 3 to 4 months. Due to possible individual oscillations in the concentrations of HIV1-RNA and to variability in the assays in use, the baseline viral load measurement before initiation of treatment and any measurement thereafter that indicates a viral “rebound” significant enough to warrant considering a change in therapy, is routinely confirmed by a repeat test.

Table 2a. HIV-RNA measurements in monitoring antiretroviral therapy

HIV-RNA levels that suggest initiation of therapy	<ul style="list-style-type: none"> <li>• above 30,000 copies/ml by RT-PCR</li> </ul>
Target level of HIV-RNA after initiation of treatment	<ul style="list-style-type: none"> <li>• “below the limits of detection” (at present taken as below 50 copies/ml RT-PCR) (&lt; 400 copies/ml may be acceptable in some settings)</li> </ul>
Timing of target response	<ul style="list-style-type: none"> <li>• “below the limits of detection” within 3 to 4 months of initiating ART (in patients with high baseline HIV-RNA levels, maximal suppression may not be for 6-8 months)</li> </ul>
Frequency of HIV-RNA measurements at baseline:	<ul style="list-style-type: none"> <li>• 2 measurements 3-4 weeks apart</li> <li>• within 1 month of starting therapy to confirm antiviral activity of the regimen</li> <li>• every 2 months until viral load is below the limits of detection every 3 to 4 months thereafter together with CD4 count (shorter intervals before critical decisions on therapy)</li> </ul>

### 2.4.1 TREATMENT FAILURE

The most frequent reasons for changing treatment are drug toxicity, drug intolerance, difficulties with adherence to the regimen and treatment failure i.e. a drug regimen that is providing insufficient control of viral replication as indicated by lack of an adequate and sustained suppression of plasma HIV-RNA,

lack of a satisfactory increase in CD4+ cell count or clinical progression of disease.

In clinical trials, a substantial proportion of patients (over 30%) do not achieve viral loads below the limits of detection. This is dependent on many factors such as baseline viral load and CD4+ count, primary acquisition of drug resistant virus, prior antiretroviral treatment, occurrence of adverse events and poor quality of adherence. In clinical practice, up to one year after the initiation of potent combination antiretroviral therapy, up to 1/3 of patients on ART may have viral loads above 20,000 copies/ml. (RT-PCR) Failure to reach the virologic target of therapy prompts investigation into probable problems of drug adherence, drug absorption or the presence of drug resistant virus.

Table 2b. Viral load in treatment failure

**Changes in HIV-RNA that suggest treatment failure**

- insufficient viral suppression 4-6 months after starting ART
- confirmed return above 400 copies/ml (by RT-PCR) in a patient with previously undetectable viral load

The management of treatment failure depends on the reasons for failure. Where toxicity and intolerance are the main problems, supportive medication, dosage alteration or substitution of the offending drug is reasonable. When adherence difficulties are responsible for treatment failure, measures aimed at improving the patients' compliance are advised. If poor control of viral replication has been going on for an extended period of time, the presence of drug resistance is likely and resistance testing may, in this instance, guide the choice of subsequent treatment.

#### 2.4.2 HIV RESISTANCE TO ANTIRETROVIRAL DRUGS

The high rate of replication that is found throughout the course of HIV infection and the variability of HIV, coupled with the relative inaccuracy of the enzyme HIV reverse transcriptase, are the main reasons for the frequent occurrence of copying errors in the transcription of viral genetic information. HIV replicates at the rate of around  $10^8$  to  $10^{10}$  virus particles per day, probably giving rise daily to about  $3 \times 10^{-3}$  spontaneous changes (mutations) in its genetic sequence. The ultimate size of a viral population containing a mutation is probably determined by three concurrent factors: the forward mutation frequency, the replicative capability of the mutated virus and the "age" of the viral population containing the mutation i.e. how long ago this population was generated. With the on-going production of genetic variants of HIV there is then a continuous selection for the "fittest" virus population.

Sub-optimal ART regimens that allow replication of HIV to continue in the presence of antiretroviral drugs, encourage the growth of viral populations that are carrying a genetic mutation which protects against these drugs. It is likely that many of these drug resistance mutations already exist before any antiretroviral drug is introduced and are further encouraged to proliferate under the selective pressure exerted by drug treatment.

Antiretroviral therapy can minimise the emergence of drug resistance in two ways:

- by maximising and sustaining the suppression of viral replication
- by using drugs where multiple mutations are required before resistance can occur.

In recent years laboratory testing for antiretroviral drug resistance has become available raising the possibility of using resistance testing to guide therapeutic choices. The testing methods in use, however, are still hampered by technical complexity, poor sensitivity, difficulties in interpretation and high cost. The place of resistance testing in every day clinical practice remains to be clearly defined because while it appears useful in patients experiencing treatment failure, its utility in other situations (treatment naive patients, patients who have failed on multiple regimens or pregnant HIV-positive women) is still under investigation. When performing testing for antiretroviral drug resistance, it is important to ensure that this is done while the patient is still on therapy in order to maximise accuracy.

Cross resistance among the available classes of antiretroviral drugs is common and is an important consideration when assessing the possibility of sequencing (replacing one drug with another) should it become necessary to change a therapeutic regimen (Table 3). Cross-resistance implies that a population of virus resistant to one drug in a class is also resistant to other drugs of the same class. This is particularly liable to occur with the NNRTIs especially if they are used as part of a regimen that produces incomplete suppression of viral replication. The NNRTIs in general present a very low "genetic barrier" to resistance because a single mutation is sufficient to produce resistance. PIs and NRTIs are more robust in this respect since multiple mutations are required to confer resistance to drugs in these classes.

### 2.4.3 FUTURE APPROACHES TO THERAPY

The seemingly large number of possible antiretroviral drug combinations is only apparent. Therapeutic options are actually limited by cross reactivity within the currently available classes of antiretroviral drugs. New drugs with increased potency that are safer, easier to take, with more favourable pharmacologic properties and with activity against drug-resistant viruses, are needed. Validation of drug resistance testing for use in clinical practice will provide clinicians with a helpful patient management tool and the choice of therapy will hopefully be guided by individual resistance profiles, allowing for more effective treatment.

It is becoming increasingly evident that the course and the outcome of HIV infection are mostly determined by events that take place during primary infection. Future treatment strategies, through controlled studies, will focus on the early recognition and treatment of primary HIV infection. There is evidence that a specific and effective cellular immune response to HIV occurs in infected subjects. This has led to the exploration of alternative approaches to therapy that would aim at enhancing this host immune response such as therapy with drugs like Interleukin 2 and with certain HIV-derived immunogens. Studies are ongoing to design further strategies of treatment based on immunologic intervention.

The example of the "long term non-progressor" (individuals whose HIV infection is effectively controlled by their own specific CD4+ T cell response) suggests that enhancing the immune response may lead to a stable equilibrium between virus and host. A similar response is observed in other persistent viral infections such as those caused by herpes viruses, where the host's immune system is able to keep a virus silent. One approach to ART that is under investigation is antiretroviral therapy with structured treatment interruptions. The hope is that intermittent interruptions in ART, by allowing host immunity to be exposed to HIV, may act to augment the duration and the strength of host immune responses to HIV and therefore increase immunologic control of the infection. Additional potential advantages of structured interruptions of ART are: reduced toxicity, improved tolerance, greater adherence to treatment and reduced overall cost. Results from a few uncontrolled studies are available which indicate that the majority of patients seem to experience a rapid rebound in plasma HIV-RNA during treatment interruptions as well as a rapid decline in CD 4+ cell counts. The implications of these results and the possibility of boosting HIV-specific immune responses through this approach still remain controversial and need to be further clarified by controlled studies.

A variety of other approaches to stimulating the immune system are under investigation. While research into eradication of HIV also continues, a combination of potent ART with immune-based therapies may be the most durable approach to achieving long term containment of HIV replication.

Table 3. Cross resistance among available classes of antiretroviral drugs and possibilities of subsequent sequencing of drugs from the same class.

	Likelihood of Possibility of Cross-Resistance	Possibilities of Sequencing	Comments
<b>NNRTIs</b>	High	No	may only have one chance
<b>PIs</b>	High/Moderate	Yes	Recommendations about optimal sequencing cannot be made from ART history alone
<b>NRTIs</b>	Moderate/Low	Yes	Cross resistance may be due to unique pathways of multi-drug resistance

### 3 SECTION TWO SOME EXPERIENCES WITH ART IN RESOURCE LIMITED SETTINGS

Experiences with ART in resource limited settings are a source of important information in terms of defining the standards of clinical practice in those settings as well as the social and economic contexts which influence the use of antiretroviral drugs. National programmes and pilot initiatives from six low and middle-income countries are described in the pages that follow. All have in varying ways fulfilled the essential pre-conditions (See section 3.1) for introduction of ART programmes.

#### 3.1 ART COVERAGE

The proportion of people with symptomatic HIV infection who are receiving ART ranges from small to insignificant. In Uganda, probably less than 1% of people with HIV related illnesses are receiving ART. In Thailand, in 1996, nearly 10% of people eligible for treatment were being treated through the Ministry of Public Health (MOPH) programme in 58 hospitals, but that proportion has substantially decreased since then. In Brazil, however, nearly 100,000 out of 530, 000 people with HIV infection are receiving ART following a presidential decree, in November 1996, that access to antiretroviral drugs be made universally available through the public health system.

#### 3.2 CONTEXT: PUBLIC OR PRIVATE SECTOR, DONOR SUPPORTED AND RESEARCH PROJECTS

With some exceptions such as Brazil, where ART is provided at no cost within the public health sector, "ability to pay" is determining access to drugs in many low and middle-income countries. The drugs themselves may be obtained privately and medical care as well as related services such as laboratory monitoring is often provided through the private sector. The public/private distinction is however blurred by the fact that private patients who can pay for the drugs are often treated and monitored in "centres of excellence" (e.g. the teaching hospitals of major cities) which themselves are publicly funded. A few patients receive drugs at subsidised cost through donor supported projects such as the UNAIDS Drug Access Initiative in Ivory Coast. Similarly, in Senegal, less than one hundred patients are being treated with antiretroviral drugs, through an initiative supported by the National Aids Control Programme, Agence Nationale de Recherche sur le SIDA – France, Institut de Médecine et d'Epidémiologie Africaine – Paris and Fondation d'Espoir – France.

A minority of PLHA receive free treatment through participation in clinical trials which may be externally and/or nationally funded. This is the case in Thailand, where patients are receiving drugs through the HIV-NAT clinical trials conducted in 19 hospitals around the country.

### **3.3 QUALITY OF CARE AND OUTCOMES**

Available data suggest that the clinical outcomes of treatment, in the context of centres of excellence, externally funded projects or clinical trials, are very similar to those in industrialised countries. From about 1997, HIV care centres in 2 large Brazilian cities have recorded a significant decrease in the number of AIDS deaths, a reduction in the prevalence of major HIV related opportunistic infections and an overall decrease in the number of hospitalisations for HIV related illnesses. In the context of unregulated practice, the quality of care and the outcomes of treatment may be different but because such situations are difficult to evaluate, there is no information available.

### **3.4 LABORATORY MONITORING SERVICES**

Access to reliable laboratory monitoring is limited in low and middle-income countries and is concentrated in the major cities. Within the public health system in Brazil, there is a network of 70 laboratories with capacity to perform CD4+ counts and 56 laboratories with the capacity to measure plasma viral load. Elsewhere, the necessity for regular CD4+ cell counts and estimations of plasma viral load to evaluate the effectiveness of treatment adds to the overall cost of ART and within the private sector, laboratory monitoring is largely dependent on financial resources, so that patients themselves will often request for less monitoring in order to pay for more drugs. Treatment centres accredited to the UNAIDS HIV Drug Access Initiative in Uganda, have been able to carry out the required virologic monitoring of ART through the collaboration and aid of a donor funded research laboratory, which provides the tests at no costs to patients, as part of the evaluation of that pilot initiative. Similarly laboratory monitoring has been provided at not cost to patients within the Drug Access Initiative in Ivory Coast, while in Thailand, regular immunologic and virologic monitoring form part of the research protocols for clinical trials.

### **3.5 SURVEILLANCE FOR DRUG RESISTANCE**

Monitoring for resistance is rarely undertaken in any developing country setting but its importance as a public health responsibility is recognised. Within every ART programme, as for any antimicrobial treatment, lies a public health responsibility to protect the future utilisation of the drugs by minimising the emergence of drug resistance. Modalities for surveillance of HIV drug resistance are a necessity and though the technology is too costly for most resource limited countries to afford, there exist innovative ways to strike a balance between resource constraints and good clinical/public health practice. To this end, Ivory Coast, Senegal and Uganda have initiated collaboration with international laboratories that have the capacity to carry out monitoring for antiretroviral drug resistance.

### **3.6 SUPPLY AND DISTRIBUTION OF THE DRUGS**

By and large, the entire range of antiretroviral drugs is available anywhere in the world through private channels. Where resources permit, the supply may be adequate and consistent. Through the public sector, however, and for low-income patients, the choice of drugs may be somewhat restricted. This has implications for decisions such as when to start therapy, which therapeutic regimens to use, and what to do when treatment fails. In the context of clinical trials, reliability of supply and quality of

drugs is relatively well assured. In the donor – supported projects, despite the subsidised cost of antiretroviral drugs, it is still not unusual for financial constraints to lead to cessation of treatment. In Brazil, a substantial and rapidly increasing proportion of antiretroviral drugs are being produced in the country with considerable cost savings and a positive impact on sustainability and supply.

### **3.7 INITIATION OF TREATMENT**

The majority of patients in low income countries start treatment at an advanced stage of HIV disease as illustrated by records from some of the treatment centres: in one treatment centre in Ivory Coast, 55% of patients were in CDC category 3 at the start of the treatment, in Senegal this proportion was 75%, while 68% of the patients at the Mildmay centre in Uganda had advanced disease at the start of therapy. This is due to a combination of factors such as late care seeking through fear or denial, a lack of accessible counselling and testing services so that many people are unaware of their HIV infection and the high cost of the drugs which leads to treatment being deferred.

Initiation of treatment for private patients may follow the same criteria as established in industrialised countries. At the same time, private sector patients are often advised to save scarce resources and delay initiation of ART until the occurrence of the first serious HIV related illness. In the context of clinical trials and donor-supported projects, treatment is initiated according to biological criteria determined by in-country technical committees. In Senegal, treatment for symptomatic patients is started when the CD4+ cell count is below 350/mm<sup>3</sup> and the viral load above 10,000 copies/ml, while the eligibility criterion for asymptomatic patients is a viral load above 100,000 copies/ml. In the public health system in Brazil, the recommendation is that PLHA be treated when CD4+ cell count is between 200 and 350 cells/mm<sup>3</sup> or if the viral load is over 50,000-copies/ml.

### **3.8 CHOICE OF THERAPEUTIC REGIMEN**

Most of the ART initiatives particularly those linked to clinical trials and in the externally funded projects have aimed to use the highly potent three-drug combination therapies i.e. regimens containing a Protease Inhibitor, as recommended by international guidelines. In Brazil, 55% of patients on ART are on triple combination therapy as are 43 of 109 patients treated in one centre in Ivory Coast. Generally speaking, however, as the choice and sustainability of ART regimens is largely determined by cost, there is widespread use, especially in private practice, of dual nucleoside regimens (2 NRTIs) because of simpler monitoring requirements, improved compliance and lower cost. There is also a significant amount of use of Hydroxyurea containing regimens. The implications of these therapeutic practices seeking to adapt ART combination regimens to the resources of low-income countries are discussed in section 3.4.

## **4 SECTION THREE GUIDE TO ART IN RESOURCE LIMITED SETTINGS**

### **4.1 WHAT SHOULD BE IN PLACE BEFORE INITIATING ART PROGRAMMES \***

Due to the high cost of antiretroviral drugs, the complexity of the regimens and the need for careful monitoring, specific services and facilities must be in place before considering the introduction of ART into any setting.

The following conditions are essential to the introduction of ART:

- Assured access to voluntary HIV counselling and testing (VCT) and institution of follow up counselling services for ART to ensure continued psychosocial support and to enhance adherence to treatment.
- Capacity to recognise and appropriately manage common HIV related illnesses and opportunistic infections.
- Reliable laboratory monitoring services including routine haematological and biochemical tests for the detection of drug toxicity as well as access to facilities for monitoring the immunologic and virologic parameters of HIV infection.
- Assurance of an adequate supply of quality drugs, including drugs for the treatment of opportunistic infections and other HIV related illnesses.
- Identification of sufficient resources to pay for treatments on a long-term basis.
- Information and training on safe and effective use of antiretroviral drugs for health professionals in a position to prescribe ART.
- Establishment of reliable regulatory mechanisms against misuse and misappropriation of antiretroviral drugs.

#### **4.1.1 COUNSELLING FOR ART**

ART may be a lifelong undertaking. A relationship of confidence needs to be established from the outset between the patient and the care team. It is important that adequate time is set aside for counselling so that appropriate and informed decisions on therapy and its implications are made by the patient, based on information given to them that is as accurate and as complete as possible. Many people seeking ART will have had prior counselling at the time of diagnosis (pre & post-test counselling). The positive messages and future plans initiated during pre and post-test counselling should be reinforced during counselling for ART.

**ART must not detract from HIV prevention messages. Even though the aim of treatment is to lower the amount of HIV in the blood, often to levels below the limits of detection by sensitive laboratory assays, patients must not conclude that it is no longer necessary to use protective measures to prevent the transmission of HIV. Counsellors should stress that HIV can still be transmitted even while on ART.**

Whenever available, the services of a care provider with counselling skills are invaluable. However, the counselling and psychosocial support process is an ongoing component of ART requiring contributions from the prescribing physician, the pharmacist, other health workers, family members and peer support groups of PLHA. An assessment of psychosocial support needs should be made right from the start with the intention of assuring that this will be maintained through out the period of therapy. The issues that need to be addressed during counselling may be broadly classified into 5 categories: Financial considerations, Drug information, Emotional support, Issues of disclosure and Adherence.

#### **4.1.2 FINANCIAL CONSIDERATIONS**

In many developing countries the patient or their family meets the cost of ART. Alternatively, drugs may be obtained as part of a clinical trial; as part of an "expanded access" program; through private sector funding, e.g. employment health insurance; or as a donation. It is important to discuss how the drugs are going to be paid for before embarking on treatment since financial constraints are a common reason for default from treatment. The importance of adherence to therapy and the consequences of intermittent therapy, cessation of therapy or of taking sub-optimal doses to minimise drug costs, should be candidly discussed with all concerned.

### 4.1.3 DRUG INFORMATION

Antiretroviral drugs have received a large amount of publicisation in the popular press. Even in low-income countries many people with HIV know about antiretroviral drugs and may at times have unrealistic expectations about the availability and effects of ART. Counsellors should be equipped answer questions on the different ART drug regimens, the requirements for clinical monitoring of ART, the expected results, the possibility of treatment failure and the criteria for changing or cessation of therapy. Sources of reliable medical information on ART which are patient oriented, should be identified and provided.

The counsellor must inform that ART is not a cure. Elimination of HIV from the body has not been achieved using the most potent antiretroviral combination therapies available and even when HIV viral RNA is not detectable in the plasma, there is still ongoing viral replication. The drugs will therefore need to be taken for an indefinite period of time. It is equally important to convey an understanding that knowledge on ART is still evolving and that up to date information about the positive and the possible negative outcomes of treatment will constantly be provided.

Some adverse effects such as headache, nausea and minor allergic reactions are common in the first few weeks of ART. Counsellors should be aware of these and reassure clients that some initial adverse effects will usually lessen with time while simple symptomatic remedies can alleviate many of them. The nausea and vomiting that is commonly experienced at the onset of treatment with zidovudine, for example should not lead to discouragement or discontinuation of treatment. Counsellors should at the same time give detailed information on the possibility of potentially serious adverse effects in the event of which drug therapy must be discontinued. Examples are the polyneuritis and hepatitis, which can occur with Reverse Transcriptase Inhibitors and the skin rash that results from a severe hypersensitivity reaction to abacavir. Patients need to know how to recognise the symptoms of these adverse effects and where to go for help should they occur.

The presence and types of food in the stomach affects the absorption of some of the Protease Inhibitors. Dietary changes will have to be made and meals will often have to be planned carefully around a drug regimen. This can be inconvenient and disrupt family and social life. If family members can be involved in discussions about these issues, it will help them to understand the importance of timing meals and changing routines. The counsellor may have to take time to work out a "meal and drug taking time table" that fits in with the client's and the family's life style. Many PLHA may resent the constraints that taking drugs imposes on their lives and this has to be acknowledged and explored when starting therapy. Asymptomatic PLHA who feel unable to embark on the strict regime that some regimens will impose on them may do better to postpone treatment and the implications of this advice should also be discussed.

### 4.1.4 EMOTIONAL SUPPORT AND DIFFICULT DECISIONS

Many PLHA commencing ART in developing countries, experience feelings of guilt, fear, anxiety and isolation because this therapy is extremely costly and not universally available. Many may have partners and/or children who also require treatment and who cannot access it for financial reasons and vital family resources may be being diverted to buy the medications. Patients often know and associate with other PLHA who themselves are not being treated but who were a source of encouragement and support before the decision to commence ART. Very often patients themselves question the wisdom of commencing antiretroviral therapy at all. Time taken to work through these feelings and doubts will significantly enhance commitment to therapy.

ART in symptomatic patients often results in remarkable clinical improvement. This improvement however, is not universal. Furthermore, clinical improvement may be incomplete or short lived particularly in patients who have had prior antiretroviral treatment or when drug resistance or severe adverse effects supervene. Additionally, in many resource-limited settings, treatment is often put off until such advanced stages of immune deficiency that the outcome is less favourable. Counsellors will have to support patients through the disappointment of treatment failure and balance optimism and

realistic caution. Depression and despair are common when CD4+ counts do not rise and weight is not gained as had been expected. This is aggravated when the patient is aware of draining his or her financial resources into a treatment that may be viewed as futile. There will also come a time when counsellor and patient will have to discuss cessation of treatment and end of life issues.

#### **4.1.5 CONFIDENTIALITY AND SHARING HIV STATUS\***

The disruption of life style brought about by complicated lifelong ART regimens should not be underestimated. Involving a partner or significant other in treatment counselling will make taking antiretroviral drugs much simpler. The counsellor should encourage disclosure of HIV status to partners and/or close relatives so that the burden of the drug-taking schedule can be understood and shared. Informing sexual partners of the continuing risk of HIV transmission, even while on ART, also ensures that protective action is maintained. It is however, important to explore the patient's own perception of the risks associated with disclosure so that reassurance and support can be planned against such barriers to disclosure as the fear of rejection, abandonment and violence; the risk of losing one's employment or the refusal of insurance. Antiretroviral treatment of children presents a special challenge for counselling on disclosure. Should children be told about their own serostatus? Should their siblings be told? Should the school be told?

#### **4.1.6 ADHERENCE TECHNIQUES**

Incomplete adherence to the prescribed drug regimen is a major factor that limits the effectiveness of ART. The drug regimens are complex and the duration of treatment indefinite. In order to maximise the benefits of treatment immense personal discipline and commitment are required of the patient. Possible barriers to adherence such as number and timing of doses, number and size of pills, food restrictions and fear of undesirable side effects, should be identified and used to design programs to support adherence. A "drug timetable" is useful and helps patients with their drug-taking schedule. Reassurance concerning the immediate and long-term side effects of the drugs is also very helpful and enhances adherence. In addition, the patient should be given explanations on the variety of alternatives available in the event that an initial drug regimen becomes intolerable.

#### **4.1.7 CLINICAL EVALUATION BEFORE INITIATION OF ART**

A detailed clinical evaluation is essential prior to initiating ART and should aim to:

- assess the clinical staging of HIV infection
- identify past HIV related illnesses
- identify current HIV related illnesses that will require treatment
- identify co-existing medical conditions that may influence the choice of therapy

The standard detailed medical history should include questions on the following:

- when the diagnosis of HIV infection was first established
- the current symptoms and concerns of the patient
- symptoms of all past illnesses and if known the diagnosis and treatment given
- a history of symptoms of or previous treatment for tuberculosis
- a history of possible contact with tuberculosis
- past symptoms of sexually transmitted infections the possibility of pregnancy in a woman
- social habits and sexual history

The following are important components of the physical examination:

- patient's weight
- skin and lymphnodes:

- herpes zoster, Kaposi's sarcoma, lymphadenitis, HIV dermatitis
- oropharyngeal mucosa ☐ candidiasis, Kaposi's sarcoma, leucoplakia
- examination of the heart and lungs including examination of a Chest x-ray
- examination of the abdominal system particularly for liver and spleen size
- examination of neurological and musculoskeletal systems for: ☐ mental state, motor or sensory deficits.
- whenever possible examine the optic fundus ☐ retinitis or papilloedema
- examination of the genital tract

The initial laboratory evaluation should provide the following:

1. confirmation of diagnosis of HIV infection ☐ HIV testing should be done or repeated, particularly where no prior documentation is available and especially if the patient is asymptomatic
2. indicators of the patients immune status ☐ CD4+ cell counts \* are good indicators of immune function in HIV infection. ☐ The total lymphocyte count correlates very well with CD4 cell counts, particularly in advanced HIV disease, and can be used as an indicator of immune function.
3. information on the patients baseline haematological, hepatic and renal function ☐ The baseline blood count complete with examination of a peripheral blood film is necessary because of the frequent occurrence of anaemia, neutropenia and thrombocytopenia both as complications of HIV infection and as adverse effects of ART. ☐ Biochemical tests of liver function are needed to exclude co-existing hepatitis and as baseline references in case of ART drug induced hepatic toxicity. A complete urine analysis comprised of a test for glycosuria, proteinuria and careful microscopy of the urine sediment is adequate initial screening
4. screening for tuberculosis ☐ Tuberculosis is the most common OI in HIV infection in developing countries and must be actively excluded and/or treated. Examination of a chest X-ray is therefore considered an essential part of initial clinical evaluation.
5. diagnosis of other intercurrent illnesses ☐ Several "supplementary" laboratory investigations, for the diagnosis of HIV related or other illnesses that may require treatment, will be indicated by findings from the patient's history and physical examination. Examples are histological examination of skin lesions to confirm Kaposi's Sarcoma, aspiration or biopsy of enlarged lymph nodes and screening tests for sexually transmitted infections (STIs). This list is by no means exhaustive.

Table 4. Initial laboratory evaluation for ART : A number of alternative techniques to the conventional cytofluorometry

Essential lab investigations	Desirable investigations	Supplementary investigations that may be indicated by symptoms and signs
HIV Serology CD4+ counts or Total lymphocyte count Complete Blood Count Tests of Liver Function Complete Urinalysis Chest X-ray 4.	HIV – 1 RNA	Histology on skin biopsy/lymph nodes Screening for STIs  Pregnancy test Abdominal ultrasonography

#### 4.1.8 HIV-RNA TESTING

Plasma HIV-1 RNA assays/viral load assays are useful for indicating the prognosis of HIV infection, for indicating when asymptomatic patients should be treated and as a reference for subsequent monitoring of the virological response to therapy. In settings where resources are limited the availability and the cost of these assays are important considerations for the patient. Though desirable, there is no need to routinely perform a viral load assay as part of the initial laboratory evaluation of a patient who is symptomatic.

Some of the first generation viral load assays give falsely low results of viral load on samples from patients with subtype A/E infections and do not detect HIV-1 group O or HIV-2 RNA. The relative regional prevalence of HIV subtypes should therefore be taken into consideration when recommending viral load assays.

## **4.2 INITIATION OF THERAPY**

### **4.2.1 WHOM TO TREAT**

Most countries with ART programmes have established criteria for initiating ART developed by national technical committees, which balance the need to extend access to treatment as widely as possible against the feasibility of ART. Wherever possible national criteria should be developed by countries themselves. In resource limited settings, where the conditions necessary for the introduction of ART have been fulfilled, priority for treatment should be given to symptomatic patients with severe immune damage (i.e. CD 4 count below 200 cells/mm<sup>3</sup>), because these patients are at a high risk for disease progression. In the event that initial viral load testing is available, patients identified to have very high plasma viral loads, (i.e. above 100 000 copies/ml RT-PCR) have a poor prognosis and should also be offered treatment.

### **4.2.2 CHOICE OF THE REGIMEN**

The use of combinations of antiretroviral agents aimed at maximal suppression of viral replication is the standard of care. (see Table 1)

No currently available antiretroviral agent is sufficiently potent to provide sustained suppression of viral replication on its own. At best, monotherapy yields incomplete viral suppression for a very limited duration of time: 0.6 to 0.8<sub>log</sub> reduction in the viral load for 6 to 8 months. Thereafter, drug resistance is inevitable and cross-resistance to other antiretroviral agents may emerge. Monotherapy is therefore not recommended for the treatment of HIV infection. However, for the specific indication of prevention of mother to child transmission of HIV infection, short course monotherapy is still recommended.

#### **Dual Nucleoside Therapy (2 NRTIs)**

Historically, controlled clinical trials comparing dual nucleoside regimens of 2 NRTIs to monotherapy demonstrated enhanced 'virologic' efficacy as well as a survival benefit, in patients with advanced HIV infection (CD4 counts below 350 cells/mm<sup>3</sup>). Therapy with 2 NRTIs can potentially achieve a 1.5log reduction in "viral load".

Between 1995 and 1997, before the potent three-drug combinations became the standard of treatment, many PLHA were treated with dual nucleoside regimens. A small proportion of patients in industrialised countries are today still maintained on 2 NRTIs because this regimen is relatively well tolerated by the patients and careful clinical monitoring indicates continuing suppression of viral replication. It should nevertheless be noted that during the 'era' of dual nucleoside therapy in industrialised countries, despite some benefits on an individual level, there was no record of a significant beneficial impact at population level in terms of reduction in HIV related mortality.

Experiences from the resource limited countries where dual nucleoside regimens are presently being used indicate that there is some benefit from dual nucleoside regimens, but that these regimens do not achieve or sustain suppression of HIV replication to the same extent as the three-drug regimens. Despite the limitations of dual nucleoside regimens, where a more potent regimen is not available: 2NRTIs may be suitable for treating patients with advanced HIV disease, who are at high risk for

disease progression (e.g. CD4 count below 200 cells/mm<sup>3</sup>).

Patients with advanced immune suppression often have high levels of HIV activity as measured by the plasma viral load. Because of the limited duration of the clinical and immunological benefits of dual nucleoside therapy and because viral replication is very likely to continue during dual nucleoside therapy, every effort should be made to switch the patient to a maximally suppressive regimen in order to minimise the progressive accumulation of drug resistance mutations.

Table 5. Advantages and disadvantages of dual nucleoside regimens

Advantages of 2 NRTI	Disadvantages of 2 NRTI
low cost lower pill burden/better tolerance easier to monitor	lower antiviral potency emergence of resistance more likely

### The place of Hydroxyurea

In many resource limited settings, Hydroxyurea + Didanosine or Hydroxyurea + Stavudine are occasionally used in the treatment of HIV because of the low cost of these combinations. Hydroxyurea has no direct antiretroviral activity and is not considered as an antiretroviral drug. Hydroxyurea may, however, enhance the antiviral activity of nucleoside analogue reverse transcriptase inhibitors (NRTIs) through various possible mechanisms:

- depletion of host cellular enzymes that are essential for cell replication;
- repletion of cellular enzymes necessary for metabolising NRTI's to active form;
- depletion of numbers of activated lymphocytes vulnerable to HIV infection.

This specific targeting of host rather than viral proteins provides an alternative approach to antiretroviral therapy so that efficacy of hydroxyurea is not affected by emergence of HIV mutations resistant to NRTIs. The main disadvantage is that these effects are also exerted on other replicating cells in the host and this is the basis for the common toxic effects of hydroxyurea i.e. reduction in the numbers of circulating blood cells. The slight increase in antiviral efficacy when hydroxyurea is added to Didanosine or Stavudine is therefore offset by a significant decrease in the CD4+ cell numbers. This effect can be harmful in patients with low CD4 counts who also have active opportunistic infections. There have also been recent reports of fatal acute liver insufficiency as well as pancreatic insufficiency among patients receiving a Hydroxyurea + Didanosine regimen. Much of the evidence for the therapeutic effectiveness of Hydroxyurea combined with Didanosine and/or Stavudine comes from small studies with short follow-up periods. Before any recommendation can be given, further safety and efficacy data are needed.

## 4.3 MONITORING ANTIRETROVIRAL THERAPY \*

Patient on ART should be closely followed to assess adherence to therapy as well as tolerance of the treatment and efficacy of the treatment. At the start of treatment it is advisable for patients to be seen monthly and once stabilised they can then be seen every three to four months. More frequent visits may certainly be dictated by various intercurrent needs so follow up plans should be tailored to individual patient requirements.

### 4.3.1 Monitoring adherence to ART

PLHA from resource poor countries have identified the following as important determinants of adherence to ART:

- the quality of initial and continuing counselling resulting in well-informed decisions and

- commitment by the patient to start and to maintain ART.
- the availability of accessible, knowledgeable and committed medical support teams.
- the assurance of a continued supply of antiretroviral medications

At each follow up visit, adherence to the treatment should be discussed in depth. The “drug timetable” which was made at the onset of ART should be revisited to see how this is functioning in real life and the patient should be assisted to work through any difficulties they have encountered. Close co-operation and communication between clinicians, pharmacists/dispensers, other counsellors, patients and family are vital. Carers need to remain aware of the issues surrounding individual patients’ access to ART in order to anticipate difficulties in adherence and to plan support.

#### 4.3.2 Monitoring tolerance to ART

The causes of any new symptoms or signs developing after the initiation of ART should be identified whenever possible. New symptoms may be related to intercurrent illness or due to adverse effects of antiretroviral drugs. Shortly after commencing ART, certain opportunistic infections may become clinically apparent as a result of the syndrome of immune reactivation, and these should be diagnosed and treated.

If new complaints are due to adverse effects of drugs, these should be explained to the patient and appropriate measures implemented, be this by adapting the drug regimen, providing symptomatic treatment or giving simple reassurance. Direct questioning on early symptoms of the documented clinically serious adverse effects of antiretroviral drugs is mandatory, as is systematic physical and laboratory examination to look for indicative signs. In this way adverse effects like severe anaemia and neutropenia; polyneuritis; pancreatitis; hepatitis; nephrolithiasis and serious hypersensitivity dermatitis can be detected early and remedial actions taken. Table 6 lists the ancillary laboratory tests that should complement patient interview and physical examination to monitor for drug toxicity. The necessity for these tests will vary according to the antiretroviral drugs being used and to whether or not tests are indicated by the patient’s symptoms.

Table 6. Laboratory monitoring for tolerance of ART

Laboratory Tests	Antiretroviral drug class		
	NRTI	NNRTI	Protease inhibitor
Essential to monitor routinely and at baseline:			
Complete blood count	X		
Urine (glucose, protein, microscopy)	X		X
Necessary when indicated by clinical features:			
• Serum transaminases	X	X	X
• Serum amylase	X		
• Serum creatinine/Urea	X		X
• Creatine phosphokinase	X		
• Serum triglycerides			X
• Blood glucose			X

\* Further Reading: Laboratory Requirements for the Safe and Effective Use of Antiretrovirals. Guidance Module number 5. Guidance Modules on Antiretroviral Treatments. WHO/UNAIDS. WHO/ASD/98.1; UNAIDS/98.7



### 4.3.3 Monitoring the efficacy of ART

The efficacy of ART is indicated by clinical improvement of the patient and by a favourable response of the biological markers of HIV infection, namely CD4+ cell counts and plasma “viral load”. Some clinical indicators of disease progression and response to treatment:

- a gain in body weight
- increase in total lymphocyte count
- decrease in frequency/severity of opportunistic infections
- decrease in occurrence/severity of HIV related malignancies

#### CD4 lymphocyte counts\*

The clinical manifestations of HIV infection are mostly dependent on the levels of CD 4+ cells; the CD4 count. Where viral load assays are not available, a rise in the CD4 count is an acceptable indication of treatment efficacy. In addition, CD4+ cell levels are very useful when deciding on the time to start or to stop prophylaxis against certain opportunistic infections. In patients in whom undetectable viral load levels have been achieved, which indicates the desired suppression of retroviral activity, a median increase in CD4+ cells of about 100-200 cells per year may be expected. The magnitude of this increase in CD4+ cells will depend on the baseline CD4 count as well as other factors which influence the outcome of ART. It is worth noting that following initiation of therapy, the “CD4 response” as evidenced by rising CD4+ cell counts, is much slower than the “viral load response” and may take several months to years to be complete. A reasonable frequency of CD4 count measurements in patients on ART is every 3-6 months.

#### Plasma HIV-1 RNA assay or “viral load”\*

The plasma viral load is a measure of HIV replication and the suppression of viral replication is one of the primary goals of antiretroviral therapy. Sustained suppression of HIV replication is not only an indication of the efficacy of treatment but also may delay or prevent the emergence of drug resistance. It is advisable to measure viral load shortly after initiating ART i.e. within 1 to 3 months, as a check on the effectiveness of the therapy. It also becomes necessary to measure the viral load when the response to therapy, as shown by the other indicators, is unfavourable and whenever a change in the therapeutic regimen is contemplated. When interpreting the results of viral load assays caution is advised for several reasons:

- viral load levels vary according to the technique that has been used, the laboratory where the test has been done, the time and the way the sample was transferred to the laboratory.
- viral load levels may be increased after a recent infection, vaccination or lapse in treatment;
- certain viral strains that are particularly frequent in developing countries may be difficult to detect with some of the commercially available testing methods.

Wherever ART is introduced, a reliable reference laboratory, where the necessary biological monitoring tests can be assured, should be established.

## 4.4 CONSIDERATIONS OF DRUG INTERACTIONS

The majority of patients presenting for care in resource limited countries have symptomatic HIV infection and so, in addition to antiretroviral agents, they are likely to be taking other medications:

- for the control of HIV/AIDS related symptoms
- for prophylaxis of opportunistic infections
- for treatment of opportunistic infections and tumours
- for treatment of other coincident infections

Successful ART results in amelioration of many HIV/AIDS related symptoms and a decreased likelihood of opportunistic infections. It may even be possible, once immune competence has been restored, to discontinue primary prophylaxis for some of the opportunistic infections. There are nevertheless, numerous possibilities for drug interactions of which clinicians need to be aware. Drug interactions are of clinical importance if they increase the likelihood of drug toxicity or if they decrease the therapeutic effectiveness of an administered drug. The longer the duration of any drug therapy, the more significant this becomes. In the context of ART clinically important interactions are likely:

- between the different antiretroviral drugs that are prescribed
- between prescribed drugs and alternative or non-prescription medications,
- between drugs and food (see section 3.2.2)
- with certain "recreational" drugs

A detailed synopsis of all possible drug interactions is beyond the scope of this publication and only a few important examples are cited on the following pages. There exist several sources of information on potential drug interactions, particularly where access to the Internet is available and these are well worth referring to.

#### 4.4.1 ANTIRETROVIRAL DRUGS AND THE TREATMENT OF TUBERCULOSIS

The Rifamycin antibiotics (Rifampin & Rifabutin) stimulate the activity of the enzyme system in the liver (cytochrome P450) that metabolises Protease Inhibitors (PIs) and Non Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). This can lead to a reduction in the blood levels of the PIs and the NNRTIs. Conversely, PIs and NNRTIs may also enhance or inhibit this same enzyme system, although to individually different extents, and can ...1

...1 lead to altered blood levels of the Rifamycin antibiotics. The potential drug to drug interactions may result in ineffectiveness of the antiretroviral drugs, to ineffective treatment of tuberculosis or to an increased risk of drug toxicity. It is worth noting that:

- Rifabutin, can be used with all PIs (except Saquinavir) and with all NNRTIs (except Delavirdine), although dosage adjustments are sometimes necessary.
- Isoniazid, which is recommended for the preventive therapy of tuberculosis, is free from any interactive effect with PIs and NNRTIs.
- The Nucleoside Reverse Transcriptase Inhibitors (NRTIs) are not metabolised by the cytochrome P450 enzyme system and are free from interaction with either of the Rifamycin antibiotics.

Tuberculosis is an important public health problem in many resource-limited countries and also a common "opportunistic infection" in HIV infected individuals. With time, as the use of antiretroviral drugs increases, it is likely that the concurrent treatment of these two infections will become more frequent. It has been suggested that in resource limited settings, patients with active tuberculosis should not commence ART until chemotherapy for tuberculosis has been completed. While this would greatly simplify treatment regimens and enhance adherence, the effects of this approach on the overall outcomes of treatment have not been fully evaluated and further research is needed. In general, the treatment of tuberculosis should be in accordance with the recommendations of the National Tuberculosis Programme in each country. Since Rifabutin is often not available in resource limited countries, the following are possible options for the treatment of tuberculosis in patients receiving ART, which are drawn from published guidelines.

#### Possible options for ART in patients with active Tuberculosis (TB)

- Defer ART until TB treatment is completed
- Defer ART until 'the continuation phase' of treatment for TB and use Ethambutol + Isoniazid as

continuation.

- Treat TB with Rifampin containing regimen and use Ritonavir + 2 NRTIs \*
- Treat TB with Rifampin containing regimen and use Ritonavir/Saquinavir + 2 NRTIs \*
- Treat TB with Rifampin containing regimen and use Efavirenz + 2 NRTIs \*
- Treat TB with Rifampin containing regimen and use a 2 NRTIs regimen, then change to maximally suppressive ART once TB treatment is completed.

#### **4.4.2 INTERACTIONS WITH DRUGS COMMONLY USED FOR THE PREVENTION AND TREATMENT OF OIs**

Trimethoprim/Sulfamethoxazole, Ganciclovir and Hydroxyurea can potentially cause additive haematologic toxicity when given together with Zidovudine. In these situations, careful monitoring of haematologic indices is necessary. Dapsone, may lead to additive neurotoxicity when used together with Stavudine, Zalcitabine, and Didanosine. The antifungal agents Ketoconazole and Fluconazole may inhibit the metabolism of Protease Inhibitors and the resultant increase in the serum levels of PIs, increases the risk of toxicity.

### **4.5 FURTHER RESEARCH NEEDS**

Research is vital to inform future treatment and care decisions as well as for the advancement of scientific knowledge. To date there has been a paucity of controlled clinical trials in low and middle-income countries. However some programmes such as HIV-NAT in Thailand and HIV-NET in South Africa have paved the way for successful needs based research applicable to local requirements. This has been achieved through interaction between local researchers, governments and international funding and research agencies. Such partnerships for clinical research not only provide locally applicable evidence for treatment strategies but also build research capacity in low and middle-income countries.

It is vital to ask appropriate research questions that will have an impact locally but which could also be applicable to other settings. Most treatment advances will have initially been evaluated during the licensing process in industrialised countries. Whilst not aiming at duplicating research, an evidence base for local application of ART interventions must be developed for resource limited settings.

A vast amount of medical research is underway worldwide in the field of HIV. Researchers have a duty to establish that their studies are not unnecessarily repetitive, ask appropriate questions and do not unduly raise expectations in advance of favourable findings. The establishment of local research committees and a Data and Safety Monitoring Board for individual studies can help to maintain transparency and probity of the research process. All research conducted must adhere to the ethical guidelines which exist in individual countries and which reflect those established by International regulatory authorities. Suitable topics for research could be:

- Research in supportive medication and processes related to medication
- Alternative therapies including traditional approaches to care and treatment
- Assessment of cost-effectiveness of novel treatment strategies using antiretrovirals, particularly those investigating simplified regimens, new induction-maintenance regimens and pulsed/cycled antiretroviral therapy.
- Treatment and monitoring strategies adapted to resource limited settings.
- Research related to treatments which have not been studied in the populations in which they will be used
- Research on utility of treatments against local viral strains and HIV-2

## 4.6 INFORMATION AND TRAINING NEEDS

Quality information is the basis of good decision making in health care provision, and in-service training or continuing medical education for health personnel ensures that standards of good clinical practice are maintained. Even when antiretroviral drugs are not yet directly available or affordable by the health systems or patients, the attention generated by these drugs in the media is such that carers need to be equipped with regularly updated information that is technically sound and regularly updated. Information needs to be at a level appropriate for the user and in suitable language. The targeted populations should include: Decision-makers, Health-care professionals in both public and private sectors, Patients, Family and carers in the General Public.

Every HIV care centre accredited or regulated to provide and monitor ART should therefore design an information and training plan as an integral part of the treatment programme. This represents a cost-effective intervention in its own right and training programmes on comprehensive clinical care of HIV, including ART, should be initiated at country level and tailored to local needs.

**7**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



**UNAIDS**  
United Nations Joint Programme on HIV/AIDS  
UNICEF • UNDP • UNFPA • UNDCP  
UNESCO • WHO • WORLD BANK

11 17  
17.1  
13.6.

Oct  
Jel

# NATIONAL AIDS PROGRAMMES

## A GUIDE TO MONITORING AND EVALUATION



**unicef**  
United Nations Children's Fund



THE  
SYNERGY PROJECT

**MEASURE**  
Evaluation

**Impact**  
Implementing  
AIDS Prevention  
and Care Project

**CDC**  
CENTERS FOR DISEASE CONTROL  
AND PREVENTION  
MEASURE DHS+

# TABLE OF CONTENTS

<b>1</b>	<b>INTRODUCTION TO THE GUIDE</b>	<b>1</b>
1.1	Components of the toolkit	1
1.2	The importance of monitoring and evaluation for AIDS programmes	4
1.3	The use of indicators at different levels	5
1.4	The different functions of surveillance, monitoring and evaluation	7
<b>2</b>	<b>A MONITORING AND EVALUATION SYSTEM</b>	<b>11</b>
2.1	The monitoring and evaluation unit	13
2.2	Clearly stated programme goals	14
2.3	Indicators	14
2.4	A data collection and analysis plan	19
2.5	A data use plan	21
<b>3</b>	<b>INDICATORS</b>	<b>25</b>
3.1	Policy and political commitment	29
3.2	Condom availability and quality	35
3.3	Stigma and discrimination	43
3.4	Knowledge about transmission of HIV	49
3.5	Voluntary counselling and testing services	59
3.6	Mother to child transmission	69
3.7	Sexual negotiation and attitudes	77
3.8	Sexual behaviour	79
3.9	Sexual behaviour among young people	89
3.10	Injecting drug use	99
3.11	Blood safety	105
3.12	STI care and prevention	113
3.13	Care and support for the HIV-infected and their families	121
3.14	Impact: HIV, STIs, mortality and orphanhood	133

# 1 Introduction to the Guide

In the early years of the HIV/AIDS epidemic, programme managers had little information about what interventions were likely to work in reducing the spread of the virus, and little idea of how they might measure the success of their interventions beyond simply tracking HIV or AIDS itself. What's more, it was widely believed that sensitive behaviours such as sex and drug injection – known to spread the virus – could not be reliably measured at all. There was an urgent need to respond in any way possible. Measuring the success of the response was not high on the list of priorities for most programme managers.

Over the last decade, this thinking has changed. Much more is known about how HIV spreads through a population, and what changes are needed to slow the spread. It has been amply demonstrated that people will answer questions about their sex lives, and there is growing evidence that their answers give a fairly reliable picture of trends in behaviour over time.

As the body of knowledge surrounding HIV grows, so does the interest in monitoring and evaluating the success of programmes designed to reduce the spread of infection and the impact it has on the lives of families and communities. This interest comes from national governments as well as from the taxpayers, programme directors and international donors who support their efforts. The need for better monitoring and evaluation has also spawned a growing number of data collection instruments and indicators.

Many different countries and institutions have contributed to the current understanding of how best to monitor and evaluate HIV and AIDS programmes. This guide, the result of a broad consultation with country programme staff, donor representatives and evaluation specialists from institutions all over the world, attempts to bring together their experience. It aims to summarise the best practices in the field of monitoring and evaluation (M&E) of

national HIV and AIDS programmes at the end of the 1990s, and to recommend options for M&E systems in the future. By consolidating existing data collection instruments and creating a framework within which improved instruments can be developed, this guide and the toolkit which accompanies it aim to simplify an increasingly complex field.

This introduction outlines the contents of the toolkit and gives an overview of the different functions of surveillance, monitoring and evaluation. The next part of the guide describes the main features of a sound M&E system. Finally, indicators for key areas of HIV prevention, AIDS care and STI control programmes are proposed. It should be stressed that this is not an attempt to reinvent the wheel. In proposing indicators, the guide takes into account existing standards and experience. New indicators are only proposed in those areas where none previously existed, or where country experience suggests that existing indicators are not useful or have been overtaken by the HIV epidemic.

## 1.1 Components of the toolkit

This guide is accompanied by a number of data collection instruments and guidelines needed to construct the proposed indicators. These are based on existing materials from a variety of sources, and cover different areas of AIDS programmes: knowledge, attitudes, sexual behaviour; programme context, input and output; service provision; and health status. They include various types of data collection instruments, for example population surveys and health facility assessments. Some of the instruments have been in existence for many years and have been widely tested, others are relatively new, and a few are still being tested. If specific instruments improve with experience, previous versions can simply be replaced with newer versions. To enable users to access the latest version of a given data collection

instrument, all updates will be posted on the Internet at a UNAIDS Web site, initially operated by the MEASURE Evaluation Project ([www.cpc.unc.edu/measure](http://www.cpc.unc.edu/measure) and [www.unaids.org](http://www.unaids.org)).

**Panel 1** lists the data collection instruments included, grouping them according to which aspect of programming they measure. **Panel 5** cross references individual indicators by programming area data collection instrument.

The choice of indicators and therefore of data collection instruments will depend on a number of things, including the stage of the epidemic, available resources and capacity for data collection. These choices are discussed at greater length in the second section of this guide.

**Panel 1: Monitoring and evaluation tools** (*Instruments in italics are still under development*)

Monitoring of programme performance and context	Population Surveys	Facility-Based Assessment	
AIDS Programme Effort Index (Futures/POLICY project)	General population survey (UNAIDS)	Assessment of STI services (WHO/UNAIDS)	HIV surveillance: policy guidelines (WHO/UNAIDS)
<i>MEASURE Evaluation/WHO/PSI Compiled Condom Retail Availability and Quality Protocol</i>	AIDS Module DHS (MEASURE DHS+)	Assessment of VCT services (UNAIDS)	HIV surveillance in sub-populations of high-risk behaviour (WHO/UNAIDS)
<i>Monitoring spending and budget allocations (UNAIDS, Futures Group)</i>	Youth target group behavioural surveillance (FHI/IMPACT)*	<i>Assessment of MTCT services (UNICEF, WHO, UNAIDS, Horizons)</i>	STI surveillance (RPR, other lab data, disease reporting) (WHO)
Assessment of discriminatory practices and legislation (UNAIDS)	Female sex workers behavioural surveillance (FHI/IMPACT)*	<i>Protocol for the evaluation of HIV/AIDS care and support (WHO/UNAIDS)</i>	
<i>Media review-based tools and indicators (MEASURE Evaluation)</i>	General adult population behavioural surveillance (FHI/IMPACT)*	<i>Blood safety draft protocol (MEASURE Evaluation)</i>	
	Men who have sex with men behavioural surveillance (FHI/IMPACT)*	<i>MEASURE Service Provision Assessment (SPA)</i>	
	Intravenous drug users behavioural surveillance (FHI/IMPACT)*		

\* Part of the Behavioral Surveillance Surveys (BSS): Guidelines for repeated behavioral surveys in population groups at risk for HIV

### **Monitoring of programme context and effort**

Programme context monitoring focuses on the compilation of input and output data that can be used to monitor changes in effort and context over time. This includes the assessment of condom distribution and quality, based on instruments developed by WHO/GPA and Population Services International (PSI), as well as indicators of STI drug distribution. The newly developed AIDS Programme Effort Index, co-ordinated by the Futures Group's POLICY Project, attempts to capture some of the contextual and programmatic aspects of the national response. UNAIDS Country Profiles provide a series of indicators that can help describe the socio-economic and demographic background of the epidemic.

### **Monitoring of knowledge, attitudes and sexual behaviour**

Tools for monitoring knowledge, attitudes and sexual behaviour include guidelines for household surveys in the general population, and in specific sub-populations, including information on sampling methods and questionnaires.

Such surveys yield most of the information necessary for constructing indicators of knowledge, attitudes and sexual behaviour, together with some information that can be used in indicators of stigma. Surveys also give information about access to or utilisation of services such as counselling and testing, home-based care for the terminally ill, and orphan support services. Guidelines for the collection of qualitative data are also available.

The instrument for collection of behavioural data in the general population draws heavily on the general population survey section of the WHO/GPA's Prevention Indicators and other WHO/UNAIDS work, as well as on the new AIDS module of the Demographic and Health Survey (MACRO International). The sub-population surveys were developed by Family Health International (FHI), and are based on FHI's considerable body of experience in implementing Behavioural Surveillance Surveys

(BSS). Recent surveys conducted with help from MEASURE *Evaluation* have also contributed to these tools.

### **Monitoring and evaluation of the availability and quality of health and other services**

Information in this area can be gathered by conducting regular and systematic surveys at health facilities and at other facilities providing HIV-related services such as voluntary counselling and testing centres. Instruments include protocols for collecting information related to STI care, counselling and testing, prevention of transmission of HIV from mother to child and blood safety. The STI care section is based heavily on protocols developed by the WHO/GPA. However, it offers additional and/or alternative methodologies further developed and tested by several countries, often in collaboration with FHI.

In other areas covered by the facility survey, little existing material is available upon which to draw, and new guidelines have been developed.

### **Monitoring HIV, AIDS and STIs**

The guidelines for monitoring the presence of HIV itself, together with syphilis and other STIs, have been developed by UNAIDS and WHO. They are based on a framework for second generation surveillance developed by the two institutions in partnership with others. The guidelines give advice on selection of sentinel groups and sites and provide information on using data from a number of sources for most effective monitoring of the spread of the virus in a given epidemic state. Other data collection instruments in this area include guidelines for STI surveillance (RPR, other laboratory data, syndromic or disease reporting), collection of specimens for HIV/STI testing in household or sub-population surveys and collection of data on AIDS-related morbidity and mortality. Guidelines on the collection of blood, urine, saliva or other specimens for HIV or STI testing are also available.

## **1.2 The importance of monitoring and evaluation for AIDS programmes**

Monitoring and evaluation of programmes designed to improve health and promote development are old news. Basically, M&E systems track what is being done and whether the programme is making a difference. M&E systems allow programme managers to calculate how to allocate resources to achieve the best overall result.

All of this is familiar to anyone who has worked in family planning, child nutrition, primary education or a host of other health and development fields. Indeed, efforts by the Development Assistance Committee of the OECD and other bodies to develop evaluation and resource allocation tools in other fields of development have laid the groundwork upon which this guide is built. So is a separate guide for the monitoring and evaluation of HIV and AIDS programmes really needed? Yes. The HIV epidemic is different from many other issues in health and development because it is relatively new, and no one knows exactly where it is headed. New interventions are constantly proposed, and each must be shown to be effective to justify becoming part of a national or international response. Operations research can show that a given intervention can be effective – for example that sex education in selected high schools can reduce risk behaviour. For a strong national M&E system, much more is needed to track more generalised success. In this case, repeated behavioural surveys among a national sample of high-school students would be needed to reflect changes in risk behaviour following the integration of sex education into the nation-wide curriculum.

The epidemic itself continues to shift. For years, everyone's attention was focused on prevention. As HIV epidemics turn into AIDS epidemics in one country after another, care of the sick and social support to people with AIDS and their families become more important. These programmes are often hard to deliver and potentially expensive – monitoring

their implementation and evaluating their impact will be important in ensuring that the best possible services are delivered.

HIV is politically charged in most countries. Important religious and political lobbies, along with the general population, may oppose intervention, and senior decision-makers may be reluctant to tackle the issue in consequence, preferring to focus on maternal mortality, child nutrition or other more "politically neutral" programmes. It is in this context that M&E is perhaps most useful of all. Only careful measurement and recording of the success of existing initiatives will persuade reluctant policy-makers to expand programme efforts.

When conducting monitoring and evaluation activities, because so many different disciplines contribute to the field of evaluation and there are cross-cultural variations, it is always useful to start with definitions that include not only surveillance, monitoring and evaluation, but also the terms "programme", "intervention", and "project". In the context of this document, "programme" refers to an overarching national or district-level response to HIV. Within a national programme there are typically a number of different areas of programming, such as the blood safety programme, the STI control programme or the HIV prevention programme for young people. The term "intervention" or "intervention strategy" refers to specific types of activities designed to achieve the goals of an area of programming. The training of a large number of teachers in HIV-related communication might, for example, be an intervention within the HIV prevention programme for young people. The term "project" is sometimes used interchangeably with intervention, since in practice interventions are often limited in scope to specific projects funded from a single source, at least in their initial or "pilot" phases. More often "projects" are a mix of interventions that aim at a specific population, defined geographically or otherwise.

### 1.3 The use of indicators at different levels

This guide identifies a set of indicators and methods for measuring them to be used at the national level. These indicators are intended to measure a broad range of issues regarding the HIV epidemic and the country's response to that epidemic. The selected indicators help to focus attention in the country on key prevention and care components of the response and the resulting impacts. They provide a way to track changes over time in specific prevention and care areas. They also allow comparison of the overall implementation and effectiveness of the national response in different countries.

However, because the set covers so many topics and because substantial resources can go into collecting indicators at a national level, the number of indicators in any particular area must remain limited. This means that the set presented here will not comprehensively address all the specific monitoring and evaluation needs of the national program in a given country, nor will it cover the much more detailed monitoring and evaluation needs of individual projects to prevent and mitigate the impacts of HIV. In this section we will briefly discuss the roles which these indicators play in monitoring and evaluation at three levels: international, national, and project.

#### International level

At the international levels, the collection of these indicators in different countries will help international agencies and donors to:

- track the trends in the epidemic and the response on a global scale
- identify regional trends or patterns in the epidemic and the response
- highlight persistent global and regional problems in responding to the epidemic
- advocate for expanded resources to address the pandemic
- allocate financial and technical resources so as to have the greatest impact on the global pandemic

It is therefore important that the indicators are defined and measured in the same way, so that they are understandable when viewing at the global level and between countries and regions. This guide provides detailed recommendations as to how to measure each of the indicators. Although contextual information is needed to form a full picture behind any particular indicator, taken roughly they can be compared directly from country to country.

#### National level

At the national level the indicators presented here can be used for many of these same purposes: tracking trends, identifying problem areas, advocating for and allocating resources. However, at the national level they will also inevitably contribute to evaluation of the effectiveness of the country's overall response, that is the sum total of all activities going on in a country which relate to the HIV/AIDS epidemic. For example, varied and aggressive prevention activities among young people might be expected to produce increased condom use or greater levels of abstinence from sexual activity. The young people's sexual behaviour indicators presented here can track whether this is happening or not.

In deciding on a national set of indicators, it is important that countries realise they are not limited to this set of indicators, nor should they necessarily collect all of them. The choice of indicators should be driven instead by the objectives, goals, and activities which constitute the national response to HIV and by the local epidemiology and nature of HIV and risk behaviours, keeping in mind that it costs time and money to collect and analyse data for each indicator. There is no point collecting information about risk behaviours or groups which are not relevant to the local epidemic. In this guide, the indicators have been divided into core and additional indicators, with this designation varying with the stage of the epidemic, as described below. Core indicators relate to important factors influencing the epidemic or tracking its course and are recommended for collection in all countries at a particular epidemic stage. Additional indicators are only recommended in countries where they have

relevance to the local epidemic or the local national response. The applicability of each additional indicator and suggestions for its use are discussed in detail in the indicator description later in this volume.

Where they fit the needs of a country, national AIDS programmes are encouraged to use the indicators defined here to ensure standardisation of information across countries and over time. When necessary, however, countries should add or delete indicators to make certain the data collected is linked to improving the national response. For example, in a low-prevalence country where voluntary counselling and testing for pregnant women is not a national program emphasis, little value will be added by collecting many of the indicators listed here on mother to child transmission. If resource constraints limit the number of indicators collected, these might be dropped or only one or two of them collected. On the other hand in a country with a severe generalised epidemic, a supplemental series of indicators measuring response at the local level might be required, e.g., the number of provinces implementing an active provincial AIDS committee chaired by the local governor. In a country with a concentrated epidemic among men having sex with men and injecting drug users, the set of indicators here might be expanded to include specific nationally relevant indicators such as percent of drug users in methadone treatment receiving counselling on HIV or percent of gay bars distributing condoms.

### **District level**

In the context of decentralisation and health sector reform, districts are playing an increasingly important role in health programmes, including AIDS programmes. Even though monitoring and evaluation functions of districts have not been specified in most countries, it is likely that districts will have two main functions. The first pertains to district level monitoring of AIDS programmes, the second concerns the provision of data relevant for national level monitoring and evaluation.

Many of the indicators listed in this guide are suitable for district monitoring purposes. Resources however are much more limited at the district level. A large survey could easily consume more than half of a district's AIDS budget in a single year. Furthermore, districts generally do not have the human resources to carry out a population-based survey. In some districts it may be possible to carry out regular behavioural surveys of specific groups, such as school youth, with limited outside assistance. In general, however, district monitoring should focus on programme inputs and outputs and assess whether or not implementation of activities progress according to a district plan. A small facility assessment as part of routine supervision could serve to provide information on the quality of STI care or the availability and utilisation of voluntary counselling and testing services, or AIDS care by health facilities. In addition, districts can make use of the existing routine health information system to obtain data on the incidence of sexually transmitted infections. Between 3 percent and 5 percent of district financial resources for AIDS should be devoted to monitoring and evaluation activities.

The district contribution to national level monitoring and evaluation also focuses on reporting of input and output data in line with national guidelines. Good reporting by districts would tremendously help national level monitoring and evaluation. For instance, if a country had actual data on condom distribution by district instead of one national overall figure, monitoring of trends in condom use may become more meaningful and more accurate. In many ways the considerations listed below for project level evaluation also apply to districts.

### **Project level**

There is often a strong desire to use the indicators presented in this guide for evaluation of specific prevention and care projects and a belief by many that this can be done easily. However, while some of these indicators may remain relevant at the level of monitoring and evaluating a specific project, they will certainly not cover the full range of project moni-

monitoring and evaluation needs. Good project monitoring and evaluation requires a mix of input, process, output, outcome and impact indicators which are directly tied to the project activities, goals and objectives. These should then feed directly back into the project to improve the implementation of activities and maximise the project's impacts.

Many of the indicators in this volume are defined for use in the population at large or in specific HIV/AIDS service settings. Collection and reporting of the data in the way specified in this document may not, therefore, meet the needs of a specific project to be assessed. And even if they are, unless the data collection simultaneously includes measures of exposure to the project or an examination of other outcomes which are unique to the project's target audience, directly attributing any change in the indicator to the project will not be possible.

This is a limitation of general indicators such as those defined here when applied to national level assessment. Even if they measure behaviour change, the change cannot generally be tied to one specific project since the populations in question have also been exposed to mass media and other sources of HIV/AIDS information, friends and relatives with HIV and AIDS, and other national and local prevention and care activities in addition to the project undergoing evaluation.

Thus if it is necessary to determine or demonstrate the effectiveness of a specific project, the design of that project must include its own baseline and follow-up assessments which measure not only project-specific outcomes (e.g., increased condom use among a specific sub-population or increased social support for those living with HIV in the community), but also level of exposure to the project and its activities.

While much of the impetus for standardising indicators has come from international bodies wishing to make cross-country comparisons, the value of standardised indicators within a country cannot be overemphasised. In designing its own evaluation activities, a project should bear in mind the national standard for indicators in that field. Projects may have their

own information needs that conform to a rigorous evaluation design. However they are often able to choose indicators with standard reference periods, denominators, etc. that would allow the data they collect to be fed easily into the national M&E system.

If a measurement method comparable to one proposed here is used or if the project evaluation activities can be altered slightly to allow data to be collected as specified in this document without compromising the evaluation of the project, then those indicators which are relevant to the project should be collected and reported to the national program.

Using comparable measures can provide the national program with valuable measures of the same indicator in different populations, permitting triangulation of findings and allowing regional or local inconsistencies and differences to be noted and addressed. This can help to direct resources to regions or sub-populations with greater needs, identify areas for intensification or reduction of effort at the national level, and aid in improving the overall effectiveness of the national response.

#### **1.4 The different functions of surveillance, monitoring and evaluation**

While surveillance, monitoring and evaluation serve different functions, they do overlap. This section attempts to clarify how the terms are used in this guide.

Surveillance, monitoring and evaluation all play a role in providing information to help determine the links between programme efforts and resources, and the goals the programme is trying to achieve. In the case of national AIDS programmes, the ultimate goals will be to reduce the spread of HIV, to improve care for those infected, and to minimise the social and economic impact on affected families and communities. For a programme to achieve its goals, **inputs** such as money and staff time must result in **outputs** such as stocks and delivery systems for drugs and other essential commodities, new or improved services,

trained staff, information materials, etc. If these outputs are well designed and reach the populations for which they were intended, the programme is likely to have positive short-term **effects or outcomes**, for example increased condom use with casual partners, reduced needle-sharing among drug injectors, or later age at first sex among young people. These positive short-term outcomes should lead to changes in the longer-term **impact** of programmes, measured in fewer new cases of STIs or HIV, or less HIV-associated death.

### Monitoring

**Monitoring** is the routine tracking of priority information about a programme and its intended outcomes. This is likely to include monitoring of inputs and outputs through record-keeping and regular reporting systems as well as health facility observation and client surveys. Data are usually compiled at the district level and later forwarded to the national level to be aggregated. Such monitoring is called programme, process or output monitoring.

The linked interpretation of data from different sources is a key component of useful monitoring systems. Often, one indicator alone will be unconvincing – this is especially true of indicators that rely on self-reported data in sensitive areas such as extra-marital sex. The advocacy value of an indicator showing increased self-reported use of condoms is greatly strengthened if it is presented together with data showing an increase in condom distribution and a reduction in the caseload at STI clinics.

In tracking the status of HIV infection, the behaviours that spread it and the strength of different areas of response, monitoring indicators function like the “vital signs” of the HIV epidemic at a district, regional or national level. They help programme managers determine which areas are in need of greater effort, and flag questions which might contribute to an improved response but that can only be answered by more refined outcome research methods than those used in routine surveillance and monitoring.

Monitoring can also include the tracking of short-term programme outcomes and long-term impact. Such data frequently come from surveillance systems. **Surveillance** is the routine tracking of disease (disease surveillance) or, less commonly, risk behaviour (behavioural surveillance) using the same data collection system over time. Surveillance helps describe an epidemic and its spread, and can contribute to predicting future trends and targeting needed prevention programmes. In the case of HIV, surveillance systems typically track impact in terms of HIV and sometimes STI prevalence, and outcomes in terms of sexual risk behaviour. It is typically performed at both the district and the national levels.

### Evaluation

**Evaluation** is a collection of activities designed to determine the value or worth of a specific programme, intervention or project. That means being able to link a particular output or outcome directly to a particular intervention. There are three sequential levels or phases of evaluation. The first phase – **process evaluation** – involves the assessment of the programme’s content, scope or coverage, together with the quality and integrity of implementation. If the process evaluation finds that the programme is not even being implemented, or is not reaching its intended audience, then it is not worth going on to the next phase of evaluation. If the reality is that there is no programme, then the programme cannot be having any effect. However if process evaluation shows progress in implementing the programme as planned, then it is worth going ahead with an evaluation of short-term outcomes, a phase known as **outcome evaluation**. (In HIV prevention, HIV-related knowledge, attitudes and beliefs have conventionally been considered outcomes, as well as HIV-related behaviours. But as discussed on page 15 (Framework for indicator selection), an increase in knowledge about HIV can only be translated into lower infection rates through changes in sexual or drug-taking behaviour. This guide therefore does not consider simply monitoring changes in knowledge, attitude, and beliefs to be able to provide evidence of

the effectiveness of a specific program. Outputs of programme efforts to increase knowledge are important, but cannot lead directly to changes in impact without first being reflected in an outcome indicator such as higher levels of condom use or lower levels of sexual activity.)

What is the difference between outcome monitoring and outcome evaluation? Essentially, outcome *monitoring* tracks changes in outcomes following the implementation of a programme or project, but is not able to attribute those changes directly to the intervention. In outcome *evaluation*, however, the evaluation is designed specifically with the intention of being able to attribute the changes to the intervention itself. Without the appropriate evaluation design, the monitoring of outcome indicators alone cannot produce causal evidence about the effectiveness of a specific program. At the very least, the evaluation design has to be able plausibly to link observed outcomes to a well-defined program, and should also be able to demonstrate that changes are not the result of non-programme factors.

In evaluating HIV prevention programmes, if no positive changes can be seen in outcome measures such as risky sexual or drug-taking behaviour, then there is little point looking at impact measures such as HIV or STD preva-

lence. Even if there is a change in prevalence, the change cannot be plausibly attributed to programme activities unless it is preceded by a change in risk behaviour. Without changes in risk behaviour, observed changes in HIV prevalence may well be attributed to other factors such as rising mortality or changes in service use. However if outcome indicators show that behaviour is changing, then it is time for **impact evaluation**. True impact evaluations, able to attribute long-term changes in HIV infection to a specific programme, are very rare. Rather, monitoring impact indicators such as HIV prevalence or adult death, taken in conjunction with process and outcome indicators, are considered to be sufficient to indicate the overall impact of a national response to the epidemic. Taken together, monitoring indicators can give programme managers and decision-makers an idea of whether the sum total of all HIV-related efforts in a district, region or country is making any difference. For example, when HIV prevalence levels among young pregnant women attending antenatal clinics began to fall in Uganda, a wide range of monitoring indicators on condom distribution, condom availability, sexual activity among youth, the prevalence of multiple partnerships, and condom use were used to assess whether behavioural changes may have caused the decline in HIV prevalence among antenatal women.

## 2 A Monitoring and Evaluation System

Until the mid-1990s, most monitoring and evaluation has been done in a relatively piecemeal fashion. A surveillance system for HIV is often in place but not functioning well, a few behavioural studies may have been done here and there, though not necessarily using the same sampling methodologies or indicators. Very few countries are able to track changes in behaviour, and they may never be able to attribute such changes to interventions. Research studies may have contributed extra information in some areas, but the results are often not used for programmes and policy making. Extensive evaluation of a donor-sponsored project may have been carried out in an important area of programming, without the results ever being shared with others in the field. Rapid Plasma Reagin (RPR) for sero-syphilis testing may happen at local antenatal clinics (ANC) for diagnostic purposes without the results ever being passed on to the district or central level for use in monitoring. In short, the utility of much of the HIV-related measurement in a country may be lost because there is no coherent M&E system.

A coherent system has several advantages. It contributes to more efficient use of data and resources by ensuring, for example, that indicators and sampling methodologies are comparable over time and by reducing duplication of effort. Where resources are scarce, this is an important asset. Data generated by a comprehensive M&E system ought to serve the needs

of many constituents, including programme managers, researchers or donors, eliminating the need for each to repeat baseline surveys or evaluation studies when they might easily use existing data. Good co-ordination should lead to better use of resources.

From the point of view of the national programme, a coherent M&E system helps ensure that donor-funded M&E efforts best contribute to national needs, rather than simply serving the reporting needs of agencies or legislatures overseas. A further advantage of co-ordination in monitoring and evaluation is that it encourages communication between different groups involved in the national response to HIV. Shared planning, execution, analysis or dissemination of data collection can reduce overlap in programming and increase co-operation between different groups, many of whom may work more efficiently together than in isolation.

The ultimate use of data and indicators for programme planning and evaluation is crucial in any M&E system. Data that cannot or will not be used should not be collected. Countries have different M&E needs, dictated in part by the state of the HIV epidemic in that country, in part by the efforts being made by the AIDS programme and in part by the resources available. Yet successful M&E systems will share common elements. A list of some of these elements is given in Panel 2.

**Panel 2: Checklist of features of a good M&E system.**

<b>M&amp;E UNIT</b>	<ul style="list-style-type: none"> <li>• An established M&amp;E unit within the Ministry of Health</li> <li>• A budget for M&amp;E that is about 10 percent of the national HIV/AIDS/STI budget</li> <li>• A significant national contribution to the national M&amp;E budget</li> <li>• A formalised (M&amp;E) link with the research institutions</li> <li>• A formalised (M&amp;E) link with leading NGOs and donors</li> <li>• Epidemiological expertise in the M&amp;E unit or affiliated with the unit</li> <li>• Behavioural/social science expertise in the M&amp;E unit or affiliated with the unit</li> <li>• Data processing and statistical expertise in the M&amp;E unit or affiliated with the unit</li> <li>• Data dissemination expertise in the M&amp;E unit or affiliated with the unit</li> </ul>
<b>CLEAR GOALS</b>	<ul style="list-style-type: none"> <li>• Well-defined national programme goals and targets</li> <li>• Regular reviews/evaluations of the progress of the implementation of the national programme plans</li> <li>• Guidelines and guidance to districts and regions or provinces for M&amp;E</li> <li>• Guidelines for linking M&amp;E to other sectors</li> <li>• Co-ordination of national and donor M&amp;E needs</li> </ul>
<b>INDICATORS</b>	<ul style="list-style-type: none"> <li>• A set of priority indicators and additional indicators at different levels of M&amp;E</li> <li>• Indicators that are comparable over time</li> <li>• A number of key indicators that are comparable with other countries</li> </ul>
<b>DATA COLLECTION &amp; ANALYSIS</b>	<ul style="list-style-type: none"> <li>• An overall national level data collection and analysis plan</li> <li>• A plan to collect data and analyse indicators at different levels of M&amp;E</li> <li>• Second generation surveillance, where behavioural data are linked to HIV/STI surveillance data</li> </ul>
<b>DATA DISSEMINATION</b>	<ul style="list-style-type: none"> <li>• An overall national level data dissemination plan</li> <li>• A well-disseminated informative annual report of the M&amp;E unit</li> <li>• Annual meetings to disseminate and discuss M&amp;E and research findings with policy-makers and planners</li> <li>• A clearinghouse for generation and dissemination of findings</li> <li>• A centralised database or library of all HIV/AIDS/STI-related data collection, including ongoing research</li> <li>• Co-ordination of national and donor M&amp;E dissemination needs</li> </ul>

## 2.1 The monitoring and evaluation unit

Monitoring and evaluation of HIV/AIDS/STI programmes generally rests with the Ministry of Health at a national level. A special HIV M&E unit has often been set up within the national AIDS programme. Where the Ministry of Health has an effective health information system, HIV and the response to it can be monitored along with other diseases by a central epidemiological unit such as Thailand's Centre for Disease Control. Where the AIDS programme is steered by an inter-ministerial committee, the responsibility for co-ordination of M&E activities may be located outside the Ministry of Health, although this tends to make M&E more complicated. This co-ordination role of the national AIDS programme or its affiliates is one whose importance cannot be stressed strongly enough. Even while it is recognised that many countries have limited funding for tracking projects and inputs sponsored by different donors and researchers, maintaining an overarching picture of the inputs into the M&E system is crucial. To be sustainable, this must be in place as part of an effective and coherent national M&E system and national programmes should not hesitate to advocate for a better use of resources from both within and outside the national programme.

Clearly there is a wide variation in funding for HIV/AIDS and STI programmes from country to country. If spending on the programme is minimal, the amount dedicated to M&E systems for HIV will also be minimal. The reverse, however, is not always true. In some countries with relatively good resources for drugs and treatment, monitoring of the epidemic is either neglected, or funds for monitoring are allocated inefficiently. Donors wanting to see if their money is well spent often push for better monitoring and evaluation. In consequence, they also fund a disproportionate share of M&E activities. This has created anxieties for recipient countries, as the end of donor

funding has in practice led to the collapse of many M&E activities. Since a good M&E system is crucial to ensuring resources are well used, it is recommended that about 10 percent of the HIV/AIDS budget be used for monitoring and evaluation activities, excluding the routine surveillance of HIV and risk behaviour. No M&E activity should be entirely donor-dependent.

**Human capacity** is a major constraint to M&E in many countries. While M&E units or committees do exist in many national programmes, they are generally dramatically understaffed and their work is often limited to managing sero-surveillance systems. Capacity building is vital if M&E systems are to be strengthened. If capacity cannot be maintained within the national programme, networks can be created to access outside skills as necessary. At a minimum, M&E units should have access to an epidemiologist, a statistician, a social scientist and a data manager. Since available data are often poorly packaged and communicated, the team should also include a professional communications specialist/lobbyist.

The central M&E unit should maintain a formalised link with universities and NGOs, in the form of a **technical support group** for M&E. In this group academic researchers and donors are actively involved along with partners from the government, NGOs and other national institutions. This support group complements the technical capacity of the central M&E unit. The involvement of academic institutions, NGOs and others assures that data generated by these bodies are integrated into the central M&E system. Furthermore, the credibility of information generated by the M&E unit is much higher if supported by a technical group.

Where health programmes are organised vertically, it is important that working groups on M&E include monitoring and evaluation specialists from other sectors sharing interests with the HIV programme. Specialists and programmes with a focus on reproductive health including STI care and Tuberculosis (TB) programmes, for example, are obvious sources of

data which should be integrated into the M&E of HIV/AIDS/STI programmes.

## **2.2 Clearly stated programme goals**

It is not possible to monitor – much less to evaluate – progress towards goals unless the overall national programme goals are clear. If the national programme has no interventions in place to reduce vertical transmission, there is not much point in monitoring efforts to reduce HIV transmission from mother to child. Time and money may be better spent on tracking whether knowledge, attitudes and sexual behaviour among school children are changing following the introduction of a sexual health education programme in primary schools. An important step in developing an M&E plan, therefore, is to understand interventions and systems in place and how they are currently monitored and evaluated.

A clear statement of programme goals will generally be made in a national strategic plan or other strategy document. Such a document generally includes an overall goal (something along the lines of: “to reduce transmission of HIV and minimise its negative impact on those infected and affected”) and then more specific goals for particular areas of prevention and care. These may, for example, include a reduction of sexual transmission among adolescents, the increased provision and use of quality STI care services, or the provision of social support including health care and schooling to orphans. M&E systems should be designed with the nation’s stated goals in mind. Ideally the national plan should include quantifiable goals, although in practice this is often not the case.

In the earlier years of the epidemic, the key national planning instruments were WHO/GPA-supported medium term plans, usually spanning five years. Review of a medium term plan was a very useful M&E exercise in many countries. Increasingly, planning exercises involve a greater breadth of actors and take more careful note of the existing situation and of the response to date. This process, supported by UNAIDS and its part-

ners and described in the UNAIDS Guide to Strategic Planning for HIV and AIDS, includes a comprehensive situation analysis and response review. These exercises, which often increase the resources available for data collection and analysis, are likely to provide invaluable information to complement the routine M&E system. They also provide important opportunities for the dissemination of information and for the strengthening of partnerships necessary in a solid M&E system.

## **2.3 Indicators**

The programme goals will dictate the areas in which progress might be expected, and therefore the areas in which it might be measured. But how can “progress” in these areas be measured? This is where the choice of indicators comes in. Indicators exist or can be constructed for many areas of programming. (Details on choosing and constructing indicators will be discussed further in part three of this guide.)

What indicators should be selected? A number of guiding principles can help us choose the most appropriate set of indicators for M&E of AIDS programmes. First, we need to use a conceptual framework for M&E to select indicators and to interpret results. Second, we should consider specific qualities of the indicators, such as the link with programme goals, the indicator’s ability to measure change, the cost and feasibility of data collection and analysis, and comparability with past indicators, and comparability between countries or population groups.

### Framework for indicator selection

The most commonly used framework for the selection of indicators for M&E is the input-output-outcome-impact framework described in Panel 3. The indicators can measure what goes into a programme (money, number of condoms, drugs for treating opportunistic infection, test kits, training, etc. – these are known as the input indicators) and what comes out of it (trained nurses, safe units of blood, adolescents educated about safe sex, orphans supported with school fees, condom sales, etc. – these are known as output indicators). Programme outcomes are often described as better knowledge, changed attitudes, adoption of safer sexual behaviour, etc., and ultimately such outcomes may have impact on HIV or STI transmission.

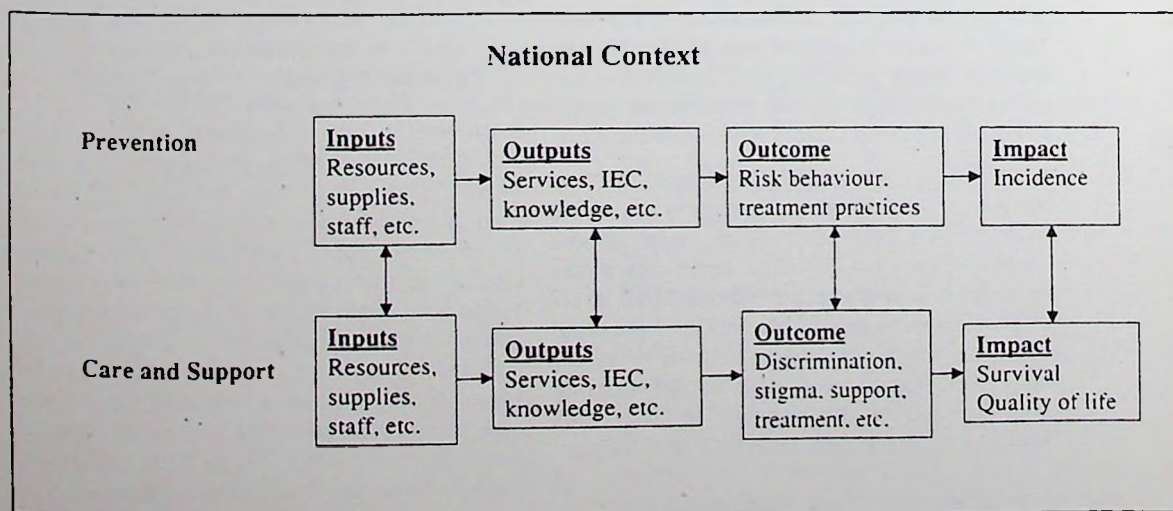
The input and output of programmes and the extent to which outputs lead to short-term outcomes (such as behavioural changes or better STI treatment practices) are influenced by the context in which the programme operates. This context includes socio-economic factors, and health system factors, but also the level of political commitment. For instance, introducing the syndromic approach for STI treatment

by training of health workers and improving drug supply is likely to be more successful in the context of a strong health system with well-paid workers than in a low-coverage weak health system. Promotion of condoms may be more effective if the policy and religious climate is favourable to condom use.

Short-term outcomes for HIV prevention programmes can be defined more strictly by using the same logic as that used in the proximate determinants frameworks used extensively in the study of the determinants of fertility and of child mortality. In this framework an outcome (or proximate determinant) must have two features: it can be changed by behavioural changes (and interventions), and, if it changes, it must have a direct effect on HIV transmission. Knowledge of HIV transmission is not a programme outcome indicator but an output indicator, since it has no direct effect on HIV transmission. Only if better knowledge leads to adoption of safer sexual practices can a reduction in HIV transmission be achieved.

Based on infectious disease epidemiology, several factors affect the spread of HIV and can be defined as programme outcomes:

Panel 3: Framework for monitoring and evaluation of AIDS programmes.



- *Risk of transmission per contact:* affected by condom use, by the presence of other STIs, by the age and sex of the uninfected person, by type of sexual practices, by the stage of the seropositive person's infection and by injecting practices
- *Risk of sexual or blood contact with an HIV infected person:* affected by the overall prevalence of HIV in the population, the number of contacts a person has, and the characteristics of those contacts, including their age and their levels of risk behaviour, as well as by needle exchange and drug preparation practices: risk of receiving contaminated blood: affected by blood screening and transfusion practices
- *Duration of infection:* affected by the treatment and care available for infected people

Social, cultural and economic context affect behaviour as well as programme implementation. They do not, however, greatly affect the link between behaviour and infection. If risk behaviours change, changes in new infection rates must inevitably follow, whatever the country context.

This specification of programme outcomes is most relevant to the prevention component of national AIDS programmes. Obviously, many national programmes do more than just HIV prevention work: they also try to care for people who are infected with the virus, and to reduce the impact of the epidemic on families and communities. These programmes, too, affect the proximate determinants of infection. Better care for an HIV-infected person means a longer, healthier life. Therefore, success in the care component of AIDS programmes can be measured in lower morbidity and mortality – the “impact” level indicator for care. But it also may mean that infected people remain in the pool of infectious partners, increasing the chances of epidemic spread. Many aspects of care and support aim to increase the quality of life of people with HIV, and do not directly affect the course of the epidemic. It is, however, recognised that there is a strong link between care and prevention programmes which is just now becoming a focus for attention

among programme managers. Many aspects of care and support programmes also feed back into indicators at the context level and the success of care and support programmes depends upon the context in which they operate. For example, many programmes attempt to reduce the stigma surrounding HIV infection. Programmes address stigma mostly because stigma may lead to active discrimination against HIV-infected people. But addressing stigma has a wider implication for prevention efforts. Where HIV is highly stigmatised, people may avoid condoms simply because they do not want anyone to think they are concerned about their own HIV status. A reduction in stigma surrounding HIV produces a more favourable context in which programme inputs and outputs might affect behaviours. In this example stigma reduction could contribute to an increase in condom use, with a direct effect on the likelihood of transmission per act of sex, and therefore on HIV incidence. Another example: prevention programmes are beginning to provide services to reduce transmission of HIV infection from mother to child. Since little can be done to save the life of the mother, a reduction in HIV incidence among children born to HIV-positive mothers leads inexorably to an increase in orphanhood. Monitoring success in this part of the national prevention effort will illustrate the need to plan for more care and support services for orphans.

As links between care and prevention become clearer, the framework for monitoring HIV prevention programmes will certainly expand to include care and support components of national AIDS programmes. The prevention framework, however, already provides a good starting point for considering the measurement of HIV-related indicators.

### Selection of indicators

Good indicators for the M&E of AIDS programmes need to be relevant to programmes, feasible to collect, easy to interpret and able to track changes over time. The choice of indicators will depend upon what the programme aims to do. Many commonly used indicators have grown out of international survey programmes such as Demographic and Health

Surveys (DHS), or out of protocols promoted by international bodies such as the United Nations. While such indicators allow for comparison between different countries, some may be of limited local relevance.

As a first step, programmes should monitor their inputs and outputs. Unless these change, any change in outcome can not in any case be ascribed to programme effort. Input and output indicators are often relatively easy and cheap to collect; where they register change, they indicate the need for monitoring and evaluation at the outcome or impact level.

Indicators should be chosen to measure change in areas of programme effort. Since most national AIDS programmes tailor their responses to the state of the epidemic in their country, it follows that the appropriate indicators will also differ according to epidemic state. This is discussed in far greater detail in the section of this guide dedicated to the choice of indicators.

### **Needs for data collection**

Ideally, indicators should be measurable with already available data. Most frequently, however, special data collection efforts are needed to construct reliable indicators. In general, the costs and difficulty of data collection increase as indicators shift from input through output and effect to impact. It should be possible to collate data for input and output indicators centrally from regular health reporting systems, whereas data for many outcome and impact indicators must be collected through surveys (or surveillance) of health facilities, or in population-based surveys. The cost and incremental benefit of more regular or more extensive data collection must also be borne in mind. It may be worthwhile to increase the sample size for sentinel surveillance so that data can be disaggregated by age, yielding important information. The trade-off may, however, be to reduce the number of sentinel sites, or to reduce the frequency of surveillance.

### **Why use indicators?**

Tracking changes in indicators over time will help programme managers and decision-

makers tell how successful the national programme is in meeting its goals. Indicators are just that – they give an indication of the magnitude or direction of changes over time. They can not, however, tell managers much about why the changes have or have not occurred, and so are not always useful for diagnostic purposes. National level monitoring systems are generally unable to do much more than track changes in behaviour or infection country-wide. When HIV prevalence falls following a reported fall in risk behaviour, and the change in behaviour follows an intervention designed to promote just such a change, it may be inferred that the national response is contributing to the fall in HIV infection. It is rarely possible however to attribute the impact directly to a particular intervention.

Most indicators are not designed to explain why a situation has changed or has failed to change – they are designed simply to measure the change. Only smaller scale qualitative studies can answer the “why” question, although understanding “why” and inquiring about “how” change occurs are essential first steps in deciding what to do about a problem. While small explanatory studies do not necessarily form part of a nation’s regular tracking system for HIV and the behaviours that spread it, they are an essential link between M&E systems and policy formulation. It is worth stressing that small explanatory studies do not yield standard indicators that are comparable across countries: by definition they are trying to explain something that is situation-specific.

Operations research also has a contribution to make. Once small-scale research studies have demonstrated that an intervention can produce the desired result under ideal research conditions (in evaluation jargon, once the efficacy of the intervention has been demonstrated), operations research puts the intervention through its paces to demonstrate its effectiveness under real world conditions. Inputs and outputs are carefully monitored in a programme context rather than a strictly research environment, and the outcome is evaluated.

### Composite indicators

In many areas of health and development, there is a tendency to develop indices, composite or summary indicators, which encompass several aspects of service provision or its outcome. These summary indicators are useful in that they limit the number of statistics that need to be presented at the highest policy level, or to people who are not specialists in the field and just need a general idea of whether things are getting better or worse.

The limitation of summary indicators is that changes are harder to interpret. A higher score may mean an improvement across all components measured by the index, or may be the result of a massive improvement in one area but an actual deterioration in another. Programme managers, who need to know about the performance of all components, will be interested in disaggregated data that allow them to see progress in each area of service

provision separately. A good example is the WHO/GPA prevention indicator 6, which is correct management of STI patients using the syndromic approach. Correct management is defined as sound history taking, physical examination *and* appropriate treatment.

The history taking and examination practices may go up significantly, but if treatment practices don't improve because drugs are not available, then the best training programme in the world will have little effect on the composite indicator. The good news is that the same data set can usually meet both sets of needs – it is just a matter of aggregating or disaggregating the data. It is important to bear the potential uses in mind when designing the data collection instrument and in analysis. Aggregation too early in the process of data collection or analysis may mean that disaggregated indicators cannot then be calculated to meet the needs of programme or project managers.

## 2.4 A data collection and analysis plan

Once a decision has been made about what to measure, a coherent plan must be made. This plan foresees all necessary indicators and takes into account all major data collection efforts within the country, leading to the most efficient use of resources in data collection. For example, a large and nationally representative household survey on reproductive and sexual health may be planned. Such surveys are expensive and generally infrequent: they represent an opportunity to collect a range of data that may be important for monitoring progress in the national programme. They may, for instance, be expanded to include questions on antenatal care service use which could be used in the analysis of HIV prevalence data, or questions on orphans within the household which may be used in the analysis of orphan support data. The best-known international household survey programme is the Demographic and Health Surveys (DHS). In many developing countries, DHS surveys are conducted once every five years or so. In addition, regular census rounds, typically held every 10 years, can include questions which can help monitor some areas of programming, especially demographic and household impact.

The inclusion of an AIDS module in the DHS may be sufficient to obtain data on a number of key indicators at the national and sub-national level. Therefore, if possible, the timing of the last and next DHS should be taken into account in devising a data collection plan.

Data collection plans should not forget to include data that are already collected by agencies not directly involved in HIV work, and that can help in monitoring HIV-related trends or behaviours. Data generated by TB programmes can be useful in illustrating trends in HIV, particularly in the male population where sentinel surveillance data for HIV is scarce. Reproductive health programmes may already have data on service use or sexual behaviour which can eliminate the need for some data collection in general population surveys or

health facility surveys. The data collection plan should stipulate systems by which data from other sources will be collected, reported and analysed by the M&E system for HIV.

A data collection plan will detail the sampling frame and the frequency of data collection. It will stipulate who is responsible for what, how much it will cost and who will pay. Since few countries have the financial or human resources to collect every bit of data they would like to monitor their programmes, the process of detailing responsibilities and a budget will often lead to a re-examination of priorities.

A national M&E system should act as a clearinghouse for both generating and disseminating data. A formal mechanism for screening data collection efforts can ensure that whatever is collected best meets the country's M&E needs. In general, every extra layer of bureaucracy carries with it the potential for unnecessary delays. The "clearinghouse" function should not be viewed as an approval process. Rather, it should be a registration and rapid review mechanism that ensures that the national programme is aware of all data collection efforts that could contribute to national needs. It also allows the programme to check that suggested indicators conform to the national standards chosen by the programme, so that comparisons can be made between different populations and across time. This is especially useful in countries where responsibility for data collection has devolved to the provincial or district level.

A centralised database or library of all HIV/AIDS/STI-related data collection contributes immensely to the efficiency of M&E efforts. What has already been done should be noted and tracked to avoid duplicating studies unnecessarily. Biological and behavioural data generated by the second generation surveillance system, baseline studies, academic research and project evaluation reports should all be centrally filed and universally available. (Tracking and accessing evaluation reports are the most problematic, since many government agencies, NGOs and donor agencies involved in programming are reluctant to share evaluation reports, especially if the project in ques-

tion has achieved less than spectacular results.) The database should list ongoing data collection efforts as well as those already completed, to avoid the duplication of studies before their results are published. It is also exceptionally useful to keep a record of research protocols and questionnaires so that they can be repeated to maintain consistency between populations and over time.

Unfortunately – partly because M&E of HIV/AIDS/STI-related interventions have been so fragmented to date – donors all have their own institutional requirements. Most programme managers are all too familiar with a repetitive and seemingly endless stream of reporting forms, log frames and mid- and end-of-cycle evaluations. Each of these may require indicators which differ only marginally but which require a new data collection effort each time. Even when donors are funding the data collection, the cost in time and national expertise of meeting all these different demands can be considerable. And yet where resources are strained, it is hard for national programmes to refuse to jump through the hoops set up by the many different supporters of the national response. A national M&E system should take into account the needs of the countries and the requirements of the donors, so that duplication of efforts and waste of resources can be minimised. Donors are increasingly aware of the need to adapt their own reporting needs to fit in with a national monitoring and evaluation system that is well designed and well co-ordinated. The indicators suggested in this guide have been endorsed by a large number of international supporters of HIV programmes.

Many countries are now engaged in decentralising their health systems, bringing decision-making, planning and resource allocation to the provincial or even district level. Part of the impetus for this move is a belief that decisions made at the local level will be more relevant to the beneficiaries than decisions made in a distant capital. In the best case scenario, monitoring of HIV prevalence and evaluation of the response at the local level does indeed provide information that is locally relevant. This information is far more likely to be acted upon in

a decentralised system than more general, nationally aggregated information. Where M&E systems do function at a local level, there is still a need for central co-ordination of the M&E system. Indicators must be as compatible as possible and information exchange should be guaranteed between different provinces or districts. In addition, core indicators should be compiled on a national level for advocacy with the central government as well as to contribute to the information needs of the international supporters of the national response. Therefore, a national M&E system plan should include guidance to districts on indicators, data collection and analysis and dissemination.

### **Multisectoral response to HIV**

In several countries attempts are being made to expand the response to the HIV/AIDS epidemic from the health sector to a "multisectoral approach." Planning, and in some countries implementation, of HIV prevention and AIDS care programmes has been broadened to include all social and economic sectors. To date, multisectoralism has been more talked about than implemented. However, if a substantial proportion of HIV-related programmes do indeed shift from health ministries to other sectors, multisectoralism will provide new opportunities to gather more data and have a broader basis to influence policy making. For example, data from the Ministry of Education may provide information about the schooling of orphans. On the flip side, the involvement of multiple sectors will also complicate the task of monitoring and evaluation. The more diffuse the response, the more important it becomes to have a strong centrally co-ordinated M&E system to which each sector can contribute information.

### **Cross level linking of indicators**

A data collection and analysis plan should also focus on the linking of indicators at the different levels of measurement. Programme outputs should be interpreted in relation to programme inputs. Programme outcomes, such as an increase in self-reported condom use, should be analysed in relation to changes in programme

outputs, such as numbers of condoms sold. HIV prevalence trends should be interpreted in association with changes in sexual behaviour. The latter is one of the key principles of the "Second Generation Surveillance" initiative.

This global effort aims to strengthen or revitalise existing HIV surveillance systems and to improve the linking of behavioural data with biomedical surveillance for HIV. Panel 4 describes the main features of second generation surveillance.

## **2.5 A data use plan**

There is no point at all in collecting data that cannot or will not be used. The ultimate use of the data should guide the design of a coherent M&E system, especially the selection of the most appropriate indicators in a country. A clear plan for data use and dissemination will include a stipulation of the end users for each indicator, and how the data will be presented to them. It may include a plan for developing a shared database of information, and for sharing data between programme elements, researchers, donor agencies and others. A framework for regular dissemination of information to the public may also be included. In general, the data generated by M&E systems are used in three major ways: advocating for action; planning, revising and improving programs; and attributing change in the epidemic to interventions undertaken.

### **Advocating for action**

Good information about levels of HIV infection and the risk behaviours that spread it are critical to generating a will to act. Information about the social and economic impact of the epidemic is also powerful in this regard. In planning M&E systems, public health officials should consider individuals or groups with the power to act to change the course of the epidemic. Public health officials should generate data most likely to persuade those individuals or groups to act and should package it to meet the needs of their audience.

### **Planning, revising and improving programmes**

Both monitoring systems and evaluation studies generate information that should be used to improve existing programmes and to plan more successful interventions in the future. Monitoring information can be fed into programming immediately to correct for weaknesses and improve performance. This mechanism can provide information on whether an intervention is on track or on budget, or whether it is producing the desired number of trained nurses or the targeted increase in condom sales outlets. Evaluation results can be used to inform future programme design, prompting a decision to replicate an intervention in other areas, or to scrap it altogether because it is expensive and not making any difference.

Information on HIV and STI prevalence and risk behaviour generated by second generation surveillance systems should produce a swift response from programmers, indicating new populations at risk and suggesting behaviours most in need of addressing through intervention.

### **Attributing change to interventions and generating resources**

It is said that nothing succeeds like success. If successes in HIV prevention or care are not measured and recorded, the opportunity to generate further success is lost. Evaluation studies demonstrating the success of particular interventions or of national prevention efforts are instrumental in keeping HIV high on the agenda. They encourage increased funding of prevention and impact mitigation efforts and may bring in more resources for monitoring and evaluation.

Success stories should never be exaggerated, however. They demonstrate successful strategies rather than outright victory. A feeling that the war has been won often leads to a drop in interest and in resources. Many countries undertake comprehensive programme reviews as part of their regular planning cycle. As countries move to a more strategic, less normative planning framework for HIV programmes,

reviews and the situation analysis that precedes them become broader in scope. Planning also involves a broader spectrum of people, bringing representatives of all sectors of government together with others involved in the response. Strategic planning exercises provide an

excellent opportunity to review the M&E framework itself, to ensure that indicators remain relevant and cover all priority areas of the response and to set up mechanisms for the regular sharing of data where they do not already exist.

## Panel 4: Second Generation Surveillance Systems: What's new?

### Second generation systems look at behaviour as well as HIV infection

Traditional surveillance systems tracked HIV infection or other biological markers of risk such as STIs. Since HIV infection among adults must be preceded by one of a limited number of behaviours, such as unprotected sex with an infected partner or injection with contaminated needles, we know that if these behaviours change, there will be a change in the spread of HIV. Second generation surveillance systems monitor risk behaviours, using them to warn of or explain changes in levels of infection. Thus, second generation surveillance uses data from behavioural surveillance to interpret data gathered from sero-surveillance efforts.

### Second generation systems are tailored to the type of epidemic

As the diversity of HIV epidemics becomes more apparent, it also becomes evident that there is no "one-size-fits-all" surveillance system. Efficient surveillance of a predominantly heterosexual epidemic in a country where one adult in six is infected will differ radically from surveillance in a country where HIV infection is growing rapidly in drug injectors but has yet to spread to the general population. In general, surveillance systems can be divided into three broad types directly related to the type of epidemic:

- In *generalised* epidemics where HIV is over one percent in the general population, surveillance systems concentrate on monitoring HIV infection and risk behaviour in the general population.
- In *concentrated* epidemics where HIV is over five percent in any sub-population at higher risk of infection (such as drug injectors, sex workers, men who have sex with men), surveillance systems monitor infection in those groups and pay particular attention to behavioural links between members of those groups and the general population. They might ask, for example, whether male sex workers have wives or girlfriends, or whether drug users finance their habit through sex work. In these situations, surveillance systems also monitor the general population for high-risk sexual behaviour that might lead to rapid spread of the virus if it were introduced.
- In *low-level* epidemics where relatively little HIV is measured in any group, surveillance systems focus largely on high-risk behaviours, looking for changes in behaviour which may lead to a burst of infection. Such changes have recently been recorded in several Eastern European countries, for example, where a surge in injecting drug use was followed by very rapid growth in HIV infection.

### Second generation systems use data in ways that maximise their power to explain the epidemic

A classic antenatal clinic (ANC) surveillance system may show that HIV prevalence among women 15-49 years attending ANCs rose rapidly from 0 to 12 percent over eight years, and then levelled off. In the rising phase the upward trend meant more new infections (increasing HIV incidence), probably at all ages. But once the curve flattens out, the explanatory power of that single figure is lost. Prevalence may be unchanged for any number of reasons: because as many women are dying as are becoming newly infected, for example, or because many infected women are no longer becoming pregnant and so have dropped out of the pool of women tested at sentinel sites.

Some of these problems of interpretation can be reduced by concentrating analysis to women in the youngest age groups, who are less subject to biases of mortality or reduced fertility and whose infection is more likely to reflect recent trends in the epidemic. Analysing the ANC data together with data from other sources, such as general population surveys or behavioural surveys, also increases the explanatory power of sero-surveillance systems. The need to focus on young women in antenatal clinics was acknowledged several years ago when WHO/GPA designated two of its prevention indicators to HIV and sero-syphilis prevalence among women 15-24 years.

### Second generation systems make the best possible use of resources

By concentrating surveillance in areas where it provides the most information and tailoring systems to a country's capacity, second generation surveillance ensures that money and expertise are used as efficiently as possible. For example, sentinel sites are carefully chosen to provide reliable information from a minimum number of sites, while sampling for behavioural data collection takes sentinel sites into account so that strong inferences can be made in comparing behavioural and serological data sets.

Strengthened surveillance systems also make an effort to ensure that all data gathered are actually used, something which, perhaps surprisingly, has not been the case in the past. Syphilis data from ANC clinics have rarely been analysed for surveillance purposes, for example. Despite the association between HIV and TB, TB surveillance data are rarely included in HIV surveillance reports. For more information see [www.unaids.org](http://www.unaids.org).

**8**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS  
SALVATORSTR. 22  
D-97074 WÜRZBURG  
GERMANY**

**June 2001**



## Rejection of hypothesis associating an experimental polio vaccine with the origin of HIV

### Background

Since the beginning of the AIDS epidemic, there has been much speculation in both the scientific literature and in the popular press on the origin of the human immunodeficiency virus (HIV). One such theory, first put forward about 10 years ago, was that HIV was initially spread through contamination of an experimental attenuated type 1 oral polio vaccine virus strain called CHAT, developed at the Wistar Institute in Philadelphia, and produced only at Wistar and at *Recherche et industrie thérapeutiques* (RIT), Belgium. CHAT was used during vaccination campaigns conducted in the Congo (then a colony of Belgium) between 1957 and 1959. The theory alleged that some lots of the vaccine were manufactured using chimpanzee kidney cells, causing contamination with a relative of HIV – simian immunodeficiency virus (SIVcpz) – which was said to have infected vaccines and transformed itself into the HIV known today. The theory also contends that early cases of AIDS in Zaire (now Democratic Republic of the Congo) occurred within close proximity of vaccination sites where CHAT vaccine was used.

### New scientific findings

A meeting was held at the Royal Society in London in September 2000, to examine available evidence for the origin of HIV. Several hypotheses were considered.

The following evidence and scientific findings presented to the Royal Society allow rejection of the hypothesis that an early experimental oral polio vaccine was the origin of HIV:

- Using ultrasensitive molecular methods, early samples of the experimental CHAT polio vaccine (which have been in safe storage since the late 1950s) have recently been tested, and were found negative for HIV and SIV.
- The same samples also tested negative for chimpanzee DNA. This finding refutes the allegation that chimpanzee kidney tissue was used to prepare the experimental CHAT vaccines that were tested. Contemporaneous documents show that macaque monkey cells, not chimpanzee cells, were used to produce the vaccine. Macaque monkeys derive from Asia and are not naturally infected with SIV.
- Many persons present at the meeting with first-hand knowledge of the situation at the Wistar Institute and the RIT laboratories in Belgium, where the CHAT vaccine was manufactured, deny categorically that chimpanzee cells were ever used to produce the vaccine.

## Rejet de l'hypothèse d'une association entre un vaccin antipoliomyélitique expérimental et l'origine du VIH

### Historique

Depuis le début de l'épidémie de SIDA, l'origine du virus de l'immunodéficience humaine (VIH) a donné lieu à d'abondantes spéculations aussi bien dans la littérature scientifique que dans la presse grand public. Une de ces théories, avancée pour la première fois il y a une dizaine d'années, était que le VIH avait été à l'origine propagé par contamination d'une souche expérimentale de virus poliomyélitique de type 1 atténué servant à la préparation du vaccin buccal, baptisée CHAT, développée à l'Institut Wistar de Philadelphie et produite uniquement à Wistar et Recherche et industrie thérapeutiques (RIT), Belgique. Le vaccin CHAT a été utilisé lors de campagnes de vaccination menées au Congo (alors colonie belge) entre 1957 et 1959. Selon cette théorie, certains lots de ce vaccin auraient été fabriqués à partir de cellules de rein de chimpanzé, entraînant une contamination par un virus parent du VIH – le virus de l'immunodéficience simienne (SIVcpz) – dont on pensait qu'il avait infecté des personnes vaccinées et s'était transformé en VIH, le virus connu aujourd'hui. La théorie veut également que les premiers cas de SIDA apparus au Zaïre (désormais République démocratique du Congo) soient survenus à proximité immédiate des sites de vaccination où le vaccin CHAT avait été utilisé.

### Nouvelles constatations scientifiques

Une réunion a été organisée à la *Royal Society* de Londres en septembre 2000 pour examiner les données disponibles sur l'origine du VIH. Plusieurs hypothèses y ont été étudiées.

Les données et constatations scientifiques suivantes présentées à la *Royal Society* permettent de rejeter l'hypothèse selon laquelle un vaccin antipoliomyélitique buccal expérimental aurait été à l'origine du VIH:

- Des échantillons du vaccin antipoliomyélitique expérimental CHAT (qui avaient été soigneusement conservés depuis la fin des années 50) ont récemment été testés au moyen de méthodes moléculaires ultrasensibles et se sont révélés négatifs aussi bien pour le VIH que pour le VIS.
- Les mêmes échantillons ont également donné des résultats négatifs pour l'ADN de chimpanzé. Cette constatation réfute l'allégation selon laquelle des tissus de rein de chimpanzé auraient été utilisés pour préparer les vaccins expérimentaux CHAT qui ont été testés. Des documents de l'époque montrent que l'on a utilisé des cellules de macaque et non de chimpanzé pour produire le vaccin. Or les macaques proviennent d'Asie et ne sont pas naturellement infectés par le VIS.
- De nombreuses personnes présentes à la réunion et directement au courant de la situation à l'Institut Wistar et dans les laboratoires de l'Institut royal de médecine tropicale de Belgique où le vaccin CHAT a été fabriqué nient catégoriquement que des cellules de chimpanzé aient jamais été utilisées pour produire le vaccin.

- Assertions that CHAT vaccine was produced in what was then the Belgian Congo, using tissue from a chimpanzee colony near Kisangani, are denied by persons directly involved in the trials. No documentary evidence has ever been produced to prove that CHAT vaccine was produced in Africa.
- Phylogenetic data from 3 laboratories suggest that HIV first entered the human population around 1930, well before the CHAT vaccine trials of the 1950s. Also, there is substantial laboratory evidence to show that the SIV strains most closely related to HIV-1 were not found in Congo but in West Africa.
- Experiments carried out in several laboratories showed that the process used to manufacture the vaccine could not have permitted the experimental vaccine to be contaminated with SIV or HIV. Production of the experimental vaccine included treatment with trypsin (a powerful proteolytic enzyme), freezing, thawing and filtration, each of which is known to destroy or remove SIV or HIV.
- Early cases of AIDS in Zaire were detected in cities, where sexual transmission was more likely and where medical surveillance was better. The assertion that early AIDS cases occurred in close proximity to previous vaccination sites using CHAT vaccine was also contradicted by the demonstration of crucial errors in the information used to support the putative association.
- Vaccination trials conducted in the United States and in Europe with the same lots of CHAT vaccine cannot be associated with the early occurrence of AIDS cases.
- Les affirmations selon lesquelles du vaccin CHAT aurait été fabriqué en ex-Congo belge, à partir de tissus provenant d'une colonie de chimpanzés proche de Kisangani, sont réfutées par les personnes ayant participé directement aux essais. Aucune preuve écrite établissant que le vaccin CHAT a été fabriqué en Afrique n'a jamais été produite.
- Les données phylogénétiques provenant de 3 laboratoires suggèrent que le VIH a pénétré pour la première fois la population humaine aux alentours de 1930, c'est-à-dire bien avant les essais du vaccin incriminé dans les années 50. D'autre part, il existe suffisamment de données de laboratoire montrant que les souches de SIV les plus proches du VIH-1 n'ont pas été trouvées au Congo mais en Afrique occidentale.
- Les expériences pratiquées dans plusieurs laboratoires ont montré que la méthode de fabrication utilisée n'aurait pas permis la contamination du vaccin expérimental par le SIV ou le VIH. La production du vaccin expérimental comportait un traitement à la trypsine (enzyme protéolytique puissante), la congélation, la décongélation et la filtration, chacune de ces étapes étant connue pour détruire ou supprimer le SIV ou le VIH.
- Les premiers cas de SIDA décelés au Zaïre l'ont été dans les villes, où la transmission sexuelle était plus probable et où la surveillance médicale était meilleure. L'affirmation selon laquelle les premiers cas de SIDA se sont produits à proximité d'anciens sites de vaccination où le vaccin CHAT aurait été utilisé ont aussi été contredits par la révélation d'erreurs cruciales dans l'information utilisée pour soutenir l'association putative.
- Des essais de vaccination effectués aux États-Unis et en Europe au moyen des mêmes lots de vaccin CHAT ne sauraient être associés à l'apparition des premiers cas de SIDA.

## Conclusions

The new findings presented at the Royal Society meeting are consistent with previous epidemiological, biological and virological evidence, and strongly contradict the hypothesis on the origin of AIDS put forward.

Rumours linking the use of vaccines to negative health events, but especially to AIDS, can seriously damage immunization programmes, since they undermine the acceptance of all immunization efforts. This negative impact is particularly unfortunate in Africa, where thousands of children still die every year of vaccine-preventable diseases, and where progress in the control and eradication of these diseases is most urgent. It is important to differentiate between the early, experimental CHAT vaccine and the modern oral polio vaccine (OPV) used today.

Using OPV, the global campaign to eradicate polio has achieved a 95% decrease in the number of polio cases worldwide since it was launched. Polio eradication is progressing well in Africa. However, achieving global polio eradication will largely depend on further intensifying supplementary OPV immunization to interrupt transmission of wild poliovirus in key areas of western and central Africa. ■

## Conclusions

Les nouvelles constatations présentées lors de la réunion de la *Royal Society* correspondent aux données épidémiologiques, biologiques et virologiques dont on disposait déjà et qui démontrent formellement l'hypothèse sur l'origine du SIDA qui a été avancée.

Les rumeurs reliant l'utilisation de vaccins à des manifestations indésirables, mais plus particulièrement au SIDA, peuvent porter un préjudice grave aux programmes de vaccination, car elles minent la confiance dans les efforts de vaccination dans leur ensemble. Cet impact négatif est particulièrement regrettable en Afrique où des milliers d'enfants meurent encore chaque année de maladies évitables par la vaccination et où les progrès de la lutte contre ces maladies et de leur éradication sont les plus urgents. Il est important de faire la différence entre le vaccin expérimental CHAT du début et le vaccin antipoliomyélitique buccal moderne utilisé aujourd'hui (VPO).

La campagne mondiale d'éradication de la poliomyélite au moyen du VPO a permis de réduire de 95% les cas de poliomyélite dans le monde depuis son lancement. Les progrès sur la voie de l'éradication sont satisfaisants en Afrique. Toutefois, l'éradication mondiale dépendra en grande partie d'une intensification de la vaccination supplémentaire par le VPO afin d'interrompre la transmission du poliovirus sauvage dans des zones clés d'Afrique centrale et occidentale. ■

9

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

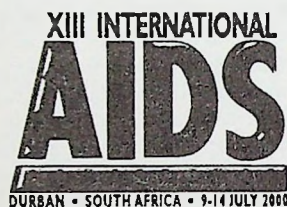
# Vaccines at Durban: A Closer Look

*Beyond the calls to action on behalf of PWAs with no medical care and poor countries struggling to turn the tide on AIDS, Durban offered abundant information relevant to vaccines*

by Patricia Kahn

Even before the 12,700 delegates at this summer's XIII International Conference on AIDS had left for home, the meeting was already being hailed as a landmark event in the history of the epidemic. From the impassioned calls to bring treatment to PWAs in poor countries to the outrage over South African President Mbeki's espousal of AIDS "dissident" ideas, the meeting created a momentum which — if it truly lasts — will mark a turning point in the fight against AIDS.

The conference was also a landmark event for vaccine development, solidifying its place as a top priority in that battle, particularly in poor regions. Unlike earlier meetings of the series,



where vaccines were largely a side issue, this year's event offered a profusion of vaccine-related sessions. With the dust now settled on the remarkable politics of Durban, the *IAVI Report* looks at some of the notable vaccine science and news presented there.

## A vaccine by 2007?

In this succinctly-titled plenary talk on vaccine development, Margaret Liu, former head of the HIV vaccine program at the Chiron Corp. (and now vaccine advisor to the Gates Foundation) outlined what she sees as the field's major achievements and most promising ways forward. Key items on her list were:

- The demonstration of protection against SIV or SHIV in primate models by several different types of experimental vaccines, providing both proof of concept and systems for studying correlates of protection;
- Detection of HIV-specific immune responses in a small minority of people who seem resistant to either HIV infection (exposed but seronegative people) or disease (long-term non-progressors). Such cases suggest that the immune system can contain the virus and pointed researchers towards strategies that target cellular immunity and mucosal responses;
- Illumination of viral structure, which is providing invaluable information for more rational vaccine design, especially of vaccines that might elicit neutralizing antibodies;
- Advances in vaccine technology and design concepts, such as prime-boost approaches, new gene delivery vehicles and adjuvants, vaccines directed to mucosal responses, and optimization of DNA vaccines.

Liu said that the question posed in the title of her talk could not yet be answered, although she expressed confidence that good candidates will be in advanced trials by 2007. But getting an effective vaccine on this timescale will take both a greatly increased effort and a commitment to be guided by scientific data and "rational empiricism" rather than by biases, which she said can creep into issues such as the debate on subtypes (see

below). She also emphasized the importance of pushing multiple vaccine approaches forward in parallel and of preparing trial sites so they are ready when the candidates are.

## AIDS vaccines for Africa

One major session focused on efforts to make vaccines targeted specifically to African needs and on vaccine work within Africa.

Immunologist Malegapuru William Makgoba, who heads South Africa's Medical Research Council, led with an overview of his country's HIV vaccine program, which has received strong government backing despite President Mbeki's questioning that HIV causes AIDS. The program is coordinated by the South African AIDS Vaccine Initiative (SAAVI), whose goal is the development of an affordable, subtype C-based vaccine owned by the public sector. SAAVI's scientific activities range from developing candidate vaccines (4 different approaches are now in the works) to immunological evaluation of vaccines and helping to prepare clinical trial sites. South Africa will also participate in testing candidates developed with international partners. The first one likely to enter clinical trials in the country is based on the Venezuelan equine encephalitis virus (VEE) vector made by AlphaVax, a North Carolina-based company, and funded by IAVI. Also under consideration are DNA vaccines from the Chiron Corporation and a vaccine from Targeted Genetics based on adeno-associated virus (AAV).

Carolyn Williamson of the University of Cape Town described how her lab derived subtype C sequences representative of southern African strains to use in the VEE vaccine. The researchers began by collecting samples from 14 commercial sex workers who were recent seroconverters and isolating virus from 10 of them. After confirming that these isolates infect cells via the CCR5 receptor, they sequenced 800 base pair regions from the *gag*, *pol* and *env* genes and compared them to over 70 known sequences from southern African subtype C strains, including some isolates from infected but asymptomatic individuals. In this way they arrived at 2 consensus sequences, which became the basis for this vaccine.

With Kenya now poised to launch Africa's second AIDS vaccine trial (see article, p.1), clinical investigator Dorothy Nbori-Ngacha of the University of Nairobi described the ongoing preparations. Efforts are now focused on finalizing the planning and oversight committees, such as the data safety and monitoring board, clinical steering committee and community advisory board, and getting the remaining scientific and ethical approvals. [Since the Durban conference, work is also focusing on patent and intellectual property issues; see [www.iavi.org](http://www.iavi.org).]

Rounding out the session, Peter Mugenyi, clinical director for Africa's first AIDS vaccine trial, described Uganda's long journey from the time of its early interest in AIDS vaccine development to the recently-completed trial at the Joint Clinical Research Center (JCRC) in Kampala (see below). Wayne Koff, who heads IAVI's R & D program, gave an update

on IAVI-supported projects to develop AIDS vaccines geared to circulating African strains (see *IAVI Report*, Jan-Mar. 2000, p.5).

#### **The Nairobi Declaration: An African Strategy**

At a press conference following the above session, several African scientists, along with Jose Esparza of the WHO/UNAIDS HIV Vaccine Initiative, presented "The Nairobi Declaration: An African Appeal for an HIV Vaccine." They also unveiled the broad outline of a strategy to move the vaccine agenda forward within Africa and to achieve greater coordination across the continent. Signed by 38 African scientists, community advocates and policy makers, the statement came after a process that solicited the views of African researchers and then formulated a set of principles and proposals, which were adopted at a 14 June meeting in Nairobi under the auspices of WHO/UNAIDS, AfriCASO (an umbrella for African AIDS service organizations), the Southern African Development Community (SADC) and the Society on AIDS in Africa (SAA).

The strategy outlines 5 areas for activity: advocacy and education; coordination; promotion of promising candidate vaccines; building capacity to conduct trials; and ensuring access. It also lays out specific milestones, including the development of candidate vaccines based on African subtypes by 2002; completion of at least 4 Phase I/II trials by 2003; and initiation of at least one Phase III trial by 2005. South Africa's Makgoba described the initiative as a way for African scientists to "speak with one voice [and to] be responsible for our own future." Makgoba will help coordinate the effort, which is now working to turn the strategy into a specific action plan and to raise political support and funds for its activities.

#### **Vaccine Trials: Tracking the VaxGen trial cohorts**

VaxGen's first two HIV vaccine efficacy trials are now in full swing and have a combined enrollment of nearly 8000 volunteers. Several speakers presented data on the experiences and self-reported risk behaviors of these trial cohorts, with an apparent downward trend in risk behavior.

Kachit Choopanya of the Bangkok Metropolitan Administration gave an update on the VaxGen trial in Thailand. Participants were recruited among intravenous drug users at 17 methadone clinics in Bangkok. [On 31 August, VaxGen announced that enrollment of 2500 volunteers was complete.] The cohort is about 93% male and has an annual HIV seroincidence estimated at 6%, based on studies of a similar population over the years 1995-1999. Two-thirds of the volunteers will receive 7 doses of vaccine (made of recombinant gp120 subunit from two different HIV subtypes) over 24 months, while the rest will be given placebo. Choopanya also reported that retention in the trial is over 95% and that the vaccine is well-tolerated and immunogenic in all participants.

Another trial investigator, Suphak Vanichseni of the Bangkok Vaccine Evaluation Group, presented interesting findings on trends in risk behaviors. Based on data from the 1174 volunteers who had reached their 6-month follow-up, she reported that the frequencies of nearly all risk behaviors (except recent incarceration) had dropped - some dramatically so - since the trial began: the proportion of volunteers injecting drugs decreased from 72% to 57%; needle sharing fell from 32 to 13% and condom use

increased from 51% to 62% with casual partners and from 8% to 12% with steady partners. Since such changes will lower HIV seroincidence, Vanichseni was asked whether the trial retains sufficient statistical power (it is designed to detect 30% vaccine efficacy). She responded that the study is powered for a reduction in seroincidence from 6% to 4% and that the cohort is still within that range, according to the Data Safety and Monitoring Board that is closely following the trial data.

Clayton Harro of Johns Hopkins University (Baltimore) reviewed the North America/Amsterdam trial, which is spread over more than 60 sites and is fully enrolled. Its 5414 volunteers are mostly men who have sex with men (MSM), along with 311 high-risk women. Annual seroincidence in the cohort is approximately 1.5%, and retention as of January 2000 was over 98%.

John Jermano of VaxGen presented data on the social impact of participation in the North America/Amsterdam trial, based on information reported by volunteers as of June 2000. The most frequent negative effects so far (reported by 7.5% of the participants at 6 months) are disturbances in relationships with family or friends, usually stemming from negative comments about participation or misperceptions that the volunteer is infected. Few volunteers (<1%) said they had experienced discrimination in employment or insurance due to their participation. Sexual risk behavior also decreased, with the median number of male partners reported by MSM during the past 6 months dropping from 5.0 (for the period prior to entering the trial) to 4.0 (during the first 6 months in the trial).

#### **New adjuvant boosts gp120 immunogenicity**

Jorge Flores (NIH, Bethesda) presented a potentially important finding concerning the adjuvant QS21, a saponin made from the soapbark tree and already used in veterinary vaccines. Reporting on a study by the NIH HIV trials network (study AVEG036) involving 60 volunteers, Flores said that 0.5 µg of VaxGen's bivalent gp120 vaccine (subtypes B/E) prepared in QS21 gave the same immune response as 300 µg in alum, the current adjuvant. This 600-fold reduction in the amount of antigen per dose would greatly cut the cost of the vaccine and make it far more economically feasible to produce polyvalent vaccines (containing gp120 subunits from multiple subtypes or strains, including breakthrough viruses). The trial also showed that a new formulation of QS21 reduced, but did not eliminate, the problem of relatively severe local reactions. According to study chair Tom Evans of the University of Rochester, a new trial is in planning to test whether reducing the amount of QS21 will reduce its reactogenicity but not its immune-enhancing effect.

#### **Clinical studies on canarypox vaccines**

In a late-breaker session, H. Cao of the Massachusetts General Hospital (Charlestown) presented results from a Phase I study of the ALVAC vCP205 canarypox HIV vaccine, conducted at the JCRC in Kampala and supported by the U.S. NIAID. The vaccine contains the *gag* and *pol* genes from HIV-1 subtype B. Several Phase I and II trials in the U.S.A. and France found it to be safe and to induce CTLs in a minority of volunteers. The Ugandan study enrolled 40 volunteers (20 immunized 4 times over 6 months with the test vaccine, 10 with rabies vaccine and 10

continued on page 18

with placebo) and analyzed CTL responses against the vaccine antigens and against Gag and Pol from two non-matching subtypes, A and D.

Cao reported that immunogenicity was similar to earlier trials, with 4/20 of the volunteers positive for CTLs at some point during the study. In the 4 positive individuals, CTLs were no longer detectable 100 days after the last vaccination. CTLs in 2 of the 4 responders recognized subtypes A and/or D antigens (at about 80% of the level seen against B). Results were confirmed with the ELISPOT assay.

Luwu Muscy from the University of Washington (Seattle) presented data showing that the ALVAC vCP205 vaccine can also induce mucosal responses. Although mucosal immunity is widely viewed as potentially important for protection, it has not been monitored so far in HIV vaccine trials. Muscy analyzed immune responses in 12 participants of a Phase II study (AVEG202/HIVNET014), 6 of whom had CTLs in the blood at some earlier point in the trial. Seven of these volunteers received vaccine and 5 received placebo. HIV-specific mucosal responses (measured by CTL in rectal tissue) were seen in 4/7 vaccinated people, with 2 of the 7 showing both blood and mucosal CTLs; 3/7 had CTLs only in the blood. Mucosal response was not affected by a gp120 boost. Results were confirmed with the ELISPOT assay.

#### HIV Diversity

In two talks, including a plenary lecture, Francine McCutchan of the Henry M. Jackson Foundation (Rockville, Maryland) reviewed the current state of knowledge about HIV variation and the challenge that continuous, rapid evolution of the HIV genome poses for vaccine development.

McCutchan pointed out that new molecular data are changing the view of how this diversity arises. While previously attributed mostly to HIV's high mutation rate, it is now emerging (from analysis of the many new full-length genome sequences becoming available) that recombination also plays a major role. Moreover, the likelihood of inter-subtype recombination is rising as subtypes continue to spread worldwide and more regions have multiple subtypes in circulation. (For example, non-B subtypes are increasingly seen in western countries, while 4 or more subtypes are common in parts of western Africa).

Based on analysis of 145 full-length sequences, 65 of them previously unreported, McCutchan described some important patterns. Many recombinants seem to be unique to one person, and some show an unexpectedly high complexity (e.g., an AFGJK recombinant). Other recombinants have entered the circulation in certain regions and are as common as some local subtypes; for instance, 56% of the circulating HIV in Cameroon is a circulating recombinant form (CRF) called CRF02\_AG. Other examples include the AE strain in southeast Asia, a BC recombinant in China and an AB form in Russia's IDU population. In the latter group, where infection rates are skyrocketing, McCutchan noted the highly puzzling fact that there is little genetic diversification of the transmitted

strain – a stark contrast to all non-IDU transmission chains that have been followed, including blood-borne chains such as the Florida dentist group or the Sydney blood transfusion cohort.

Addressing the implications of these findings for vaccine development, McCutchan said that comprehensive data on the pool of circulating strains is crucial for designing vaccines based on local strains, especially in regions with multiple subtypes. Without it, there is a danger of basing designs on a unique recombinant isolate rather than an important circulating strain. But the central issue for vaccines remains just how much the diversity of HIV sequences affects immune recognition of the encoded proteins, and consequently, whether vaccines based on one strain will protect against others.

#### Should vaccines always match local strains?

Focusing on this uncertainty, an interesting debate session featured two speakers presenting opposing views on whether vaccines tested in the developing world should always be based on an important subtype in the host country.

Rosemary Musonda of the Tropical Diseases Research Center (Ndola, Zambia) made the case against requiring a match. There is ample evidence that vaccines based on one subtype can elicit immunity against other subtypes, she said, especially in terms of

cellular immune responses. With the need for a vaccine so urgent, unnecessary restrictions on trials should be avoided. And it is only by testing such "mismatches" that the true relevance of subtype to vaccine efficacy can be clearly determined.

Arguing the other side, Carolyn Williamson of the University of Cape Town stated that neutralizing antisera from HIV-infected people appear to

work better against virus of the same subtype than against unmatched subtypes. Such data suggest that matching will maximize the chances of success for a candidate vaccine. It may also contribute to community acceptance of vaccine trials, since it sends a message that the test vaccines are genuinely geared to local needs.

During the discussion, audience members raised some key questions. If a matched vaccine proves to be effective in a Phase III trial, what's next? Will countries with other subtypes in circulation have to repeat the trial? And what if new subtypes or recombinants enter the region, or vaccinated people move to areas where different subtypes predominate? Matched trials will not test whether there is protection under these circumstances. Session moderator Peggy Johnston of the U.S. NIAID made the crucial point that even if a vaccinee responds less strongly to an unmatched HIV subtype, this weaker response might still be enough to protect. Vaccinologist Don Burke of Johns Hopkins University (Baltimore) responded that a similar dilemma facing developers of a vaccine against Japanese encephalitis virus was addressed by a Phase III trial with three arms: matched vaccine, unmatched and placebo. It is likely that HIV vaccine trials will ultimately require a similarly systematic approach.

---

*If a "matched" vaccine is found to  
be effective in a Phase III trial,  
will countries with other subtypes  
have to repeat the trial?*

---

## Immune correlates

Clinical studies of people exposed to HIV but seronegative (ESN), which have been done mostly in commercial sex workers, have pointed to key role for cellular immunity in this apparent protection. Lawal Garba of the University of North Carolina (Chapel Hill) presented new ESN data from a collaborative study of discordant couples in Zambia. Looking at 37 ESN individuals (all married or in steady partnerships with infected people for at least 3 years), the researchers found HIV-specific CTL in 9 of them. Intriguingly, the presence of CTL was correlated with high viral load in the infected partner, suggesting that total antigen dose may be an important aspect of stimulating CTLs.

Y.-M. Chen (Taipei) reported an observation which could imply the presence of enhancing antibodies to Tat in some HIV-positive people. (For a discussion of enhancing antibodies, see *IAVI Report*, April-June 2000, p.5). The researchers looked at transmission to the wives of 52 HIV-positive men drawn from blood bank donors who became infected primarily through contact with commercial sex workers. Among 52 men, 1 of 17 infected with subtype B, 14 of 33 with subtype E and 2 of 2 with subtype C transmitted virus to their wives. The transmitters had a higher level of anti-Tat antibody than non-transmitters (65% vs 26%), as determined by ELISA tests. The odds ratio of men infected with subtype E transmitting to their wives if they also had anti-Tat antibodies was extremely high (OR=18). The researchers are now analyzing whether anti-Tat antibodies might selectively enhance infectivity of different HIV subtypes. All current Tat vaccines have used subtype B *tat* genes, and enhancement of transmission has not been previously reported. ♦

## OXFORD TRIALS

*continued from page 1*

became the first person to be injected with the vaccine. Pending approvals from the appropriate Kenyan authorities, it is hoped that the DNA vaccine will enter human trials in Nairobi early in 2001.

The vaccine candidates are being moved into clinical studies by the research teams of Andrew McMichael at Oxford University and J.J. Bwayo at the University of Nairobi. Both vaccines are designed to generate HIV-specific cellular immune responses, which researchers increasingly believe can provide some protection against HIV infection or disease progression. Koff made the announcement of the MVA vaccine approval in Bonn, Germany, noting that "two IAVI-sponsored vaccine candidates have now moved from concept to clinic in less than two years, near record time for these type of products." He added that the HIV MVA vaccine is the first of its kind to be approved for human testing. ♦

## NEW VACCINE STUDY

*continued from page 4*

vaccine as an immune therapy, both in SIV-infected monkeys and HIV-infected individuals. Letvin himself supports the idea of such studies, but says he may be unable to do so himself. Yet there is clearly interest from the outside in seeing the therapeutic approach pursued: Greg Gonsalves of the New York-based Treatment Action Group has already written to Letvin to request that the vaccine approach be moved quickly into therapeutic trials.

On the whole, there is no question that Harvard study will have an impact on AIDS vaccine development. It also begins to show how the newer, more precise methods of quantifying T-cell responses will assist researchers in evaluating candidate HIV vaccines. These tests - known as tetramer binding and ELISPOT assays - will hopefully enable researchers to evaluate and compare a new generation of more potent vaccines, including cytokine-augmented HIV DNA vaccines in human studies.

"The study represents a major advance toward making a vaccine that really works," says Neal Nathanson, the former director of the U.S. NIH's Office of AIDS Research. And, he predicts, "it will help energize the whole field." ♦

# IAVI REPORT

## Editor

Patricia Kahn

## Founding Editor

David Gold

## Reviewers

Michael Cowing, Peggy Johnston, Alan Schultz, Wayne Koff

## Writers

Vicki Burkitt, Bob Huff, Richard Jefferys

## Design Advisor

Robert Fiedler

## Copy Editor

Michael Hariton

## Art Design

Jean Rothstein  
Type Impressions

## Founding Managing Editor

Denise Gray-Felder

The *IAVI Report* is published bi-monthly by the International AIDS Vaccine Initiative. To obtain a subscription to *IAVI Report*, send name and address, by e-mail to: [iavi\\_report@iavi.org](mailto:iavi_report@iavi.org); by fax to: 1-212-847-1112; by mail: IAVI, 110 William Street, 27th floor, New York, NY 10038, USA.

Copyright © 2000. All rights reserved.

IAVI is a scientific organization founded in 1996 whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. IAVI focuses on three key areas: accelerating scientific progress; education and advocacy and creating a more supportive environment for industrial involvement in HIV vaccine development.

IAVI is a UNAIDS Collaborating Centre. Its supporters include the Rockefeller, Alfred P. Sloan, Starr, Bill and Melinda Gates, Until There's A Cure and Vincent P. Belostsky, Jr. Foundations, as well as the U.K., Dutch, Canadian, Irish and U.S. governments, the World Bank, UNAIDS, the National AIDS Trust and Fondation Marcel Merieux. IAVI has also received support from Crusaid, the Elton John AIDS Foundation, Levi Strauss International, and other generous corporate and individual donors around the world.



**10**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

## BOOK REVIEW

### CATHOLIC ETHICISTS ON HIV/AIDS PREVENTION

Edited by J.F. Keenan, with J.D. Fuller, L.S. Cahill, and K. Kelly. The Continuum International Publishing Group Ltd. 2000. ISBN 0-8264-1230-0, 351 pages, \$24.95.

There is little doubt that the problem of HIV/AIDS is presently the worst human scourge, and no part of the globe is immune. In recent times, in the developing world, there are frequent claims by both orthodox and non-orthodox medical practitioners to having acquired magical cure for AIDS, but we all know that these claims are almost baseless. We all realise that at present, major efforts should be directed at prevention, and while aiming at this, the afflicted should be treated with compassion and not as social outcasts. The catholic church has played major roles in prevention and cure of very many diseases in the past and are currently playing very vital roles in the control of HIV/AIDS pandemic. However, day to day catholic teachings see some aspects of the preventive measures eg. the use of condom, as encouraging contraception and promiscuity; and the introduction of needle exchange programme, as encouraging drug addiction. In this exciting book, catholic moral theologians and others, argue that these measures do not run counter to catholic moral teachings.

The editors are to be congratulated on gathering together many acknowledged international moral theologians to write on this topic. The first part of the book presents cases from different parts of the world highlighting the peculiarities in HIV prevention in each locality and the ability of the catholic moral theological tradition to address HIV prevention; while the second part addresses the fundamental moral issues that theologians recognise in HIV prevention globally. In the first part, five main themes were recognised among the cases presented: (1) Inadequate power of women in the face of HIV/AIDS pandemic (2) Religious scrupulosity still inhibits ineffective prevention work (3) The integrity of the traditional religious practices that existed before christianity, still exist today and need to be respected (4) Homosexuals and lesbians have not been accepted into the mainstream society and AIDS control among them is therefore difficult (5) Children are helpless and very vulnerable.

The second part discusses magisterial teachings about moral theology and medical ethics; demonstrates that the central themes of the catholic social ethics tradition urgently need to be applied to HIV/AIDS prevention; and argues that casuistry is a way that individuals and communities negotiate their ethical beliefs when faced with moral issues.

This book made good efforts to cover different parts of the globe, however, there are repetitions in the moral interpretation of the different essays in the first part. On the other hand, there are occasional contradictions in the interpretation of the catholic moral teachings by different authors. These, the editors had noted and had advised that each essay should be seen as the singular contribution of each author and not necessarily of the editors.

This book covers very well what the editors had originally intended and in this age of HIV/AIDS pandemic, it should be a required reading by all and especially those catholics who feel that some aspects of the publicised methods of HIV/AIDS prevention run counter to their religious beliefs. Catholics intermarry with non-catholics, and HIV/AIDS knows no religious barrier. This book is generally easily readable and factual. It is informative and the main message is clear, though the theological aspects may be slightly difficult to be fully understood by lay people. The references cited were appropriate for the text in most instances. The binding is quite attractive and in the developed world, it is worth the price, though in the third world where the values of the local currencies have been bastardised, the price seems to be on the high side for

the low income earners.

The contributors have put human faces to the topic of HIV/AIDS prevention, and the editors have also presented this book as an invitation to engage moral theologians and their students on the ethics and moral theology of HIV/AIDS prevention. This book is very highly recommended.

AB = 14/7/00  
Aloy E. Aghaji FRCS  
Editor-in-Chief,  
Journal of College of Medicine,  
University of Nigeria Teaching Hospital,  
Enugu, Nigeria.

**11**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

# **MOTHER-TO-CHILD TRANSMISSION OF HIV**

**An overview of current knowledge and implications for policy  
with a special focus on safe infant feeding**



**Joost Hoppenbrouwer**  
**Coordinator HIV/AIDS**  
**Netherlands Network of Sexual & Reproductive Health and AIDS**  
**j.hoppenbrouwer@kit.nl**  
**February 2001**

## Acknowledgements

Special thanks go to the following persons for their support in preparing this report:

- Geert Haverkamp, IATEC - Amsterdam, The Netherlands
- Lida Lhotska, UNICEF HQ - New York, USA
- Rachel Baggaley – London, UK
- Arjan van de Wagt, UNICEF ESARO - Nairobi, Kenya
- Elizabeth Preble, SARA Project/USAID – Washington, USA
- Maaïke Arts, UNICEF - Tegucigalpa, Honduras
- Tim Farley, UNAIDS - Geneva, Switzerland

## **CONTENTS**

	Executive summary	4
0.	Introduction	5
1.	Overview of the main facts	6
1.1	Mechanisms of mother-to-child transmission	6
1.2	Prevention of mother-to-child transmission	8
2.	Experiences with implementation of MTCT prevention	19
2.1	UNICEF MTCT prevention pilot projects	19
2.2	Critical remarks	19
3.	Current IATT guidelines for MTCT prevention	22
3.1	Short-course antiretroviral prophylaxis	22
3.2	Support for safe infant feeding	22
4.	Discussion and policy implications	24
4.1	Preventing mother-to-child transmission of HIV: knowledge and gaps	24
4.2	Towards implementation of prevention programmes: Guidelines and guiding principles	25
4.3	Key programme components	26
4.3.1	Counselling services for HIV testing (VCT) and safe infant feeding	26
4.3.2	Antiretroviral prophylaxis	27
4.3.3	Safe infant feeding	29
5.	Conclusions	33
	References	34
	List of abbreviations used	37

## **EXECUTIVE SUMMARY**

Vertical transmission of HIV from mother to child constitutes a considerable percentage (10%) of overall new HIV infections worldwide. Mother-to-child transmission of HIV (MTCT) can take place during pregnancy or delivery, or through breastfeeding.

Short-course antiretroviral (ARV) prophylaxis has proven quite effective at preventing MTCT, while decreasing cost, especially of nevirapine, has made it increasingly affordable in resource-poor settings. However, ARV prophylaxis is only one element of a comprehensive package for MTCT prevention. Other key elements include comprehensive antenatal services, voluntary counselling and testing, optimal obstetric practices and support for safe infant feeding.

Since the positive effect of perinatal ARV prophylaxis can be undone by MTCT through breastfeeding, safe infant feeding is a major issue for MTCT prevention. However, a balanced breastfeeding policy does not only focus on minimising MTCT, but carefully weighs the multiple benefits of breastfeeding for the vast majority of infants – born both to HIV-positive and HIV-negative mothers – against the risks of MTCT through breastfeeding.

Given the current lack of conclusive knowledge about the relative risks of exclusive breastfeeding, mixed feeding or replacement feeding, it is difficult to provide clear-cut guidelines for safe infant feeding. For the majority of HIV-infected women in resource-poor settings for whom replacement feeding is not acceptable, feasible, affordable, sustainable and safe, exclusive breastfeeding during the first months of life is recommended, followed by a rapid shift to alternative safe infant feeding with formula or household-based options. Existing UN guidelines on HIV and infant feeding are still the best, while implementation of the International Code of Marketing Breast-milk Substitutes continues to be crucial to avoid a “spill-over” effect of non-breastfeeding recommendations to non-infected mothers.

Voluntary counselling and testing (VCT) and counselling on safe infant feeding are key elements for successful MTCT prevention, as counselling allows women to make informed decisions – with the support of health staff and counsellors – on MTCT prevention in their personal situation. Therefore, increased access to high-quality counselling services is a key priority.

More basic research on the exact mechanisms of MTCT and the relative risk of various infant feeding options, as well as into the efficacy and feasibility of MTCT prevention interventions in “real-life” conditions in resource-poor countries, is a key priority to be able to provide clear and practical guidelines for MTCT prevention.

MTCT prevention should not just focus on transmission of HIV from an already infected mother to her child, but also include prevention of unwanted pregnancies in HIV-infected women, and primary prevention of HIV infection in men and women of reproductive age. It has become clear that the involvement of men in all these aspects of MTCT is crucial. In this context, preventing *parent*-to-child, rather than just mother-to-child transmission, should be the key focus.

## 0. INTRODUCTION

The HIV/AIDS pandemic has not only reached enormous proportions in Sub-Saharan Africa, but is also spreading at a high rate in parts of Asia, Eastern and Central Europe, Latin America and the Caribbean.

By the year 2000, almost 35 million people were living with HIV/AIDS worldwide. An estimated 5.4 million new HIV infections took place in 1999, one-tenth of which was due to transmission from mother to child (MTCT).

Therefore, prevention of MTCT is a key priority in overall strategies to reduce new HIV infections and the impact of HIV/AIDS on children, parents and society as a whole.

In the past years, research has provided in-depth knowledge of the mechanisms of MTCT, as well as ways to prevent it. However, serious knowledge gaps regarding MTCT require more basic research as well as close monitoring and evaluation of MTCT field interventions.

This report provides an overview of current knowledge and experiences with MTCT prevention and their policy implications. Clear guidelines are still difficult to provide: actual decisions on MTCT prevention need to be made by mothers, with active support from public health staff, taking into account the local context and personal situation of people involved.

## **1. OVERVIEW OF THE MAIN FACTS**

Women of childbearing age constitute nearly half of the 33 million adults currently living with HIV/AIDS worldwide (UNAIDS, 2000). Mother-to-child transmission (MTCT) of HIV is the most significant source of HIV infection in children below the age of 10 years. It is responsible for about 10% of the total number of new HIV infections, with about 1600 cases of MTCT per day, or some 570,000 per year (2000), most in developing countries.

### **1.1 Mechanisms of mother-to-child transmission**

Mother-to-child transmission can take place:

1. during pregnancy (*in utero*)
2. during labour and delivery (*intrapartum*)
3. after delivery (*postpartum*), through breastfeeding

Most infected infants acquire HIV around delivery or through breastfeeding, while *in utero* infection is a less important mechanism. Without external interventions, HIV infection occurs in some 20-45% of children born to HIV-positive women. Not-breastfeeding reduces this rate to 15-25%.

#### **In utero transmission**

Transmission during pregnancy (*in utero*) is related to a number of factors such as the mother's immunological status (high plasma viral load, low CD4 count) and stage of HIV disease, type of HIV and the mother's general health and nutritional condition. In particular advanced HIV disease of the mother and the associated higher viral load is associated with an increased risk of in utero transmission, which in turn, can lead to an increased rate of disease progression in the infant.

#### **Intrapartum transmission**

HIV transmission during labour and delivery (*intrapartum*) is a major mechanism of vertical transmission, accounting for some 60-85% of MTCT. The skin and mucous membranes of a new-born child are ineffective barriers against infective organisms such as HIV. Thus, high maternal viral load, prolonged or traumatic delivery, presence of sexually transmitted diseases (especially in the presence of ulcers) or premature ruptured membranes increase the risk of HIV transmission, due to longer or more intensive exposure of the child to HIV infected secretions in the birth canal.

#### **Transmission through breastfeeding**

A third way of MTCT is through breastfeeding. The additional risk of transmission from breast milk is estimated to be about 15%; this also depends on duration of breastfeeding. The exact mechanisms of transmission are not yet fully understood. HIV is present in cells and in cell-free components of breastmilk of infected mothers. MTCT through breastfeeding may occur if the consumed virus enters the infant's intestinal mucosa through a damaged epithelial layer (e.g. due to food antigens and pathogens); through small defects in the

junctions between epithelial cells resulting from nutritional deficiencies; or with other pathogens (Van de Perre, 1999a). Other, yet undefined mechanisms are also possible.

Factors associated with an increased risk of MTCT through breastfeeding include (UNICEF et al, 1998c):

- maternal viral load, virus type and other viral characteristics;
- maternal immune status;
- breastfeeding duration;
- type of breastfeeding practised;
- presence of breast abscesses, mastitis, cracked nipples; and
- damage to the infant's mucous membranes, such as oral lesions

### ***Maternal viral load and virus type***

Recent infection of the mother, during pregnancy or the breastfeeding period, is associated with a higher viral load, which may increase the risk of HIV transmission through breast milk.

In contrast with HIV-2, which is rarely transmitted from mother to child (Adjorlolo-Johnson et al, 1994), HIV-1 is transmitted far more frequently (13-48%)(Van de Perre, 1999a).

### ***Breastfeeding duration***

In many countries, breastfeeding is most frequent during the first six months of life; after that it declines slightly. While a majority of women will breastfeed for at least one year, a considerable number continues up to two years; any deviant pattern is suspicious to the community, and may be associated with AIDS.

A study in Malawi (Miotti et al, 1999) found that risk of MTCT through breastfeeding decreases with infant age. Infants uninfected at birth were followed over 18 months: in the first five months, incidence of new HIV infections was 0.7% per month; from 6-11 months incidence was 0.6% per month, and 0.3% from 12-17 months.

However, the net effect of breastfeeding duration on HIV infection is difficult to assess due to selective attrition: women who breastfeed for a longer period are relatively healthy (lower viral load, less transmission) (Haverkamp, 2001), so the effect of duration of breastfeeding may be underestimated.

### ***Type of breastfeeding practised***

*Exclusive* breastfeeding refers to breastfeeding without supplementary feeds such as water, other liquids, or semi-solid foods. In general, exclusive breastfeeding is recommended for the first six months of life; it reduces the risks of infant mortality from diarrhoea and respiratory infections (Victora et al, 1987; 1989), and it also protects against other diseases, such as neonatal sepsis, acute otitis media and necrotising enterocolitis (Piwoz, 2000).

Two studies have suggested that *mixed* infant feeding (breastmilk plus other liquids or semi-solid foods) is associated with a higher risk of MTCT than exclusive breastfeeding (Tess, 1998). A study in Durban, South Africa (Coutsoudis et al, 1999a), showed that infants of HIV-positive mothers who were exclusively breastfed for at least three months, had a significantly lower HIV transmission risk by three months (14.6%) than those who also received other fluids or foods in early infancy ("mixed-breastfeeding"; 24.1%): a 48% reduction in transmission risk, after adjusting for confounding variables. The MTCT rate for exclusively breastfed and never breastfed infants was similar through the first six months (about 20%).

The rationale behind these differences is that mixed feeding may lead to gastrointestinal infections and inflammation in the infant. Cow's milk, allergic reactions to complementary foods and infectious illness such as oral thrush can all result in intestinal damage, increasing the gastrointestinal mucosa's vulnerability to HIV-1.

These findings suggest that exclusive breastfeeding followed by early and abrupt weaning may be one option for reducing MTCT through breastfeeding, while minimising the adverse consequences of replacement feeding, particularly in Africa. Further studies are underway to confirm this hypothesis.

### ***Breast pathology***

*Poor breastfeeding techniques*, especially poor attachment of the infant to the breast, may result in fissured nipples, increasing the risk of MTCT.

*Mastitis* is a local inflammation of the breast, which affects up to one-third of breastfeeding women, usually during the first two months after delivery. Mastitis has nutritional risk factors. Studies suggest that deficiencies of vitamin E and selenium, two antioxidants, may increase risk of mastitis (Filteau et al, 1999).

HIV infection itself does not appear to be a risk factor for mastitis, but HIV-positive women with mastitis have higher HIV plasma levels; lower CD4 cell counts; higher viral loads detected in their breastmilk; and increased rates of MTCT at 6 weeks and 12 months of age than HIV-infected women without mastitis (Semba et al, 1999a).

## **1.2 Prevention of mother-to-child transmission**

The UN recommends the following strategies to prevent MTCT of HIV (WHO/LATT, 2001):

- a. Primary prevention of HIV infection among future parents to be;
- b. Prevention of unwanted pregnancies in HIV-infected women; and
- c. Prevention of HIV transmission from HIV-infected women to their infants.

### **Primary prevention of HIV infection among future parents and prevention of unwanted pregnancies in HIV-infected women**

A comprehensive approach to MTCT prevention will not only target HIV infection in the infant, but will also address HIV prevention in mother and father. Ultimately, *primary prevention* of HIV infection in men and women of reproductive age is of course the best way to prevent transmission of HIV from mother to child. In many countries, women get infected with HIV by their husband: being faithfulness to their partner is often the highest risk factor for HIV infection.

At the same time, in 25% of the cases where a person tests positive for HIV, his/her sexual partner is still seronegative. Voluntary counselling and testing (VCT) is a major intervention for primary HIV prevention among this high percentage of serodiscordant couples.

VCT should also be an integral part of family planning services to ensure that women and men can make informed choices about their fertility: where one or both partners are HIV-infected, they should be counselled in order to be able to make informed decisions about future pregnancies. Prevention of unwanted pregnancies in HIV-positive women is an important strategy to reduce MTCT.

In all these cases, access to family planning and counselling services is crucial. Therefore, it is important to ensure youth-friendliness of these services, and promote active involvement of men.

### **Prevention of HIV transmission from HIV-infected women to their infants**

While the best ways to prevent HIV infection in infants remain primary prevention of HIV infection and reduction of unwanted pregnancies among women who are infected with HIV, many HIV-infected women become pregnant. A number of interventions can support prevention of HIV transmission from HIV-infected women to their infants. These include (Preble & Piwoz, 2001):

- a. Comprehensive antenatal services
- b. Voluntary counselling and testing
- c. Optimal obstetric practices
- d. (Short-course) antiretroviral prophylaxis
- e. Support for safe infant feeding
- f. Nutritional supplementation

#### **a. Comprehensive antenatal services**

In this context, the IATT recommends that: "HIV-infected women should have access to information, follow-up clinical care and support, including family planning services and nutritional support. Family planning services are particularly important for HIV-infected women who are not breastfeeding."

#### **b. Voluntary counselling and testing (VCT)**

A basic aspect of MTCT prevention is informing pregnant women and their partners about HIV/AIDS and the possibility of MTCT. Information and education are necessary conditions for people to be able to prevent getting infected themselves and passing it on to their children.

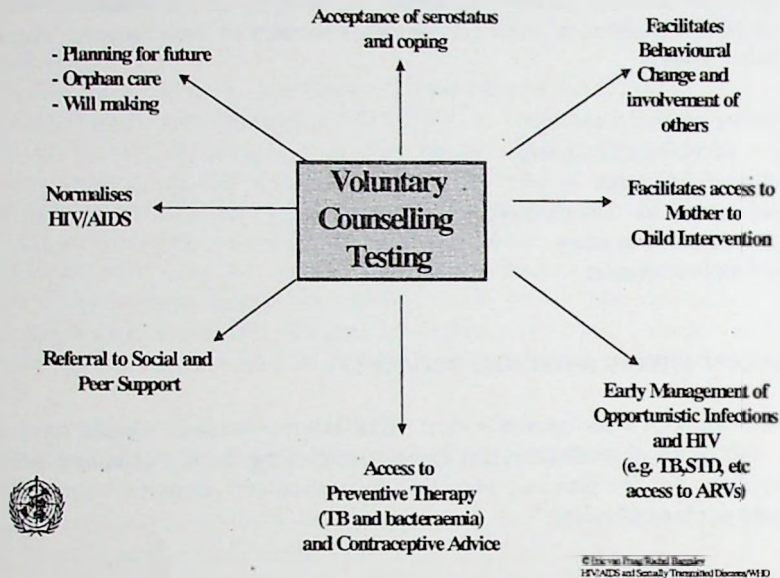
Voluntary counselling and testing (VCT) has become an integral part of HIV prevention and care programmes in many countries. Services have diversified in accordance with developments in care and treatment and the importance of VCT for HIV prevention. VCT is the entry point for medical, psychosocial, legal and sometimes material care and support for all those in need, as shown by the diagram on the next page (WHO, 1999).

#### ***Multiple benefits of VCT for pregnant women***

VCT allows early access to prevention and care for mothers who know their serostatus: knowing and accepting one's HIV status is a prerequisite to benefit from these interventions and other advantages of VCT. Currently, most women attending antenatal care in areas of high HIV seroprevalence do not know their serostatus and have no access to voluntary counselling and testing. Therefore, improving access to VCT is a key priority, especially in areas where MTCT interventions are planned.

The increasing feasibility of ARV prophylaxis for MTCT prevention in resource-poor settings has also increased the need for VCT. Where this ARV prophylaxis is being offered, adherence to the complex procedures requires detailed explanations, monitoring and follow-up. Health workers will also have to explain that the ARV intervention is not always successful. In these cases, mothers and infants will still need continuing medical care, and social and emotional support. Given the strong variance in local availability and access to MTCT prevention services, personalised counselling is crucial to help women and their partners make informed decisions on the most appropriate solutions in their personal situation.

## VCT as an entrypoint for HIV Prevention and Care



For pregnant women, VCT facilitates access to the following specific elements of care (WHO, 1999):

*In case of a negative HIV test result:*

- Prevention education to remain negative
- Standard antenatal and delivery care
- Family planning

*In case of a positive HIV test result:*

- Post-test counselling and then ongoing sessions
- Prevention education
- Counselling on continuation of the pregnancy and referral to appropriate services
- Antenatal and delivery care, taking into account HIV serostatus
- Counselling for, and access to MTCT prevention interventions
- Counselling for infant feeding support
- Family planning counselling and services
- Clinical care for HIV related illness

While MTCT prevention is the major rationale for introducing VCT services into the antenatal setting, there are other important benefits.

For *seronegative* women, VCT can play a major role in *primary prevention* of HIV infection: many men and women in high prevalence areas assume they are infected, when in fact the majority of people are not. Whatever the result of the HIV test, *safer sex counselling* is crucial: for women who acquire HIV *during* the antenatal or breastfeeding period, the risks of MTCT are particularly high as the viral load is high at the time of acute HIV infection. Therefore, VCT should also involve partners of women attending antenatal care services, especially because up to 25% of couples in which one partner is seropositive, are serodiscordant. If both partners are counselled HIV transmission can be reduced. Some

women may wish to involve other family members in the VCT process as well. "Aunties", mother or sisters may have important supportive roles which may be particularly valuable in ensuring the success of follow-up care including interventions for the prevention of MTCT. (Baggaley, 1998).

Women who are offered VCT during the antenatal period and test *seropositive* before they become symptomatic, will have an opportunity to earlier access to appropriate health care, including preventive therapies and emotional and social support. Women with symptomatic HIV disease can be referred for appropriate treatment of HIV-related illnesses, for home-based care and community-based social support (e.g., associations of people living with HIV/AIDS, post-test clubs and other HIV-positive pregnant women).

Women who test seropositive in early pregnancy can make informed decisions about continuation or termination of the pregnancy (if abortion services are available and safe). Women who choose to continue with their pregnancy, can be given better antenatal care as well as during and after delivery, including MTCT prevention interventions; in this context, VCT also allows women to make informed decisions about safe infant feeding.

*Family planning* should be discussed and provided in the postnatal period for HIV-infected women who decide to carry through their pregnancy. This is especially important if women choose *not* to breastfeed as they will lose the contraceptive effect of breastfeeding.

VCT also allows women to better plan for the future care of their children (Sangiwa et al, 1998). Women with HIV often worry about what is going to happen to their children if they become sick or die. Counsellors should be able to refer for spiritual and legal support if available.

### ***Other benefits of VCT***

Stigma, denial and rejection, are major barriers to HIV prevention. People are rarely open about their positive HIV status, and the vast majority of people have not been tested (Baggaley, 1997). If VCT were more available more people would know their HIV status. This could help decrease the stigma and fear attached to the disease and lead to a more open approach to HIV prevention and care (De Cock et al, 1998; Godfrey-Faussett et al, 1998).

VCT can also raise awareness and acceptance among health workers, which may improve HIV care in health care settings; even in high HIV prevalence areas HIV remains a stigmatised condition in many health care settings. Health care staff may be reluctant to raise the possibility of HIV as a diagnosis and are uncomfortable about talking directly to patients about HIV.

Referral to services as an entry into a continuum of care is one of the counsellors' key roles. Knowledge of related services and organisations in the local area is essential so that the client can be directed appropriately and promptly for care and support at all stages of illness.

### ***Minimum conditions for VCT services in antenatal settings***

A number of issues need to be addressed in order to create the minimum conditions for proper functioning of VCT services in antenatal settings (WHO, 1999):

*Acceptability* of VCT services requires confidentiality. Informed consent must be the basis for the woman's individual decision and there should be no coercion into HIV testing or MTCT interventions. VCT needs to be organised in such a way that stigmatisation is avoided: e.g., attendance for VCT should be indistinguishable from attendance for an antenatal check-up.

For VCT to be *accessible*, distance, availability of transport and opening hours need to be taken into account. Other aspects of accessibility include the possibility of partners, family members or a friend attending for VCT with the pregnant woman.

For services to be *affordable* to all women in need, they will almost certainly have to be provided at low cost or free of charge. In terms of affordability for the health services, cost effectiveness needs to be demonstrated. Reducing the number of children born with HIV

infection may represent a substantial saving in treatment and care costs whether this has been achieved through ARV treatment, provision of family planning services or termination of pregnancy.

High-quality VCT services also require *adequate numbers of qualified staff*, who receive regular update-training. Staff costs in developing countries rarely represent the major cost of VCT services. However, additional staff is needed, especially when MTCT prevention interventions are offered. ANC visits currently average less than four minutes in many developing countries. However, expanding VCT services as part of MTCT prevention programmes requires substantial increases in staffing, especially in high prevalence areas. Another alternative is to recruit lay or peer counsellors and volunteers to reduce pressure on health staff. Some pre-test information can also be given in groups which can cut down the time required for individual pre-test counselling.

VCT also requires *additional space* to ensure privacy: antenatal care often does not take place in privacy. However, VCT and free discussion of risk factors, sexual relationships and MTCT interventions will not be possible unless women requires certain privacy. Also, providing a space where children can play supervised by other waiting mothers or health care staff enables counselling to proceed without interruptions.

Finally regular *support and supervision* should be planned and provided to counsellors in order to minimise "burnout" and avoid losing valuable and experienced staff (Kalibala, 1995).

### **c. Optimal obstetric practices**

*Elective caesarean section* as an alternative to natural vaginal birth, can contribute to reducing transmission *during* delivery, as they reduce the chances of the child getting in contact with HIV in maternal blood or vaginal secretions, especially because caesarean sections eliminate the risk of premature rupture of the membranes.

A randomised controlled trial from 1999 shows that caesarean section performed before labour and membrane rupture reduces MTCT of HIV-1 by 50-87% in women receiving no ARV therapy or ZDV prophylaxis (EMDC, 1999; IPHV, 1999)

Maternal viral load is a critical determinant of transmission risk. The question is whether the potential benefits of caesarean sections in women whose viral load is unknown, outweigh the substantial risks involved under less-than-optimal conditions, as is often the case in developing countries (Bulterys et al, 1996). Therefore, the role of caesarean sections in MTCT prevention seems to be confined to HIV-positive women receiving no ARV treatment, with known high viral loads, in more-developed countries.

*Avoiding unnecessary invasive procedures:* Invasive procedures, which increase the possibility of mixing of maternal and foetal blood, should be avoided to reduce the chances of transmission during pregnancy and delivery.

#### ***Virucidal cleansing of the birth canal***

Washing the birth canal with *vaginal antiseptics* such as chlorhexidine seems to contribute slightly to a further reduction of MTCT.

A study from Malawi (Taha et al, 1997) showed no reduction in MTCT rates as a result of washing the birth canal around delivery and the newborn with 0.25% chlorhexidine. However, overall maternal and neonatal mortality and morbidity were significantly reduced. A study with higher concentrations of chlorhexidine is currently being carried out in Soweto, South Africa (Mofenson & McIntyre, 2000).

#### ***Prevention of placental membrane inflammation***

Placental membrane inflammation has been identified as a risk factor for MTCT (Wabwire et al, 1999), and can possibly be treated by short-course antibiotic treatment.

#### **d. (Short-course) antiretroviral prophylaxis**

##### ***Efficacy of antiretroviral prophylaxis***

Several ARV treatments (zidovudine (ZDV) alone, ZDV+lamivudine (3TC) and nevirapine (NVP)) have shown *short-term* efficacy for preventing MTCT in randomised controlled clinical trials. This reflects the reduction of *in utero*, intrapartum and early postpartum transmission.

The main mechanism is through decreasing viral replication in the mother and/or prophylaxis of the infant during and after exposure to virus. *Long-term* efficacy (infant infection status through 12-24 months) has been demonstrated for short-course ZDV and NVP regimens, showing that the early reduction in HIV transmission persists despite continued exposure to HIV during breastfeeding. Analysis of long-term efficacy of the ZDV+3TC regimens is in progress: analysis based on 18 months' data (mortality and HIV status) from the PETRA study shows that almost no effect of ARV can be found anymore due to HIV infection through breastfeeding (Haverkamp, 2001)

In the last decade, antiretroviral regimens that are applicable to resource-poor settings and breastfeeding populations have also shown to be effective.

##### ***Zidovudine PACTG 076 regimen***

Since 1994, several clinical trials have shown the potential of administering zidovudine (ZDV) to mothers and their new-born babies. The strongest reduction in MTCT (from 26% to 8%: a 68% reduction), was obtained by the PACTG 076 ZDV regimen: a long and complex three-part regimen of ZDV to the mother during pregnancy and delivery, as well as postnatally to both the mother and the new-born child. (Connor et al, 1994)

Since then, this ZDV regimen was implemented in most industrialised countries and overall perinatal transmission rates there dropped to about 5% of deliveries by HIV-positive mothers; currently, MTCT hardly takes place in industrialised settings, as most HIV-infected mothers receive potent ARV treatment.

##### ***Short-course ZDV regimens and other alternatives***

However, the complex PACTG 076 regimen was of little practical value for resource-poor settings, given its prohibitive cost, especially since this only reflects the actual costs of the *drugs* per person treated, not per HIV-infection averted. However, more appropriate *short-course* ZDV regimens – starting later in pregnancy – also proved to be effective.

A 1998 study using a *short* regimen of ZDV among *non-breastfeeding* women in Thailand, showed a reduction of MTCT by 50% (Shaffer et al, 1999). While slightly less effective, this cheaper and less complex regimen provides a more feasible option for implementation in developing countries.

Other studies in breastfeeding women in Côte d'Ivoire (Wiktor et al, 1999; Dabis et al, 1999; DITRAME, 1999) and Burkina Faso in 1999, show that the effect – though somewhat less than in non-breastfeeding women – of short-course treatment with ZDV is sustained for at least six months, with reductions of MTCT by 35-40%.

Comparison of the various regimens used in these studies, shows that adding one week of *postnatal* ZDV to an ante- and intrapartum regimen to mother or infant, shows no added reduction in MTCT. However, when *no* antepartum prophylaxis is given, addition of

postpartum to intrapartum ZDV is critical: this finding is particularly important for HIV-positive mothers who present themselves in a late stage, just before delivery.

Similarly, a combination of ZDV and lamivudine (3TC) during delivery only was ineffective (Saba et al, 1999), but combining it with post-delivery administration in the PETRA study or the two-dose nevirapine (NVP) HIVNET 012 study had a significant effect (47% reduction) (Guay et al, 1999).

In the HIVNET 012 study among breastfeeding mothers in Uganda, the two-dose intrapartum-neonatal nevirapine regimen not only proved to be almost 50% more effective than a short course of ZDV (47% vs. 25%), but the cost of treatment was also reduced dramatically to about US\$4.- (against about US\$30.- for short-course ZDV), making MTCT prevention a more viable option for resource-poor nations.

Several other regimens all show different outcomes, but the HIVNET 012 NVP-regimen offers the cheapest and simplest intervention for resource-poor settings, with significant effect in breastfeeding populations at least up to four months.

Based on the most recent research data, the latest WHO Technical Consultation (WHO/LATT, 2001) draws the following key conclusions regarding prophylactic use of ARVs for MTCT prevention:

#### ***Safety of antiretroviral prophylaxis***

All clinical trials on prophylactic ARV use have shown short-term safety and tolerance, while research on long-term safety is ongoing. The regimens have not shown severe adverse effects and did not seem to affect normal growth, neurologic development and immunologic parameters in uninfected children with *in utero* or neonatal exposure to ZDV.

Furthermore, antiretroviral prophylaxis does not seem to affect HIV-related disease progression in mothers, nor HIV-disease progression or mortality in children who became infected despite receipt of prophylaxis. The only adverse effects associated with ARV prophylaxis was mild transient anaemia in infants receiving ZDV-containing regimens, as well as mitochondrial dysfunction in a small number of infants in France exposed *in utero* or neonatally to (ZDV or ZDV+3TC) (Mofenson et al, 2000). The recent upheaval on the possible (un)safety of nevirapine for post-exposure prophylaxis (PEP) seems to have no implications for its use for short-course prophylaxis for MTCT prevention.

In conclusion, current data indicate that if negative side-effects are present, they are rare and the risk of toxic effects is clearly outweighed by the benefit of reducing MTCT.

#### ***Development of drug resistance***

There is currently no evidence that drug-resistant viruses are more transmissible than non-resistant viruses, nor that they are more virulent than non-resistant viruses. Prophylactic ARV use does not seem to be associated with an increased risk of developing drug resistance.

### **e. Support for safe infant feeding**

#### ***Risks of breastfeeding vs. replacement feeding***

The risk of HIV transmission through breastfeeding has made safe infant feeding one of the most complex and emotional aspects of MTCT prevention, because breastfeeding is one of the most important child survival and early childhood development interventions (Preble & Piwoz, 2001). Breastfeeding has many health, nutrition, birth spacing, emotional, and psychosocial benefits.

The protective effects of breast milk against common childhood diseases such as diarrhoea and pneumonia are assumed to be working in HIV-positive women as well. In addition, breast milk contains several components that may have a protective effect against HIV, such as maternal immunoglobulins and human lactoferrin. Infants could be doubly disadvantaged by being at risk through simultaneous exposure to HIV through breastfeeding and the risks of contracting other childhood diseases associated with unsafe replacement feeding, i.e. due to lack of safe drinking water (Victora, 1987, 1989).

In addition, breastfeeding is more economical and exclusive breastfeeding provides the infant's complete nutritional needs up to the age of 4-6 months and delays the return of fertility, thus playing an important role in birth spacing.

Most of these benefits of breastfeeding are greatest in the first six months. Exclusive breastfeeding during the first 4-6 months carries greater benefits than mixed feeding with respect to morbidity and mortality from infectious diseases other than HIV. Although breastfeeding no longer provides all nutritional requirements after six months, breastfeeding continues to offer protection against serious infections and to provide significant nutrition to the infant (half or more of nutritional requirements in the second six months of life, and up to one third in the second year) (WHO/IATT, 2001).

On the other hand, breastfeeding is associated with a significant additional risk of HIV transmission from mother to child as compared to non-breastfeeding. This risk appears to be greatest during the first months of infant life but persists as long as breastfeeding continues. Half of the breastfeeding-related infections may occur *after* six months with continued breastfeeding into the second year of life.

Up to 20% of infants born to HIV-infected mothers may acquire HIV through breastfeeding, depending on duration and other risk factors. Therefore, messages promoting universal, exclusive breastfeeding for the first 4-6 months of life have become more complex.

While HIV-positive women in industrialised countries are generally advised to give exclusive formula-feeding, its high cost makes this an unfeasible option for most developing nations.

### ***Breastfeeding versus formula feeding***

Replacement feeding carries an increased risk of morbidity and mortality associated with malnutrition and infectious disease other than HIV (Victora, 1987, 1989), especially in the first six months. The risk and feasibility of replacement feeding are affected by the local environment and the individual woman's situation.

A recent clinical study in Nairobi, Kenya, comparing infant formula with breastfeeding, showed that formula-feeding by cup reduced postnatal MTCT rates by 44%. 75% of MTCT through breastfeeding occurred during the first six months of life, though transmission continued throughout the duration of breastfeeding (Nduati et al, 2000). Mortality was quite high in both groups (24% in breastfed and 20% in formula-fed infants), despite the fact that women were enrolled in an urban setting with running water in their homes and access to free formula. Although participating women had on average 8 years of education, compliance with formula was only 70%. However, given these rather untypical enrolment criteria, it is difficult to apply these results to the common situation in developing countries where clean water and free formula are not available (Lhotska, 2001).

### ***Changing infant feeding practices***

Understanding attitudes and practices related to breastfeeding and perceptions and stigma associated with not breastfeeding is critical for the development of appropriate interventions to reduce MTCT through breastfeeding.

### ***Stigma attached to changes in infant feeding practices***

In many African cultures women who do not breastfeed are often considered 'bad mothers'. The emergence of HIV in Africa has enhanced this stigma, as described recently in studies in Botswana; Côte d'Ivoire; Zambia; and Zimbabwe. This stigma may increase as efforts to test and counsel women about HIV and infant feeding (e.g., encouraging HIV-infected mothers to breastfeed exclusively and practice early and abrupt weaning) are put in place (Preble & Piwoz, 2001).

In order to destigmatise changes in infant feeding practices among HIV-infected mothers, the family and community need to be educated as well, since infant feeding decisions are rarely made by the mother alone. In addition, health workers need training to better the views of women and their families.

### ***Guidelines for replacement feeding***

In 1998, the UN published guidelines for HIV and infant feeding that outline various feeding options for HIV-infected women including commercial infant formula, home-prepared infant formula, expressed and heat-treated breast milk, and early cessation of breastfeeding (UNICEF/UNAIDS/WHO, 1998).

These guidelines clearly state that all women should have access to information about MTCT. While guidance on optimal breastfeeding should be given to all mothers, information on specific replacement feeding options should be provided only for women who know they are HIV-infected and can decide which option works best for them and their families. This targeting of replacement feeding advice is needed to ensure confidentiality and to minimise the erosion of optimal breastfeeding practices in the general population. (Preble & Piwoz, 2001).

When governments provide *breastmilk substitutes* (BMS) for free or at subsidised prices, they should ensure sufficient quantities (at least six months) to individual infants; this should be done in a sustainable way, avoiding dependency on donors. BMS should not be promoted to the general public or through the health care system (UNICEF, UNAIDS, and WHO, 1998).

### ***Cessation of breastfeeding -- avoiding mixed feeding***

As noted above, *mixed feeding* during the transition period between exclusive breastfeeding and complete cessation of breastfeeding may increase the risk of MTCT. Therefore, the period of transition should be kept as short as possible to reduce the risk of MTCT. This in turn, however, may have negative nutritional consequences for the infant, psychological consequences for the infant and the mother, and expose the mother to the risk of breast pathology, which may then increase the risk of HIV transmission (unless cessation of breastfeeding is abrupt. Currently, the best duration for this transition is unknown and may vary according to the age of the infant and/or the environment (WHO/IATT, 2001).

As most transmission occurs during the first months of breastfeeding, early weaning alone would be ineffective to prevent MTCT. At the same time, complete avoidance of breastfeeding is unfeasible in many resource-poor settings. On the other hand, if it is confirmed that *truly* exclusive breastfeeding (which is uncommon in most countries) lowers the risk of MTCT, it would mean women could offer their infants the advantages of breastmilk while limiting the risk of MTCT after delivery.

More research is needed to confirm the findings from these two studies. In addition, ARV treatment of mother, infant or both during breastfeeding, combined with early cessation, is a potentially effective intervention.

### ***Infant feeding counselling***

Infant feeding counselling, long recognised as important for all mothers, has become even more important with the emergence of HIV. In Africa, although nearly all women breastfeed and the duration of breastfeeding is often greater than 24 months, breastfeeding patterns are rarely optimal. For example, only 31 percent of children in sub-Saharan Africa get the benefits of exclusive breastfeeding. Also, the introduction of water and watery gruels, which occurs early, often in the first month of life, endangers infants (Preble & Piwoz, 2001).

Overall knowledge about safer infant feeding options to prevent MTCT is quite low. While general information on safer infant feeding is often not enough for women to make a choice, infant feeding counselling can provide the guidance women need to make the choice that is most feasible, acceptable and appropriate for their situation. It may help women to choose and practise safer infant feeding options that may be uncommon in their environment, such as exclusive breastfeeding or complete avoidance of breastfeeding. In addition, it may reduce breast health problems that increase the risk of MTCT. However, there are relatively few trained people in this field (WHO/LATT, 2001).

### **Breast health**

There is some evidence that breast conditions including mastitis, breast abscess, and nipple fissure may increase the risk of HIV transmission through breastfeeding, but the extent of this association is not well quantified.

*Treatment of mastitis* at low cost with antibiotics may reduce MTCT through breastfeeding. It is not known whether micronutrient supplementation (vitamin E, selenium, vitamin A or beta-carotene) reduces mastitis-related HIV transmission.

Multiple *micronutrient supplements*, however, appear to have many beneficial impacts for infants from HIV-infected women and may improve the immune status of postnatal HIV-infected women. Trials among uninfected women are being carried out in several countries to assess the benefits of multivitamin supplementation in the general population of pregnant women in developing countries (UNICEF, 1999).

## **f. Nutritional supplementation**

*Vitamin A* may play a protective role in various routes of vertical transmission. Vitamin A deficiency impairs the functioning of the immune system, which may result in an increased maternal viral load; alternatively, vitamin A deficiency could also be a sign of advanced HIV disease in the mother.

Vitamin A deficiency may also lead to impaired integrity of the inner surfaces of vagina and cervix as well as increased vaginal shedding of HIV, both associated with a higher risk of MTCT during delivery. Furthermore, vitamin A deficiency in HIV-positive women may be associated with fissured nipples, which may facilitate HIV transmission through breastfeeding.

Adding vitamin A to the diets of HIV-positive mothers seems to be a promising option for reducing the risk of HIV transmission through breast milk.

The impact of vitamin A or multivitamin supplementation was assessed in three trials in Africa (Coutsoudis, 1999b; Semba et al, 1994; Fawzi, 1998), but results did not show reduced MTCT. However, all studies showed significant decreases in adverse pregnancy outcomes, and continued multivitamin supplements to the mother after delivery was associated with higher CD4 counts in one study (Fawzi et al, 1998).

A study in Malawi in 1994 showed a positive association between vitamin A deficiency in mothers and HIV transmission through breast milk (Semba et al, 1994), and subsequent infant (Semba et al, 1995) and maternal mortality (Semba, 1997).

A study in Kenya also found that low serum retinol levels were associated with HIV levels in breastmilk and in vaginal secretions, suggesting that vitamin A status could affect MTCT during delivery and through breastfeeding (Nduati et al, 1995).

A study in Zimbabwe is providing high-dose vitamin A supplements to mothers and/or babies within 96 hours of delivery. Mothers and babies are followed prospectively to assess infant mortality, MTCT during breastfeeding and incident HIV infection among the postpartum women. 14,000 mother-baby pairs have recently been enrolled, which will be followed for two years (Humphrey et al, 2000).

In conclusion, from a strictly medical point of view, the best way to prevent MTCT in HIV-positive pregnant women is the three-stage regimen of ZDV, combined with elective caesarean section and safe replacement feeding. However, in practice, only industrialised countries can afford and safely implement this intervention. In situations where the necessary health care environment may not always support the intervention, such as in most developing countries, individuals, communities and policy makers are faced with difficult dilemmas in making the best possible choice out of medically less effective interventions.

## **2. EXPERIENCES WITH IMPLEMENTATION OF MTCT PREVENTION**

### **2.1 UNICEF pilot projects**

The earlier mentioned "Thai" 1998 study, which showed that short-course ZDV starting from 36 weeks of pregnancy reduced the MTCT rate by 50%, led to the development of a comprehensive strategy for MTCT prevention. Under the umbrella of the UN Inter-Agency Task Team (IATT) on MTCT, UNICEF initiated pilot projects on MTCT prevention in 17 (resource-limited) countries, which have so far yielded a lot of experience with implementation outside strict trial conditions, particularly showing problems regarding safe infant feeding recommendations.

The pilot projects comprise the following elements:

- Voluntary counselling and testing (VCT);
- ZDV from 36 weeks and during labour to mothers who are HIV-infected;
- Counselling on infant feeding options.

Since the first pilot projects started, more recent clinical trials have shown that other short-course ARV regimens using ZDV, the combination ZDV+3TC, and nevirapine (NVP) are also effective in reducing the risk of transmission. NVP is now being used alongside ZDV in a number of pilot studies (Haverkamp, 2001).

### **2.2 Critical remarks**

While UNICEF's current pilot studies provide valuable information on the actual implementation of MTCT prevention beyond strictly controlled research settings, they still take place under very special circumstances, limiting extrapolation of the results to the wider context of actual field conditions. The overall impact of MTCT prevention programmes will always be much lower than what is found in the current studies and pilot projects, because they take place under artificially improved conditions (Haverkamp, 2001).

In the current pilot studies, it has proven extremely difficult to motivate already overburdened staff for additional tasks and further increase their workload without extra financial remuneration. Furthermore, the UNICEF protocol is only feasible in big reference hospitals that receive extra support, especially for counselling: the biggest problem is lack of trained people.

Counselling practice in the UNICEF pilot studies is far from ideal: in relatively well-functioning hospitals pre-test counselling takes place in groups. After delivery there is usually no follow-up, as most women come for delivery only, unless their infant has a specific health problem: this is a major source of bias. Only those women who come back for vaccinations (20-40%) are examined for general health status, while their infants are tested for HIV. These HIV tests are usually only done after 15-18 months, which makes it difficult to assess the most likely cause of any HIV infection. During the postnatal care visits, there is a lot of attention for safe infant feeding options (Haverkamp, 2001).

The problem with the pilot studies is that while UNICEF supports hospitals with training, HIV testing and antiretroviral prophylaxis, the hospitals are supposed to bear the brunt of the extra work, while no additional human resource capacity is created.

As for HIV testing, the currently used rapid tests are very easy to implement and require far less laboratory capacity than previous tests. While they are ideal for project implementation (faster test results), psychologically they are a lot more difficult for the women who get tested, because there is no time period allowing women to 'escape' the test results. With the new rapid tests, women go to a clinic, get tested, and may shortly thereafter leave with what they consider a death sentence: a positive test result (Haverkamp, 2001).

While the main goal of these pilot studies is not to collect data on efficacy of MTCT programmes, but to assess practical problems arising during their implementation, it is obvious that comprehensive MTCT prevention programmes require substantial external support and resources in terms of voluntary counselling and testing, antiretroviral medications, replacement feeding and safe infant feeding counselling.

It is clear that future MTCT prevention interventions should not stand in isolation, but be integrated into existing health-care infrastructures and reproductive health services.

### *Experiences in East and Southern Africa*

From 9-10 October 2000, UNICEF ESARO (East and Southern Africa Regional Office) held a meeting on HIV and infant feeding in Nairobi, Kenya, to review experiences of MTCT prevention projects and research studies, and develop specific recommendations.

By then, several countries had developed guidelines on HIV and infant feeding based on the 1998 UN guidelines. In some countries, training of health workers and actual counselling of HIV-positive mothers on the risks of MTCT through breastfeeding and alternative infant feeding options had also started.

Besides the MTCT pilot studies, several research projects are looking at different aspects of MTCT prevention in the region. Many of these research projects have gained more experience with counselling HIV-positive mothers on infant feeding than the actual pilot projects. (Wagt A de, 2000).

Experiences in various countries in East and Southern Africa have shown discrepancies between HIV and infant feeding policies and national nutrition policies. Implementation of policies may be poor in the absence of clear guidelines.

While official policy may discourage breastfeeding in HIV-infected women, e.g. in Uganda and Tanzania, limitations for safe alternatives have led to the promotion of exclusive breastfeeding for three months, followed by abrupt cessation and replacement feeding. In many countries, however, breastfeeding may be common, but *exclusive* breastfeeding is not, and provision of free formula may actually encourage *mixed* feeding. Furthermore, it will often be difficult for governments to continue to provide free formula when MTCT prevention programmes go to scale.

In addition, women often face practical, financial and cultural barriers to early cessation of breastfeeding: expressing breast milk is hardly an option (stigma), while there are often cultural barriers against boiling breastmilk (mother then believed to be bewitched) and wet nursing. On the other hand, many mothers do not believe that exclusive breastfeeding can reduce MTCT as this contradicts their knowledge that breastfeeding can transmit the virus. There is also a lack of knowledge about how to minimise the potentially adverse effects of abrupt cessation of breastfeeding. Suggestions for early breastfeeding cessation and the transition to exclusive replacement feeding include:

- Reducing the frequency of breastfeeding;
- Accustoming the infant to cup-feeding with expressed breastmilk;
- Encourage the use of a finger sucking or other means of comforting in-between feeds;
- Providing the infant with skin-to-skin contact and massage, holding and talking to the baby for stimulation to ease child and maternal depression; and

- Preventing/treating breast engorgement and mastitis.

Certain issues still need clarification: e.g., nothing is known about how much reduction in HIV-transmission can be reached by early cessation of breastfeeding and how this compares to the risk of malnutrition and mortality. Key priorities to scale up MTCT prevention programmes include the coordination of national policies and guidelines, strengthening of counselling capacity, more clarity on safe infant feeding and reduction of stigma through more active community involvement (Wagt A de, 2000).

### **3. CURRENT IATT GUIDELINES FOR MTCT PREVENTION**

On behalf of the Inter-Agency Task Team on MTCT, WHO's Department of Reproductive Health and Research, in collaboration with the HIV/STI Initiative and the Department of Child and Adolescent Health, convened a Technical Consultation on new data on the prevention of MTCT and their policy implications, which took place from 11-13 October 2000 in Geneva.

The objective was to review recent scientific data and update current recommendations on the provision of ARVs and infant feeding counselling.

The Technical Consultation focused on these two components, although it was recognised that many other components are important for a comprehensive package for MTCT prevention.

Conclusions and recommendations from this forum were approved on 15 January 2001 and can be considered the best guidelines given the current state of knowledge on MTCT and experience with pilot studies.

#### **3.1 Short-course antiretroviral prophylaxis**

Given the currently available research data on short- and long-term efficacy, safety and potential development of drug resistance, the WHO Technical Consultation (WHO, 2001) concludes that benefit of prophylactic ARV use for reducing MTCT greatly outweighs any potential adverse effects.

Therefore, they conclude that any of the prophylactic ARV regimens proven effective (ZDV, ZDV+3TC, or NVP) can be recommended for general implementation. There is currently no justification to restrict use of any of these regimens to pilot project or research settings.

The key recommendation regarding prophylactic ARV use for reducing MTCT is that MTCT prevention should be part of the minimum standard package of care for women who are known to be HIV infected and their infants. The local choice for the ARV prophylactic regimen to include in the standard package of care should be determined by issues of feasibility, efficacy and cost.

Considerations regarding the composition of the standard prophylactic package include: proportion of women attending antenatal care; time of initiation of antenatal care; frequency of antenatal visits; type of HIV voluntary counselling and testing available; logistics and acceptability antiretroviral prophylaxis administration; and cost of drugs.

#### **3.2 Support for safe infant feeding**

##### ***Risks of breastfeeding and replacement feeding***

Given the relative benefits and risks of exclusive breastfeeding, mixed feeding and replacement feeding with regard to likelihood of HIV infection, and morbidity and mortality due to other infectious diseases (described above), the IATT makes the following general recommendations, based on current – limited – knowledge:

- When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended. Otherwise, exclusive breastfeeding is recommended during the first months of life.

- To minimise HIV transmission risk, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition).
- When HIV-infected mothers choose not to breastfeed from birth or stop breastfeeding later, they should be provided with specific guidance and support for at least the first two years of the child's life to ensure adequate replacement feeding. Programmes should strive to improve conditions that will make replacement feeding safer for HIV-infected mothers and families.

### ***Cessation of breastfeeding***

The best duration for the transition from exclusive breastfeeding to complete cessation of breastfeeding, is not known and may vary according to the age of the infant and/or the environment.

There are potential harmful effects of mixed feeding during this transition period, but on the other hand shortening it may have negative nutritional, psychological and medical consequences for the infant and mother (see above).

Therefore, WHO/IATT recommends that HIV-infected mothers who breastfeed should be provided with specific guidance and support when they cease breastfeeding to avoid harmful nutritional and psychological consequences and to maintain breast health.

### ***Infant feeding counselling***

Given the complex choices HIV-positive women face regarding safe infant feeding options, counselling plays a crucial guidance role.

The IATT therefore recommends that the general public, affected communities and families should be informed and educated on MTCT. Local assessments are needed to identify the range of feeding options that are acceptable, feasible, affordable, sustainable and safe in a particular context.

Most importantly, all HIV-infected mothers should receive infant feeding counselling; this should include general information about risks and benefits of the different options, and specific guidance in selecting the most appropriate option for their situation. Whatever they decide, they should be supported in their choice.

Given the shortage of skilled staff, adequate numbers of people should be trained as infant feeding counsellors, deployed, supervised and supported. This includes updated training on new information and recommendations.

### ***Breast health***

Given the fact that breast conditions such as mastitis, breast abscess, and nipple fissure may increase the risk of HIV transmission through breastfeeding, the IATT recommends that:

"HIV-infected women who breastfeed should be assisted to ensure that they use a good breastfeeding technique to prevent these conditions; if they occur nevertheless, they should be treated promptly."

### ***Maternal health***

In one trial, the risk of dying in the first two years after delivery was greater among HIV-infected women who were breastfeeding than among those who were formula feeding. In addition, women who do not breastfeed or stop breastfeeding early are at greater risk of becoming pregnant.

In this context, the IATT recommends that: "HIV-infected women should have access to information, follow-up clinical care and support, including family planning services and nutritional support. Family planning services are particularly important for HIV-infected women who are not breastfeeding."

## 4. DISCUSSION AND POLICY IMPLICATIONS

### 4.1 Preventing mother-to-child transmission of HIV: knowledge and gaps

Much is known about the main mechanisms of MTCT of HIV, and about potentially effective ways to prevent HIV transmission from mothers to their children. While primary prevention of HIV infection of the mother (and father), as well as prevention of unwanted pregnancies of HIV-positive mothers are ultimately the best options, the generally low percentage of women aware of their HIV status and overall high fertility rates in non-industrialised countries still result in many pregnancies among HIV-positive women.

This high amount of pregnancies among HIV-infected women has led to an ever-increasing body of knowledge on how to prevent HIV transmission to the infant, either *in utero*, *intrapartum* or *postpartum*. In addition to this technical knowledge, MTCT prevention pilot studies and other studies in several countries have also yielded an increasing experience with MTCT prevention. However, the conditions in which the ongoing UNICEF pilot projects are taking place are often artificially improved and cannot automatically be extrapolated to the generally worse conditions of ordinary health facilities, particularly in African countries. The question therefore remains how MTCT prevention programmes will behave under *actual* field conditions.

Yet, crucial information is missing to be able to provide practical guidance to HIV-positive mothers, health staff and policymakers as to the best ways to prevent MTCT.

#### *Specific research priorities*

In the area of **basic clinical research** we need to know more about the type, duration, efficacy and safety of ARV prophylactic regimens and possible development of resistance. Similarly, we need to know more about the risks and benefits of different patterns of infant feeding, in particular about the influence of exclusive breastfeeding, exclusive formula feeding, mixed feeding and duration/timing of breastfeeding cessation on MTCT, overall infant morbidity and mortality and birth spacing.

Regarding MTCT reduction during breastfeeding, more research is needed on the efficacy of ARV treatment of mother and/or infant for the prevention of MTCT through breastfeeding; and the best ways to minimise MTCT, nutritional and psychological risks for infant and mother during the transition period between exclusive and no breastfeeding.

In the area of **programme implementation**, more research is needed on the barriers to voluntary counselling and testing in pregnant women in different settings. A crucial area of research is related to the effect of infant feeding recommendations on breastfeeding behaviour of HIV-infected women, as well as that of HIV-negative women ("spill-over" effect), and the overall impact on HIV transmission and infant mortality rates.

The important role of social stigma necessitates research on ways to enhance involvement of partners, families and communities in supporting alternative infant feeding options.

While many other specific research priorities can be mentioned, these are the main areas, which indicate that much basic knowledge is still lacking to be able to provide clear guidelines on the prevention of MTCT.

## 4.2 Towards implementation of prevention programmes: Guidelines and guiding principles

The current *guidelines* on MTCT prevention prepared by the IATT –while reflecting the best current knowledge— are still insufficient and lack clear, practical guidance for HIV-positive women and health workers. In the end, women are left with the responsibility of making difficult decisions related to VCT, antiretroviral prophylaxis and especially infant feeding options, based on inconclusive knowledge.

The problem is that the advice that is currently being given on the preferred ways to prevent MTCT, may turn out to be equivocal after more research has been done in the areas mentioned above: the damage may then be difficult to repair. This applies particularly to the area of breastfeeding.

While it may be difficult to provide clear, practical guidelines, the general *guiding principles* that need to guide current MTCT prevention programmes *can* be distinguished:

### *a) Human rights-based approaches*

The first guiding principle for MTCT prevention should be the protection of human rights of mother and child, including the mother's sexual and reproductive rights.

MTCT prevention should not be driven only by the public health concern to reduce HIV incidence among infants, but should depart from a genuine concern to protect and promote the woman's and child's health, autonomy and human rights. A first prerequisite is respecting the principle of informed choice: efforts to prevent MTCT should start with guaranteeing access to sexual and reproductive education and other services for all women and girls, men and boys. This is a precondition to avoid HIV infection in the first place. In the more specific context of preventing HIV transmission from the already infected mother to her child, the starting point should be access to voluntary counselling on issues related to HIV testing and the various ways to prevent MTCT, especially regarding safe infant feeding options. Women should not only be given full information and personal advice, but also be supported in their choice.

### *b) Focus on overall infant survival*

Reduction of MTCT rates in itself should not be the golden standard for success of interventions: in the end, the wider impact on child survival and maternal health and rights needs to be the main criterion for success. This is a particularly important issue given the risks and benefits of (exclusive) breastfeeding vs. replacement feeding.

### *c) Comprehensive instead of vertical approaches*

MTCT prevention cannot be achieved by a "magic bullet" of antiretroviral prophylaxis alone. Many issues need to be taken into account for successful MTCT prevention. Integration of HIV/AIDS (and MTCT) into nutritional and reproductive health policies and services (e.g., family planning and antenatal services and optimal obstetric practices, postnatal care and support), voluntary counselling and testing, support for safe infant feeding *and* antiretrovirals are elements of a truly comprehensive approach to MTCT prevention.

Most of all, however, MTCT prevention programmes should be sensitive to local notions of what is socially, culturally and financially acceptable and sustainable.

Moreover, MTCT prevention should be seen as part of a wider response to HIV/AIDS, which includes expanding access to care and support for HIV-infected mothers and their families, including treatment of opportunistic infections and accelerating access to HIV treatment.

### *d) Strengthen primary prevention*

A comprehensive, non-vertical approach to MTCT prevention should avoid an exclusive focus on preventing HIV transmission from the infected woman to her child. While much of the current knowledge and research focuses on this area, the ultimate goal is to prevent women and men from becoming HIV-infected in the first place. If comprehensive approaches to HIV/AIDS are not in place, isolated, vertical interventions to prevent HIV transmission from infected women to their children will always remain an admission of weakness.

***e) The right to access to the fruits of scientific research***

While basic and clinical science provide a growing insight into the (theoretical) possibilities of preventing MTCT, monitoring and evaluation of MTCT prevention pilot projects show the actual potential and limitations of applying scientific progress to "field" conditions.

However, while the practical limitations of implementing MTCT prevention should be taken into account, they should never be used as an excuse to deny resource-constrained countries and groups access to the fruits of scientific progress. Where resource constraints limit MTCT prevention, they should be used to trigger action for social and political change rather than complacency.

***f) Involving partners and communities***

MTCT prevention activities are usually health facility-based and mostly target pregnant women alone: the burden of MTCT prevention and the associated risks of stigmatisation and social rejection seems to be placed exclusively on women. However, men are vital partners in MTCT prevention and their exclusion is a major cause of poor rates of uptake of MTCT prevention services (Wagt A de, 2000). Since decisions on pregnancy, delivery and wider reproductive health issues are seldom taken by women alone, more attention should be given to involving men, families and communities in MTCT prevention and reproductive health issues in general. Issues of HIV prevention and care should become a shared family and community responsibility.

## **4.3 Key programme components**

### **4.3.1 Counselling services for HIV testing (VCT) and safe infant feeding**

VCT and infant feeding counselling are a *conditio sine qua non* for effective interventions. It is clear that voluntary counselling and testing (VCT) is a key component of any MTCT prevention programme. VCT not only allows women (and men) to know their HIV status, which is a prerequisite for them to make subsequent decisions on MTCT prevention and other issues; VCT is also crucial for MTCT-related decision-making, including continuation or termination of pregnancy, safer sex (during pregnancy) and ARV prophylaxis, safe infant feeding and family planning, while it also allows for access to a wide variety of preventive and care services for the mother, including antenatal care, safe delivery and postnatal care, care and treatment for opportunistic infections and community-based support groups.

***Counselling on MTCT prevention***

Current ARV prophylactic regimens seem to be both effective and safe, and are increasingly becoming affordable options for resource-poor settings. However, availability and access to ARV prophylactic regimens may differ considerably from one place to the other.

In addition, *safe infant feeding* options are crucial to avoid postnatal HIV infection through breastfeeding. This requires difficult decisions on (exclusive) breastfeeding and other infant feeding options to be made, often based on inconclusive or contradictory information.

Counselling is therefore crucial for pregnant women (and their partners and families) to make informed decisions on the MTCT prevention interventions most appropriate to their personal situation. Experience shows that adequate counselling services can indeed help women and men make the best decisions in support of MTCT prevention and other HIV-related issues.

However, counselling is not a cheap service, and the need to scale up MTCT prevention programmes requires urgent attention for improving the basic requirements of high-quality counselling, including:

- more and better testing facilities
- adequate numbers of counselling staff
- training and support (to avoid burnout) for counsellors
- adequate facilities for counselling (privacy).

In this context, links between the MTCT prevention and infant feeding teams should be strengthened, and directly involve people trained in breastfeeding counselling.

Experience with MTCT pilot projects and other studies are increasingly showing that lack of access to counselling services is a critical limitation to scaling up MTCT prevention programmes. Therefore, the basic requirements mentioned need to be addressed urgently.

### 4.3.2 Antiretroviral prophylaxis

The advent of relatively effective antiretroviral prophylactic treatment for prevention of MTCT has opened new opportunities, as well as new challenges.

PACTG 076, a complex regimen involving ZDV, not only proved to be the most effective, but also the most difficult regimen to implement in resource-poor settings, given its high cost and complexity of administration.

However, *short-course* antiretroviral prophylaxis has shown to be relatively effective as well, which has made MTCT prevention a lot more feasible, as the regimens are easier to implement and far cheaper. At present, NVP seems to be the cheapest and most cost-effective intervention. Thus, these short-course regimens have substantially increased access to the fruits of these scientific developments.

However – as has been made clear – MTCT prevention involves far more than ARV prophylaxis and a couple of issues still need urgent attention in this field.

#### ***ARV prophylaxis: one element in a comprehensive MTCT prevention package***

The experiences with UNICEF's MTCT prevention pilot studies in a number of non-industrialised countries have brought to light several issues that require attention. E.g., the lack of access to reproductive health services and voluntary counselling and testing, as well as problems in the field of safe infant feeding and other areas need urgent attention before MTCT prevention programmes can be scaled up. Otherwise, there is a risk that these programmes are reduced to interventions to make antiretroviral prophylaxis available.

Careful monitoring and evaluation of these pilot studies is necessary to identify the critical factors for success or failure. One lesson learned from these pilot studies and other studies is their limited applicability to more "standard" conditions in developing countries, as they often take place under beefed-up conditions. These conditions are seldom achieved once the programme is expanded to a wider population and the actual effectiveness is likely to be less.

#### ***Long-term efficacy and safety***

Furthermore, issues of sustainability and feasibility remain important in the context of ARV prophylaxis. While short-term efficacy and safety do not seem to present serious problems,

too little is known about the long-term safety and efficacy of antiretroviral prophylaxis. This is especially relevant in the context of resource-constrained countries, where other components of a comprehensive approach to MTCT prevention – such as safe infant feeding and lack of access to counselling – may indeed threaten not only the initial reduction of MTCT rates due to ARV treatment, but also the overall impact on infant mortality. In addition, the use of new drugs or combinations thereof for MTCT prevention needs to be evaluated.

### ***Long-term support to mother and infant***

Increased opportunities to prevent MTCT and higher HIV-free infant survival rates, also present serious ethical questions in relation to maternal health and rights issues, as well as future support for an increasing group of vulnerable children, many of whom will not only lose one or both parents to AIDS, but will also have far less opportunities in life due to constrained resources, lack of access to education, proper nutrition et cetera.

The relative success of saving infants from becoming HIV-infected, also raises the ethical question of care and support for the mother's health and right to access to care and support. This includes access to highly active antiretroviral treatment, which is increasingly becoming available in some resource-constrained countries. It also raises questions about access to treatment of opportunistic infections, as well as psychosocial and other forms of support to mothers parents and others involved in the care of children infected or affected by HIV/AIDS.

### ***Improving efficacy and cost-effectiveness of short-course ARV prophylaxis***

A number of key issues can be distinguished regarding the actual use of ARV medications for MTCT prevention. First of all, given the strong relation between MTCT and maternal viral load (without intervention, MTCT will only occur in the approx. 30% of HIV-infected women with high viral load), we need to find ways of *better distinguishing and selecting* this 30% high-risk group, in order to be able to better target MTCT prevention interventions. Better targeting will allow programmes to become more effective and more cost-effective, as limited resources will be used more efficiently.

One way to do this would be to determine maternal viral load immediately prior to delivery. This would not only require far more HIV testing, but also a substantial expansion of access to voluntary counselling services. After assessment of maternal viral load, two distinct interventions could be offered: the 30% high-risk (high viral load) group could be offered antiretroviral prophylaxis, while more efforts and resources would be available to guarantee safe replacement feeding, in order to minimise the risk of MTCT through breastfeeding in this group. The underlying assumption would be to avoid breastfeeding as much as possible, given the fact that 30% of HIV-infected mothers will have high viral loads. The relatively low-risk group (low viral load) would not require ARV prophylaxis and should be advised to exclusively breastfeed, without serious risks of MTCT through breastmilk (Haverkamp, 2001).

In essence, this approach would make replacement feeding safer for the high-risk group, while breastfeeding would be made safer for the low-risk group. It is obvious that feasibility, safety, efficacy and cost-effectiveness of this two-group approach would need to be assessed first, before it could possibly be implemented full-scale.

Another idea that needs further study focuses on making exclusive breastfeeding safer. As the results of studies on the impact of breastfeeding indicate a direct relationship between MTCT and duration and pattern of breastfeeding (among other factors), the possibility of also providing antiretrovirals to infant and/or mother *during* the period of (exclusive) breastfeeding (the first 3-6 months at least) seems to be an interesting idea, especially given the price reductions for various ARV drugs (Wagt A de, 2001).

This is a particularly interesting option as “acceptable, feasible, affordable, sustainable and safe” replacement feeding is not always a viable option in developing countries.

A study is currently going on in which mothers receive ARV prophylactics for 4 weeks *antepartum* (ZDV or ddI); after delivery, infants receive a daily dose of NVP or 3TC for a period of 6 weeks–3 months (alternatively, mothers could be treated after delivery). While final results are still pending, at current drug prices, the daily doses make this regimen too expensive for resource-poor countries (Haverkamp, 2001).

### 4.3.3 Safe infant feeding

The bottom line in safe infant feeding is not to focus on reduced HIV transmission alone, but on overall child survival. Breastfeeding has important benefits for overall reduction of infant morbidity and mortality. The risk of MTCT through breastfeeding among HIV-infected mothers is approximately 20%. Even in countries with an HIV prevalence rate of 30% among antenatal women, the MTCT risk would only be some 6% of all breastfeeding mothers.

At the same time, the so-called “spill-over” effect to HIV-negative women – which may occur as a by-result of advising HIV-positive women not to breastfeed – may result in increased child morbidity and mortality due to diarrhoeal diseases and respiratory infections. Therefore, breastfeeding needs to be protected for the >90% majority of infants who can benefit from it, while HIV-positive mothers should be supported in making informed choices on alternative infant feeding options and assisted in carrying them out.

### Finding safer infant feeding options for HIV-infected mothers

In essence, two questions need to be answered:

- 1) How can we make breastfeeding safer?
- 2) How can we make replacement feeding safer?

To answer these two questions, it is critical to know *when exactly* during the breastfeeding period most HIV transmission takes place. This knowledge can be used to decide on optimum timing of cessation of breastfeeding and shifting to other forms of safe infant feeding.

Therefore, the issue is not exclusive breastfeeding *or* formula-feeding, but to find the best *overall* safe infant feeding strategy, in accordance with local and personal conditions. This will often include a period of exclusive breastfeeding during the first 6-12 months (to benefit from breastmilk’s multiple benefits), followed by safe replacement feeding (to avoid unnecessary risk of MTCT through breastfeeding, when the child is less dependent on breastmilk). Furthermore, replacement feeding does not necessarily mean formula, but also includes alternative, home-based feeding options, often based on existing local practices.

## Making breastfeeding safer

Given the risks of formula-feeding, only HIV-positive women who can *safely* use formula and *afford* it, should be advised *not* to breastfeed: in many developing countries this is a small minority.

So far, one study in South Africa has suggested that *exclusive* breastfeeding is safer than mixed feeding (Coutsoudis, 1999). The outcome of this and ongoing studies is critical for the advice women will be given regarding breastfeeding. If it is confirmed that exclusive breastfeeding indeed reduces HIV transmission, compared to mixed feeding, it will be a major thrust to protect and support *exclusive* breastfeeding. Promotion of exclusive breastfeeding entails good management of lactation, which encourages proper attachment of the infant to the nipple and frequent emptying of the breasts, both of which are important for preventing cracked nipples, engorgement and mastitis, which have been suggested to be risk factors for transmission of HIV.

However, cultural practices and practical problems will make it difficult to achieve truly exclusive breastfeeding. In addition, experiences in Ndola, Zambia, have shown that many mothers do not believe that exclusive breastfeeding can reduce the transmission of HIV, because this contradicts their knowledge that HIV can be transmitted through breastfeeding (Wagt A de, 2000). Therefore, promotion of exclusive breastfeeding will require intensive infant feeding counselling and true support for mothers.

Despite the many questions that still remain around the safety of breastfeeding, a number of recommendations on infant feeding counselling can already be made:

### ***Strengthening infant feeding counselling: a critical issue***

Infant feeding counselling is critical for fully informing women about the relative benefits and risks of breastfeeding vs. alternative infant feeding options, so that they can make an informed choice. This does not just mean presenting the different options and leaving the decision up to the mother: in many settings, women do not go to a health care facility to be presented with a variety of "choices" that they must then choose for themselves. Most women rather expect "someone more knowledgeable" (the health worker) to tell them what is the best solution for their particular situation (Cohen, 2001).

Therefore, the health worker/counsellor should actively support mothers in making their decision and in carrying it out: those who choose to breastfeed – no matter their HIV status – should be encouraged and supported to breastfeed *exclusively* for about 6 months.

A woman's decision *not* to breastfeed often comes with personal risks, including the stigma or suspicion of being infected with HIV, which may carry grave social, emotional, and even physical consequences. Therefore, individual counselling must cover not only the risks of morbidity and mortality for the infant but also the potential consequences for the mother (Preble & Piwoz, 2001).

To avoid possible stigma associated with infant feeding counselling, efforts to support breastfeeding and appropriate infant feeding practices must be strengthened where MTCT prevention programmes are being implemented so that health workers feel comfortable counselling all women and not only those who know their HIV-status. (Preble & Piwoz, 2001) This will also minimise confusion about HIV and breastfeeding and avoid the erosion of breastfeeding in the general population ("spill-over").

*Safer sex* should be promoted for uninfected pregnant and breastfeeding women, as recent HIV infection is associated with very high viral load, and an increased risk of MTCT. In

addition, safer sex should of course always be promoted for primary prevention of HIV infection in men and women.

*Wet nursing* practices should be avoided, especially the practice in some health care institutions of “pooling” breastmilk from several women, which is then used to provide breastmilk to infants whose mothers cannot breastfeed themselves. There is evidence that wet nursing practices are indeed declining, as a result of counselling (Haverkamp, 2001).

### **Making replacement feeding safer**

While exclusive breastfeeding offers important benefits to all infants, irrespective of their mother’s HIV status, breastfeeding by HIV-infected mothers always carries a substantial risk of MTCT. Besides, its relative advantages over mixed feeding still need to be confirmed.

At a certain point in time, the relative benefits of exclusive breastfeeding are outweighed by its incremental risks of MTCT. Therefore, the period of exclusive breastfeeding should be kept as short as possible, to avoid unnecessary risk of MTCT.

However, there is no data about when is the best moment to stop breastfeeding and start replacement feeding. Recommendations vary from a minimum of 6 weeks to 3 months, up to 12 months of exclusive breastfeeding. More research is clearly needed to provide better insights.

What *is* seen in practice is that the breastfeeding period is getting shorter: 6 weeks-6 months (Haverkamp, 2001). However, it is very difficult to assess the relative mortality risk of breastfeeding, cow’s milk or formula.

### ***Transition to safe infant feeding alternatives***

In any case, the current state of knowledge suggests that mixed feeding should be avoided at all times, given the associated higher risk of MTCT. This implies that the transition period from exclusive breastfeeding to other forms of infant feeding should be limited to a strict minimum.

The key question is how feasible is it to achieve really *exclusive* breastfeeding for at least 6 months (see above) *and* realise a drastic, almost instantaneous, shift to safe replacement feeding. In addition, it is not clear *what* would be the best replacement feeding.

The problem here, too, is that we don’t know *how* mothers can make this switch rapidly: any rapid cessation of breastfeeding is difficult: it can lead to mastitis and other breast health problems (Lhotska, 2001). The mother would always need to express her breastmilk for a certain period; this could then be heat-treated. A study in Pretoria, South Africa, has shown some good results with pasteurisation under household conditions.

At a certain point, the infant would need complementary foods, such as cow’s milk (possibly enriched with sugar), or formula. The question here is how can programmes ensure adequate replacement feeding between 6 and 24 months.

### ***Implementing the International BMS Code***

Implementation of the International Code of Marketing of Breast-milk Substitutes (BMS) has become even more important in the context of HIV and infant feeding. The code protects artificially-fed infants by ensuring that the choice of replacement feeding is made on the basis of non-commercial information and that all products are clearly labelled to ensure safe preparation and use. The Code also addresses issues of minimum supplies of formula and avoiding “spill-over”.

Countries providing free or subsidised infant formula to HIV-infected women who choose not to breastfeed, should put monitoring mechanisms in place to avoid “spill-over” of breastmilk substitutes: formula should be used exclusively (i.e., women who choose to use infant formula should not breastfeed as well) and appropriately.

Another Code requirement is to ensure a minimum supply of formula for 6 months for each infant. A pilot study in Rwanda seems to indicate that this international standard should be extended beyond 6 months. Normally, breastmilk still covers 50% of a baby’s needs after 6 months; thus, it is increasingly clear that some form of milk is necessary after 6 months for the replacement feeding to be of an adequate nutritional quality (Lhotska, 2001).

Some countries have developed their own national codes: these should be adhered to and enforced in all MTCT interventions involving BMS. Countries that have not implemented the Code at the national level should be encouraged to do so (Preble & Piwoz, 2001; Wagt A de, 2000).

### ***Specific formula feeding issues***

In order to provide formula in the context of MTCT prevention programmes in an appropriate way, a number of questions need to be answered first:

- How to provide formula to HIV-positive mothers who choose to formula-feed in a *confidential* manner to avoid stigmatisation and social rejection?
- How to ensure that individual teaching of preparation of formula feeds (commercial or home-prepared) can be carried out in maternity settings in a manner that ensures that mothers/caregivers can handle these practices in a safe, sustainable and acceptable way, including cup feeding?
- How to put in place adequate arrangements for follow-up of safe use of the product within households?
- What are the various cost implications for women/families in household resources in case artificial feeding becomes the preferred option: women’s time, fuel, water, utensils, household organisation, birth spacing?
- What are the outcomes in infant health, nutrition and development of use of generic formula and other replacement feeding?

Formula feeding has always been a *political* issue, and continues to be so in the context of MTCT. Some people accuse the formula industry of trying to use MTCT prevention to improve its image. In some cases, the industry still seems to try and sneak around the International Code. In a recent article on the international press, the industry has been successful in portraying UNICEF as a key obstacle to MTCT prevention, as it continues to insist on strictly applying the Code in MTCT settings as well (Wall Street Journal, Dec. 2000). The negative impact of these articles in the press may make it necessary to monitor media coverage of MTCT, including infant feeding issues, to ensure that coverage is accurate and does not create confusion about appropriate feeding practices. (Preble & Piwoz, 2001).

### ***Household options for safe infant feeding***

Many questions still surround the issue of feasibility of exclusive breastfeeding vs. formula. There may be other options than these two, but we don’t know the feasibility of using the various infant feeding options that have been identified at the household level. For example, home-prepared formula seems to be a feasible option, e.g. cow’s milk as supplement or in a way treated (e.g. adding sugar). Another possible option is a complex of micronutrients, a tiny package that can be used with one feed (per day). Feasibility studies on this are difficult to conduct, in particular because the necessary human resources to do this are lacking.

## 5. CONCLUSIONS

While a vast body of knowledge and experience exists regarding mother-to-child transmission of HIV and its prevention, key questions still remain unanswered, especially in the field of safe infant feeding.

While this makes it difficult to provide clear guidelines and policy recommendations for MTCT prevention in general – and safe infant feeding in particular – the bottom line in MTCT prevention policies should be to focus on the overall impact on infant morbidity and mortality, not just on reducing MTCT prevention rates *per se*. Therefore, it is necessary to weigh the benefits and risks of breastfeeding vs. replacement feeding, making both breastfeeding and replacement feeding safer.

Voluntary counselling and testing (VCT) and counselling on safe infant feeding are key elements for successful MTCT prevention, as counselling allows women to make informed decisions – with the support of health staff and counsellors – on MTCT prevention in their personal situation. Therefore, increased access to high-quality counselling services is a key priority.

Since short-course antiretroviral prophylaxis seems to be safe and effective, and can be made available at low cost, use of these ARV regimens should be promoted in the context of MTCT prevention.

Involving men is not only crucial because of their important role in decision-making regarding infant feeding and other elements of MTCT prevention, but also because of their obvious role in preventing unwanted pregnancies in HIV-infected women and primary prevention of HIV infection in sexually active men and women. 25% of couples where one partner tests HIV-positive, turn out to be serodiscordant, making primary prevention among couples a particularly burning issue. Safe sex is even more important *during* pregnancy and breastfeeding, because recent infection is associated with high maternal viral load and increased risk of MTCT. Given men's crucial role in MTCT, the term *parent*-to-child transmission is in fact more appropriate.

More basic research is needed, especially to identify the safest infant feeding options in resource-poor settings, while currently ongoing pilot programmes should be scaled up to allow more parents and children to benefit from MTCT prevention interventions. Careful monitoring and evaluation of these interventions is needed to provide the missing information on feasibility and efficacy of MTCT prevention in actual field conditions.

Finally, while MTCT prevention requires a comprehensive package of interventions – including structural strengthening of services and facilities – the obvious difficulty to realise this on the short term should not be used as an excuse for inaction and complacency: the appropriateness of any combination of MTCT prevention interventions should be determined at country level, adapting international guidelines and policies to local situations. These local solutions deserve our support.

## REFERENCES

- Adjorlolo-Johnson G, De Cock KM, Ekpini E et al (1994). Prospective comparison of mother-to-child transmission of HIV-1 and HIV-2 in Abidjan, Côte d'Ivoire. *JAMA* 1994, 272: 462-66.
- Baggaley R.(1997). *Fear of knowing: why 9 in 10 couples refused HIV tests in Lusaka Zambia*. Abstract number E.1266 Xth International conference on AIDS and STDs in Africa Abidjan December 1997.
- Baggaley R (1998). *Kara coping study; interim report UNAIDS*.
- Bulterys M, Chao A, Dushimimana A & Saah A (1996). Fatal complications after caesarean sections in HIV-infected women. *AIDS* 1996; 10: 923-24.
- Cohen S (2001). *UNAIDS MTCT electronic discussion list*.
- Connor EM, Sperling RS, Gelber R, et al (1994). Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med* 1994; 331: 1173-80.
- Coutoudis A, Pillay K, Spooner E, et al (1999a). Influence of infant-feeding patterns on early mother-to-child transmission of HIV-1 in Durban, South Africa: a prospective cohort study. *The Lancet* 1999; 354: 471-76.
- Coutoudis A, Pillay K, Spooner E, et al (1999b). Randomized trial testing the effect of vitamin A supplementation on pregnancy outcomes and early mother-to-child HIV-1 transmission in Durban, South Africa. *AIDS* 1999; 13: 1517-24.
- Coutoudis A (2000). *Method of feeding and transmission of HIV-1 from mothers to children by 15 months of age: Prospective cohort study from Durban*. Abstr, LbOr6. Paper presented at the XIII International AIDS Conference, Durban, South Africa.
- Dabis F, Msellati P, Meda N, et al (1999). 6-month efficacy, tolerance and acceptability of a short regimen or oral zidovudine to reduce vertical transmission of HIV in breastfed children in Côte d'Ivoire and Burkina Faso: a double-blind placebo-controlled multicentre trial. *Lancet* 1999; 353: 786-92 (DITRAME trial)
- De Cock K & Johnson A (1998). *From exceptionalism to normalisation: a reappraisal of attitudes and practice around HIV testing*. *BMJ* 316: 290-93
- DITRAME ANRS 049 Study Group (1999). 15-month efficacy of maternal oral zidovudine to decrease vertical transmission of HIV-1 in breastfed African children. *Lancet* 1999; 354: 2050-51.
- (EMDC) European Mode of Delivery Collaboration (1999). Elective caesarean-section versus vaginal delivery in prevention of vertical HIV-1 transmission: a randomised clinical trial. *Lancet* 1999; 353: 1035-39.
- Fawzi WW, Msamanga GI, Spiegelman D, et al (1998). Randomized trial of effects of vitamin supplements on pregnancy outcomes and T cell counts in HIV-1-infected women in Tanzania. *Lancet* 1998; 351: 1477-82.
- Filteau SM, Lietz G, Mulokoze G, et al (1999). Milk cytokines and subclinical breast inflammation in Tanzanian women: Effects of dietary red palm oil or sunflower oil supplementation. *Immunology* 94:595-600.
- Godfrey-Fausett P & Baggaley R (1998). *Exceptionalism in HIV, challenges for Africa too*. *BMJ* 316: 1826-27.
- Guay LA, Musoke P, Fleming T, et al (1999). Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999;354: 795-802.
- Haverkamp, G. (2001). *Personal communication*.
- Humphrey J, Iliff P, Kusum N et al (2000). *Rationale and design of the ZVITAMBO trial (Zimbabwe Vitamin A for Mothers and babies)*. Paper presented at XIII International AIDS Conference, Durban, South Africa.

- (IPHV) **International Perinatal HIV Group** (1999). The mode of delivery and the risk of vertical transmission of HIV type 1: a meta-analysis of 15 prospective cohort studies. *N Engl J Med* 1999; 340: 977-87.
- **Kalibala S** (1995). *Research, interventions and current issues in burnout and response*. In: Health workers and AIDS. Eds. Bennett L, Miller D, Ross M. Hardwood Academic Publishers, Switzerland.
- **Lhotska L** (2001). *Personal communication/MTCT electronic forum*.
- **Miotti PG, Taha TET, Kumwenda NI, et al** (1999). HIV transmission through breastfeeding: A study in Malawi. *JAMA* 282: 744-49.
- **Mofenson LM & McIntyre JA** (2000). Advances and research directions in the prevention of mother-to-child HIV-1 transmission. *The Lancet* 2000; 355: 2237-2244.
- **Nduati R, John G, Mbori-Ngacha D, et al** (2000). Effect of breastfeeding and formula feeding on transmission of HIV-1: a randomized clinical trial. *JAMA* 2000; 283: 1167-74
- **Perre P van de** (1999a). Mother-to-child transmission of HIV-1: the 'all mucosal' hypothesis as a predominant mechanism of transmission. *AIDS* 1999, 13: 1133-38.
- **Perre P van de** (1999b). Transmission of human immunodeficiency virus type 1 through breastfeeding: How can it be prevented? *J Infect Dis* 179 (Suppl 3): S405-407.
- **Piwoz EG** (2000). *Patterns of breastfeeding: What do the data say about the benefits of exclusive breastfeeding?* Paper presented at the XIII International AIDS Conference Satellite meeting on HIV and Breastfeeding, Durban South Africa.
- **Piwoz EG & Preble EA** (2000). *HIV/AIDS and Nutrition: A review of the literature and recommendations for nutritional care and support in Sub-Saharan Africa*. Washington: SARA Project/USAID.
- **Preble EA & Piwoz EG** (2001). *Mother-to-child transmission (MTCT) of HIV in Africa: A framework for prevention* - Draft document 29-30 January 2001.
- **Saba J, on behalf of the PETRA trial study team** (1999). *Interim analysis of early efficacy of three short ZDV/3TC combination regimens to prevent mother-to-child transmission of HIV-1: the PETRA trial*. 6<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (Chicago, 1999) (Abstr S7).
- **Sangiwa G, Balmer D, Furlonge C et al** (1998). *Voluntary HIV counselling and testing (VCT) reduces risk behaviour in developing countries: results from the multisite voluntary counselling and testing efficacy study*. Abstract 33269 presented at the 12<sup>th</sup> International Conference on HIV/AIDS, Geneva, Switzerland
- **Savage-King F** (2001). *UNAIDS MTCT electronic discussion list*
- **Semba RD** (1997). Overview of the potential role of vitamin A in mother-to-child transmission of HIV-1. *Acta Paediatr Suppl* 421: 107-112.
- **Semba RD, Kumwenda N, Hoover DR, et al** (1999a). Human immunodeficiency virus load in breast milk, mastitis, and mother-to-child transmission of human immunodeficiency virus type 1. *J Infect Dis* 180:98-98.
- **Semba RD, Miotti PG, Chipangwi JD et al** (1994). Maternal vitamin A deficiency and mother-to-child transmission of HIV-1. *The Lancet* 343: 1593-97.
- **Semba RD, Miotti PG, Chipangwi JD et al** (1995). Infant mortality and maternal vitamin A deficiency during human immunodeficiency virus infection. *Clin Infect Dis* 21: 966-72.
- **Shaffer N, Chuachoowong R, Mock PA, et al** (1999). Short-course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised controlled trial. *Lancet* 1999; 353:773-80.
- **Taha TE, Biggar RJ, Broadhead RL, et al** (1997). Effect of cleansing the birth canal with antiseptic solution on maternal and newborn morbidity and mortality in Malawi: clinical trial. *BMJ* 1997; 315: 216-19.
- **Tess BH, Rodriguez LC, Newell M-L, et al** (1998). Infant feeding and risk of mother-to-child transmission of HIV-1 in Sao Paulo State, Brazil. *J Acquir Immune Defic Syndr* 1998; 19: 189-94.

- **UNAIDS/WHO/UNICEF** (1999). *HIV and infant feeding counselling: a training course*. (UNAIDS/99.55E-58E). Geneva: UNAIDS.
- **UNAIDS** (2000). *Report on the global HIV/AIDS epidemic; June 2000*. Geneva: UNAIDS.
- **UNICEF, UNAIDS & WHO** (1998). *HIV and infant feeding: A review of the literature*. WHO/FRH/NUT/CHD/98.2; UNAIDS/98.4; UNICEF/PD/NUT/(J) 98.2.
- **Victora CG, Smith PG, Vaughan JP, et al** (1987). Evidence for protection by breast-feeding against infant deaths from infectious diseases in Brazil. *Lancet* 2(8554): 319-322.
- **Victora CG, Smith PG, Vaughan JP, et al** (1989). Infant feeding and death due to diarrhea: A case-control study. *Am J Epidemiol* 129: 1032-41.
- **Wabwire-Mangen F, Gray RH, Mmiro FA, et al** (1999). Placental membrane inflammation and risks of maternal-to-child transmission of HIV-1 in Uganda. *J Acquir Immune Defic Syndr* 1999; 22: 379-85.
- **Wagt A de** (2000). *Draft Report on Meeting on HIV and infant feeding, Nairobi, 9-10 October 2000*. Nairobi: UNICEF ESARO.
- **Wiktor SZ, Ekpini E, Karon JM, et al** (1999). Short-course zidovudine for prevention of mother-to-child transmission of HIV-1 in Abidjan, Côte d'Ivoire: a randomised controlled trial. *Lancet* 1999; 353: 781-85
- **WHO** (1999). *Voluntary Counselling and Testing for HIV Infection in Antenatal Care; Practical considerations for implementation*. Geneva: WHO.
- **WHO/IATT** (2001). *New data on the prevention of mother-to-child transmission of HIV and their policy implications. Conclusions and recommendations*. (Report on a WHO Technical Consultation on behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on Mother-to-Child Transmission of HIV). Geneva: WHO

## List of abbreviations used

- AIDS: acquired immuno-deficiency syndrome
- ART: antiretroviral treatment
- ARV: antiretroviral
- AZT: zidovudine (ZDV)
- ddi: didanosine
- HAART: highly active antiretroviral treatment
- HIV: human immunodeficiency virus
- IATEC: International Antiretroviral Therapy Evaluation Centre
- IATT: (UNFPA/UNICEF/WHO/UNAIDS) Inter-Agency Task Team (on Mother-to-Child Transmission of HIV)
- IMR: infant mortality rate
- MTCT: mother-to-child transmission
- NVP: nevirapine
- PEP: post-exposure prophylaxis
- PETRA: perinatal transmission
- PLWHA: person/people living with HIV/AIDS
- 3TC: lamivudine
- UN: United Nations
- UNAIDS: United Nations Programme on HIV/AIDS
- UNFPA: United Nations Population Fund
- UNICEF: United Nations Children's Fund
- VCT: voluntary counselling and testing
- WHO: World Health Organization
- ZDV: zidovudine

12

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22  
D-97074 WÜRZBURG  
GERMANY**

**June 2001**



# Toward a New Communications Framework for HIV/AIDS

**COLLINS O. AIRHIHENBUWA**

Pennsylvania State University  
University Park, Pennsylvania, USA

**BUNMI MAKINWA**

UNAIDS  
Geneva, Switzerland

**RAFAEL OBREGON**

Universidad del Norte  
Colombia, South America

*In response to the overwhelming burden of new cases of human immunodeficiency virus (HIV) in Africa, Asia, Latin America, and the Caribbean, the Joint United Nations Programme on HIV/AIDS (UNAIDS), in 1997, initiated a project to examine the application of existing communication theories/models to HIV/acquired immune deficiency virus (AIDS) prevention and care in these regions. In the past 2 years, 103 leading researchers and practitioners from different parts of the world were invited by the UNAIDS to participate in one of five consultative workshops designed to review these theories/models and rethink their adequacy for Africa, Asia, Latin America, and the Caribbean. A new communications framework for HIV/AIDS was developed to move from a focus on the individual to a focus on five domains of "contexts" that influence behaviors: government policy, socioeconomic status (SES), culture, gender relations, and spirituality.*

## Introduction

UNAIDS (1999) has reported that 90% of the new cases of HIV are in Africa, Asia, Latin American, and the Caribbean. Given the reality of the epidemic, information, education, and communication on HIV/AIDS is still very important to reduce the spread of the disease and to strengthen efforts and programs in care and support. Also, there is a need for an evaluation of current approaches to prevention and care, especially in terms of the relevance of theories and models currently used to guide HIV/AIDS communications in Africa, Asia, Latin America, and the Caribbean. Specifically, what are the strengths and weaknesses of existing theories and models used in HIV/AIDS communication? How well has communication been a factor in behavior change? What are the new challenges in HIV/AIDS communications in light of the discovering and attendant media coverage of the new combination drug therapies and efforts to develop an HIV vaccine? What are the ethical and practical

---

Address correspondence to Collins O. Airhihenbuwa, Ph.D., Associate Professor of Behavioral Health, Department of Biobehavioral Health, Pennsylvania State University, 304 East Health and Human Development, University Park, PA 16802, USA. E-mail: aou@psu.edu

issues such as affordability of these new drugs by governments and individuals and how do they affect decisions and policies on prevention? Even if these drugs were affordable, availability and accessibility cannot be taken for granted, and indeed the capability of skilled medical personnel and institutions to monitor compliance and adherence to drug regimens is problematic (Makinwa, 1997). These questions prompted UNAIDS to initiate a project designed to evaluate the adequacy of theories and models used in HIV/AIDS communications, particularly in Africa, Asia, Latin American, and the Caribbean.

This article discusses the five contextual domains—government policy, SES, culture, gender relations, and spirituality—that were identified in five UNAIDS consultative workshops implemented by Pennsylvania State University. These domains now form the cornerstone of the UNAIDS new communications framework for HIV/AIDS. Although this framework was developed under the rubric of communications, it should be noted that it is considered relevant to all aspects and strategies (e.g., human rights) of HIV/AIDS prevention, care, and support. The development of the plan is based on collective experiences gained from several years of HIV/AIDS prevention, care, and support programs worldwide.

## Background

Trends in HIV seroprevalence show that about 90% of all the new cases occur in Africa, Asia, Latin America, and the Caribbean and that nearly 95% of people living with HIV/AIDS are in the developing world (UNAIDS, 1999). UNAIDS and the World Health Organization (WHO) estimate that 33.6 million people were living with HIV at the end of 1999 (UNAIDS, 1999). Although sub-Saharan Africa bears the major burden of HIV (close to 70%), it is estimated that by the year 2005, India alone will have more HIV/AIDS cases than the entire continent of Africa (Fogarty Workshop, 1998). The projections for China are equally alarming although current reported cases appear to be low.

The discovery of antiretroviral drugs may have brought some hope; however, "the vast majority of people living with HIV are in the developing world, access to anti-retroviral drugs for most is difficult if not impossible, and consequently mortality rates are unlikely to decline" (UNAIDS Progress Report, 1998, p. 8). In a 1997 World Bank Policy Report, entitled *Confronting AIDS*, persuasive evidence was offered demonstrating that, particularly in countries where the disease is still believed to be nascent, "an early, active government response encouraging safer behavior among those most likely to contract and spread the virus has the potential to avert untold suffering and save millions of lives" (p. xv).

Thus prevention of HIV/AIDS infections remains crucial to curb the epidemic. Central to prevention strategies designed to transform individual and normative behavior in a society is communications. Yet despite several years of HIV/AIDS communication programs in developing countries infection rates continue to rise. Therefore, an evaluation of communication theories and approaches to HIV/AIDS prevention and care (see the article by Airhihenbuwa and Obregon in this volume) was necessary to verify their adequacy particularly in parts of the world that bear the burden of the pandemic.

The need for a new framework is further underscored by the increasing recognition that HIV/AIDS communication programs should address the full "HIV/AIDS continuum," which covers not only prevention but also care and support. This continuum involves planning and program implementation on a sustained, coherent,

and long-term basis within various phases of HIV/AIDS through prevention, care, support, and management of the disease.

### **UNAIDS and the Future of Communications for HIV**

Between 1997 and 1999, 103 researchers and practitioners were invited to participate in two global (Geneva and Washington, DC) and three regional (Abidjan for Africa, Bangkok for Asia, and Santo Domingo for Latin America and the Caribbean) consultative meetings. A mixed group of practitioners and scholars in communication and behavioral sciences represented Africa, Asia, Latin America, and the Caribbean as well as North America and Europe. Meetings were designed to review past and current approaches to HIV/AIDS communications and behavior change and propose new directions that will accommodate a global and regional framework yet remain flexible enough for adaptation by countries and organizations. This effort involved synthesis of experiences from Latin America and the Caribbean, Africa, and Asia at consultative workshops through a participatory process, guided by inputs of experts on the methodology and outcomes. As indicated earlier, five domains were identified, by consensus as critical factors in the physical and social environment that influence health behaviors related to prevention, care, and support. These domains are crucial to effectiveness of HIV/AIDS communication programs since they permeate and affect decision making in the context of HIV/AIDS. The discussions on regional issues also led to the identification of specific domains that have particular relevance to each region. For instance, in Latin America and the Caribbean the framework should emphasize advocacy as a crucial component, whereas in Africa community involvement was seen as fundamental.

### **Context as a Focus for a New Framework**

The limitation of focusing on the individual at the exclusion of the context has long been a concern for leading research organizations. The Institute of Medicine (1994) in the United States raised this concern in its report on the future of preventive intervention research. Similarly, the Rockefeller Foundation sounded a call for a paradigm shift in its report on communication for social change (1999). Increasingly, researchers (Kelly, 1999; McKinlay & Marceau, 1999) are questioning the serious methodological limitations in focusing on individuals to change their health behavior without adequate attention to social and physical environmental factors that shape individual roles and expectations and thus their health behavior. Thus the identification of the five contextual domains is quite consistent with the call by institutions, scholars, and practitioners to develop a new direction for disease prevention.

Participants acknowledged that the individual is a crucial part of the context and that the new framework should recognize the role of the individual even though it is focusing on the context. To this extent, the new framework could draw on salient elements of existing theories and models. For example, the use of opinion leaders, a major component of diffusion of innovations, could be incorporated at the operational level by regions, countries, and communities as deemed appropriate. Such flexibility is a major feature of the new framework recognizing differences in cultures and locations. A discussion of the characteristics of each domain of the contextual framework follows.

The framework (UNAIDS Penn State, 1999) is represented as a house whose structure varies according to regions and countries. Every house has a foundation, a roof, and a body designed to respond to the conditions in the environment—the context. In the new HIV/AIDS communications framework, the five domains are represented in the foundation, the roof, and the body of the house depending on the goals, objectives, and strategies that will be employed in a given communications program. For example, communication programs for condom availability and use by clients of commercial sex workers may locate the government at the roof in terms of policy to mandate 100% availability and use of condoms. At the same time, gender can be located at the foundation to address the role and societal expectation of women in sexual negotiation while carefully examining the interrelatedness of other contextual domains—culture, SES, and religion. On the other hand, the reported inability to translate public awareness into positive health behavior may necessitate locating the government at the roof. This will be crucial in terms of political will to invest in varied strategies to focus on different population subgroups while locating culture at the foundation in terms of utilizing known aspects of learning processes within the culture to move families and communities from awareness to behavior change. In this latter example, the role of gender, SES, and religion will be examined in determining appropriate strategy.

Finally, as one would expect in any house (Figure 1), there should be doors for entrance and exit. In this framework, the double door will have the key issues and processes for implementing a strategy on one panel and the key steps and processes for evaluation on the other panel. The windows will offer opportunity for every region and country to address their specific conditions consistent with the stage of the epidemic in their context.

### **Government and Policy**

Governmental policy and law play a critical role in programs aimed at controlling the spread of HIV/AIDS (World Bank, 1997). Diop, in this volume, demonstrated how government action in Senegal has been a major factor in keeping the epidemic under control. Phoolcharoen (1998) reports how early government intervention at the policy level became a key factor in the successful response of Thailand to the HIV/AIDS epidemic. The government quickly introduced legislation that supported nongovernmental organizations (NGOs) and community organizations' prevention efforts. Similarly, Maadra and Ruranga-Rubaramira (1998) have pointed out that in Uganda "the openness of the government has created a conducive environment for interested agencies and organizations working in HIV/AIDS activities to work together" (p. 53). This attitude, coupled with political will on behalf of government officials, is highlighted as an important element in the Ugandan efforts to control the epidemic.

Government policy can either promote or hinder efforts at reaching the goals of HIV/AIDS communications programs. Yet, according to Deane (1997) the reality is that public debate on HIV/AIDS issues remains, in many countries, too often poorly informed, sensationalist, and damaging to HIV/AIDS prevention. There are ethical, legal, and financial considerations that must be taken into account when discussing and planning communications programming to address these issues. Some of these challenges could be met by working through regional organizations such as Economic Community of West African States (ECOWAS), Southern African Development Community (SADC), Association of South East Asian Nations

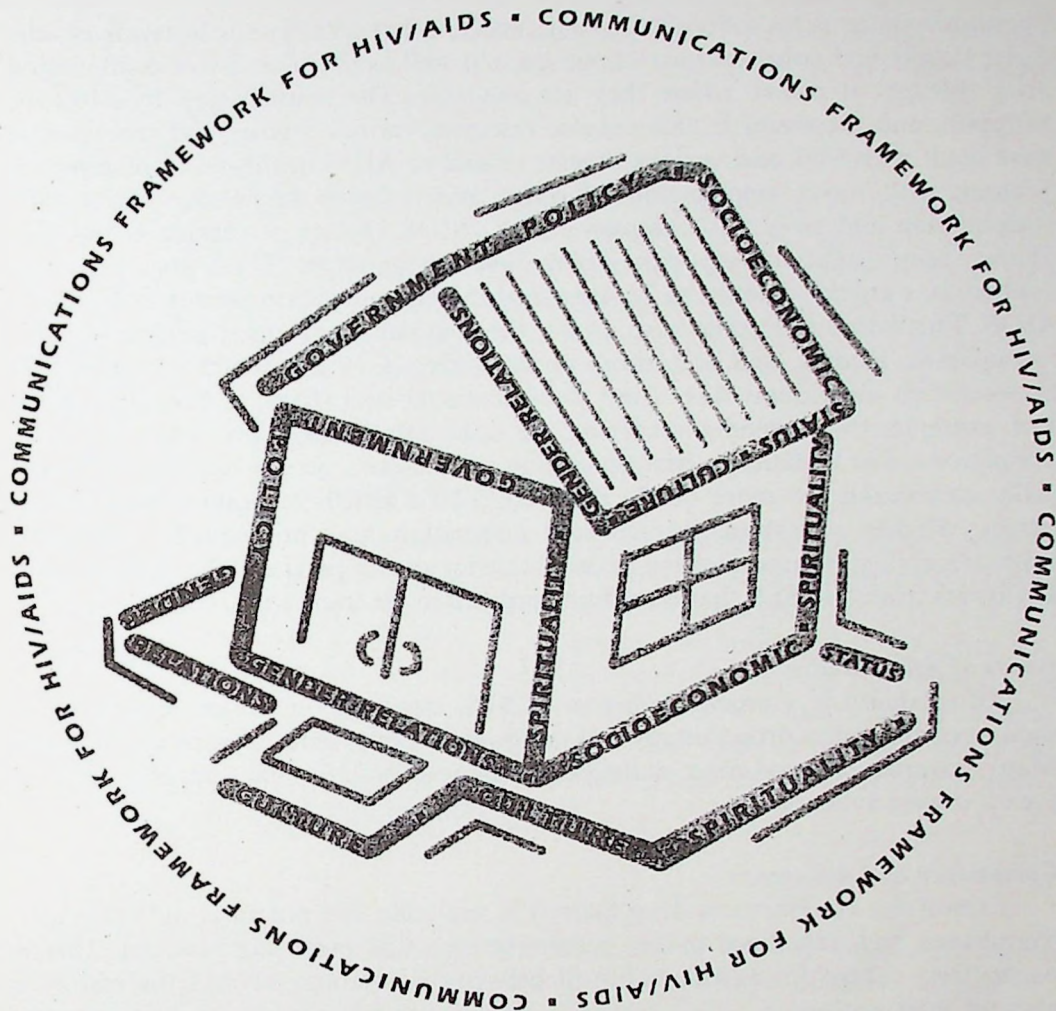


FIGURE 1. House to home.

(ASEAN), Organization of American States (OAS), Caribbean Community and Common Market (CARICOM), and Central American Common Market (CACM), which can provide important channels for addressing some regional issues relating to HIV/AIDS. Some of the critical issues identified in this domain are as follows.

#### *Agenda Setting*

Role of government in setting the media agenda and how HIV/AIDS fits into it should be a part of the initial information gathering and analysis.

#### *Image Management*

Issues of tourism, migration, violence, and rape of women by military men require government support for adequate solution.

#### *Collaboration*

An important role of government is fostering interregional and intraregional collaboration in HIV/AIDS programs such as sharing lessons learned within and between regions and facilitating cross-border interventions.

## SES

Economic status is an individual, group, and governmental factor in terms of adequate supply and consistent use of condoms as well as affordability of combination drug therapy in places where they are available. The contribution by Melkote, Muppidi, and Goswami in this volume discusses various studies and reports that have dealt with SES and various aspects related to AIDS in the developing world. Women with lower income and education report lower knowledge about HIV transmission and more misconceptions about AIDS. In fact, perception of risk was almost nonexistent among this impoverished population. Thus, socioeconomic context is a crucial domain to be examined in communication strategies for HIV/AIDS. Furthermore, studies have shown that the commonly used criteria for SES (occupation, income, and education) do not reflect how the context differentiates between two individuals who share these characteristics (King & Williams, 1995). For example, two individuals earning the same salary may have different family obligations. For instance, a first-generation middle-class person tends to be financially responsible for more family members than a fourth-generation middle-class person. Higher education, income, and occupation may not equally leverage a woman's ability to negotiate the sexual behavior of her partner. The following are key issues related to SES that must be considered in the framework.

### *Issues of Affordability*

Affordability is a crucial indicator of SES, especially in clinical interventions such as combination drug therapy and technological interventions such as condoms. Many governments and most individuals cannot afford combination drug therapy even if it were available.

### *Compliance and Adherence*

Even if the combination drug therapy is available, the potential difficulty with compliance and adherence makes preventive messages even more crucial. This is particularly salient for sustainability of behavioral outcome beyond the end of a planned intervention.

### *A Social and Developmental Problem*

HIV/AIDS should be considered a developmental and a social problem. As a result the pandemic should be addressed within the context of other social and development problems in the regions relative to allocation and distribution of resources. Given that HIV/AIDS is a developmental problem, issues of accessibility of health care in general must be analyzed within a given context and the result incorporated into the planning of HIV/AIDS communications for media and interpersonal communications.

## Culture

Culture refers to a collective consciousness of a people often shaped by a shared history, language, and psychology. As the contribution by Airhihenbuwa and Obregon in this volume indicates, culture is too often appropriated as a static and unchanging set of codes and meanings. Armed with a list of negative individual health beliefs and practices, the conclusion inevitably leads to blaming those beliefs and calling them cultural barriers. Western cultures, to varying degrees, tend to view

the self as a production of the individual, whereas many other cultures view the self as a production of the family, community, and other environmental influences for which we do not have, or desire, total control. The following key issues related to culture were considered in the framework.

### *Language Elasticity*

This refers to differences in rules and codes of languages (Airhihenbuwa, 1999). Whereas some languages may be rigid and linear in their application, others are elastic and robust. A linear and rigid rule in cultural production (as in classical music) should not be applied to an elastic and robust cultural production (as in jazz or calypso). By the same token, that a language is elastic does not suggest that such language lacks direction, nor does it imply that the rules are simple and easily understood.

### *Relationships within the Family and Community*

This should be explored particularly in the context of making decisions about adoption of preventive health behavior and caring for the ill. The centrality of family and community rather than the individual in decision making must be taken into account. That is, the focus must be on group and family more than just on the individual. In fact, individual beliefs do not necessarily explain the cultural context even though such beliefs may be a part of the culture. It is critical to understand who the caregivers are and their role in a culture. For example, the use of home-based care in many cultures requires a systematic and regular information update to improve patient management and support.

### **Gender**

Gender has been increasingly recognized as one of the key dimensions in efforts aimed at transforming and improving the lives of large numbers of people and around the world. Mendoza provides a comprehensive definition of gender:

Gender is what it means to be a male or a female and how that defines a person's opportunities, role, responsibilities, and relationships. Gender is a sociocultural variable and refers to the roles, behavior, and personal identities that the society or culture proscribes as proper for women and men. These attributes, opportunities, and relationships are socially constructed and learnt through socialization processes. Gender roles vary across determinants such as race, culture, community, time, ethnicity, occupation, age, level of education. While sex is biological, gender is socially defined. (1997, p. 1)

In HIV/AIDS communication gender plays an important role in defining how programs respond to the needs of both men and women. This means creating supportive environments that would allow males and females to have adequate means of protection against the disease as well as access to care and support when infected. For instance, numerous HIV/AIDS prevention programs have been carried out with a gender-based approach. However, a closer look suggests some key problems that hinder women's equal chances of benefiting from these programs. Mendoza (1997) argues that these programs are related to gender roles in a society and include

sexual norms that limit women's access to information by implying that they must be ignorant about sexual matters. Also, women's economic dependence on men, violence against women, and widespread acceptance of male promiscuity have worked against women's chances of protection against the disease. For instance, in Zimbabwe, Kenya, South Africa, and Zaire, the increasing financial insecurity that exists among a large number of female-headed households make transactional sex a "rational means of making ends meet" (Social Science Medicine, 1993, p. iii; also Gill & Mohammed, 1994).

Researchers and practitioners convened by UNAIDS agreed that in addition to suggestions made at recent international conferences on population and women issues, HIV/AIDS communication must take into account other dimensions. The following are key issues related to gender considered in the framework.

### *Male/Female Relationships*

Attention should be paid to the roles and responsibilities of men and women, to sociocultural factors, and to how these factors affect their relationship. There must be recognition that in addressing gender, we are referring to not only women but also to men. It is critical to understand gender roles and the relations of power and negotiation within and between those roles.

### *Stereotyping*

Communication materials should be designed to eliminate negative stereotypes of women and, on the contrary, used to promote positive images of women. Gender equity might be increased through reduction of negative stereotypes of men and women, which may influence ways and modes HIV is or has been spreading in the community.

### *Inclusiveness of Women in Planning*

Needs assessment must have a gender analysis component. Gender issues should be taken into consideration not only at the initial stage of planning a communication program but also through implementation and evaluation of those programs. In communication programs for young people, be it formal or informal education, it is important to take into account that both boys and girls are being targeted, as opposed to targeting a mass of young people only.

### *Spirituality*

Spirituality is a much broader and a more inclusive concept than religion even though the two terms are often used interchangeably. According to Relv (1997)

Spirituality encompasses hope; faith; self-transcendence; a will or desire to live; the identification of meaning, purpose and fulfillment in life; the recognition of mortality; a relationship with a "higher power," "higher being" or "ultimate," and the maintenance of interpersonal and intrapersonal relationships. (P. 2)

Evidence from HIV/AIDS literature shows that there is a relation between spirituality and HIV/AIDS (Gray, 1997). This and the increasing urgency of the epidemic has prompted the World Council of Churches' Executive Committee (1997) to issue a challenge to all churches to respond to the urgent call for actions resulting from

the spread of HIV/AIDS worldwide. Spirituality encompasses beliefs and value systems that range from organized religion to individual or collective values or both whose belief represent a guiding principle on which meanings are based. Spirituality is grounded in the belief that there is a supernatural being/force that regulates the interaction of living beings with their visible and nonvisible environment. The scientific literature has given increased attention to the link between spirituality and positive health behavior. This link has always been known to exist among traditional healers whose healing modality is in part based on the belief in the power of supernatural forces to regulate human behavior (Airhihenbuwa, 1995). The following are key issues related to spirituality to be considered in the framework.

### *Leadership Initiatives*

Leaders of the different religious organizations have important roles to play in HIV/AIDS prevention and care. At the very least, they can appeal to the moral conscience of their followers. Most importantly, they can provide a supportive environment for persons and families of persons living with HIV/AIDS.

### *Tolerance*

One cannot assume that religion is a hindrance and that tenets are the same in all countries. For example, Senegal is 95% Muslim, and yet condom use appears to be readily accepted in the country, if the current high level of distribution and consumption serves as an indication.

### *Mind and Body*

Traditional healers should be involved in planning of programs where possible.

### **Conclusion**

The long-term solution to bridging symbolic and material inequity lies in structural reforms that change the manner in which resources are distributed in society. However, such transformations cannot be achieved in a short span of time. In the context of HIV/AIDS, short- and medium-term solutions are needed to alleviate the impact of AIDS along with long-term change strategies. The contextual domains present some challenges to be addressed since they do not lend themselves to linear intervention strategies directed to solving a problem without focusing on the causes. In fact, many of the relative success stories reported to date can be attributed to a focus on one or more of the five contextual domains identified. A focus on context not only addresses the physical and social environment, it also recognizes the importance of bringing a project to scale rather than perpetuating pilot projects only that focus on individual behavior. As the contributions in this volume show, countries are reporting success in their collective efforts to address HIV/AIDS through a focus on government policy (Diop), SES (Melkote, Muppidi & Goswami), culture (Airhihenbuwa & Obregon; Diop), gender (Esu-Williams; Melkote et al.) and spirituality (Diop). Peter Piot, executive director of UNAIDS, has called for social vaccines to aggressively control HIV/AIDS. These social vaccines include promoting continuation of mass education about HIV/AIDS prevention, 100% condom policy, nondiscrimination against persons living with HIV/AIDS, and a protective environment for disclosure. Achieving these important objectives will

require collective efforts at different levels. The new UNAIDS framework offers an opportunity to meet these challenges.

## References

- Airhihenbuwa, C. O. (1999). Of culture and multiverse: renouncing "the universal truth" in health. *Journal of Health Education*, 30(3), 267-273.
- Deane, J. (1997). *Surrendering the agenda: The future of HIV/AIDS communications*. Paper presented at the UNAIDS Consultation Meeting on Communications Programming, Geneva, Switzerland. November 7-11.
- Fogarty Workshop on International HIV/AIDS Prevention Research Opportunities. (1998). University of California, San Francisco (UCSF) AIDS Research Institute. San Francisco, CA, April 17-20.
- Gill, H., & Mohammed, S. (1994). Factors affecting control of AIDS in Nigeria. *International Conference on AIDS*, 10(2), 252 (abstract no. PC0371), August 7-12.
- Gray, J. (1997). Spiritual perspective on social support in women with HIV infection: Pilot study. *Image: The Journal of Nursing Scholarship*, 29(1), 97.
- Institute of Medicine. (1994). Reducing risks for mental disorders: Frontier for preventive intervention research. In P. J. Mrazek & R. J. Haggerty (Eds.); Washington, DC: National Academy Press.
- Kelly, J. A. (1999). Community-level interventions are needed to prevent new HIV infections. *American Journal of Public Health*, 89(3), 299-301.
- King, G. & Williams, D. R. (1995). Race and Health: A multidimensional approach to african-american health. In Amick, Levine, Tarlov, & Walsh (Eds.), *Society and Health*. Oxford: Oxford University Press.
- Maadra, E., & Ruranga-Rubaramira, M. (1998). *Experience from Uganda, in UNAIDS: Partners in prevention: International case studies of effective health promotion practice in HIV/AIDS*. Geneva, Switzerland: UNAIDS.
- Makinwa, B. (1997). *Communications programming and emerging challenges: Treatment drugs, vaccine trials, and rapidly changing science*. Paper presented at the UNAIDS Consultation Meeting on Communications Programming, Geneva, Switzerland. November 7-11.
- McKinlay, J. B., & Marceau, L. D. (1999). A tale of 3 tails. *American Journal of Public Health*, 89(3), 295-301.
- Mendoza, A. M. (1997). *Bridging information towards transformation: Can it work?* Paper presented at the UNAIDS Consultation Meeting on Communications Programming. Geneva, Switzerland. November 7-11.
- Phoolcharoen, W. (1998). *Experience from Thailand, in UNAIDS: Partners in prevention: International case studies of effective health promotion practice in HIV/AIDS*. Geneva, Switzerland: UNAIDS.
- Relv, M. V. (1997). Illuminating meaning and transforming issues of spirituality in HIV disease and AIDS: An application of Parse's theory of human becoming. *Holistic Nursing Practice*, 12(1), 1-8.
- Rockefeller Foundation. (1999). *Communication for social change* [A position paper and conference report]. New York: Author.
- Social Science Medicine (1993). Reassessing priorities: Identifying the determinants of HIV transmission [Editorial]. *Social Science Medicine*, 36(4), iii-viii.
- Ugboajah, F. (1985). Oramedia in Africa. In Ugboaja (Ed.), *Mass Communication, Culture, and Society in West Africa*. New York: Hans Zell.
- UNAIDS. (1999). *AIDS epidemic update: December 1999* Geneva, Switzerland: UNAIDS/WHO.
- UNAIDS/Penn State. (1999). *Communications Framework for HIV/AIDS: A New Direction. A UNAIDS/Penn State Project*. C. O. Airhihenbuwa, B. Makinwa, M. Frith, R. Obregon (Eds.). Geneva: UNAIDS.

World Bank. (1997). *Confronting AIDS: Public priorities in global epidemic*. New York: Oxford University Press.

World Council of Churches Executive Committee. (1997). *The impact of HIV/AIDS and the churches' response. Facing AIDS. The challenge, the Council's response*. Geneva: WCC Publications.

**13**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

Senegal II 11.2, 11.3



## Lessons from the Field

# **From Government Policy to Community-Based Communication Strategies in Africa: Lessons from Senegal and Uganda**

**WALY DIOP**

West Africa Project to Combat AIDS, CCISD  
Senegal, Africa

### **Introduction**

More than a decade after the appearance of acquired immune deficiency syndrome (AIDS) cases in West Africa, the rate of HIV infection remains low in Senegal (between 1% and 1.6%). Naturally, this relatively stable rate, confirmed through regular epidemiological surveillance, appears to be an exception in a region where the infection rates range from 3% to 10%. It is this fact that has created growing interest among researchers and practitioners in recent years. However, the low infection rate at the national level conceals some worrisome situations in some parts of the country. As early as 1989, Fadel Kane et al. (1993) documented, in an epidemiological study, an HIV 1 infection rate of 10% among the spouses of emigrants in the Matam zone. This region situated in the north of Senegal is well known for its singularly high rate of emigration. Another study conducted in localities within the Ziguinchor region in the south of the country had produced nearly the same results. However, for those who have followed closely the evolution of AIDS in Senegal, it can be maintained that there was not really an epidemic of human immunodeficiency virus (HIV) to date within any single group.

Several factors can explain this Senegalese "exception." These factors can at once be linked to the performance of one of the oldest programs addressing sexually transmitted diseases (STDs)/AIDS in the region and also the sociocultural, religious, and political influences. In fact, many anthropological studies have brought to light a certain number of factors that should explain the lower exposure to HIV risk in the Senegalese population. These factors include: the universality of marriage; rapid remarriage of widow(er)s and divorced persons; a severe moral condemnation of all forms of cohabitation not sanctioned by a religious act and that may involve sexual rapport; and social networks that serve to control irresponsible sexuality (extended family circles of step-parents, cousins, relatives, neighbors, and so on). Even though long years of economic crisis along with a rapid urbanization have combined to change sexual morals especially in the big cities, there still remains deep rooted

---

Address correspondence to Waly Diop, BP 7670, Dakar-Medina, Senegal, Africa. E-mail: waly.diop@ccisd.bf

control over an individual's sexuality by family and society in general. Fear of dishonoring one's family and the subsequent "what will they say" notion plagues the individual's conscience. In addition, familial and social solidarity is maintained even during economic crisis or even its attendant unemployment.

Yet it can be affirmed without a doubt that the major factor that triggered the fight against AIDS in Senegal was the absence of denial. Health officials recognized the existence of the disease very early in 1986, even through only the first six cases were recorded. The mass media became involved, followed by nonprofit organizations and community associations. All these efforts were reinforced in 1988 by the testimonials on television of two people living with HIV. It could even be said that Senegal initiated the fight against AIDS before the disease could gain a foothold in the country.

### Role of Government

Senegal is the only country in the region to have a legislation regulating commercial sex, as a part of the control of STDs. A 1962 decree and a series of laws (Law 63-17 on February 5, 1963, Law 66-21 on February 1, 1966, Law 69-27 on April 23, 1969) established the conditions for the practice of prostitution and set the framework for the fight against STDs. Accordingly, plans for the control of STDs incorporating the use of medical and social personnel were implemented in all of the capitals of the 10 regions of the country and at the departmental level (subdivisions of the regions) throughout the 1970s. Such a policy, with its regular police enforcement, requires commercial sex workers (CSWs) to make use of regular medical services, notwithstanding the fact that the social context frowns on commercial sex. This unique and specialized plan for the treatment of STDs has allowed the health system to maintain control of the disease by regular treatment of CSWs. The system also includes counseling of sex workers to use condoms. All this occurred more than 10 years before the advent of HIV. It was thus a natural transition for the national HIV/AIDS and STDs programs to become resolutely engaged in strategies to take charge of HIV, a form of STD.

From 1989 to 1997 HIV infection rate among CSWs varied between 6% and 36% with a downward trend supported by vigorous educational campaigns and the promotion of condom use. An important point that must be taken into consideration in the analysis of the measures of combating AIDS is that in the course of the last 10 years, Senegal has become one of the leading consumers of condoms thanks to the national program of family planning, the "Programme national de lutte contre le SIDA" (National AIDS Control Program [NACP]), and nonprofit organizations. These efforts were discreet and made without any *public* social marketing of condoms. The quantity of condoms distributed through the NACP alone has increased from 800,000 units in 1988 to more than 7 million in 1996. Statistics on the use of condoms show an appreciable success in terms of their availability and accessibility. The 1997 study on sexual behavior reveals that 67% of men and 45% of women reported that they consistently used condoms in their casual sexual relations. These rates are particularly higher among widow(er)s, divorced, and separated couples who (for diverse reasons, especially economic) could have new and occasional partners. Among CSWs of the big urban centers the rate of condom use is more than 90%.

The government strategy has supported the activities of civil society organizations through dissemination of their valuable works, praising them through the media and providing resources directly to support their programs. Many journalists

have been trained by not-for-profit projects such as the Family Health International AIDS Control and Prevention (AIDSCAP) project and the Canadian project to give them the necessary tools to develop information and sensitization programs on a permanent basis, regardless of the health issue or problem. The NACP has involved other sectors such as political parties, unions, and businesses, in HIV/AIDS programs.

Another important factor is the political engagement of key leaders in the country. Through dialogue with parliamentarians who each took a course concerning the issues surrounding AIDS, political support at national, regional, and district levels has been strengthened. Even the head of government has spoken out and acted in support of the fight against HIV/AIDS. Perhaps the general mobilization of communities in Senegal against AIDS is also psychological. Although the information and educational projects and tools adapted to the sociocultural context of the country were being used, images of deeply affected countries such as Uganda and other Central African nations were presented early on to the population to show the devastating effects of the epidemic.

At the beginning of the 1990s, the NACP rallied its foreign partners to consider as a priority the allocation of resources to the social sector. The project *Support à la lutte contre le SIDA au Sénégal* (Support for the Fight against AIDS in Senegal), financed by the Canadian International Development Agency (CIDA/ACDI), began its activities in 1992 to provide technical and financial support to nonprofit organizations and community associations. This project was followed by AIDSCAP, the Alliance Nationale Contre le SIDA (National Alliance Against AIDS), UNICEF, and other UN agencies. Indeed, several international organizations were encouraged to support the HIV/AIDS programs of Senegal but in a planned, orderly manner.

### Role of Religion

Senegal is a predominantly Islamic country, with a more than 90% Muslim population who follow doctrines set forth by the powerful and respectable religious brotherhoods known for their orthodoxy but who are far from being religious fundamentalists. Dialogue with religious and secular authorities on HIV/AIDS started very early, even though some formal approaches by organizations and institutions were initiated later to consolidate and legitimize the dialogue. Two national symposia on the response of Islam and the Catholic Church to the epidemic were held. The initiatives, principally conducted by the community and nonprofit organizations, already had succeeded at the end of the 1980s in securing the contribution of local religious leaders (Imams of the neighborhood or the village). These leaders used their sermons to draw the attention of their followers to the reality of AIDS and the appropriate behaviors encouraged by the various religions. Jamra (an Arabic word that means embers), a nonprofit Islamic organization, played a large role in crisscrossing the country each year to meet with the leaders of the different Muslim brotherhoods, sensitizing them to the issues concerning AIDS and soliciting their intervention and support in the education of the population at large. A number of these religious leaders participated and continue to participate in this effort through the association of Imams. For its part, the *Association des postes de santé privé* (Association of Private Catholic Health Services), which is directly dependent on the Catholic church, has carried out sensitization and educational programs for many years. Also in this context, few voices of opposition rise up publicly against condoms in the fight against HIV/AIDS. Neither religious nor poli-

tical authorities have spoken out against them in a sort of *modus vivendi*, resulting from a long and regular dialogue between the NACP and religious leaders of all faiths, leading to an understanding that no one should oppose the other's message publicly out of respect for the diversity in public opinion.

### Community and Social Action

Senegal has an unusually developed network of associations. This network was immensely useful to start off the HIV/AIDS campaigns. For example, The Environnement et Developpement dans le Tiers Monde (ENDA Tiers Monde), an international nongovernmental organization (NGO) based in Dakar, with others created and provided support for a general mobilization throughout the entire country. In each neighborhood and village there exists an Association Sportive et Culturelle (ASC—Cultural and Sports Association) composed of both young people and adults, just as in each village and neighborhood there are women's associations. All of these groups have been active continually for the past several years on information, education, counseling, and other aspects of the fight against HIV/AIDS.

In 1992, for example, the youth associations, encouraged by their leaders and the NACP, made AIDS the theme of their annual theater competition. ENDA put all of its efforts into forming and providing support for an enormous network of community volunteers, the result of collaboration between the ASCs, the women's groups, and the developmental associations of each region. This general mobilization of youth associations, women's groups, and nonprofit organizations in the communities is reinvigorated periodically through three annual government initiatives. These initiatives, supported by several ministers, districts, and communities are: youth week against AIDS, women's week, and the World AIDS Day campaign. Added to these initiatives and the activities of the neighborhood and village associations and nonprofit organizations are the integrated programs of various government ministries such as that of the Ministry of Education, which introduced teaching curriculum on HIV/AIDS in elementary schools.

The success of the fight against AIDS in Senegal, including the 100% blood safety, control of STDs, and general mobilization of leaders and communities, would still have been limited without the involvement of the private sectors who have invested a lot in AIDS prevention, especially the education of the general population. All social groups are encouraged to be involved in activity where the problem of AIDS is brought up in schools, associations, religious sermons, recreational activities, the media, in the markets, the bus stations, and the home.

### Lessons from Uganda

According to UNAIDS, Uganda ranks among countries hardest hit by HIV/AIDS, but it has come up with several measures and responses that have not only stemmed the rise of the epidemic, but also are actually beginning to show reduction in its spread among some groups in the country. The examples of the response of Uganda may be instructive in showing how HIV/AIDS can be brought under control. The country is fortunate to have strong political recognition of the problem that was posed by the epidemic early on. This has been demonstrated by the engagement of President Yoweri Museveni with combating HIV/AIDS soon after he came into office. The political involvement has prompted a number of intervention strategies such as establishment of the National AIDS Commission and National AIDS Programme with separate but complementary responsibilities. The government has

created a supportive environment for community responses to the epidemic through fostering a climate of destigmatization, which has enabled several role models and key figures to publicly disclose their HIV infection. Indeed, Uganda is the first country where people living with HIV/AIDS established organizations and actively helped others affected or infected to cope with the epidemic. Several often-cited indicators of success in Uganda include the increased demand for voluntary testing by people who would like to know their HIV status; involvement of many youth and community organizations in HIV/AIDS; formation of networks of organizations that help with coping mechanisms for the disease; extensive collaboration between national institutions/agencies and international collaborators to synchronize programs and efforts; increased funding and resources for HIV/AIDS programs; and monitoring and evaluation of the effectiveness of programs and interventions.

## Conclusion

The lessons of Senegal and Uganda are both very important. In both cases, the absence of denial; focus on the larger context of HIV/AIDS (beyond the biomedical approach); coordinated and concerted programs; political commitment of the highest level; forging alliances with social, religious, and economic sectors; and mobilization of community organizations are all vital to fight HIV/AIDS. Now, Senegal and Uganda provide us with proof that African countries contain inestimable resources to efficiently respond to the AIDS pandemic. These resources should be carefully and intelligently identified and rationally invested.

## References

- Kaleeba, N. (with Ray, S. & Willmore, B.). 1991. *We miss you all*.
- Kane, F., Michel, A., Ibra, N., Coll, A. M., Mboup, S., Guèye, A., Kanki, P. J., & Joly, J. R. 1993. *Temporary expatriation is related to HIV-1 infection in rural Senegal*, *AIDS*, 7(9), 1261-1265.
- Islamic Medical Association of Uganda (IMAU) *AIDS education through Imams: A spiritually motivated community effort in Uganda*. [UNAIDS Case Study]. Geneva, Switzerland, UNAIDS.
- Meda, N., Ndoeye, I., Wade, A., Ndiaye, S., Niang, C., Sarr, F., Diop, I., Mboup, S., & Caraël, M. 1998. *Contrôle de l'épidémie de VIH/SIDA en Afrique: Examen de la situation au Senegal*.
- Ndiaye, S., Wade, A., Guèye, M., & Diagne, M. 1998. *Enquête sur les comportements de prévention en matière de MST/SIDA dans la population générale à Dakar (Senegal): Rapport d'analyse*. Dakar: CNLS-ONUSIDA.
- Nunez, A. 1993. *Une approche micro-réalisation dans la lutte contre le SIDA*. *Halte SIDA*, 1(3), 10-12.
- UNAIDS. 1998. *Partners in prevention: International case studies of effective health promotion practice in HIV/AIDS*. Geneva, Switzerland. pp. 49-57.
- UNAIDS. (1998, May). *A measure of success in Uganda, the value of monitoring both HIV prevalence and sexual behavior*. [UNAIDS Case Study]. Geneva, Switzerland, Author.
- UNAIDS. (1999, January). *Key political, institutional, and program elements of successful national HIV/AIDS programs: The cases of Uganda and Thailand*. [UNAIDS Draft Technical Note]. Geneva, Switzerland.
- UNAIDS, WHO. 1998. *Senegal epidemiological fact sheet on HIV/AIDS and sexually transmitted diseases*. Geneva, Switzerland.
- UNICEF. 1998. *Uganda: The survival of a new generation*. Location: Author.
1999. *World Views: AIDS in Uganda, Ancient healers join fight against modern disease*.

14

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

## Unit for Health Services and HIV/AIDS

Von: break-the-silence@hdnet.org  
Gesendet: Donnerstag, 3. Mai 2001 14:00  
An: UNGASS-BTS  
Betreff: UNGASS News and Events - UN Secretary General in Abuja

The UN Secretary General —

Address to the African summit on HIV/AIDS, Tuberculosis and other infectious diseases

Abuja, 26 April 2001

Thank you, Mr. Salim/President Obasanjo  
Excellencies,  
Dear friends,

This is a conference about Africa's future.

The incidence of HIV/AIDS, tuberculosis and other infectious diseases is higher on this continent than on any other.

Of course, this fact is connected to Africa's other problems.

Africans are vulnerable to these diseases because they are poor, undernourished, and too often uninformed of basic precautions, or unwilling to take them.

Many are vulnerable because they have neither safe drinking water nor access to basic health care.

They are vulnerable, in short, because their countries are underdeveloped. And therefore the best cure for all these diseases is economic growth and broad-based development.

We all know that.

But we also know that, in the best of cases, development is going to take time. And we know that disease, like war, is not only a product of underdevelopment. It is also one of the biggest obstacles preventing our societies from developing as they should.

That is especially true of HIV/AIDS, which takes its biggest toll among young adults - the age group that normally produces most, and has the main responsibility for rearing the next generation. That is why AIDS has become not only the primary cause of death on this continent, but our biggest development challenge. And that is why I have made the battle against it my personal priority.

In short, my friends, we are here to face a continent-wide emergency. We cannot afford to treat it as just one aspect of the battle for development, because it will not wait for us to win that battle. The cost - whether measured in human misery today, or in loss of hope for tomorrow - is simply too high. We have to turn and face it head on.

First, let us be clear what our objectives are. I believe they can be put very simply, under five headings:

Number One: Prevention.

Our first objective must be to halt and reverse the spread of the virus - as all world leaders resolved to do at last year's Millennium Summit - and so to save succeeding generations from this scourge. Prevention can save many millions of lives, and in several African countries it has been shown to work.

Everyone who is not yet infected must know what they need to do to avoid infection. We must give young people the knowledge and power to protect

themselves. We need to inform, inspire and mobilise them, through an awareness campaign such as the world has never seen - using radio, television and professional marketing techniques, as well as more conventional tools of education.

That campaign must reach girls as well as boys. At present, in sub-Saharan Africa, adolescent girls are six times more likely to be infected than boys. That is something which should make all of us African men deeply ashamed and angry.

And once they know what they need to do, young people must have the means to do it. That means they must have support from their families and communities, as well as access to voluntary counselling and testing and - when appropriate - to condoms.

Number Two: We must prevent the cruellest, most unjust infections of all - those that pass from mother to child.

All mothers must be able to find out whether they are HIV-positive or not. And those who are must have access to short-term anti-retroviral therapy, which has been shown to halve the risk of transmission.

In some cases, the risk can also be reduced by alternatives to breast-feeding. But these must be approached with caution, since breast-feeding is the best protection against many other diseases.

Number Three: we must put Care and Treatment within everyone's reach.

Even a year ago few people thought that effective treatment could be brought within reach of poor people in developing countries. Those already infected with HIV were condemned to be treated like lepers in earlier times - as people from whom the healthy had to be protected, but for whom nothing could be done.

Now, however, there has been a world-wide revolt of public opinion. People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.

Earlier this month I met the leaders of six of the world's biggest pharmaceutical companies. They now accept the need to combine incentives for research with access to medication for the poor. They are ready to sell drugs to those countries at greatly reduced prices.

This crisis is so grave that developing countries must face it by exploiting all options to the full - including the production and importation of "generic" drugs under licence, within the terms of international trade agreements.

Everyone who is infected should have access to medicine and medical care. Now we know that that is possible, it is surely an ethical imperative. It is also essential to any successful prevention strategy - because, so long as testing positive is a death sentence without hope, many people will not even want to know their HIV status.

In short, we cannot and should not choose between prevention and treatment. We must do both.

Number Four: we must deliver Scientific Breakthroughs.

We are still a long way from finding a cure for HIV/AIDS, and a long way from finding a vaccine against it. We must make sure that the search is given the highest priority in scientific budgets, and be ready, as soon as it produces results, to make them available where they are most needed -- not only to those who can afford them.

And finally, Number Five: we must protect those made most vulnerable by the epidemic, especially orphans.

Millions of children, because they have lost one or both parents to AIDS, are growing up malnourished, under-educated, marginalised, and at risk of

being infected themselves. We must break this cycle of death. And we must not wait for parents to die before we intervene. We must help them secure their children's future while they are still fit enough to do so.

Agreeing on those five objectives should not be difficult. But what are the means we need to achieve those ends?

First of all, we need leadership. And my friends, that must start with you, the leaders of Africa. Only you can mobilise your fellow-citizens for this great battle. Only you can give it the priority it deserves in your national budgets.

Above all, you must take the lead in breaking the wall of silence and embarrassment that still surrounds this issue in too many African societies, and in removing the abuse, discrimination and stigma that still attach to those infected. The epidemic can be stopped, if people are not afraid to talk about it.

Secondly, we need to involve local communities. It is ultimately at that level that the battle will be fought and won. It is only with the fullest support of their families and communities that young people will be able to change their behaviour and protect themselves. Above all, we must involve those already living with HIV-AIDS in the struggle against it. They, after all, are the ultimate experts.

Thirdly, we need a deep social revolution that will give more power to women, and transform relations between women and men at all levels of society. It is only when women can speak up, and have a full say in decisions affecting their lives, that they will be able to truly protect themselves - and their children - against HIV.

Fourth, we need stronger healthcare systems. This should be obvious, but both governments and development agencies often lose sight of it when setting their budgets and priorities. If our aim is to make care and treatment available to all those infected, we need a far more efficient and extensive system of public health than most African countries even begin to provide at present.

Cheaper anti-retroviral drugs, however vital, will not by themselves provide the answer. Without proper health care, they may even do more harm than good - for example, if potentially life-threatening side effects are not addressed, or if the therapy is interrupted, leading to drug-resistant forms of HIV. And too many patients still do not have access even to relatively cheap antibiotics and other effective drugs for the many illnesses that prey on their weakened immune systems.

Finally, we need money. The war on AIDS will not be won without a war chest, of a size far beyond what is available so far.

Money is needed for education and awareness campaigns, for HIV tests, for condoms, for drugs, for scientific research, to provide care for orphans, and of course to improve our healthcare systems. At a minimum, we need to be able to spend an additional seven-to-ten billion dollars a year on the struggle against HIV/AIDS in the world as a whole, over an extended period of time.

It sounds a lot, and it is a lot. Somehow we have to bring about a quantum leap in the scale of resources available. But it is not at all impossible, given the amount of wealth in the world. In fact it is little more than one per cent of the world's annual military spending. We just have to convince those with the power to spend - public and private donors alike - that this would be money well spent.

We need to mobilise the widest possible range of donors -- who must all agree on the same broad objectives -- and we need to win their commitment for the long haul.

Over the past few weeks and months, there have been several exciting suggestions for a new fund or funds from a variety of people -- Governments, private foundations and academics. All these initiatives must now converge towards a common vision of what we are trying to achieve.

I propose the creation of a Global Fund, dedicated to the battle against HIV/AIDS and other infectious diseases. This Fund must be structured in such a way as to ensure that it responds to the needs of the affected countries and people. And it must be able to count on the advice of the best experts in the world - whether they are found in the United Nations system, in civil society organisations, or among those who live with HIV/AIDS or are directly affected by it.

I intend to pursue this idea with all concerned over the next few weeks, and I hope that in the very near future the Fund will be up and running.

My dear friends and colleagues,

The ideas I have put to you today are the fruit of extensive consultations within the United Nations system, with member states, with philanthropic foundations, with private companies, and with civil society. I believe we can all agree on them, and that they can be the foundations of a common strategy.

I certainly hope so, because this battle can be won only if we mobilise and focus the efforts of a wide range of stakeholders: national leaders like yourselves, donor governments, the United Nations system, pharmaceutical and other companies, foundations, and voluntary groups - especially those that represent people living with HIV. In other words, we need a complete mobilisation of society at large.

Everyone has his or her part to play. Let us now lay aside all turf battles and doctrinal disputes. The battle against HIV/AIDS is far more important than any one institution or project. Our success will not be measured by resolutions passed, appointments made, or even funds raised. It will be measured in the lives of succeeding generations.

In the last year or so the world has begun to realise that HIV/AIDS is indeed a world-scale pandemic, which has spread fastest and furthest in Africa.

So this is a moment of hope, and potentially a turning point. Africa is no longer being left to face this disaster alone. Its plight has caught the attention, and the conscience, of the whole world.

I believe the world is ready to come to our aid. But it will do so only if we convince the world that we ourselves are making the war against AIDS our personal priority, and have a clear strategy for waging it.

In two months' time, delegates from all over the world will gather in New York for a Special Session of the United Nations General Assembly on HIV/AIDS. They will draw up a global strategy for the war against this global scourge, and I hope by then we shall have firm commitments for our war chest.

Will that strategy respond to the needs of Africa? It depends, in large part, on the signal that goes out to the world from this conference.

For my part, I promise you the full support of the United Nations family. Working together, my friends, we can defeat the scourge of HIV/AIDS. For the sake of Africa's future, we must.

Thank you very much.

---

B R E A K   T H E   S I L E N C E

UN General Assembly - Special Session on HIV/AIDS  
New York - 25 to 27 June, 2001

You are currently subscribed to break-the-silence as: [mi.health@mail.uni-wuerzburg.de](mailto:mi.health@mail.uni-wuerzburg.de)  
To unsubscribe send a blank email to [leave-break-the-silence-34782T@lists.hdnet.org](mailto:leave-break-the-silence-34782T@lists.hdnet.org)

To join email: [join-break-the-silence@hdnet.org](mailto:join-break-the-silence@hdnet.org)  
To post email: [break-the-silence@hdnet.org](mailto:break-the-silence@hdnet.org)

15

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

AFRICAN SUMMIT ON HIV/AIDS,  
TUBERCULOSIS AND OTHER  
RELATED INFECTIOUS DISEASES  
ABUJA, NIGERIA  
24-27 APRIL 2001

OAU/SPS/ABUJA/3

**ABUJA DECLARATION ON HIV/AIDS,  
TUBERCULOSIS AND OTHER RELATED  
INFECTIOUS DISEASES**

## **ABUJA DECLARATION ON HIV/AIDS, TUBERCULOSIS AND OTHER RELATED INFECTIOUS DISEASES**

We, the Heads of State and Government of the Organisation of African Unity (OAU) met in Abuja, Nigeria from 26-27 April 2001, at a Special Summit devoted specifically to address the exceptional challenges of HIV/AIDS, Tuberculosis and Other Related Infectious Diseases, at the invitation of H.E. President Olusegun Obasanjo of the Federal Republic of Nigeria and in accordance with the agreement reached at the Thirty-Sixth Ordinary Session of our Assembly in Lomé, Togo from 10 to 12 July 2000.

2. We gathered in Abuja to undertake a critical review and assessment of the situation and the consequences of these diseases in Africa, and to reflect further on new ways and means whereby we, the leaders of our Continent, can take the lead in strengthening current successful interventions and developing new and more appropriate policies, practical strategies, effective implementation mechanisms and concrete monitoring structures at national, regional and continental levels with a view to ensuring adequate and effective control of HIV/AIDS, Tuberculosis and Other Related Infectious Diseases in our Continent.

3. We are deeply concerned about the rapid spread of HIV infection in our countries and the millions of deaths caused by AIDS, Tuberculosis and other related infectious diseases throughout the Continent, in spite of the serious efforts being made by our countries to control these diseases. Africa is exceptionally afflicted by the HIV/AIDS epidemic. This generalised epidemic is affecting a wide cross-section of our people, thus decimating the adult population, the most productive group, and leaving in its wake millions of orphans, and disrupted family structures.

4. We recognize the role played by poverty, poor nutritional conditions and underdevelopment in increasing vulnerability. We are concerned about the millions of African children who have died from AIDS and other preventable infectious diseases. We are equally concerned about the particular and severe impact that these diseases have on children and youth who represent the future of our continent, the plight of millions of children orphaned by AIDS and the impact on the social system in our countries.

5. We are particularly concerned about the high incidence of mother to child transmission, especially given the challenges of infant breastfeeding in the context of HIV infection on the continent.
6. We recognize that special efforts are required to ensure that Africa's children are protected from these pandemics and their consequences and that the full and effective participation of young people in prevention and control programmes is essential to their success.
7. We recognise that biologically, women and girls are particularly vulnerable to HIV infection. In addition, economic and social inequalities and traditionally accepted gender roles leave them in a subordinate position to men.
8. We appreciate the special needs and challenges of the HIV/AIDS pandemic for the youth that make them vulnerable to infection and adverse impacts of the epidemic.
9. We recognize that the practice of injectable drug abuse with sharing of contaminated needles in some African countries is a major concern. The abuse of alcohol, marijuana and other mind-altering drugs, which is on the increase among the youth further enhances their vulnerability to HIV infection.
10. We recognize the essential place that education, in its widest sense has played and will continue to play in the fight against HIV/AIDS in Africa. Education constitutes the most powerful, cost effective tool for reaching the largest number of people with information and personal development strategies that promote long-term behaviour change.
11. We acknowledge that forced migrations due to war, conflicts, natural disasters and economic factors including unilateral sanctions imposed on some African countries, lead to an increased vulnerability and the spread of the disease; we note that special attention should be given to migrants, mobile populations, refugees and internally displaced persons in national and regional policies. We also note that special attention should be given to the problem trafficking in human beings and its impact on HIV/AIDS.
12. We are aware that stigma, silence, denial and discrimination against people living with HIV/AIDS (PLWA) increase the impact of the epidemic and constitute a major barrier to an effective response to it. We

recognize the importance of greater involvement of People Living with HIV/AIDS.

13. We recognise that the epidemic of HIV/AIDS, Tuberculosis and Other Related Infectious Diseases constitute not only a major health crisis, but also an exceptional threat to Africa's development, social cohesion, political stability, food security as well as the greatest global threat to the survival and life expectancy of African peoples. These diseases, which are themselves exacerbated by poverty and conflict situations in our Continent, also entail a devastating economic burden, through the loss of human capital, reduced productivity and the diversion of human and financial resources to care and treatment.

14. We recognize the need to intensify our efforts in all areas of research such as traditional medicines and vaccine development.

15. We are fully convinced that containing and reversing the HIV/AIDS epidemic, tuberculosis and other infectious diseases should constitute our top priority for the first quarter of the 21<sup>st</sup> Century. We are equally convinced that tackling these epidemics should constitute an integral part of our continental Agenda for promoting poverty reduction, sustainable development and ensuring durable peace and political security and stability consistent with the Millennium African Recovery Programme.

16. We recognise and commend the efforts by our respective national Governments, our continental Organisation and its Regional Economic Communities (RECs), the national and international NGOs, the civil society, including youth, women, people with disability, religious organisations, sport organizations, Trade Unions, Employers organizations, Traditional Health Practitioners, Traditional Rulers, people living with HIV/AIDS and individuals, who care for, support and sensitise our people to the threat of HIV/AIDS and the associated opportunistic infections including Sexually Transmitted Infections (STIs).

17. We acknowledge the support that the international Community, including the United Nations System, its Specialised Agencies and programmes, bilateral agencies, private sector and other communities and stakeholders have provided in raising awareness about and combating the scourge of HIV/AIDS, Tuberculosis and other related infectious diseases in Africa.

18. We further acknowledge that, to successfully implement a comprehensive and multisectoral approach and campaign to overcome HIV/AIDS, tuberculosis and other related infectious diseases, there is a need to secure adequate financial and human resources at national and international levels.

19. We recognize the need to establish a sustainable source of income to fund HIV/AIDS programmes.

20. We recognise the importance of leadership at all levels in the fight against HIV/AIDS, Tuberculosis and Other Related Infectious Diseases in our Continent. We, therefore, acknowledge the special importance of the "African Consensus and Plan of Action: Leadership to overcome HIV/AIDS" adopted at the African Development Forum 2000 as the outcome of a wide-ranging process of consultation with all stakeholders.

21. In this regard, we recall and reaffirm our commitment to all relevant decisions, declarations and resolutions in the area of health and development and on HIV/AIDS, particularly the "Lomé Declaration on HIV/AIDS in Africa" (July 2000) and the "Decision on the adoption of the International Partnership against HIV/AIDS" (Algiers 1999).

#### **WE SOLEMNLY DECLARE AS FOLLOWS:**

22. We consider AIDS as a State of Emergency in the continent. To this end, all tariff and economic barriers to access to funding of AIDS-related activities should be lifted.

23. To place the fight against HIV/AIDS at the forefront and as the highest priority issue in our respective national development plans. To that end, **WE ARE RESOLVED** to consolidate the foundations for the prevention and control of the scourge of HIV/AIDS, Tuberculosis and Other Related Infectious Diseases through a comprehensive multisectoral strategy which involves all appropriate development sectors of our governments as well as a broad mobilisation of our societies at all levels, including community level organisations, civil society, NGOs, the private sector, trade unions, the media, religious organisations, schools, youth organisations, women organisations, people living with HIV/AIDS organizations and individuals who care for, support and sensitise our population to the threat of HIV/AIDS and associated opportunistic infections and also to protect those not yet infected, particularly the women, children and youth through appropriate and effective prevention programmes.

24. To that effect, **WE COMMIT OURSELVES TO TAKE PERSONAL RESPONSIBILITY AND PROVIDE LEADERSHIP** for the activities of the National AIDS Commissions/Councils. **WE THEREFORE RESOLVE** to lead from the front the battle against HIV/AIDS, Tuberculosis and Other Related Infectious Diseases by personally ensuring that such bodies were properly convened in mobilizing our societies as a whole and providing focus for unified national policy-making and programme implementation, ensuring coordination of all sectors at all levels with a gender perspective and respect for human rights, particularly to ensure equal rights for people living with HIV/AIDS (PLWA).

25. **WE ALSO COMMIT OURSELVES TO ENSURE** that leadership role is exercised by everyone in his/her area of responsibility in the fight against HIV/AIDS and other related diseases. **WE THEREFORE ENDORSE** the "African Consensus and Plan of Action: Leadership to overcome HIV/AIDS" adopted during the Second African Development Forum on "AIDS: The Greatest Leadership Challenge" organised by the United Nations Economic Commission for Africa (UNECA) in collaboration with the OAU, UNAIDS and ILO (Addis Ababa, 3-7 December 2000).

26. **WE COMMIT OURSELVES** to take all necessary measures to ensure that the needed resources are made available from all sources and that they are efficiently and effectively utilized. In addition, **WE PLEDGE** to set a target of allocating at least 15% of our annual budget to the improvement of the health sector. **WE ALSO PLEDGE** to make available the necessary resources for the improvement of the comprehensive multi-sectoral response, and that an appropriate and adequate portion of this amount is put at the disposal of the National Commissions/Councils for the fight against HIV/AIDS, Tuberculosis and Other Related Infectious Diseases.

27. **WE REQUEST** the OAU Secretariat, in collaboration with ADB, ECA, and all other partner institutions, especially WHO and UNAIDS, to assist Member States in formulating a continental-wide policy for an international assistance strategy for the mobilisation of additional financial resources.

28. **WE CALL UPON** Donor countries to complement our resources mobilization efforts to fight the scourge of HIV/AIDS, Tuberculosis and Other Related Infectious Diseases. Bearing in mind that Africa cannot,

from its weak resource base, provide the huge financial resources needed. In this regard, **WE URGE** those countries to, among others, fulfil the yet to be met target of 0.7% of their GNP as official Development Assistance (ODA) to developing countries.

29. We support the creation of a Global AIDS Fund capitalized by the donor community to the tune of US \$5 – 10 billion accessible to all affected countries to enhance operationalization of Action Plans, including accessing Anti-retroviral programmes in favour of the populations of Africa.

30. **WE UNDERTAKE** to mobilize all the human, material and financial resources required to provide **CARE** and **SUPPORT** and quality treatment to our populations infected with HIV/AIDS, Tuberculosis and Other Related Infections, and to organize meetings to evaluate the status of implementation of the objective of access to care.

31. **WE RESOLVE** to enact and utilize appropriate legislation and international trade regulations to ensure the availability of drugs at affordable prices and technologies for treatment, care and prevention of HIV/AIDS, Tuberculosis and Other Infectious Diseases. **WE ALSO RESOLVE** to take immediate action to use tax exemption and other incentives to reduce the prices of drugs and all other inputs in health care services for accelerated improvement of the health of our populations.

32. **WE COMMIT OURSELVES** to explore and further develop the potential of traditional medicine and traditional health practitioners in the prevention, care and management of HIV/AIDS, Tuberculosis and Other Related Infectious Diseases.

33. **WE COMMIT OURSELVES** to support the development of effective affordable, accessible HIV vaccine relevant to Africa. We, therefore, support "The Africa; AIDS Vaccine Programme" (AAVP), its collaborative partners, International partners and Institutions committed to the facilitation of HIV vaccine research and testing in Africa.

34. **WE COMMIT OURSELVES** to documenting and sharing these successful and positive experiences with a view to sustaining and scaling them up for wider coverage; mindful that there are still challenges that confront us, particularly in the area of infant feeding.

35. **WE COMMIT OURSELVES** to scaling up the role of education and information in the fight against HIV/AIDS in recognition of the

essential role education, in its widest sense plays as a cost-effective tool for reaching the largest number of people.

36. **WE COMMIT OURSELVES** to the strengthening and development of special youth programmes to ensure an AIDS-free generation.

37. **WE**, within the framework and spirit of our Sirte Declaration of 9 September 1999, **RENEW THE MANDATE** of our brothers, President Bouteflika of Algeria, President Mbeki of South Africa and President Obasanjo of Nigeria to continue discussion with our debt creditors, on our behalf, with the view to securing the total cancellation of Africa's external debt in favour of increased investment in the social sector.

38. **WE ENDORSE** the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases; and **WE PLEDGE** to promote advocacy at the national, regional and international levels; and **WE ALSO PLEDGE** to ensure massive participation of Heads of State and Government at the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS slated for 25 – 27 June 2001 so as to ensure that the session comes up with concrete and urgent decisions for the fight against HIV/AIDS in Africa including the fight against poverty and deduction of Africa's debt.

39. **WE REQUEST** the OAU Secretary General, in collaboration with ECA, ADB, UNAIDS, WHO, UNICEF, UNDP, ILO, UNFPA, FAO, UNESCO, UNIFEM, IOM, UNDCP and other partners, to follow-up on the implementation of the outcome of this Summit and submit a report to the Ordinary Sessions of our Assembly.

40. **WE MANDATE** the Government of the Federal Republic of Nigeria to submit a report on the outcome of this African Summit on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases to the next Ordinary OAU Summit, which will be held in Lusaka, Zambia in July 2001.

Abuja, Federal Republic of Nigeria  
27 April 2001

**16**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



## General Assembly

Distr.: General  
16 February 2001

Original: English

Fifty-fifth session

Agenda item 179

Review of the problem of human immunodeficiency  
virus/acquired immunodeficiency syndrome in all  
its aspects

### Special session of the General Assembly on HIV/AIDS

#### Report of the Secretary-General

##### *Summary*

In the two decades since it has been with us, the acquired immunodeficiency syndrome (AIDS) epidemic has continued its relentless spread across continents, hitting harder in some places than others but sparing no country. In these two decades, it has become a truly global emergency.

That the world finally recognizes the scale of this crisis is clear in the Millennium Declaration (General Assembly resolution 55/2) adopted by the Millennium Summit of the United Nations, held in September 2000. In the Declaration, the world's leaders committed themselves to halting and beginning to reverse the spread of the human immunodeficiency virus (HIV)/AIDS by 2015; providing special assistance to children orphaned by HIV/AIDS; and helping Africa build up its capacity to tackle the spread of the HIV/AIDS pandemic and other infectious diseases. The decision by the General Assembly to convene a special session to review and address the problem of HIV/AIDS as a matter of urgency followed quickly after the Millennium Summit, and is seen as the first step in the realization of the commitments expressed in the Declaration.

The present report examines the spread of the epidemic and reviews its impacts — demographic, social, economic and from the standpoint of the security of people and nations. It approaches the epidemic from all levels, recognizing that although a global problem requires a global response, the mobilization of people and communities is also essential. It is at the household and community level, supported by civil society groupings, that open dialogue about norms, values, gender issues, health and sexuality takes place and can have a real impact on people's ability to reduce their vulnerability to infection.

widespread and affordable access to care and treatment; that successful responses have their roots in communities; that empowering young people and women is essential; that people living with HIV or AIDS are central to response; and that the epidemic must be tackled on several fronts — by addressing risks associated with behaviours and situations, vulnerability to the risk of infection and impact on the lives of individuals and their communities.

The present report assesses the response to the epidemic through the triple lens of leadership, coordination and the need for adequate resources. **Leadership** — at the global as well as the country level — is the single most important factor in reversing the epidemic.

One of the most important leadership challenges is to ensure that the full power and authority of the State is brought to bear on the epidemic, securing the mobilization of all sectors and levels of government, a decentralized implementation of interventions, solid partnerships with non-governmental actors, adequate funding from national budgets, and appropriate resource allocations across sectors and down to the district/municipal levels.

A second factor in the success against HIV/AIDS, both nationally and globally, is improved **coordination** across all sectors of social and economic planning between Governments, among government and non-governmental partners, and among international and national civil society. At a time when resources and the number of actors intervening against AIDS are increasing, the coordination of efforts becomes even more critical in a strong response. By encouraging the collective approaches and problem-solving that are crucial to a cross-cutting issue like AIDS, coordination can help focus energy and resources on specific goals in order to avoid duplication and enhance cost-effectiveness. In this way, collective approaches and problem-solving add significant weight to what might otherwise be seen as piecemeal solutions. A large-scale synergistic and systematic response is required.

A third critical factor is the need for adequate **resources**. Worldwide, financial resources allocated to HIV/AIDS, particularly in the most affected regions, is only a fraction given the magnitude of the epidemic. For example, a well-resourced response for prevention and basic care programmes in Africa alone would require at least US\$ 3 billion a year, not including antiretroviral therapy. Yet only a fraction of this amount is available despite growing evidence of political will and commitment.

These challenges are described in a conference room paper that will be issued to complement the present report.

Considerable success has been achieved in addressing the epidemic in many parts of the world. Declining HIV infection rates in many communities and in some cases across nations, especially among young people, have proven that prevention strategies work. Declining death rates from AIDS in industrialized countries and some developing countries have also demonstrated recent benefits of HIV treatment and that care is effective.

Meeting the challenge of HIV/AIDS requires a combination of approaches: strengthening leadership, alleviating the social and economic impacts of the epidemic, reducing vulnerability, intensifying prevention, increasing care and support, providing international public goods and increasing resources.

HIV/AIDS is the most formidable development challenge of our time. The

## Contents

	<i>Paragraphs</i>	<i>Page</i>
I. Introduction .....	1-3	4
II. Epidemic overview .....	4-21	4
III. Socio-economic impacts of HIV/AIDS .....	22-40	6
A. Demographic impacts .....	24-25	6
B. Social impacts .....	26-32	7
C. Economic impacts .....	33-38	8
D. Impact on security .....	39-40	9
IV. Global, regional and national responses to AIDS .....	41-86	9
A. Global response .....	41-49	9
B. Regional and national responses .....	50-86	10
V. Key lessons learned and elements of a successful response .....	87-108	15
VI. Challenges for an expanded response: the way forward .....	109-123	19
Annexes		
I. Goals set by global conferences and their follow-up processes .....		21
II. United Nations system response .....		23

## I. Introduction

1. Acquired immunodeficiency syndrome (AIDS) has become a major development crisis. It kills millions of adults in their prime. It fractures and impoverishes families, weakens workforces, turns millions of children into orphans, and threatens the social and economic fabric of communities and the political stability of nations. The negative impact of the human immunodeficiency virus (HIV) and AIDS on development, particularly in southern Africa but increasingly in such areas as the Caribbean, South and South-East Asia, cuts across development sectors and across society. AIDS spreads rapidly, undermining labour forces, business productivity, exports, investments and ultimately national economies. If the epidemic continues at its present rate, the hardest-hit nations stand to lose up to 25 per cent of their projected economic growth over the next 20 years.

2. In September 2000, the General Assembly adopted the Millennium Declaration (resolution 55/2), in which it called for concrete action on HIV/AIDS. Specifically, the Millennium Declaration commits the world's leaders to halting and beginning to reverse the spread of HIV/AIDS by the year 2015; providing special assistance to children orphaned by HIV/AIDS; and helping Africa to build up its capacity to tackle the spread of the HIV/AIDS pandemic and other infectious diseases. The Declaration came after a series of follow-up events to global conferences, including the World Summit for Social Development, the Fourth World Conference on Women and the International Conference on Population and Development, which all identified priorities on HIV/AIDS (see annex I). The year 2000 opened with a debate in the Security Council that recognized AIDS as an issue of human security and acknowledged its growing impact on increased regional instability and issues of national security.

3. In recognition of the severity of the epidemic, the United Nations decided to convene, as a matter of urgency, a special session to review and address the problem of HIV/AIDS. The special session will aim to secure a global commitment for enhanced coordination and intensified national, regional and international efforts to combat the epidemic. The present report provides a brief global overview of the epidemic and examines its critical aspects. The report also analyses lessons learned in the fight against AIDS to date, and

highlights areas that will require urgent attention in the years to come.

## II. Epidemic overview

4. In December 2000, the Joint United Nations Programme on HIV/AIDS (UNAIDS) secretariat and the World Health Organization (WHO) reported that by the end of 2000, 36.1 million men, women and children around the world were living with HIV or AIDS and 21.8 million had died from the disease. The same year saw an estimated 5.3 million new infections globally and 3 million deaths, the highest annual total of AIDS deaths ever. The spread of HIV has brought about a global epidemic far more extensive than was predicted even a decade ago, with the number of people living with HIV or AIDS worldwide 50 per cent higher than the figure projected in 1991. Modes of transmission continue to be unprotected sex, unscreened blood and blood products, contaminated needles, mother-to-child transmission and breastfeeding.

### Africa

5. AIDS is now found everywhere in the world but has hit hardest in sub-Saharan Africa. Africa is home to 70 per cent of adults and 80 per cent of children living with HIV, and to three quarters of the nearly 22 million people worldwide who have died of AIDS since the epidemic began. During 2000, an estimated 3.8 million people became infected with HIV in sub-Saharan Africa and 2.4 million people died. AIDS is now the primary cause of death in Africa. Today, an estimated 25.3 million Africans are living with HIV or AIDS, and in 16 countries more than one tenth of all adults (people aged 15 to 49) are infected. A tragic aspect of the epidemic is the growing population of orphaned children: of the world's 13.2 million children orphaned by AIDS, 12.1 million are in Africa.

6. Within sub-Saharan Africa, Southern Africa has more people living with HIV than any other region. One in four women aged 20 to 29 is infected. In West Africa, infection rates are up, and they continue to be high in East Africa. The countries of North Africa and the Middle East have so far been the least affected by the epidemic. With the exception of the Sudan and Djibouti, prevalence rates are 1 per 1000 adults or lower. However, recent data suggests that these countries are not immune to the epidemic. There are reports of increasing prevalence among pregnant

women in some areas, as well as among some high-risk populations.

7. In 2000, for the first time the number of new infections in the region was not higher than in the previous year. Two factors may be responsible. First, the epidemic has existed for so long that it has already affected many sexually active persons, shrinking the pool of available people to whom the infection could still spread. Second, successful prevention programmes in a handful of countries — notably Uganda, parts of Zambia and the United Republic of Tanzania — have reduced national infection rates, particularly among young people. In Senegal, the prevalence rate appears to be stable, at the low level of 1.7 per cent of the general population, while South Africa and Kenya's rates may have stabilized but at much higher rates, of 19.9 and 13 per cent, respectively.

8. Africa faces a triple challenge of daunting proportions: it must reduce new infections by enabling individuals to protect themselves and others; it must bring health care, support and solidarity to an increasingly infected population; and it must cope with the cumulative impact of millions of AIDS deaths on survivors, communities and national development.

#### Asia and the Pacific

9. Asia has so far escaped the high infection rates registered in Africa. Only three countries — Cambodia, Myanmar and Thailand — have prevalence rates exceeding 1 per cent among 15- to 49-year olds. But infections are rising. In South and South-East Asia during the past year, 780,000 adults, almost two thirds of them men, became infected. East Asia and the Pacific registered 130,000 new infections. In Thailand, the strong response that was built around a programme promoting 100 per cent condom use in commercial sex has cut prevalence in young men by over 50 per cent.

10. The HIV/AIDS epidemic is relatively recent in Asia and its dynamics vary greatly across the continent, both among and within countries. These differences hide broadly recognizable patterns, however, including a considerable spread of HIV among the heterosexual population, a large concentration in drug-injecting groups, and a high incidence of HIV among sex workers and among men who have sex with men. While infection rates are low in the general population in countries like China and India — which between them account for more than

one third of the world's total population — even a low rate of infection means that huge numbers of people are affected. China is experiencing population movement that dwarfs any other in recorded history. Having practically eradicated sexually transmitted infections by the 1960s, China is now witnessing a steep rise in these rates, which could translate into higher HIV spread. In India, HIV surveillance has found prevalence rates of above 2 per cent among pregnant women in some areas, and in studies among injecting drug users in Manipur State, rates have varied between 40 and 75 per cent.

#### Eastern Europe and Central Asia

11. The countries of the former USSR present some of the most dramatic trends in the worldwide AIDS epidemic. Previously characterized by very low prevalence rates, the region now faces an extremely steep increase in the number of new infections, up from 420,000 at end-1999 to at least 700,000 one year later. In 2000 alone, more new infections were registered in the Russian Federation than in all previous years combined. Of the region's 250,000 new infections, most occurred among men, the majority of them injecting drug users. However, recent data in the Ukraine has found increasing prevalence among pregnant women.

12. A complicated backdrop of economic crisis, rapid social change, increased poverty and unemployment, growing prostitution and changes in sexual norms have all contributed to fuelling the rapid spread of HIV throughout the region.

13. The Central Asian Republics have until recently been little affected by the HIV/AIDS epidemic, but recent data from some countries suggest that the spread of HIV has begun to spread among injecting drug users.

#### Latin America and the Caribbean

14. The epidemic in Latin America is a complex mosaic of transmission patterns, in which HIV continues to spread through sex between men, sex between men and women, and injecting drug use. An estimated 150,000 adults and children became infected during 2000, bringing the total number of infected to 1.4 million. Brazil, the most populated country in the region, has the largest number of people living with HIV — 540,000. At the same time, the number of

AIDS cases, especially the number of AIDS-related deaths, has significantly decreased as a result of widespread access to life-prolonging treatments. From 1995 to 1998, mortality from AIDS in Brazil fell by 30 per cent.

15. The Caribbean has the highest rate of HIV infection in the world after sub-Saharan Africa, and AIDS is already the single greatest cause of death among young men and women in this region. In Haiti, the Caribbean's worst-affected country, about 8 per cent of adults in urban areas and 4 per cent in rural areas are infected. Across the Caribbean, the epidemic is spreading particularly fast through heterosexual transmission. It is driven by early sexual activity combined with frequent partner changes and age mixing — younger women having sex with older men.

16. In Central American countries — ravaged by years of armed conflict, environmental destruction and uneven social development — the epidemic is concentrated among disadvantaged and mobile populations, with increasing prevalence rates among women.

17. A major challenge that cuts across the region remains the need for awareness programmes aimed at men who have sex with men and injecting drug users.

#### High-income countries

18. High-income countries witnessed a major decline in AIDS-related deaths in the 1990s from AIDS because effective treatment, mainly antiretroviral therapy, is keeping people alive longer. However, that good news is tempered by a stall in prevention efforts and by new infections, which show no sign of slowing. In 2000, despite years of awareness about AIDS, 30,000 people in Western Europe were infected and 45,000 in North America.

19. Thousands of new infections occurred through unsafe sex between men. In recent years, fewer young men have lost friends to AIDS and many mistakenly consider antiretrovirals a cure, reflecting a growing complacency among this high-risk population. At the same time, stigma around homosexuality persists, hampering prevention efforts and reinforcing discriminatory attitudes.

20. Heterosexual sex is now the main mode of HIV transmission in some European countries. In the United States, HIV/AIDS is also affecting minority

populations disproportionately, with disadvantaged young African-Americans in rural areas one of the groups at high risk of HIV infection.

21. The bulk of new infections continues to occur in men who have sex with men and injecting drug users, however. While prevention programmes consisting of AIDS education, condom promotion, needle exchange and drug treatment have proven effective, strong political determination is now needed in order to apply energetic prevention measures and reach out to marginalized people and their partners.

### III. Socio-economic impacts of HIV/AIDS

22. AIDS, while continuing to be an important health issue, has evolved into a complex social and economic emergency. HIV primarily affects young adults, cutting a broad path through society's most productive layer and destroying a generation of parents, whose death leaves behind orphans, desocialized youth and child-headed households. AIDS has a significant impact on the more educated and skilled segments of society because HIV primarily infects productive young adults rather than children or the elderly. The stigma attached to HIV and AIDS adds to the impediments encountered in mounting a response to AIDS, in addition to the discrimination already faced by infected individuals. HIV also increases social and economic vulnerability among women.

23. In the hardest-hit regions, AIDS is now reversing decades of development. It changes family composition and the way communities operate, affecting food security and destabilizing traditional support systems. By eroding the knowledge base of society and weakening production sectors, it destroys social capital. By inhibiting public and private sector development and cutting across all sectors of society, it weakens national institutions. By eventually impairing economic growth, the epidemic has an impact on investment, trade and national security, leading to still more widespread and extreme poverty. In short, AIDS has become a major challenge for human security.

#### A. Demographic impacts

24. AIDS deaths are premature deaths. In countries where HIV spreads mainly through unsafe sex between

men and women, the majority of infected people acquire HIV in their twenties or thirties and will die of AIDS on average a decade later. In a number of countries, AIDS has resulted in increased mortality among children under five, and is now wiping out half a century of development gains, including increases in life expectancy at birth, particularly in southern Africa, where life expectancy increased from 44 years in the early 1950s to 59 in the early 1990s. Between 2005 and 2010, it is expected to fall to 45 years and even lower in some countries.

25. The lifetime risk of dying of AIDS is far higher than the general prevalence rate would suggest. For example, where prevalence is 15 per cent and rates continue to apply through their lifetime, over half of today's 15-year olds will die. In Botswana, which has a prevalence rate of 36 per cent, over three quarters would die of AIDS. In some countries, these trends are reshaping the traditional population pyramid into a new "population chimney", with a narrowing base of young people and children. The most dramatic change in the pyramid occurs when young adults, infected early, begin to die of AIDS. Only those adults who escape HIV infection can expect to survive to middle and old age. Also, recent studies among various African populations indicate that rates of HIV infection in young women aged 15 to 19 may be five to six times higher than in young men.

## B. Social impacts

26. The premature death of large numbers of young adults has an inevitable impact on those societies most affected by AIDS.

### *Households and families*

27. Households and families bear the brunt of the misery caused by AIDS. Those who fall ill become unable to work, forcing family members to care for them rather than producing food or income. According to studies of rural families in Thailand and urban families in Côte d'Ivoire, farm output and income fell between 52 and 67 per cent in families affected by AIDS. Families are also subject to discrimination if they have members who are HIV-positive, often facing reduced access to publicly available social and economic benefits.

### *Gender*

28. The gender dynamics of the epidemic are far-reaching due to women's weaker ability to negotiate safe sex and their generally lower social and economic status. More women than men are caretakers of people with AIDS, which may saddle them with the triple burden of caring for children, the elderly and people living with AIDS — as well as financial responsibility for their family's survival. Girl children or older women may find themselves at the head of households, and many girls from families facing poverty risk exploitation, especially sexual exploitation, when trying to bring in additional income. Mother-to-child transmission is also a concern.

### *Education*

29. Where AIDS is widespread, education — an essential building block of development — is being impaired. The epidemic is eroding the supply of teachers and diluting the quality of education. AIDS also reduces the amount of money available for school fees, and forces an increasing number of children — more girls than boys — to drop out of school in order to help at home. As teachers become ill and unable to work, some schools are closing. In parts of Southern Africa, one fifth of teachers and secondary school students are estimated to be HIV-positive.

### *Health services*

30. Since the beginning of the epidemic, 21.8 million people have fallen sick and died of AIDS, placing ever-increasing demands on health services in the worst-affected countries. Often, this increased demand stretches already over-burdened public health systems. In 1997, public health spending on AIDS alone exceeded 2 per cent of gross domestic product (GDP) in seven of 16 African countries sampled, a staggering amount for countries whose health expenditure for all diseases accounts for 3 to 5 per cent of GDP. Adding to these increased demands is the crushing burden of AIDS on health workers themselves. A study in Zambia showed that in one hospital, deaths among health-care workers increased by a factor of 13 over a decade, largely because of HIV. Overburdened public health systems may also further marginalize minority, disabled and elderly women with HIV/AIDS. HIV-positive people also lack access to medicines and to health care, often facing discrimination from hospital staff or health-care systems.

### *Orphans*

31. AIDS has a dramatic impact on children, particularly through the emergence of an entire generation of orphans to families affected by HIV. To date, the epidemic has left behind 13.2 million orphans, children who before the age of 15 have lost either their mother or both parents to AIDS. Studies have shown that children orphaned by AIDS are at greater risk of malnutrition, illness, abuse and sexual exploitation than children orphaned by other causes. The stigma and discrimination they face can also deprive them of basic social services and education. Today, in many African countries 20 to 25 per cent of all households are fostering orphans. The long-term consequences of such shifts in socialization are incalculable.

### *Human Development Index*

32. The Human Development Index (HDI), a generally accepted measure of development based on economic and social indicators, is also affected by AIDS. In Namibia, for example, the HDI is predicted to fall 10 per cent by 2006 and in South Africa by 15 per cent before 2010 because of AIDS.

## **C. Economic impacts**

### *Economic growth*

33. Growing evidence suggests that AIDS is having a devastating effect on economic growth and incomes. According to the World Bank, had average national HIV prevalence in sub-Saharan Africa not reached 8.6 per cent in 1999, per capita income on that continent would have grown 1.1 per cent, nearly three times the actual growth rate of 0.4 per cent achieved during 1990-1997. In the case of a typical sub-Saharan African country with a prevalence rate of 20 per cent, overall GDP growth would be 2.6 per cent lower each year. At the end of 20 years, the economy would be two thirds smaller than it would otherwise have been.

### *Workers*

34. AIDS reduces the number of healthy workers, especially experienced workers in their most productive years. This raises dependency, diminishes human capital, and may cut productivity growth by as much as 50 per cent in the hardest hit countries.

### *Public sector*

35. In the public sector, AIDS reduces government revenues and puts severe strain on budgets as spending on health and social welfare mount. Scarce capacity is depleted, and the return on other public investments falls.

### *Governance*

36. Governance suffers as a result of the epidemic: HIV/AIDS has a disastrous impact on the capacity of Governments, especially on the delivery of basic social services. Human resources are lost, public revenues reduced and budgets diverted towards coping with the epidemic's impact. Similarly, the organizational survival of civil society institutions is under threat, with a corresponding impact on democracy.

### *Private sector*

37. In the private sector, firms face higher costs in training, insurance, benefits, absenteeism, medical costs, sick leave, funerals and pensions. At the same time, the average experience of their labour force falls, reducing accumulated knowledge within firms. The most seriously affected businesses are those that are labour-intensive, such as transport. Companies in Africa have already felt the impact of AIDS on their bottom line. One sugar estate in Kenya quantified the cost of HIV infection as 8,000 days of labour lost to illness in two years, a 50 per cent drop in processed sugar recovered from raw cane in four years, and a tenfold increase in health costs. The company estimated that more than three quarters of all illness was related to HIV infection.

### *Agriculture*

38. AIDS also threatens the basic livelihood of people living in developing countries, especially the poor. In many countries, agriculture provides a living for as much as 80 per cent of the population. As adults in rural areas fall ill, productivity drops off dramatically. Patterns of cropping shift from cash crops to subsistence farming, reducing household income and forcing the family to sell such assets as equipment or cattle to get by. Children may be withdrawn from school to help with work or tend to the sick, impairing their own development. In some areas, women dominate agricultural labour — up to 80 per cent —

and this requires a gender-sensitive response to HIV/AIDS.

#### **D. Impact on security**

39. The reverse in economic growth and development gains being experienced in some countries affected by AIDS is magnified by the fragility and complexity of geopolitical systems. The epidemic is present in a number of countries already facing conflict, food scarcity and poverty, and poses real threats to social and political stability where it is most concentrated — in Africa. The Security Council redefined security as an issue going well beyond the presence or absence of armed conflict, one which affects health and social services, family composition and social structure, economies and food security.

40. There is now broad acknowledgement that AIDS has become a global development crisis, potentially affecting national security in some countries. Armed conflict and associated population movements provide fertile ground for the spread of AIDS, while the epidemic itself can be seen as a risk factor in the breakdown of social cohesion and in social and political instability, in addition to a threat to security forces.

### **IV. Global, regional and national responses to AIDS**

#### **A. Global response**

41. Until recently, the response to AIDS lacked an essential element: political recognition and commitment at the highest global and national levels. Today, AIDS is on the world's global political agenda and is considered an issue of utmost urgency in nearly every country. Given the societal root causes, the breadth of impact of HIV and the continuing stigma it attracts, a purely medical or public health response is insufficient. Political leadership at the highest levels is needed to mobilize an effective multisectoral response.

##### *Joint United Nations Programme on HIV/AIDS*

42. In 1996, to mobilize the main United Nations agencies in a coordinated response and individually in their respective areas of work, the United Nations drew together six agencies — the United Nations Children's

Fund (UNICEF), the United Nations Development Programme (UNDP), the United Nations Population Fund (UNFPA), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization (WHO) and the World Bank — in a joint and co-sponsored programme, the Joint United Nations Programme on HIV/AIDS (UN/AIDS). A seventh, United Nations International Drug Control Programme (UNDCP), joined in 1999. The urgent need for concerted action on AIDS was further emphasized in April 2000, when the Administrative Committee on Coordination called on all United Nations agencies to engage in AIDS through policy development and resource allocation to HIV/AIDS activities, and developed measures designed to improve support to United Nations staff and dependants living with HIV or AIDS.

43. UNAIDS co-sponsors have made significant progress in mainstreaming HIV/AIDS into their programmes, and AIDS is now an institutional priority in the respective organizations (for individual co-sponsors' activities, see annex II). Collectively, UNAIDS co-sponsors and the UNAIDS secretariat have established a joint budget and work plan and are developing a United Nations system-wide strategic plan on HIV/AIDS. Cooperation with non-co-sponsoring United Nations organizations and agencies, including the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Office of the United Nations High Commissioner for Human Rights, the United Nations Development Fund for Women (UNIFEM) and the World Food Programme (WFP) is also expanding.

##### *Development agencies*

44. International development agencies have taken significant steps to elaborate comprehensive strategies on HIV/AIDS and to increase technical and financial resources for the fight against the epidemic. Most donor countries have also begun to mainstream AIDS into their overseas development cooperation programmes, and have developed global HIV/AIDS strategies as an integral part of their overall development assistance programmes.

##### *Non-profit foundations*

45. Non-profit foundations are increasingly in the forefront of the response. For example, the Bill and Melinda Gates Foundation has made large grants to

support AIDS prevention among youth and health-care work in several African countries. The United Nations Foundation (UNF) funds AIDS-related activities in a Southern Africa initiative and in Ukraine, and will expand efforts to support activities in India, South Asia and Central America in 2001. UNF has also funded several other projects that integrate AIDS work into broader projects on education, health and development. Support early on in the epidemic was provided by the Rockefeller Foundation.

#### *Civil society*

46. Civil society has led the way on some of the most sensitive issues, such as drug-related prevention, human rights promotion and protection of people living with HIV/AIDS. NGOs have made significant contributions to the development of appropriate models for community care and support. Along with several treatment action groups, they have initiated advocacy programmes and placed the issue of equitable and affordable access to care, treatment and support onto global and national agendas. Civil society groups are also key actors in regional and international partnerships, such as the International Partnership Against AIDS in Africa.

#### *Corporate sector*

47. The corporate sector has an important contribution to make, particularly in the regions of the world hardest hit by HIV/AIDS. Organizations involving and representing businesses, such as the Global Business Council on HIV/AIDS, are taking the lead in promoting the involvement of business in cross-sectoral partnerships with Governments and NGOs. Such companies as MTV, Standard Chartered Bank, Coca-Cola and Unilever are increasingly showing leadership in the partnership field.

48. As well as researching and developing new HIV drugs, multinational pharmaceutical companies have initiated corporate responsibility programmes to help support global responses to HIV/AIDS, including training of health-care professionals in developing countries and support for community-based organizations. As part of broader endeavours to improve access to HIV care, support and treatment in developing countries, five companies agreed in May 2000 to collaborate with the UNAIDS secretariat, WHO, UNICEF, the World Bank and UNFPA by reducing the prices of their medicines. This reflects an

increasing acceptance by the industry of tiered pricing of commodities and treatments (namely, significantly reduced pricing for developing countries), within a wider review of options for improving access to and the affordability of HIV-related commodities and services. The manufacture and distribution of generic drugs in line with international agreements and the provisions that they make provide further opportunities to widen access to care and treatment. However, much more needs to be done. All options for improving access to care should be pursued at the global and national level. Options at the country level would include support for strategic plans for care that address the needs of health and social systems, as well as equity issues and the use of public subsidies for commodities and medicines. Globally trade policy provisions need to be used more effectively to increase access to care. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with a guarantee of their quality. The relevance of compulsory licensing and the development of national manufacturing capacities need further expansion.

#### *Research and academic organizations*

49. With no cure for HIV/AIDS in sight, further research on effective prevention and care technologies — such as vaccines, microbicides and potent new treatments — remains crucial. International initiatives, such as those on vaccines development, including the International AIDS Vaccine Initiative and the African Vaccine Initiative, are becoming increasingly essential to the response. Academic research institutions from both the public and private sectors also have an important role to play. In addition, new technologies, innovative financing and delivery systems need to be developed so that access is as prompt and broad as possible.

### **B. Regional and national responses**

50. While global responses to AIDS are essential, regional and national responses are key elements in halting the spread of the epidemic, both in their own right and since regional responses facilitate support to national-level initiatives. The real success in the fight against HIV and AIDS will be fought or won at the national level.

### *United Nations theme groups on HIV/AIDS*

51. The principal avenue of United Nations support to national-level AIDS responses is provided by United Nations theme groups on HIV/AIDS, made up of co-sponsoring and other relevant agencies, bilateral donors, NGOs and representatives of the host country. Working through the United Nations resident coordinator system, theme groups — guided by national priorities and by Governments — support national efforts to curb the epidemic by working together on joint programme design and planning, monitoring and resource mobilization, while increasing their own HIV/AIDS activities.

### *Non-governmental organizations and community-based groups*

52. Civil society, especially non-governmental organizations and community-based groups at the national level, such as groups of people living with HIV/AIDS, have made critically important contributions to responses to HIV/AIDS. This has often been done with the support of international organizations, international networks of groups representing people living with HIV/AIDS, AIDS-specific NGOs and mainstream NGOs, ranging from faith-based groups to membership organizations and service groups, that go beyond a basic response to HIV/AIDS and address the development issues that fuel the epidemic.

### *Businesses*

53. Businesses — both large and small — can provide HIV prevention and related programmes in the workplace, including support for employees infected or affected by HIV. As well as participating in HIV/AIDS programmes in the local communities where they are based, businesses can be active in cross-sectoral partnerships with Governments and NGOs. The emergence of national business coalitions on HIV/AIDS helps to engage and support the response of local companies.

### *Africa*

54. African leaders are courageously breaking the silence surrounding the epidemic, publicly and repeatedly declaring AIDS a national emergency and establishing the institutions and mechanisms needed to respond swiftly to the spread of HIV.

55. While the epidemic in Africa continues to spread, there is well documented evidence of successes in the response to HIV/AIDS, particularly among young people. The epidemiological information coming from Zambia, Uganda and the United Republic of Tanzania is evidence of a new generation responding to the threat of HIV/AIDS by changing their behaviour in ways that appear to be protecting them from HIV. Infection rates among young women in Lusaka have been halved since 1993 through prevention efforts, which have also resulted in less premarital sex, increased male sexual abstinence and less frequent casual sex. In some parts of Uganda, the first African country to reverse its own epidemic, infection rates among teenage girls dropped dramatically during the 1990s, as did teen pregnancies. Successes have also been recorded in the Mbeya region of the United Republic of Tanzania, where prevention efforts have reduced HIV infection rates among pregnant women attending clinics by 25 per cent.

56. Partnerships are being established at several levels. The International Partnership Against AIDS in Africa (IPAA) is a coalition of United Nations agencies, donors and the private and community sectors, under the leadership of African countries, which is designed to intensify the response to AIDS across Africa. A number of partnerships are being established at national level, including a partnership forum in Tanzania and a local-level care and support initiative in South Africa's Gauteng province.

57. Strong national strategic responses are being forged through single, powerful national AIDS plans involving a wide range of actors — government, civil society, people infected with and affected by HIV, the private sector and donors. More than 30 countries in sub-Saharan Africa have completed strategic planning processes which have helped build consensus and mobilize resources, at times leading to successful round-table discussions with all interested parties and to significant funding commitments, as was the case in Malawi and Zambia in 2000. In many countries, high-level councils and national AIDS commissions have been created under the responsibility of the head of State to provide leadership for a true multisectoral response. Nevertheless, with some important exceptions, there has been insufficient engagement from social and economic sectors outside the health sector, which remains a key challenge for national responses.

58. Africa has demonstrated to the world the importance of local responses to HIV/AIDS, which aim to empower communities through local partnerships consisting of social groups,<sup>1</sup> service providers and facilitators. Initiatives are being implemented in Burkina Faso, Ghana, the United Republic of Tanzania and Zimbabwe, for example, with increasing involvement in the response of local leaders, such as mayors or traditional leaders.

59. Beyond Governments and development institutions, civil society — made up of NGOs, religious groups and the private sector — is intensifying its involvement in the response against HIV/AIDS. An increasing number of communities are mobilizing to face the multiple challenges of prevention and care, including denial, silence and the predominantly negative attitudes adopted towards people living with HIV/AIDS.

60. There is increasing evidence that businesses are recognizing the impact of HIV on the human, financial and social costs of their operations and host communities. They have responded in many different ways, from action to protect workforces to community outreach and philanthropy. In Zimbabwe, a workplace-based peer education programme in 20 companies resulted in 30 per cent fewer HIV infections than in 20 companies without a similar programme. In Côte d'Ivoire, the national electrical company has implemented prevention methods, improved medical monitoring of employees and increased participation by companies in employee health insurance schemes. Companies have also begun to collaborate through business coalitions on HIV/AIDS at the national level.

61. Children are especially vulnerable to the epidemic, and examples abound of responses to mobilize political will, reallocate national resources, bolster the capacity of families and communities to care for and support orphans, stimulate and strengthen community-based responses and ensure that Governments protect the most vulnerable children.

62. The vast majority of children living with HIV or who have already died of AIDS in Africa were born to HIV-infected mothers. The most vulnerable of populations, these children acquired the virus in the womb at about the time of childbirth or during breastfeeding. Making HIV counselling and testing services widely available so that infected women can decide whether to take preventive drugs during

pregnancy is a measure that could save the lives of hundreds of thousands of children. This technology, which has been demonstrated in pilot settings, has enormous potential to affect the epidemic. The challenge is to apply the technology on a large scale. The Uganda AIDS Information Centre, which has provided voluntary counselling and testing (VCT) to over 350,000 clients since 1990, is beginning to introduce same-day VCT services; previously, clients had to wait two weeks to receive their HIV test results, and 25-30 per cent did not return to get them.

63. The provision of HIV care is a major challenge for many African countries, where health services face dwindling resources and are already hard pressed to cope with a host of older diseases. The need to invest in prevention and essential services has, in the past, taken precedence. However, building on the strengths of local communities, grass-roots home-based care services have played a critical role in providing basic care for people living with HIV/AIDS. The feasibility of incorporating care into broader HIV public health programmes has been increasingly accepted, and many more African countries are developing national strategic plans, which include a strong care component, helped by wider discussions on options to improve the affordability of HIV-related commodities and treatments.

64. An enormous resource gap continues to exist, however, even though resources are being mobilized by African Governments and international donors. In South Africa, the nation's regular budget includes substantial allocations for AIDS prevention and care programmes. In Zimbabwe, the Government mobilized additional funds for AIDS by instituting an AIDS levy among the general population.

65. Additional — albeit insufficient — funds are also forthcoming through debt relief, and AIDS now figures prominently in funding activities for Africa. Through the heavily indebted poor countries initiative, some US\$ 30 billion in debt reduction had been achieved by the end of 2000, with specific funding set aside for AIDS representing US\$ 20 million in 2001. The World Bank is reviewing its portfolio in countries to retrofit unused funds into the fight against AIDS, and has created a multi-country AIDS project to make more funds available to the HIV/AIDS response. AIDS is a priority among United Nations agencies and major multilateral and bilateral partners in sub-Saharan

Africa, many of whom are mainstreaming AIDS into all their sectoral interventions.

66. Funds are also made available through round-table mechanisms, which bring together all interested parties at the country level to mobilize funds for implementation of the strategic plan. Some US\$ 121 million in Malawi was recently made available in this way, with support from the United Nations system and international donors, and an additional US\$ 113 million in Zambia.

### Asia and the Pacific

67. Success is also evident in Asia, and includes Thailand's community-based care models and its successful 100 per cent condom programme model, now being tested in Cambodia; peer outreach projects with sex workers in Calcutta, Kerala and Dhaka; projects with injecting drug users in Nepal, India and Malaysia; and the enactment of supportive national AIDS legislation in the Philippines. While diversity and Asia's huge population exacerbate the difficulties of mounting timely and effective responses, opportunities abound in a region where overall HIV prevalence is still low but where the incidence of new infections is rising. The opportunity cost of failing to act vigorously and urgently could be enormous.

68. In South Asia, the problem of underdevelopment inevitably constrains the response to HIV/AIDS. The growing gap between rich and poor, the huge numbers of rural poor, and the systematic underfunding of health and other social sector spending provide a challenging backdrop for the response to HIV/AIDS.

69. Despite Asia's diversity, the region faces some common challenges. One challenge is to act "upstream" to prevent or minimize new infections rather than reacting "downstream" to the impact of AIDS. This means vigorous prevention activity among those most at risk — the millions of migrant workers and the many thousands of refugees. It means addressing large-scale sex-related activities, including the trafficking of girls and women. It also means tackling human development issues of particular significance to Asia, such as gender inequalities. It also requires dealing with taboo and ensuring widespread information and services are available to all, especially young people.

70. Another challenge lies in confronting the pervasive exclusion and stigmatization that afflict

people living with HIV, especially in low-prevalence situations, an issue highlighted at the last regional conference on AIDS in Asia and the Pacific, held in Kuala Lumpur in October 1999. A further challenge is to adapt and apply lessons learned from successful or effective pilot projects and to step up the response. This is now being attempted among sex workers and drug users through the Kathmandu Valley Initiative in Nepal and in Tamil Nadu in India, where the AIDS prevention and control project to promote safer sex behaviours among vulnerable groups is being expanded.

71. Recent positive developments in facing up to these challenges include increased political activity. The Asian Forum of Parliamentarians on Population and Development brought together political leaders from 11 South-East and East Asian and Pacific countries last year, enhancing their personal commitment to HIV/AIDS prevention and care programmes. Member States of the Association of Southeast Asian Nations (ASEAN) have included AIDS on the agenda of their November 2001 summit in Brunei.

72. There is also growing recognition of the need for a broad-based response involving different sectors and for innovative partnerships, especially between the public and private sectors. For example, the involvement of Rotary and Lions Clubs and of business coalitions in the response to AIDS in Thailand is being reflected in similar partnerships in India, the Philippines and Bangladesh. Uniformed and armed forces are increasingly involved in prevention programmes, notably in Cambodia and India, as well as in Viet Nam, the Lao People's Democratic Republic and China. Religious leaders and groups have become more prominent in the AIDS response.

### Eastern Europe and Central Asia

73. Despite an explosive spread of HIV in several countries in the region, the epidemic is still in its early stages and confined mainly to injecting drug users and their partners. High levels of injecting drug use and sexually transmitted infections, coupled with socio-economic turmoil and a rapid rise in sexually transmitted infections after the breakdown of the Soviet Union, could lead in a few years to larger scale and more generalized epidemics. A unique opportunity still exists for effective targeted interventions, particularly among injecting drug users.

74. However, recent political and legal reforms in some countries are opening more effective avenues to HIV prevention. Ukraine and Belarus, for example, now have multisectoral committees at the highest political levels, and have removed legal barriers to needle exchange programmes, substitution treatment and other approaches to HIV prevention among injecting drug users.

75. Further evidence of a mobilizing response comes from national strategic plans that are in various stages of development in 13 countries. Joint action to support and strengthen national responses to HIV/AIDS now focuses on three regional strategic priorities: expanded coverage of HIV prevention, targeting injecting drug users; prevention and control of sexually transmitted infections; and meeting the needs of vulnerable young people. Mechanisms have also been established to improve coordination between regional support and national responses.

76. A range of initiatives supports the response to HIV/AIDS in the Russian Federation, including projects on HIV prevention among injecting drug users, strategic planning processes in 17 regions, and a joint response initiative launched recently by the United Nations theme groups on HIV/AIDS. However, there is still an urgent need to step up advocacy, social mobilization and effective use of existing resources, and to dismantle barriers, such as lack of political commitment and supportive legislative environments and lack of financial resources. Substantial support from the international community is imperative if the critical transition from short-term project activities to long-term sustainable and expanded national programmes is to be made.

77. A number of regional initiatives also help support the response to HIV/AIDS. The Baltic Sea initiative marks the start of a wide process of consultation on strategic priorities, including a Baltic Sea action plan on HIV/AIDS. In parallel, several Governments in the region and Western Europe have established a task force on communicable diseases in the Baltic Sea region to recommend joint actions. An initiative in Central Asia is seeking to reinforce collaboration among countries and agencies to develop a joint strategic framework and action plan.

78. Notwithstanding a growing number of local and national initiatives, the response remains uneven and insufficient. The development of effective, sustainable

national responses has been constrained by insufficient high-level political leadership, a climate of economic hardship, stigmas concerning sexual behaviour and injecting drug use, and legal barriers.

### Latin America and the Caribbean

79. Prevention efforts in parts of Latin America have met with considerable success: mortality and AIDS incidence are falling, while care is increasingly widespread throughout the region. For example, according to a 1999 survey in Brazil, prevention campaigns have increased condom use during first sexual contact from 4 per cent 15 years ago to 48 per cent today — and up to 70 per cent among certain groups, such as students from more privileged socio-economic backgrounds. Targeting prevention programmes towards men who have sex with men continues to be a major challenge, however.

80. While in some countries treatment of basic health needs, such as opportunistic infections, is problematic, other countries have responded to demands from groups of patients, doctors and human rights organizations to provide access to antiretroviral drugs. With a rights-based approach to care, together with local production of generic antiretrovirals in some countries, coverage of patients is increasing in Brazil, Argentina, Chile and Uruguay, where HIV-positive people are living longer, healthier lives. Since the introduction of antiretrovirals, reported AIDS deaths in Brazil have dropped more than 25 per cent.

81. Providing AIDS drugs has also been at the centre of rapidly emerging South-South cooperation, a strategy anchored in the understanding that partners sharing knowledge become more powerful and effective. At present, 19 Latin American and Caribbean countries are involved in the Horizontal Technical Cooperation Group on AIDS, a key instrument in fighting the spread of AIDS. Brazil has also championed technical exchange with other countries in the region, as well as with lusophone Africa, integrating the benefits of South-South cooperation into its response.

82. The Forum 2000 conference on AIDS held in Rio de Janeiro in November 2000 demonstrated the extent of regional cooperation and the strong role of non-governmental organizations in the response of the region, as well as a continuing need to expand programmes targeting men who have sex with men.

While homosexual transmission constitutes 40 per cent of transmission in Latin America, less than 1 per cent of AIDS programme budgets goes to prevention for men who have sex with men, with the exception of Brazil, which devotes significant resources to this area.

83. In the Southern Cone of Latin America, an important aspect of the epidemic is HIV transmission through injecting drug use. A subregional initiative to address this issue and to intensify the policy dialogue is currently under way.

84. In the Caribbean, ministries of health have long been aware of the escalating epidemic and its implications for the region, but a series of high-level meetings during 2000 ushered in a new level of public awareness and visibility for AIDS. HIV/AIDS has emerged as an urgent development priority, and a regional strategic plan of action was developed by the Caribbean Task Force on HIV/AIDS, chaired by the Caribbean Community (CARICOM), which brings together a wide range of members from national Governments, international and regional institutions, NGOs and donors. The newly established Pan-Caribbean Partnership illustrates the increasing commitment of Caribbean Governments to address HIV/AIDS, and has led to new resource commitments by the World Bank and the European Commission.

85. In Central America, vulnerable mobile populations are the main focus for regional action programmes being developed with the support of the National Institute of Public Health in Mexico, with Proyecto Acción SIDA de Centroamérica and with the Regional Initiative for HIV/AIDS and other projects for the prevention and control of sexually transmitted diseases in Latin America and the Caribbean. National strategic AIDS plans are under implementation in all Central American countries. Central America is also emerging as a region where the epidemic is increasing its pace and where greater attention needs to be placed on directing responses to priority areas, such as the epidemic among men who have sex with men.

#### High-income countries

86. In high-income countries, HIV infections are concentrated principally among injecting drug users and men who have sex with men, although transmission through heterosexual sex is on the rise. Prevalence in the total population remains low. While some communities and countries have acted

aggressively to limit HIV infection among injecting drug users, other countries have not. Needle exchange and other prevention programmes have been effective where implemented, but often the political costs of these programmes have been considered too high for implementation on a large scale. Among men who have sex with men, prevention programmes are more widely accepted and implemented, and as a result risk behaviour and the resulting HIV infection rate has dropped significantly since the mid-1980s. However, there is some recent evidence that risk behaviours may again be on the rise in some communities. There is a strong need for continued support for increased preventive efforts among men who have sex with men.

### V. Key lessons learned and elements of a successful response

87. Twenty years of fighting the AIDS epidemic have resulted in a growing understanding of what constitutes effective action. Truly effective action is underpinned by the principles set and the lessons learned from the current global and national-level responses.

88. Fundamental principles guiding a successful response to HIV/AIDS are:

- That gender inequalities fuelling the epidemic must be explicitly addressed;
- That prevention methods, life-saving treatments and the results of scientific breakthroughs in prevention and care must be made broadly available on an equitable and affordable basis to all;
- That people living with and affected by HIV/AIDS must be actively engaged and supported in their efforts to address the epidemic in communities around the world;
- That national Governments, working with civil society, must provide the leadership and means required to ensure that national and international efforts respond to country and community needs.

#### Successful responses are linked to a respect for human rights

89. A number of human rights concerns exist and must be addressed in order to combat stigma and eliminate discrimination based on HIV status. In

addition to discrimination against people infected with HIV, other important issues include the right to health care, the right to information and other social and economic rights contained in United Nations human rights conventions and the Universal Declaration of Human Rights. The international guidelines on HIV/AIDS and human rights are key to a response based on human rights, and Governments should continue their efforts to implement them.

#### **Success has been demonstrated in addressing the epidemic**

90. Collective experience with HIV/AIDS has evolved to the point where it is now possible to state with confidence that it is technically, politically and financially feasible to contain HIV/AIDS and dramatically reduce its spread and impact. The first two decades of the epidemic have generated unprecedented learning and mobilization throughout the world. HIV, the virus that causes AIDS, has been definitively established and sufficient knowledge is available about its modes of transmission to substantially slow its spread.

91. The most important lesson learned from countries that have successfully responded to the epidemic has been the critical role of government and civil society leadership in increasing the visibility of the epidemic while decreasing the stigma associated with it. In an increasing number of countries, partnerships between Governments and civil society have begun to bring together Governments, the international community and interested activists: people living with HIV/AIDS, NGOs, community-based organizations, religious and academic institutions and the private sector.

#### **A greater epidemic can be prevented**

92. Vigorous measures taken now to reduce the rate of HIV infections will pay substantial dividends in years to come in countries with high or low prevalence. Large-scale prevention programmes in virtually all settings have clearly demonstrated that the spread of HIV can be reduced, especially among young people. Prevention programmes have also been successful among hard-to-reach populations, particularly in harm reduction among injecting drug users. In Asia, Australia, Europe, Latin America and the Caribbean, North America and sub-Saharan Africa, there is strong evidence of the decline of HIV incidence in

populations with access to effective prevention programmes.

#### **Capacity and commitment to act have increased**

93. There has been tangible progress in assembling the essential political, policy and technical experience required to mount a global response equal to the scale of the epidemic. Responses with strong political support across all planning and social sectors are increasing. Financial resources are now being made available at increased rates within affected countries, from bilateral and multilateral development agencies and the commercial and foundation sectors and through debt-relief efforts. In addition, new communications capabilities, such as the Internet, are enabling partners to interact and access information at a pace unimagined even a decade ago.

#### **National plans involving multiple actors have been developed**

94. The basic lesson learned for any national AIDS plan is that interventions to reduce HIV risk and change behaviour are effective when a range of government ministries and partners in the social, economic and health sectors are involved in providing an enabling environment for large-scale prevention, care and support programmes. Single, isolated activities do not yield sustained results. Effective programmes require focused action and steadily expanding coverage. The importance of involving the target population as well as people living with HIV/AIDS in the design and implementation of interventions cannot be stressed enough.

#### **Prevention works**

95. Intensive information and education programmes are essential to reduce the risk of sexual transmission in the general population and to help promote safer sexual behaviour, for example through abstinence, fidelity and condom use. The social marketing of both male and female condoms increases their accessibility, although condoms will need to become available on a much larger scale in many countries. Comprehensive (and targeted) interventions should respond specifically to the needs of young people before they become sexually active.

96. One particularly effective intervention is the prevention of mother-to-child transmission. A short

one-month course of antiretroviral treatment given to HIV-infected mothers late in pregnancy can cut the rate of transmission to children by 20-50 per cent. Pilot projects target limited numbers of women and their unborn infants but have a huge potential for expansion. Voluntary HIV counselling and testing, at present available only to a tiny proportion of sub-Saharan African men and women, serves as a critical entry point for HIV care and prevention, with huge potential for accelerating the response.

#### **A comprehensive approach to HIV/AIDS care and treatment is essential**

97. The care and treatment of people living with HIV/AIDS represents one of the greatest challenges in the years to come. To meet it, a comprehensive approach to care must be adopted. This includes more effective support to home- and community-based care, as well as equitable access to medical treatment, including drugs for opportunistic infections and antiretroviral therapy.

98. In industrialized countries, advances in the management of opportunistic infections and the development of antiretroviral "combination" therapy for HIV infection itself have transformed the lives of people with HIV/AIDS. Increasingly, HIV/AIDS is being managed as a chronic condition, and new treatments have helped to improve people's health and enables them to continue normal lives within their communities. However, combination therapy is not a cure for HIV/AIDS and its long-term effects are not clear. Further research into new drugs and therapeutic approaches remains critical.

99. While medical care in high-income countries is significantly extending the lives of people living with HIV, the challenge now is to improve access to care in developing countries, where 95 per cent of the world's 36.1 million HIV-infected people live. Some countries, such as Brazil, have developed effective programmes that implement a comprehensive approach to care, ranging from voluntary counselling and testing, psycho-social support and good nutrition to the strengthening of health systems to ensure access to the prevention and treatment of opportunistic infections, such as tuberculosis and antiretroviral therapy. Although these programmes are not yet available to all that need them, they provide an important model for expansion. With international support, more developing countries are developing strategic plans that place

access to care at the heart of their national responses to HIV/AIDS. Experience with home-based and community care is now rapidly developing as an essential component of HIV care and treatment, particularly in Africa.

100. As well as the need to strengthen health-care systems, we must address the affordability of medicines for opportunistic infections and antiretroviral therapy, which remains one of the greatest barriers to improving access to care. Some progress towards reducing the price of medicines has been made through partnership with several research and development-based pharmaceutical companies and through the increasing availability of generic versions of antiretroviral drugs. Despite these efforts, much more needs to be done if access to care and treatment is not to remain out of reach for the majority of people living with HIV and AIDS.

101. All the options for improving access to care at the global, regional and national levels need to be explored, taking into account the close relationships between pricing, financing, trade policy and health-care systems. At the country level, strategic plans for care need to be developed that address health and social systems, equity issues and the use to which public subsidies will be put. We need to find ways of more effectively using trade policy provisions, such as compulsory licensing or parallel importation, to increase access to care. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with guarantees of their quality. Other approaches, including tiered pricing, improved global and regional procurement policies and new funding mechanisms, also need to be explored.

#### **Successful responses have their roots in communities**

102. Effective community-centred efforts have generally been both empowering, strengthening a community's capacity to make decisions, and enabling, assisting them in mobilizing the resources required to act on those decisions. Community leaders who are properly informed are better able to assess the reality of HIV/AIDS within their particular community and to analyse the determining factors of risk and vulnerability affecting them. On this basis, local actors can better address those determining factors and their

consequences and determine their priorities for action accordingly.

103. Successful strategies addressing HIV/AIDS at the community level require the development of partnerships to mobilize local responses and access national resources. These partnerships, comprised of key social groups, government service providers, NGOs, people living with HIV/AIDS, community-based groups and religious organizations, serve to strengthen the awareness and capacity of the various stakeholders. HIV-positive women's collectives in many parts of the world have demonstrated effective community counselling and prevention interventions.

#### **Empowering young people is essential**

104. An effective response involves a special focus on the needs of young people. Sexually active adolescents will require special family planning information counselling and health services, as well as treatment for sexually transmitted diseases and HIV/AIDS prevention. Governments, at the highest political levels, should take urgent action to provide education and services to prevent the transmission of all forms of sexually transmitted diseases and HIV. Governments should enact legislation and adopt measures to ensure non-discrimination against people living with HIV/AIDS and vulnerable populations, including women and young people, so that they are not denied the information needed to prevent further transmission and are able to access treatment and care services without fear of stigmatization, discrimination or violence.

#### **People living with HIV/AIDS are central to the response**

105. A renewed effort to combat stigma is needed. Effectively addressing stigma removes what still stands as a roadblock to concerted action, whether at the local, community, national or global level. Combating stigma is a human rights imperative on its own, as well as of instrumental value in fighting denial and shame, major obstacles in opening dialogue about HIV/AIDS. One of the best ways of combating denial is to give AIDS a "human face" through what is called the greater involvement of people living with HIV/AIDS, a principle formally launched at the Paris AIDS Summit on 1 December 1994. People who live with or are directly affected by HIV/AIDS bring personal experience to planning and carrying out a response to

the epidemic, challenging complacency and denial, strengthening the call for urgency in the response, and moving Governments and their leaders to action.

#### **Epidemic must be tackled on several fronts**

106. Although the complexity of the epidemic has far exceeded all expectations, we have come to recognize that there is a relationship between the basic dynamics of the epidemic and that an effective response needs to tackle three things. HIV infection is associated with specific **risks**, made up of behaviours and situations that might promote the transmission of HIV, with **vulnerability**, those factors that make it more likely that some individuals become infected rather than others, such as migrant populations or poor women, and with **impact**, the consequences of the epidemic for individuals and communities.

107. Experience has demonstrated that it is not possible to sustain a long-term and effective response to the epidemic unless each of these strands — risk, vulnerability and impact — are addressed. It is through respecting the relationship between these three dynamics — which are different for men and women — that a truly effective response can be engineered. In particular:

- Decreasing the risk of infection slows the epidemic;
- Decreasing vulnerability decreases the risk of infection and the impact of the epidemic;
- Decreasing the impact of the epidemic decreases vulnerability to HIV/AIDS.

#### **Effective response varies in different settings**

108. Different settings require a different focus and a different balance between these three elements. National strategic planning processes have stimulated central and local governments, NGOs, communities and international partners in many countries to define strategies that are tailored to the different contexts within which HIV/AIDS evolves. Regional and subregional strategies have complemented and added value to national responses. Settings with low prevalence but increasing incidence and those with high prevalence of HIV both require urgent priority. Strategy development within each setting will need to reflect its particular opportunities and constraints.

## VI. Challenges for an expanded response: the way forward

109. Action by Governments should focus on the following seven critical challenges for the present response:

- The challenge of effective leadership and coordination;
- The challenge of alleviating the social and economic impact of the epidemic;
- The challenge of reducing the vulnerability of particular social groups to HIV infection;
- The challenge of achieving agreed targets for the prevention of HIV infection;
- The challenge of ensuring that care and support is available to people infected and affected by HIV/AIDS;
- The challenge of developing relevant and effective international public goods;
- The challenge to mobilize the necessary level of financial resources.

110. In responding to the HIV/AIDS epidemic, the special session of the General Assembly on HIV/AIDS provides a unique opportunity to set out a global agenda and create consensus around a set of core commitments. These are described in greater detail in a conference room paper that will be issued to complement the present report.

### Leadership and coordination

111. The AIDS epidemic has been described as a crisis of governance and a crisis of leadership. Leadership is fundamental to an effective response. One of the key issues facing the global community is the development and sustenance of such dedicated leadership, which is vital if the nature of the epidemic is to be clearly understood throughout society and a national response mobilized. Such an understanding is essential in order to avoid stigma, secure the full commitment, involvement and accountability of all sectors, and avoid fragmentation of efforts.

112. Only through a society-wide commitment, within a framework established by strong political leadership that involves community-led interventions as well as civil society and effective partnerships with the private

sector, can a response emerge that is consistent with the scale of the epidemic.

### Alleviating the social and economic impact

113. The broad spread of the impact underlines the need for a broad multisectoral response that addresses both institutional capacity and human resources. In many countries, the epidemic has substantially undermined the capacity of the key social and economic sectors in society. The negative impact of HIV/AIDS is evident in the labour force, the education sector, the health sector and agriculture, to name but a few. Economic performance in all its dimensions is affected. Each sector needs support in order to become a stronger partner in the coordinated response to the epidemic. Assistance for poverty alleviation, infrastructure development, and education- and health-sector development needs to take into account the sectoral impact of the epidemic.

### Reducing vulnerability

114. Responding to the epidemic therefore requires effective measures to support risk reduction and reduce social and economic vulnerability. Social, economic and political intervention strategies that systematically promote social inclusion and greater participation, by extending access to information and essential services and supportive legal and social norms, can serve to reduce vulnerability and help overcome the impact of the epidemic.

### Prevention

115. An expanded prevention effort is vital to containing the spread of the epidemic and to restraining the costs of responding to it.

116. A focus on prevention is essential to significantly reduce the spread of the epidemic and the current impact. A focus on youth is needed to reduce impact in the future. Over 30 per cent of people currently living with HIV/AIDS are young people aged under 25. Targets for prevention encompass preventive methods, such as expansion of health and sex education, increased supply of female and male condoms and other commodities, expanded provisions for preventing mother-to-child transmission, measures aimed at prevention among injecting drug users, and greater access to voluntary counselling and testing.

### Care and support

117. Preventing HIV infection is inseparable from care and support for those affected by HIV/AIDS. Prevention of infection and amelioration of the impact of the epidemic go hand in hand.

118. Governments must commit themselves to ensuring health care and support to those infected and affected by HIV/AIDS. The challenge is to provide a broad approach which includes adequate care for individuals, households and communities affected by HIV/AIDS; ensuring access to voluntary counselling and testing and the continuum of affordable clinical and home-based care and treatment; essential legal, education and social services; psycho-social support and counselling; and care for children orphaned by HIV/AIDS. The capacity of health systems and social services to deliver the required interventions must be ensured.

119. Through advances in the management of opportunistic infections and the development of effective antiretroviral therapies, the treatment of HIV has reduced its social and economic impact. Access to these treatments is uneven, however, and people in developing countries are dying needlessly for lack of appropriate care. Continuing inequities in access to effective care and treatment must be specifically addressed through all possible means, including tiered pricing, competition between suppliers, regional procurement, licensing agreements and the effective use of the health safeguards in trade agreements.

### International public goods

120. A focus of international research and development should be to produce microbicides and vaccines for HIV/AIDS. Either by using current knowledge more effectively or focusing on key unresolved problems, global and national players should act in partnership to ensure that priority is given to researching and developing new HIV medicines and to making them accessible and affordable. Efforts should also be made to develop and market female-controlled contraceptives.

### Resources

121. The primary challenge for Governments is to mobilize resources to meet the scale and devastating impact of the HIV/AIDS epidemic. Greatly increased resources are needed to expand the national capacity to

respond to the epidemic; to support essential infrastructure and training; to mitigate the social and economic impacts; to expand successful prevention interventions; and to implement a broad care agenda, including access to drugs. One important way of ensuring that national budgets are reallocated towards HIV prevention is to make sure that HIV/AIDS priorities are properly integrated into the mainstream of development planning, including poverty reduction strategies, public investment plans and annual budget processes. Increased investment from donors, domestic budgets and private companies and foundations will need to be added to additional funds released through debt relief to meet global resource needs.

122. Thus, meeting the challenges of HIV/AIDS requires a combination of approaches: strengthening leadership, alleviating the social and economic impacts of the epidemic, reducing vulnerability, intensifying prevention, increasing care and support, providing international public goods and scaling up resources.

123. HIV/AIDS is the most formidable development challenge of our time. The General Assembly, in calling for a special session on HIV/AIDS, has recognized this, and at the special session will aim to secure a global commitment for intensified and coordinated action at the global and national levels.

## Annex I

### Goals set by global conferences and their follow-up processes

**Twenty-first special session of the General Assembly, on the overall review and appraisal of the Programme of Action of the International Conference on Population and Development, New York, 30 June-2 July 1999**

A new benchmark indicator to measure the reduction of HIV infection levels in young people was agreed at the special session, as follows:

"Governments, with assistance from UNAIDS and donors, should, by 2005, ensure that at least 90 per cent, and by 2010 at least 95 per cent, of young men and women aged 15 to 24 have access to the information, education and services necessary to develop the life skills required to reduce their vulnerability to HIV infection. Services should include access to preventive methods, such as female and male condoms, voluntary testing, counselling and follow-up. Governments should use, as a benchmark indicator, HIV infection rates in persons 15 to 24 years of age, with the goal of ensuring that by 2005 prevalence in this age group is reduced globally, and by 25 per cent in the most affected countries, and that by 2010 prevalence in this age group is reduced globally by 25 per cent." (General Assembly resolution S-21/2, annex, para. 70).

**International Labour Conference, Geneva, 30 May-15 June 2000**

The Conference called on Governments to raise national awareness particularly of the world of work, with a view to eliminating stigma and discrimination attached to HIV/AIDS, as well as to fight the culture of denial, thereby preventing the spread of HIV/AIDS, and to formulate and implement social and labour policies and programmes that might mitigate the effects of AIDS.

**Twenty-third special session of the General Assembly, entitled "Women 2000: gender equality, development and peace for the twenty-first century", New York, 5-9 June 2000**

At its twenty-third special session, the General Assembly identified HIV/AIDS as a priority concern from the health and gender equality perspectives.

In the further actions and initiatives to implement the Beijing Declaration and Platform for Action (resolution S/23-3, annex), the General Assembly placed a strong emphasis on the gender aspects of HIV/AIDS and STIs and other health problems. Noting their disproportionate impact on women's and girls' health, it called for action at the national and international levels to encourage, through the media and other means, a high awareness of the harmful effects of certain traditional or customary practices affecting the health of women, some of which increase their vulnerability to HIV/AIDS and other sexually transmitted infections, and intensify efforts to eliminate such practices (see resolution S-23/3, annex, para. 98 (d)). It also called for the intensification of community-based strategies to protect women of all ages from HIV and other sexually transmitted diseases and to provide gender-sensitive care and support to infected girls, women and their families (see resolution S-23/3, annex, para. 103 (b) and (c)).

With respect to AIDS orphans, the General Assembly called for action to assist boys and girls orphaned as a result of the HIV/AIDS pandemic (see resolution S-23/3, annex, para. 103 (c)).

**Twenty-fourth special session of the General Assembly, entitled "World Summit for Social Development and beyond: achieving social development for all in a globalizing world", Geneva, 26-30 June 2000**

Governments were urged to make greater commitments to act on social and economic factors that bear on vulnerability to HIV infection. In addition to the improvement of health-care services and personnel capacities, the provision of basic welfare and psychosocial support to those affected by HIV/AIDS and intensified education programmes, particularly for

young people, were highlighted as key elements for national response. In the Copenhagen Declaration, adopted by the Summit in 1995, the international community committed itself to strengthening national efforts to address more effectively the growing HIV/AIDS pandemic by providing necessary education and prevention services, working to ensure that appropriate care and support services are available and accessible to those affected by HIV/AIDS, and taking all necessary steps to eliminate every form of discrimination against and isolation of those living with HIV/AIDS,<sup>4</sup> a commitment that remains valid.

**Millennium Summit of the United Nations, on  
the theme "The role of the United Nations in  
the twenty-first century", New York,  
6-8 September 2000**

In paragraph 19 of the Millennium Declaration (resolution 55/2), the General Assembly stated the commitment of the international community to have by 2015 halted and begun to reverse the spread of HIV/AIDS, the scourge of malaria and other major diseases that afflict humanity, and to provide special assistance to children orphaned by HIV/AIDS. In paragraph 28 of the Declaration, the Assembly resolved to help Africa build up its capacity to tackle the spread of the HIV/AIDS pandemic and other infectious diseases.

*Notes*

<sup>4</sup> See *Report of the World Summit for Social Development, Copenhagen, 6-12 March 1995* (United Nations publication, Sales No. E.96.IV.8), chap. I, resolution 1, annex I, commitment 6 (q).

## Annex II

### United Nations system response

1. The purpose of the present annex is to give a brief summary of responses on HIV/AIDS under way or anticipated by United Nations system organizations and agencies.

#### United Nations Children's Fund

2. UNICEF has set the following programme priorities:

(a) To ensure that all young people know the facts about HIV and how to prevent it. This includes programmes for injecting-drug users, on the control of sexually transmitted infections (STIs) and youth life skills, and on lifestyle promotion;

(b) To support efforts to expand access to services to prevent parent-to-child transmission of HIV, which includes clearer guidance on the use of antiretroviral therapy and infant feeding in the context of prevention of mother-to-child transmission (PMTCT) projects, access to voluntary counselling and testing, and the reduction of stigma and discrimination for women living with HIV;

(c) To provide care and support by strengthening programming for orphans and vulnerable children infected/affected by AIDS and by expanding life skills training for young people. In this context, UNICEF is positioning schools as the hub in every community in the struggle against AIDS. It is working with ministries of education to dedicate time and attention to the introduction of life skills into the curricula and learning of young children. It is also negotiating with the private sector for low-cost supply of essential HIV/AIDS-related drugs;

(d) To protect young people and women from HIV in situations of conflict and emergency;

(e) To support UNICEF staff members affected by HIV/AIDS, which includes a core set of services for UNICEF staff and dependants.

UNICEF has integrated the above-mentioned priorities in all its programming at the country level and globally. It is in the process of stepping up its response in the key areas of prevention of mother-to-child transmission and care and support for children infected/affected by HIV. It is also paying particular attention to the new

flashpoints for the pandemic: the Commonwealth of Independent States/Baltic countries, South Asia and the Caribbean, besides its ongoing work in Africa and South-East Asia.

#### United Nations Development Programme

3. HIV/AIDS is one of UNDP's main corporate priorities. The role of UNDP is to help countries address the governance challenge of the epidemic, focusing on four areas of intervention:

(a) Promoting robust and action-oriented advocacy for leadership at all levels, political commitment and the mobilization of actors and institutions well beyond the health sectors;

(b) Helping countries to develop capacity for action and to plan, manage and implement their response to the epidemic, including the integration of HIV/AIDS into poverty reductions strategies, and the reallocation of resources (including debt relief savings) towards prevention, care and impact mitigation;

(c) Promoting a human rights framework and gender perspective in all aspects of the response;

(d) Providing special assistance to the worst affected countries to help mitigate the impact on human development, establish governance structures and provide essential services. As coordinator of United Nations system activities at the country level, UNDP also plays a pivotal role in ensuring a coherent and mutually reinforcing response by UNAIDS co-sponsors, bilateral donors and private foundations, through the United Nations theme groups on HIV/AIDS and the United Nations Development Assistance Framework (UNDAF).

#### United Nations Population Fund

4. The UNFPA contribution to combating HIV/AIDS derives from its long experience and expertise in negotiating and ensuring access to family planning services globally, a precedent in enabling UNFPA to address sensitive issues with national counterparts, including Governments. Since the International Conference on Population and Development (ICPD), held in Cairo in 1994, by

ensuring access to reproductive health services and programming for female and male condoms, working through its extensive network of field offices and technical experts in the country support team, UNFPA has been at the forefront of prevention activity and programming.

5. Within the UNFPA policy framework, prevention of STIs, including HIV, continues to be an integral component of reproductive health. At the country level, UNFPA works closely with United Nations partners, international agencies and national counterparts to provide assistance for STI and HIV/AIDS prevention. Such support includes advocacy, education and information for the promotion of safe sexual behaviour, including voluntary counselling and testing; improving access to and use of condoms; training of reproductive health-care providers on HIV prevention in relation to family planning, antenatal and safe delivery practices; and research on the integration of HIV prevention into reproductive health programmes and sociodemographic consequences of the epidemic. Meeting the needs of youth and adolescents forms a special focus of UNFPA support at all programming levels — national, regional and global. Adolescents need the knowledge and life skills to make responsible decisions and positive choices in life. UNFPA is contributing towards this through support in many countries for the development of educational curricula, by including information on reproductive health in general and HIV/AIDS in particular, gender issues, sexuality and family life; improving access to information, counselling and clinical services; promoting greater participation of youth and advocacy efforts, both for girls and boys — based on the key messages of ICPD and its five-year review.

#### **United Nations Educational, Scientific and Cultural Organization**

6. UNESCO efforts focus on education, basic research, social and human sciences, human rights, public information and awareness activities. Its priorities are to develop and improve educational strategies to support young people in adopting attitudes and behaviour to prevent HIV infection, particularly among schoolgirls; undertake studies on the impact of AIDS on education and programmes for orphans and children living in poverty; mobilize decision makers on educational policies; undertake primary prevention of drug use among young people; strengthen actions so

that HIV-affected groups can benefit from research efforts and means of prevention; promote the transfer of knowledge/scientific research for affordable treatment; develop a sociocultural approach to HIV/AIDS prevention and care; and integrate new preventive behaviours in the messages and training of sociocultural educators and journalists.

#### **United Nations Drug Control Programme**

7. UNDCP objectives related to HIV/AIDS are to prevent the spread of the epidemic linked to the abuse of drugs; undertake community outreach projects; develop legislation; and integrate demand reduction efforts into broader social welfare and health promotion policies. UNDCP has supported the development of projects in five Central Asian countries to strengthen their capacity in policy formulation, planning and management of HIV/AIDS and sexually transmitted diseases (STDs) and drug abuse prevention; a subregional project in the southern cone of Latin America promotes common methods and standards to conduct epidemiological surveillance. UNDCP is participating in the regional response to the problems created by the spread of the abuse of amphetamine-type stimulants and HIV/AIDS in Central and Eastern Europe, and in collaboration with other United Nations agencies has developed country projects to assist Governments in coordinating and managing HIV/AIDS, STDs and drug abuse prevention and care activities. In East Asia, the development and implementation of policies and programmes for a community-based response to support demand reduction and prevent the spread of HIV through drug injection is also a priority.

#### **World Health Organization**

8. WHO is intensifying its support for Member States' efforts and is doing so within the context of the wider multisectoral response to HIV, reflecting the overarching importance of good sexual and reproductive health. The priorities for intensified action now include support for countries' efforts to prevent and manage sexually transmitted infections; provide voluntary counselling and testing through health services; implement and monitor interventions to prevent mother-to-child transmission of HIV; ensure care and support for people living with HIV/AIDS; and implement other cost-effective interventions, as relevant to specific settings. Particular attention is paid

to the interests of populations who are at high risk or are especially vulnerable, including sex workers and injecting drug users. WHO continues to recognize the importance of meeting the particular needs of young people, and gives special attention to relieving the impact of HIV/AIDS on health systems (including the particular HIV infection risks experienced by health workers). Thus, WHO priorities include supporting and coordinating high-quality research on HIV/AIDS, providing technical support for programme development, implementation, monitoring and evaluation, and surveillance of HIV infection and its behavioural determinants. In some cases, support is provided through links with programmes on reproductive health, essential drugs, disease surveillance, the provision of health information, vaccine development, blood safety or substance use.

9. WHO has strengthened its normative functions and the technical capabilities of WHO regional and country teams. Regional and country offices are focusing particular attention on strengthening the health sector responses to the epidemic, and have prime responsibility within the United Nations system for issues related to care and support of people living with HIV/AIDS and for the availability of prevention and treatment for sexually transmitted infections. WHO regional offices are recruiting specialists to act as focal points for specific areas of work, including voluntary counselling and testing, prevention of mother-to-child transmission and other essential components of HIV/AIDS work; the coordination of HIV activities within health systems; and surveillance (with an emphasis on behavioural issues). Additional qualified staff, including national programme officers, are to be placed in countries. Subregional technical teams are being established to provide direct support to countries and facilitate the management of regional technical networks.

10. WHO is also developing a global health-sector strategy for responding to the epidemics of HIV/AIDS and sexually transmitted infections as part of the United Nations system's strategic plan for HIV/AIDS for 2001-2005, as requested by the World Health Assembly in its resolution WHA53.14. The process includes wide consultation with Governments, non-governmental organizations, WHO regional offices and country representatives, collaborating centres and experts. The global strategy proposes three main tactics: reducing the risks of HIV infection; decreasing

people's vulnerability to HIV infection; and lessening the epidemic's overall impact on people's lives and on development.

#### World Bank

11. The World Bank has made HIV/AIDS a top institutional priority, both for analysis and action. The Bank placed HIV/AIDS at the centre of the global development agenda during the April 2000 meetings of world finance ministers, detailing the severe threat the epidemic poses to development around the world. It has expanded the economic analysis of the impact of AIDS, and in connection with the UNAIDS secretariat has produced detailed estimates of the costs of mounting comprehensive national HIV/AIDS programmes. It has taken a leading role in initiatives to help bring an HIV vaccine to market in the developing world, and is one of the UNAIDS co-sponsors involved in the accelerating access initiative to make antiretroviral drugs more accessible in poor countries.

12. The Bank has also increased its support for HIV/AIDS programmes. In September 2000, it launched the first phase of the multi-country AIDS programme for Africa. Prepared in collaboration with UNAIDS, the International Partnership Against AIDS in Africa, key bilateral donors and leading NGOs, the programme is designed not only to increase resources for HIV/AIDS but also to address the key impediments to an expanded response, such as slow implementation and inadequate support to communities. The first phase of the programme has made \$500 million in credits available to countries in Africa to step up national prevention, care and treatment programmes, and to help them prepare to cope with the impact of AIDS. Programme resources may be used to support initiatives by government, civil society, the private sector and communities; special mechanisms have been designed to ensure funds flow quickly to community level. The Bank is now preparing a similar initiative for the Caribbean, and is also supporting major HIV/AIDS projects in several other countries, including Brazil, China and India.

#### International Labour Organization

13. The focus of the ILO is on the development of workplace policies and the implementation of a global technical cooperation programme on HIV/AIDS and the world of work. At the global level, an effort is being made to apply ILO concepts and methods

developed on labour and social issues to respond to HIV/AIDS. An international code of practice on HIV/AIDS and the world of work is expected to be adopted in May 2001 to provide legal and practical guidance on developing workplace policies, especially towards protecting fundamental rights at work. Programme priorities include the application of a "social vaccine" for prevention and protection, such as social inclusion and income and job security; strengthening activities against the virus through improved knowledge; documenting and disseminating information through effective labour market information systems; eliminating the stigmatization and discrimination attached to HIV/AIDS by adopting and applying ILO international labour standards; integrating HIV/AIDS in existing social security schemes and developing new ones. Initially, action by the ILO has mainly focused on Africa and the implementation of an African platform of action on HIV/AIDS; in addition, ILO global programmes now include country-level activities in Asia and the Pacific, Eastern and Central Europe, and Latin America and the Caribbean. Key activities carried out in the context of the global programme focus on promoting awareness and developing strategies concerning the impact of HIV/AIDS on the world of work, and documenting and disseminating information on national experience; incorporating workplace policies into national action plans against HIV/AIDS; integrating HIV/AIDS issues into all ILO programmes at the national and enterprise levels, particularly with respect to combating discrimination and social exclusion; and mitigating the adverse social and labour consequences of HIV/AIDS.

#### **Food and Agriculture Organization of the United Nations**

14. In response to the HIV epidemic, FAO contributes its technical expertise in sustainable agriculture and rural development, and is developing strategies through which the agricultural sector can address HIV/AIDS. With UNAIDS, FAO will undertake integrated prevention programmes that will help spread information, especially to young men and women, about HIV vulnerability, risk reduction and sustainable rural development. It is exploring ways of assisting farming communities in rural areas with high HIV prevalence, and of developing agriculture programmes that modify mobility patterns to reduce the vulnerability of migrants to HIV infection and develop strategies that focus on prevention.

#### **Office of the United Nations High Commissioner for Human Rights**

15. The objective of the Office in the area of HIV/AIDS is to contribute to an effective and sustainable human rights-based response to the epidemic at the national, regional and international levels through enhancing the integration of HIV/AIDS issues within the human rights machinery. It advocated the inclusion of HIV/AIDS on the agenda of the Commission on Human Rights and its Subcommission; has widely distributed the international guidelines on HIV/AIDS and human rights to States, United Nations agencies and NGOs; and has contributed to increasing political support for HIV/AIDS initiatives through the adoption of Commission on Human Rights resolutions on HIV/AIDS and human rights. Programme priorities include strengthening the respect of human rights as part of the response to the epidemic, reducing HIV/AIDS-related discrimination at work and elsewhere by engaging persons infected and affected in promotion, protection and respecting human rights within prevention, control and care programmes. The Office will advocate for the implementation of HIV/AIDS-related rights of populations vulnerable to HIV/AIDS so that the vulnerability of these populations to human rights violations and exposure to HIV is reduced. Together with UNAIDS, it will continue to organize training sessions on human rights in the context of HIV for experts within the United Nations human rights system and other relevant partners, such as Governments and NGOs.

#### **Office of the United Nations High Commissioner for Refugees**

16. UNHCR programme priorities addressing HIV/AIDS include the strengthening of the STI and HIV/AIDS prevention and care component of reproductive health programmes in refugee settings, as well as capacity-building of UNHCR staff and partners in the design and implementation of HIV/AIDS prevention and care activities. It also disseminates information (i.e., best practice packages and guidelines) and advocacy on HIV/AIDS prevention and care needs of refugees through international, regional and national forums. UNHCR priority geographic regions are the Great Lakes Region and West Africa.

### **United Nations Research Institute for Social Development**

17. Recognizing the undeniable importance of the HIV/AIDS epidemic affecting the world today, the Institute prepared an issues paper on HIV/AIDS and development at the invitation of the UNAIDS secretariat during 2000. During this period, UNRISD began to form a network of well-known researchers (social scientists, activists and medical specialists) with an interest in further work on HIV/AIDS. The Institute's goal in this field is to generate new knowledge about the course and consequences of the epidemic, as well as new ideas on how to strengthen the capacity of particular societies to deal with HIV/AIDS.

### **United Nations Volunteers**

18. The main focus of UNV in the area of HIV/AIDS is the strengthening of local initiatives for prevention and control of the epidemic through community-oriented, participatory involvement. UNV also strives to alleviate the devastating socio-economic effects of the pandemic by disseminating HIV/AIDS information and by providing training and general health care. Together with the UNAIDS secretariat and UNDP, it has launched a pilot project, unique in the United Nations system, by engaging people living with HIV/AIDS as national United Nations volunteers to work in their own communities. The project helps to set up women support groups for orphans of HIV/AIDS and their foster parents; provides technical assistance so that local communities can produce their own publications on HIV/AIDS; and trains co-workers to manage HIV laboratory operations. UNV programme priorities and targets include building government and community capacity in relation to information, education and communication skills for HIV prevention; providing loans to sex workers; and training community caregivers for orphans in Africa and Asia and the Pacific, its priority geographic regions.

### **World Food Programme**

19. WFP is working towards incorporating HIV/AIDS concerns into all of its programmes, both development and emergencies. WFP concentrates on using food aid as a way to improve the food security of HIV/AIDS-affected families and orphans. In collaboration with its partners, WFP will also

incorporate information, education and communication activities at its distribution sites through community partners, such as relief committees.

20. At the headquarters level, WFP is developing a strategy and guidelines to integrate HIV/AIDS into all existing and new programmes. At the field level, WFP will programme mitigation activities, including school feeding with take-home rations for families with orphans; food rations for tuberculosis patients undergoing therapy; and vocational/agricultural training for street children and orphans. Current pilot interventions also include using WFP's extensive logistics network to support HIV/AIDS education and risk-reduction activities for contracted transport workers.

### **United Nations Development Fund for Women**

21. The reality that the epidemic is fuelled in a major way by gender relations and gender inequality has led UNIFEM to expand its work on gender, human rights and HIV/AIDS. The organization's three priority areas — strengthening women's economic rights, engendering governance and leadership, and promoting women's rights — are all essential strategies in this effort. In keeping with its mandate to be catalytic, innovative and to support inter-agency mechanisms for mainstreaming gender, the UNIFEM programme for action on gender and HIV/AIDS will include work on advocacy, brokering partnerships and capacity-building.

22. UNIFEM has recently completed the first phase of a global programme, "Gender focused responses to the challenges of the HIV/AIDS epidemic", which was funded in large part by UNAIDS and UNFPA. The programme, which is currently going into phase II, was designed to link policy, research and outreach strategies on gender and HIV/AIDS in order to build bridges of support, advocacy and activism at the national and regional levels.

### **United Nations Industrial Development Organization**

23. UNIDO aims to contribute to the reversal of the devastating impact of HIV/AIDS on rural and urban livelihoods. Within the framework of the UNIDO integrated programmes being implemented in several countries, major initiatives have been taken to mobilize the private sector/business community, including

women entrepreneur groups, to support HIV/AIDS-specific activities, focusing on awareness creation, prevention and survival. In response to the spread of HIV/AIDS in Africa and in accordance with the development objective of supporting the developing countries in their efforts to accelerate socio-economic development, UNIDO will address the issue of HIV/AIDS at the global forum level and with appropriate technical assistance programmes, preferably with the support of the international private sector, especially those with interests in Africa. It is proposed to undertake action-oriented studies on the impact of HIV/AIDS on the private sector, including enterprise-level surveys, with a view to defining realistic strategies and mainstreaming HIV/AIDS awareness and "business against AIDS" prevention campaigns into the UNIDO network of industrial support institutions and enterprises. In addition, technical assistance programmes will focus on building capacities and capabilities for the production of AIDS-related health products, including support to plant-derived pharmaceutical research and pilot programmes in southern Africa and elsewhere.

#### **Resident coordinator system**

24. The resident coordinator system is responsible for the UNDAF process in which the United Nations Theme Groups play a critical role. The theme groups on HIV/AIDS are platforms for bringing the United Nations together in support of the countries affected by HIV/AIDS. They are mainly responsible for coordination, advocacy and partnership building, joint policy and strategic decision-making and integrated planning, and in some instances have played a key role, together with UNAIDS, in resource mobilization for country-based United Nations initiatives. Within the resident coordinator system, the theme groups on HIV/AIDS have been among the earliest established to lead and support an expanded multisectoral response to the HIV/AIDS epidemic.

25. The theme groups on HIV/AIDS have been expanded to facilitate dialogue and networking between partners, thereby strengthening support to the national response. Membership has been expanded to include Governments, civil society groups, NGO AIDS consortia and bilateral donors. People living with HIV/AIDS have also become members.

26. The theme groups on HIV/AIDS have been actively engaged in the UNDAF process, first through

the common country assessment process and then in UNDAF, which is based on the common country assessment, and subsequently in the elaboration of individual agencies' country programmes as well as joint programmes and projects. They have also been linked with a number of other key instruments of development cooperation, employed by the United Nations system and other partners.

#### **United Nations Secretariat**

27. The Division for Economic and Social Council Support and Coordination, in its coordinating capacity, acts as the focal point for the United Nations Secretariat on HIV/AIDS. The Division for Social Policy and Development is undertaking a study on families in the most HIV/AIDS-affected countries, and HIV/AIDS will be a topic in one of the working groups of the World Youth Forum, to be held from 5 to 12 August 2001 in Senegal. The Population Division includes HIV/AIDS in official United Nations population estimates and projections to enable the assessment of the epidemic. In order to contribute to further understanding of the issue of the increasing proportion of women living with AIDS in every region, especially in sub-Saharan Africa and among younger age groups, the Division for the Advancement of Women, in collaboration with WHO and UNAIDS, convened an Expert Group meeting on the HIV/AIDS pandemic and its gender implications in Namibia in November 2000. The Commission on the Status of Women repeatedly discusses women and HIV/AIDS, including when it reviews the critical area of concern "Women and health". The increasing proportion of women living with HIV/AIDS was raised in Commission resolution 44/22 on women, the girl child and HIV/AIDS. The Department of Peacekeeping Operations cooperates with the Civil Military Alliance to Combat HIV and AIDS, developing training programmes and educational materials for military and other personnel assigned to United Nations peacekeeping operations. HIV/AIDS is becoming part of the meeting agendas of the regional commissions, and the Economic Commission for Africa convened the Second African Development Forum in December 2000, on the theme "AIDS: the greatest leadership challenge". The results of the Forum will serve as a valuable input to the preparatory process for the special session of the General Assembly on HIV/AIDS. The Department of Public Information raises public awareness on the epidemic and its effects through

radio, television and printed matter. The United Nations Medical Service ensures that United Nations policies on HIV/AIDS for staff members and peacekeepers are implemented. It provides proper health education, training and measures for personal protection, thereby offering an effective AIDS prevention programme.

#### **World Intellectual Property Organization**

28. WIPO addresses the issue on patents for pharmaceutical products for the treatment of HIV/AIDS within the context of the Trade-Related Intellectual Property Rights agreement. It provides legislative advice, human resources and infrastructure development for tailoring solutions to the needs of a country to implement international obligations and ensuring access to health care.

#### **United Nations Relief and Works Agency for Palestine Refugees in the Near East**

29. UNRWA's current priorities concerning HIV/AIDS include the education of vulnerable groups, such as youth at school, vocational training centres and women's programme centres, as well as surveillance of STDs and HIV/AIDS. This is carried out by training health staff on counselling for epidemic prevention and control, and the production of educational kits for school teachers and students. UNRWA is represented in the national AIDS committees in the host countries and areas of Jordan, the Syrian Arab Republic, Lebanon and Palestine.

#### **World Tourism Organization**

30. WTO is an intergovernmental organization that serves as a global forum for tourism policy and issues. It addresses HIV/AIDS issues in the context of its mandate through its international campaign against organized sex tourism, specifically against child sex.

#### **Joint United Nations Programme on HIV/AIDS**

31. The Joint United Nations Programme on HIV/AIDS is the leading advocate for global action on HIV/AIDS. It brings together seven United Nations bodies in a common effort to fight the epidemic: UNICEF, UNDP, UNFPA, UNDCP, UNESCO, WHO and the World Bank. UNAIDS both mobilizes the responses to the epidemic of its seven co-sponsoring bodies and supplements these efforts with special

initiatives. The areas of focus of the UNAIDS secretariat are to sustain and build political momentum; improve support to country-level resource mobilization and national coordination, ensuring a well-coordinated United Nations response; accelerate access to HIV care, noting the inseparability of prevention and care, with attention to equity and affordability; and leverage technical support and knowledge management.

**17**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE  
UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

111 84  
 541  
 542  
 843

## Ten recommendations to improve use of medicines in developing countries

RO LAING,<sup>1</sup> HV HOGERZEIL<sup>2</sup> AND D ROSS-DEGNAN<sup>3</sup>

<sup>1</sup>Boston University School of Public Health, Boston, USA, <sup>2</sup>World Health Organization Action Programme on Essential Drugs, Geneva, Switzerland and <sup>3</sup>Harvard Medical School and Harvard Pilgrim Health Care, Boston, USA

Inappropriate prescribing reduces the quality of medical care and leads to a waste of resources. To address these problems, a variety of educational and administrative approaches to improve prescribing have been tried. This article reviews the experiences of the last decade in order to identify which interventions have proven effective in developing countries, and suggests a range of policy options for health planners and managers.

Considering the magnitude of resources that are wasted on inappropriately used drugs, many promising interventions are relatively inexpensive. Simple methods are available to monitor drug use in a standardized way and to identify inefficiencies. Intervention approaches that have proved effective in some settings are: standard treatment guidelines; essential drugs lists; pharmacy and therapeutics committees; problem-based basic professional training; and targeted in-service training of health workers. Some other interventions, such as training of drug sellers, education based on group processes and public education, need further testing, but should be supported. Several simplistic approaches have proven ineffective, such as disseminating prescribing information or clinical guidelines in written form only. Two issues that will require a long-term strategic approach are improving prescribing in the private sector and monitoring the impacts of health sector reform.

Sufficient evidence is now available to persuade policy-makers that it is possible to promote rational drug use. If such effective strategies are followed, the quality of health care can be improved and drug expenditures reduced.

### Introduction

This paper reviews the current state of knowledge about the effectiveness of strategies to improve the use of medicines in developing countries, and suggests what policy-makers and health system managers can do to accomplish this objective. In some areas, clear evidence about effectiveness already exists; in others, evidence is lacking, and advice is presented on the basis of the best available knowledge.

The World Health Organization (WHO) recommends that activities to strengthen the pharmaceutical sector be organized under the umbrella of a national drug policy.<sup>1</sup> In many countries, a national essential drugs programme is the mechanism for implementing such a policy, usually with emphasis on drug selection, procurement, distribution and use in the public sector. This paper suggests policy options specifically related to encouraging more appropriate use of medicines. On the basis of existing evidence it should be possible to refine the components of essential drugs programmes in this area. In addition, although government officials have greater power in the public sector, they can also take certain measures to encourage more appropriate drug use in the private sector.

### Summary of developments of the last 15 years

The 1985 Nairobi conference on the rational use of drugs marked the start of a global effort to promote rational prescribing.<sup>2</sup> In 1989 an overview of the subject concluded that very few interventions to promote rational drug use had been properly tested in developing countries.<sup>3</sup> Since then, the WHO Action Programme on Essential Drugs (WHO/DAP), the International Network for the Rational Use of Drugs (INRUD) and other organizations have collaborated in an international research effort to fill the knowledge gap.<sup>4,5</sup> Emphasis has been put on developing operational tools and studying the effect of different interventions through research networks, training and support to researchers in developing countries.

The first concrete results of this collaboration were a set of simple indicators for measuring the quality of drug use at health facilities,<sup>6</sup> and a WHO training manual on the principles of rational prescribing.<sup>7</sup> Annual international training courses on promoting rational use of drugs and on the teaching of problem-based pharmacotherapy have been held since 1989. In 1995, the International Conference on National Medicinal Drug Policies in Sydney, Australia, recognized

111 8.4  
841  
542  
843

## Ten recommendations to improve use of medicines in developing countries

RO LAING,<sup>1</sup> HV HOGERZEIL<sup>2</sup> AND D ROSS-DEGNAN<sup>3</sup>

<sup>1</sup>Boston University School of Public Health, Boston, USA, <sup>2</sup>World Health Organization Action Programme on Essential Drugs, Geneva, Switzerland and <sup>3</sup>Harvard Medical School and Harvard Pilgrim Health Care, Boston, USA

Inappropriate prescribing reduces the quality of medical care and leads to a waste of resources. To address these problems, a variety of educational and administrative approaches to improve prescribing have been tried. This article reviews the experiences of the last decade in order to identify which interventions have proven effective in developing countries, and suggests a range of policy options for health planners and managers.

Considering the magnitude of resources that are wasted on inappropriately used drugs, many promising interventions are relatively inexpensive. Simple methods are available to monitor drug use in a standardized way and to identify inefficiencies. Intervention approaches that have proved effective in some settings are: standard treatment guidelines; essential drugs lists; pharmacy and therapeutics committees; problem-based basic professional training; and targeted in-service training of health workers. Some other interventions, such as training of drug sellers, education based on group processes and public education, need further testing, but should be supported. Several simplistic approaches have proven ineffective, such as disseminating prescribing information or clinical guidelines in written form only. Two issues that will require a long-term strategic approach are improving prescribing in the private sector and monitoring the impacts of health sector reform.

Sufficient evidence is now available to persuade policy-makers that it is possible to promote rational drug use. If such effective strategies are followed, the quality of health care can be improved and drug expenditures reduced.

### Introduction

This paper reviews the current state of knowledge about the effectiveness of strategies to improve the use of medicines in developing countries, and suggests what policy-makers and health system managers can do to accomplish this objective. In some areas, clear evidence about effectiveness already exists; in others, evidence is lacking, and advice is presented on the basis of the best available knowledge.

The World Health Organization (WHO) recommends that activities to strengthen the pharmaceutical sector be organized under the umbrella of a national drug policy.<sup>1</sup> In many countries, a national essential drugs programme is the mechanism for implementing such a policy, usually with emphasis on drug selection, procurement, distribution and use in the public sector. This paper suggests policy options specifically related to encouraging more appropriate use of medicines. On the basis of existing evidence it should be possible to refine the components of essential drugs programmes in this area. In addition, although government officials have greater power in the public sector, they can also take certain measures to encourage more appropriate drug use in the private sector.

### Summary of developments of the last 15 years

The 1985 Nairobi conference on the rational use of drugs marked the start of a global effort to promote rational prescribing.<sup>2</sup> In 1989 an overview of the subject concluded that very few interventions to promote rational drug use had been properly tested in developing countries.<sup>3</sup> Since then, the WHO Action Programme on Essential Drugs (WHO/DAP), the International Network for the Rational Use of Drugs (INRUD) and other organizations have collaborated in an international research effort to fill the knowledge gap.<sup>4,5</sup> Emphasis has been put on developing operational tools and studying the effect of different interventions through research networks, training and support to researchers in developing countries.

The first concrete results of this collaboration were a set of simple indicators for measuring the quality of drug use at health facilities,<sup>6</sup> and a WHO training manual on the principles of rational prescribing.<sup>7</sup> Annual international training courses on promoting rational use of drugs and on the teaching of problem-based pharmacotherapy have been held since 1989. In 1995, the International Conference on National Medicinal Drug Policies in Sydney, Australia, recognized

quality use of medicines as one of the four pillars of effective national drug policy, and concluded that consumer movements play an important role in promoting rational drug use and should be supported.<sup>8</sup> In 1997, the International Conference on Improving the Use of Medicines in Chiang Mai, Thailand, was the first global scientific conference purely devoted to strategies for improving drug use in developing countries. At this conference, the available scientific evidence was critically reviewed in order to identify the most effective intervention approaches, and to identify the current gaps in experience in this area. Many of the conclusions of this paper are based on material presented and discussed at the Chiang Mai conference.<sup>9</sup> In particular, several comprehensive reviews of published and unpublished reports were undertaken for this meeting.<sup>10-13</sup>

During the last decade many industrialized countries have developed policies similar to those underlying essential drugs programmes in developing countries. For example, in Australia, the Pharmaceutical Benefit Scheme (which covers 85% of all drug use in the country) applies very strict criteria, including comparative cost-effectiveness, for the reimbursement of drugs.<sup>14,15</sup> In the US, many managed care organizations operate on the basis of clinical guidelines, recommended formularies, and generic substitution.<sup>16,17</sup> In the UK, practice formularies and budget-holding are increasingly common.<sup>18-20</sup> The US also mandates drug utilization review programmes and pharmacist counselling to improve drug use in the publicly-funded Medicaid programme.<sup>21,22</sup> In Scotland, a collaborative network of the Ministry of Health and professional bodies develops national evidence-based clinical guidelines, with the primary objective of improving the quality of care, not necessarily reducing cost.<sup>23</sup> These examples suggest that there is a global interest in programmes to improve use of medicines, and that many approaches are possible.

### Assessing patterns of use and defining problems

Before activities are started to promote rational drug use an effort should be made to describe and quantify the problem. Several well-established survey methods are available for this purpose. Probably the simplest method is an 'ABC' analysis of drugs procured to identify high-cost examples of inefficient drug use.<sup>24</sup> For example, in Yemen it was found that the top ranked drug import in terms of total cost was injectable lincomycin.<sup>25</sup> In one study in Indonesia injectable tetracycline was responsible for the second highest drug expense.<sup>26</sup> Such procurement analysis can be done at provincial, district or facility level. More refined analyses can compare the relation between morbidity statistics of certain diseases and the observed consumption of relevant drugs, or compare the consumption of alternative treatments within a certain therapeutic category, such as antidepressants or cephalosporin antibiotics.

Another assessment method is a prescribing and patient care survey, using the WHO health facility drug-use indicators.<sup>6,27</sup> These quantitative indicators are now widely accepted as a global standard for problem identification and have been used in over 30 developing countries. The indicators can also

be used to make comparisons between regions or countries, to measure the impact of interventions, and for supervision purposes. An indicator-based assessment can be followed by more detailed studies on individual drugs or specific diseases. The WHO indicators record exactly *what* is prescribed, dispensed and communicated to patients, but not *why*. For this latter aspect other techniques are needed. A simple manual of applied qualitative methods, such as focus-group discussions and structured interviews, is available from INRUD.<sup>28</sup> There are similar standard methods for investigating drug use in communities.<sup>29</sup>

Countries and institutions will benefit from regular drug-use surveys, using simple indicators. A time-series of such surveys is extremely useful to monitor performance towards set targets, and can also serve as a baseline for planned interventions. The best example of a series of biennial national drug-use surveys is from Zimbabwe.<sup>30</sup> In Indonesia monthly self-monitoring with basic rational drug-use indicators in individual health centres and at district level has proved very effective to improve drug use.<sup>31</sup>

### Recommended approaches

Several activities have proved very useful and effective in promoting rational drug use, and should now be recommended for general use. These are: standard treatment guidelines; essential drug lists; drug and therapeutic committees; problem-based basic training in pharmacotherapy; and targeted continuing education. However, when these activities are being implemented, care is necessary to ensure success. In the following section the best available advice is summarized for each of these interventions to maximize their effectiveness.

#### (1) Establish procedures for developing, disseminating, utilizing and revising national (or hospital-specific) standard treatment guidelines

Whether they are called standard treatment guidelines (STGs), clinical policies, treatment protocols or best-practice guidelines, structured approaches to diagnosis and therapy have considerable potential to promote rational drug use.<sup>32</sup> Guidelines vary in complexity from simple algorithms to detailed protocols that include diagnostic criteria, investigations needed, patient advice, and cost information. The success of guidelines in changing practice seems to depend on many factors, including: the complexity of the targeted practice; the credibility of the group developing the guidelines; involvement of end-users in the development process; the format of the resulting guidelines; and, most importantly, how they are disseminated.<sup>33</sup> In a number of settings where STGs have been developed by an expert committee and simply sent out to health workers, no impact has occurred.

Improving the use of medicines through STGs requires both initial work and continuous effort. It is now generally accepted that STGs in developing countries should be developed for each level of care, based on the prevalent morbidities and the competency of available prescribers (physician, nurse, medical assistant, community worker). Substantial involvement and

consultation of end-users helps to ensure the practicality of diagnostic and treatment recommendations, and the acceptability of guideline content and format.<sup>34</sup> As far as possible, the selection of treatments should be evidence-based and take into account local economic realities.<sup>35</sup>

When completed, the STGs should be introduced through an official launch combined with an intensive training programme. Supervision and further training should reinforce their use. In a study from Uganda by Kafuko and others, provision of STGs alone was compared with facilities receiving either training alone or training plus supervision.<sup>36</sup> Statistically significant improvements were obtained for reducing the number of drugs prescribed, injection use and increasing generic drug use. Compliance with recommended guidelines was significantly improved for malaria and diarrhoea. Improvements in consultation and dispensing times and in adequacy of drug labelling were also observed. When the two intervention groups were compared, improvements were somewhat greater in the combined (training and supervision) group, though this was not always statistically significant.

To be realistic, STGs must be time-limited and open for regular revision. STGs will gain greater acceptance if the focus is put on improving the quality of care, rather than simply reducing cost. National STG manuals should be consistent with treatment guidelines issued by national disease programmes, such as malaria, diarrhoea, tuberculosis and sexually transmitted diseases control. The first edition of the STGs should be reviewed after 1 year, as there are usually errors, omissions or ambiguities; after that, the revision interval can be 2–3 years. Once they are finalized, STGs should be used for pre-service training and examinations; in-service training; as a basis for supervision and audit; and for developing a list of essential drugs.

## **(2) Establish procedures for developing and revising an essential drug list (or hospital formulary) based on treatments of choice**

In most settings an Essential Drug List (EDL) is a very important component of an essential drugs programme.<sup>4</sup> In the past, an EDL was typically drawn up by selecting drugs from existing stock lists or formularies. However, it is now generally recommended that the selection of drugs be based on a list of common conditions and complaints and the treatments of choice for these conditions as defined in STGs.<sup>34</sup> Thus, the EDL is a natural result of the national STGs. The drugs included in the treatment guidelines for a certain level of health care will constitute the EDL for that level. Ideally, the two should be developed together, as was done in Kenya.<sup>37</sup> The recommended criteria for the selection of essential drugs are published elsewhere.<sup>38</sup> To prevent conflicts of interest, manufacturers should not be involved in the decision-making process of defining an EDL.

Many national EDLs now indicate the level of use for each drug, e.g. dispensary, health centre, general hospital, or referral hospital.<sup>39</sup> Like STGs, the leveled EDL should be revised frequently. The EDL can be used as the basis for procurement and distribution of drugs, and for developing a national

formulary. It can also be used to identify product areas for selective support to the national pharmaceutical industry, for targeted quality assurance, or as a basis for insurance reimbursement. Simply producing and distributing an EDL has been shown to have no effect.<sup>40</sup> As with clinical guidelines, EDLs must be actively implemented.

Implementing an EDL or formulary in referral hospitals is sometimes perceived as an unnecessary restriction on specialists' freedom to prescribe. Some of these perceptions can be overcome by developing supplementary STGs and EDLs for defined specialist departments (e.g. the oncology guidelines in Zimbabwe).<sup>41,42</sup> Flexibility can also be increased by reserving a certain percentage of the hospital drug budget for non-formulary items. However, a budgetary set-aside invites misuse and should be monitored carefully.

## **(3) Require hospitals to establish representative Pharmacy and Therapeutics Committees with defined responsibilities for monitoring and promoting quality use of medicines**

The beneficial effect of hospital Pharmacy and Therapeutics Committees (PTCs) in monitoring and promoting quality use of medicines and containing costs in hospital and other institutional settings has been generally accepted in developed countries.<sup>43</sup> Unfortunately, there has been little critical evaluation of the clinical or economic impacts of this approach in developing countries. Despite the lack of evidence from developing countries, we nevertheless recommend that PTCs should be established in each referral hospital, and probably in all general hospitals. This action will require both policy direction and institutional support.

Two essential tasks of a PTC are to develop and revise institutional STGs (usually adapted from national guidelines), and to maintain an institutional EDL or formulary.<sup>44,45</sup> The PTC can also perform drug utilization reviews, using drug consumption data or simple prescription surveys, and establish systems for audit of patient records, peer-review and continuing education. Antibiotic utilization and infection control are two cross-cutting topics that can serve as a focus for PTC activities.<sup>46</sup> While computerized databases may not exist in developing countries, hospital clinical and pharmacy records can be manually reviewed for audit and feedback. Operations research is needed in both public and private hospitals in developing countries to determine how PTCs can function most effectively.

If PTCs do not exist in a country, the Ministry of Health should require that they be established, at least in large hospitals. Materials to assist the committees in their initial phase may need to be developed. Publication in national journals of the results of establishing PTCs and of the success of specific approaches may help other committees to get started.

## **(4) Implement problem-based training in pharmacotherapy in undergraduate medical and paramedical education based on national STGs**

The quality of basic training in pharmacotherapy can have an impact on prescribing in the long term by helping to establish

good habits and inoculating students against future negative influences on their prescribing. Rational pharmacotherapy teaching should be linked both to national STGs and to the essential drugs list. National STGs should therefore be developed in close collaboration with senior staff of medical and paramedical teaching institutions and be used in basic curricula. All pharmacology teaching should be based on generic names. Copies of the EDL and STG manuals should be freely available to all students.

There are proven strategies to improve the quality of pharmacotherapy teaching. Probably the most important is to develop teaching objectives based on the knowledge, skills and attitudes required by students in their future professional life. These teaching objectives should be detailed, published and used for teaching, for examinations and even for staff appraisals. In most settings, the amount of basic science should be drastically reduced, and classroom lecturing should be restricted to those subjects where the transfer of knowledge is essential. Instead, problem-solving skills should be promoted and interdisciplinary problem-based learning encouraged. Examinations should reflect the teaching approach: this may imply the need to replace written examinations with continuing and skill-based assessments.

The WHO *Guide to good prescribing*<sup>7</sup> is a practical manual for medical students on the principles of rational prescribing. The manual is intended to support problem-based learning, and its positive impact on prescribing skills has been demonstrated in a randomized controlled trial.<sup>47</sup> Students from the groups receiving the training performed significantly better than controls in the seven medical schools included in the trial. The students learned how to apply their skills for problems covered in the teaching as well as new problems. The improvement was demonstrated to last for at least 6 months after the training session in all of the medical schools. Two-week practical training courses in this approach intended for university lecturers and clinical teachers are offered annually in the Netherlands, Japan and South Africa. The manual is currently being adapted for training other professions, such as pharmacists in Uganda and nurses in Indonesia and South Africa. A teacher's guide is under development.

Nowhere is an integrated approach so important (and its absence so dramatic) as in the clinical phase of the undergraduate medical training: in these few years most future prescribing habits are acquired. Pharmacotherapy teaching in the clinical phase should be objective-based, problem-based (with a focus on common conditions), interdisciplinary (both for teachers and students) and constantly referring to national or hospital STGs and EDLs.

Within nursing curricula, a problem may exist around the issue of teaching nurses to prescribe. In large hospitals nurses carry out the prescribing instructions of doctors. However, in many countries, nurses are posted to rural health facilities where they diagnose and prescribe as well as manage the drug supply of the facility. Obviously, nurses in these settings should be trained to do this work. Training of pharmacists in public health aspects of their profession and public health students in drug issues may also be beneficial.

If there is no existing focus on problem-based training in pharmaco-therapeutics, national consultative workshops may help to build awareness of the value of the approach. These would ideally bring together local medical educators with others who use this new approach from the region. Such workshops have been successfully used in Indonesia and in the Philippines. If there is no focus on public health pharmacy in schools of pharmacy, regional consultative meetings can also be used to expose pharmacy teachers to these ideas: such regional meetings were held recently in Zimbabwe and Lebanon.<sup>48</sup>

**(5) Encourage targeted, problem-based in-service educational programmes by professional societies, universities and the Ministry of Health, and require regular continuing education for licensure of health professionals**

In most developing countries, few options exist for regular in-service education of health professionals. Furthermore, doctors, paramedics and pharmacists have little incentive to participate in continuing education programmes, since their licensure rarely depends on such participation. The only well-established source of information about drugs and therapeutics is the pharmaceutical industry, whose primary motivation is the promotion of specific products rather than improvement in the quality of care. It is necessary to revise regulations for professional licensing to require regular participation in unbiased educational activities, as is done in many industrialized countries.

One strategy to which many countries devote resources and staff time is the production of printed bulletins and pharmaceutical newsletters. As an isolated activity this approach has failed universally though it may play a role as part of face-to-face education.<sup>49</sup>

Many countries have experience in organizing specific training programmes to improve the use of medicines, particularly in the public sector.<sup>49</sup> These programmes are frequently organized by the national essential drugs programme, by vertical disease control programmes, or within the context of donor-funded projects. There is a need to evaluate the success of different approaches, and to establish coordinated, ongoing quality improvement programmes as a routine Ministry of Health function. Wherever possible, students should be introduced to the need for continuing education during their basic training. Evidence for the effectiveness of continuing medical education exists in developed countries though similar results have not yet been reported from developing countries.<sup>35,50,51</sup>

Methods that have been tested include large group and small group training,<sup>52</sup> as well as focused on-site training. One study showed that both approaches may be equally effective for improving treatment for specific problems but the effects of the small group teaching may be more sustained and cost-effective.<sup>52,53</sup> In some cases, training activities have been combined with improved supervision or monitoring.<sup>54</sup> In a study from Zambia, the impact of three continuing education seminars for staff working in urban general health centres was evaluated.<sup>55</sup> In this randomized study, the average number of

drugs prescribed decreased significantly from 2.3 to 1.9 in the intervention facilities. There were improvements in history taking, examination, diagnosis and treatment of patients, including a reduction in the use of antibiotics.

Our critical review of developing country training interventions has shown that the most effective in-service education is likely to be problem-based, repeated on multiple occasions, focused on practical skills, and linked to the use of STGs. Traditional training methods have been shown to be less effective than adult education techniques which use interactive methods, such as discussion and feedback, as has been found in developed countries.<sup>56</sup> When the roles of supervisors and trainers are combined, the impact of in-service training on prescribing practice is further enhanced. These approaches may require the training of trainers and supervisors to use these adult education techniques.

Since most work identified has focused on public sector prescribers, there is a need for further study of the efficacy and cost-effectiveness of continuing education for private sector providers. In the private sector, professional societies and associations are likely to be the most effective mechanisms for providing this training.<sup>57</sup>

### Promising approaches

In some settings impressive improvements in drug use have been achieved with innovative interventions.<sup>58,59,61,63</sup> While these approaches would not be recommended yet for widespread implementation, they are worth testing in other settings and for other types of prescribing problems. Such testing will require collaboration between relevant departments of universities as an important first step. If a pilot programme is successful, it is advisable to expand the scheme slowly and not to jump from a single pilot project to a national programme. Whenever new interventions are tested, it is important to look for unintended consequences that might reduce or even negate improvements in practice.

#### **(6) Stimulate an interactive group process among health providers or consumers to review and apply information about appropriate use of medicines**

Group process has long been a fundamental strategy for encouraging behaviour change employed by social scientists.<sup>58,59</sup> Group development of treatment norms, in which small numbers of prescribers meet to review a clinical problem and develop strategies for practice improvement, has also shown remarkable potential in several settings. In Indonesia, doctors and paramedics were brought together to discuss high injection use with a group of patients. Clinical issues were discussed, but more importantly expectations and misconceptions about injections were debated. This interactive group discussion resulted in sudden sustained decline in injection use.<sup>61</sup> Prior to the intervention the rate of injections per consultation was 69.5%, which was reduced in the intervention group to 42.3%. In comparison, in the control group the decline was from 75.6 to 67.1%. In Mexico, groups of doctors reviewed diarrhoea and ARI treatment algorithms, developed common approaches and participated in peer

review for 6 months thereafter, which led to a dramatic and sustained increase in several measures of quality.<sup>61</sup> The study compared physicians who received initial training and participated in a peer review process with control physicians from the same setting. Prescription antibiotic use for acute diarrhoea decreased in the intervention group from 78.8 to 39.3%, while ORT use increased from 31.4 to 58.4%. Long-term follow-up demonstrated a prolonged effect, significantly different from that shown by the control prescribers. Similar sustained improvements occurred in the treatment of acute respiratory infections.

These interventions were then extended to district and state level facilities with similar results.<sup>62</sup> An interactive group approach has also been used with community members. In Indonesia, groups of mothers were taught how to review drug package inserts and make decisions about informed purchasing of OTC drugs; this step led to a change in the patterns of drug purchases, especially reductions in the purchase of duplicative products.<sup>63</sup> As a result of the small group intervention, families reduced their monthly purchase of brand-name drugs from 5.3 per month to 1.5 per month, compared with a seminar group in which the reduction was from 5.7 to 4.3 and a control group where the change was from 5.6 to 5.2. The impact of these interventions stems from the powerful forces generated during group discussions. Members of the group absorb group norms and are motivated to change their practices more profoundly than in a passive learning environment.

#### **(7) Train pharmacists and drug sellers to be active members of the health care team and to offer useful advice to consumers about health and drugs**

In many countries, the reality of shortages of human resources and consumer preferences dictates that pharmacies and drug shops are the major source of pharmaceutical advice and treatment to the public. However, many retail settings are staffed by personnel with little or no training in health care or pharmaceuticals. In Nepal, considerable work has been done to upgrade the skills of drug sellers, including their prescribing and dispensing practices.<sup>64</sup> Studies in Kenya and Indonesia have shown that it is possible to improve the diarrhoea treatment practice of pharmacy staff through a combination of focused small-group training and building up their self image as health professionals.<sup>57</sup> In this two country study, sales of oral rehydration salts increased by 33% in Kenya and 34% in Indonesia. Sales of anti-diarrhoeals decreased by 17% in Nairobi and by 29% in Indonesia. In the Philippines, targeted training of local drug vendors improved the quality of their practice, particularly for drugs which have an inherent safety risk.<sup>65</sup> Pharmacists and drug sellers play an important role in drug recommendation and retail purchase, and replication and extension of these studies are urgently needed.

#### **(8) Encourage active involvement by consumer organizations in public education about drugs, and devote government resources to support these efforts**

At a policy level the central government has a responsibility to ensure the quality of drugs and also of the information that

accompanies them. There may also be a need to regulate advertising, and to require clear statements of risks and potential adverse drug reactions. Consumer-oriented package inserts can increase understanding in literate communities. Public education activities have been included in some essential drug programmes, but these activities are usually carried out by NGOs and consumer organizations. In 1997, a global survey by WHO concluded that there is a great need for public education about medicines, even in developing countries with limited resources.<sup>66</sup> The survey identified many examples of public education about drugs, but unfortunately many of these projects were poorly supported, documented and evaluated. The survey concluded that gains due to these programmes are probably incremental, but that results are difficult to evaluate with classical methodologies. This important area therefore needs much more understanding, research and support.

Drug representatives and other promotional activities by pharmaceutical companies have a major influence on prescribing and on drug use by the general public. WHO has published ethical criteria for drug promotion,<sup>67</sup> but very few countries have written or enforced regulations to make these ethical criteria effective. Their impact is therefore not yet clear and much more work is needed in this area.

### Crucial gaps in experience

#### (9) Develop a strategic approach to improve prescribing in the private sector through appropriate regulation and long-term collaborations with professional associations

So far most efforts at improving drug use have focused on the public sector, particularly at the primary care level.<sup>10</sup> The private sector frequently provides better access to pharmaceuticals for the general public than does the public sector, although there tends to be an urban focus.<sup>68</sup> Yet, the private sector has unfortunately been neglected by public policy-makers. To change practices in the private sector, it is important that policy-makers understand the motivations of private providers. Public servants frequently perceive that private practitioners are purely interested in profit rather than in the quality of their practice. However, recent experiences have shown this perception to be an oversimplification. Generally, all practitioners are interested in their status as health professionals, and their position within the community. Professional associations, with a majority of their membership in the private sector, are often willing to establish programmes to improve the skills or knowledge of their members. Considerable opportunities exist for improving drug use through better licensing and inspection.<sup>69</sup> Finally, controls on advertising and regulations regarding unethical promotion of drugs can be implemented by national governments and institutional administrators.

To stimulate long-term improvements in drug use in the private sector, a range of strategies should be considered. Licensing of practitioners and premises is traditionally used by governments to regulate the private sector. When possible, enforcement of these regulations should not be simply punitive, but combined with positive efforts to improve performance. Encouraging professional associations to provide an

accreditation system and continuing education programmes has many benefits. Changing the way governments or insurance companies reimburse drug expenditures may also have positive effects on drug use.

#### (10) Establish systems to monitor key pharmaceutical indicators routinely in order to track the impact of health sector reform and regulatory changes

Fundamental changes are occurring in health systems and in the economics of health systems. These changes, which are likely to have profound effects on drug use, have been reviewed in a number of publications.<sup>13</sup> Many decisions on health system structure and financing, health reform and decentralization may have negative impacts on drug use.<sup>70</sup> For example, introducing patient fees in the form of a fixed charge may lead to over-consumption of drugs, while introducing separate fees for each drug may tend to reduce access among the poor, unless there are exemption mechanisms.<sup>71</sup> Decentralization of budgeting and control may lead to inefficient procurement processes, which result in increased drug prices as well as a breakdown in supervision systems. Within decentralized systems, problems may also develop in referral systems and in training activities, leading to inequity between districts.<sup>72</sup>

The key message for policy-makers is that policy changes that accompany health sector reform are likely to have effects on drug use. There is a need to establish simple systems to monitor key pharmaceutical indicators that might change as a result of implementing system-wide reforms. Several sets of pharmaceutical indicators have already been developed and tested.<sup>73,74</sup> Policy-makers and managers should select a few locally appropriate indicators and collect them on a regular basis in order to be able to respond in a timely way to negative changes.

### Conclusions

Experiences during the last 15 years have taught us that there are many possible approaches for policy-makers and health system managers to encourage improved use of medicines. In this paper we have recommended ten approaches that we feel would establish a sound, broad-based programme for quality drug use leading to better quality of care and improved cost effectiveness. Five strategies can be recommended on the basis of proven success in both developing and industrialized countries: standard treatment guidelines; essential drug lists; pharmacy and therapeutic committees; problem-based basic professional training; and targeted in-service education. Three approaches, while not widely tested yet, offer great promise: interactive discussions among peers; drug seller training; and consumer education. Finally, two approaches require longer-term policy commitment: private sector outreach through professional associations; and regular monitoring of key pharmaceutical indicators.

### References

- 1 WHO. *Guidelines for National Drug Policies*. Geneva: World Health Organization, 1988.
- 2 WHO. *The Rational Use of Drugs. Report of a conference of*

- experts, *Nairobi, 25–29 November 1985*. Geneva: World Health Organization, 1987.
- Laing RO. Rational drug use: an unsolved problem. *Tropical Doctor* 1990; **20**: 101–3.
  - Laing RO. International network for the rational use of drugs (INRUD). *Tropical Doctor* 1990; **20**: 201–3.
  - Quick JD, Laing RO, Ross-Degnan DG. Intervention research to promote clinically effective and economically efficient use of pharmaceuticals: the International Network for Rational Use of Drugs. *Journal of Clinical Epidemiology* 1991; **44** (Suppl 2): 57S–65S.
  - WHO. *How to investigate drug use in health facilities (selected drug use indicators)*. WHO/DAP/93.1 (in English, French and Spanish). Geneva: World Health Organization, 1993.
  - De Vries THPGM, Henning RH, Hogerzeil HV, Fresle DA. *Guide to good prescribing*. WHO/DAP/94.11 (in English and French). Geneva: World Health Organization, 1994.
  - International conference on national medicinal policies – the way forward. *Australian Prescriber* 1997; **20** (Suppl 1).
  - State of the Art and Future Directions, Chiang Mai, Thailand 1–4 April 1997. Available on-line at <http://www.who.ch/dap-icium/index.html>
  - Ross-Degnan D, Laing R, Santoso B et al. Improving pharmaceutical use in primary care in developing countries: a critical review of experience and lack of experience. Presented at the International Conference on Improving the Use of Medicines, Chiang Mai, Thailand, April 1997.
  - Ratanawijitrasin S, Soumerai S, Weerasuriya K. Do national drug policies improve drug use? A review of experiences in developing countries. Presented at the International Conference on Improving the Use of Medicines, Chiang Mai, Thailand, April 1997.
  - Homedes M, Ugalde A. Improving the use of pharmaceuticals through patient and community level interventions. Presented at the International Conference on Improving the Use of Medicines, Chiang Mai, Thailand, April 1997.
  - Cederlof C, Quick JD. Impact of economic factors on use of medicines: concepts and evidence on selected issues. Presented at the International Conference on Improving the Use of Medicines, Chiang Mai, Thailand, April 1997.
  - Drummond MF. Basing prescription drug payment on economic analysis: the case of Australia. *Health Affairs* 1992; **11**: 191–6.
  - Freund DA, Evans D, Henry D, Dittus R. Implications of the Australian guidelines for the United States. *Health Affairs* 1992; **11**: 202–6.
  - Lipton HL, Gross DJ, Stebbins MR, Syed LH. Managing the pharmacy benefit in Medicare HMOs: what do we really know? *Health Affairs* 2000; **19**: 42–58.
  - Gold MR, Hurley R, Lake T, Ensor T, Berenson R. A national survey of the arrangements managed-care plans make with physicians. *New England Journal of Medicine* 1995; **333**: 1678–83.
  - Baines DL, Whynes DK, Tolley KH. General practitioner fundholding and prescribing expenditure control. Evidence from a rural English health authority. *PharmacoEconomics* 1997; **11**: 350–8.
  - Petchey R. General practitioner fundholding: weighing the evidence. *Lancet* 1995; **346**: 1139–42.
  - Bloor K, Freemantle N. Lessons from international experience in controlling pharmaceutical expenditure. II: Influencing doctors. *British Medical Journal* 1996; **312**: 1525–7.
  - Brushwood DB. The pharmacist's duty under OBRA-90 standards. *Journal of Legal Medicine* 1997; **18**: 475–509.
  - Soumerai SB, Lipton HL. Computer-based drug-utilization review—risk, benefit, or boondoggle? *New England Journal of Medicine* 1995; **332**: 1641–5.
  - Petrie JC. Clinical guidelines in Scotland: a SIGN of the times. *Essential Drugs Monitor* 1996; **22**: 13–14. Available on-line at [http://www.who.ch/programmes/dap-icium/posters/1F4\\_TXTF.html](http://www.who.ch/programmes/dap-icium/posters/1F4_TXTF.html)
  - Quick JD, Rankin JR, Laing RO et al. (eds). *Managing drug supply*. Management Sciences for Health in collaboration with the World Health Organization. West Hartford, CT: Kumarian Press, 1997.
  - Government of Yemen. *Statistical report of the Supreme Board of Drugs and Medical Appliances*. Sanaa, 1986.
  - Bates JA, Foreman P, Ross Degnan D et al. *Child Survival pharmaceuticals in Indonesia: Opportunities for therapeutic and economic efficiencies in pharmaceutical supply and use*. Management Sciences for Health, Boston, Yayasan Indonesia Sejahtera, Ministry of Health, Indonesia, December 1987.
  - Hogerzeil HV, Bimo, Ross-Degnan D et al. Field tests for rational drug use in twelve developing countries. *Lancet* 1993; **342**: 1408–10.
  - Arhinful DK, Das AM, Hadyiyono JP et al. *How to use qualitative methods to design interventions*. Washington DC: INRUD, December 1996.
  - WHO. *How to investigate drug use in communities*. WHO/DAP/92.3. Geneva: World Health Organization, 1992 (currently being revised).
  - Trap B, Lessing C. *ZEDAP survey 1995*. Harare, Zimbabwe: Ministry of Health and Welfare, 1995. Available on-line at [http://www.who.ch/programmes/dap-icium/posters/4B3\\_TXTF.html](http://www.who.ch/programmes/dap-icium/posters/4B3_TXTF.html)
  - Sunartono, Darminto. From research to action: the Gunungkidul experience. *Essential Drugs Monitor* 1995; **20**: 21–2. Available on-line at [http://www.who.ch/programmes/dap-icium/posters/2D3\\_TXTF.html](http://www.who.ch/programmes/dap-icium/posters/2D3_TXTF.html)
  - Grimshaw J, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993; **342**: 1317–22.
  - Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *British Medical Journal* 1999; **318**: 527–30.
  - Graaf PJ, Forshaw CJ. Developing standard treatment guidelines in Malawi. *Essential Drugs Monitor* 1995; **19**: 12–14.
  - Bero LA, Grilli R, Grimshaw JM, Harvey E, Oxman AD, Thomson MA. Closing the gap between research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. *British Medical Journal* 1998; **317**: 465–8.
  - Kafuko J, Zirabamuzaale C, Bagenda D. *Impact of national standard treatment guidelines on rational drug use in Uganda health facilities*. Kampala: UNICEF/Uganda, 1994.
  - Kenya. Updating the Essential Drugs List. *Essential Drugs Monitor* 1993; **16**: 1617.
  - WHO. *The use of essential drugs*. Technical Report Series 867. Geneva: World Health Organization, 1997.
  - Ministry of Health, Zimbabwe. *Essential Drugs List of Zimbabwe*. Harare, 1994.
  - Mabadeje AF, Akintonwa AA, Ashorobi BB. The value and effects of implementing an essential drugs list in the Lagos University Teaching Hospital. *Clinical Pharmacology and Therapeutics* 1991; **50**: 121–4.
  - Levy LM, Jensen BA, Otim-Oyed D, Martin C, Powel-Smith C, Kiire CF. *Oncology in Zimbabwe*. Harare: Ministry of Health and Welfare, 1992.
  - The Oncology Committee Zimbabwe. Rational use of cytotoxic drugs in a developing country. *Health Policy and Planning* 1990; **5**: 378–85.
  - Weekes LM, Brooks C. Drug and Therapeutic Committees in Australia: expected and actual performance. *British Journal of Clinical Pharmacology* 1996; **42**: 551–7.
  - Masoswe JJ, Okpara AU. Enforcing a policy for restricting antimicrobial drug use. *American Journal of Health System Pharmacy* 1995; **52**: 1433–5.
  - Crowe HM, Quintiliani R. Antibiotic formulary selection. *Medical Clinics of North America* 1995; **79**: 463–76.
  - Jakrawantana WK, Yinsaree SN, Autapapacha AN, Presenter: Jakrawantana WK. Effect of multiple interventions on ceto-taxamine use in Lampang Provincial Hospital. Available on-line at [http://www.who.int/dap-icium/posters/2c2\\_txt.html](http://www.who.int/dap-icium/posters/2c2_txt.html)
  - De Vries THPGM, Henning RH, Hogerzeil HV et al. Impact of a

- short course in pharmacotherapy for undergraduate medical students. *Lancet* 1995; **346**: 1454-7.
- <sup>48</sup> WHO. Revision of undergraduate pharmacy curricula. Report of an informal consultation in Nyanga, Zimbabwe 18-20 April 1997. WHO/DAP/98.1. Geneva: World Health Organization.
  - <sup>49</sup> Laing RO, Ruredzo R. The essential drugs programme in Zimbabwe: new approaches to training. *Health Policy and Planning* 1989; **4**: 229-34.
  - <sup>50</sup> Davis DA, Thomson MA, Oxman AD, Haynes RB. Changing physician performance. A systematic review of the effect of continuing medical education strategies. *Journal of the American Medical Association* 1995; **274**: 700-5.
  - <sup>51</sup> Davis D, O'Brien MAT, Freemantle N, Wolf FM, Mazmanian P, Taylor-Vaisey A. Impact of formal continuing medical Education. Do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *Journal of the American Medical Association* 1999; **282**: 867-74.
  - <sup>52</sup> Santoso B. Small group intervention vs formal seminar for improving appropriate drug use. *Social Science and Medicine* 1996; **42**: 1163-8.
  - <sup>53</sup> Santoso B, Suryawati S, Prawitasari JE, Ross-Degnan D. Small-group intervention in improving appropriate drug use in acute diarrhoea. Available on-line at [http://www.who.int/dap-icium/posters/2b3\\_text.html](http://www.who.int/dap-icium/posters/2b3_text.html)
  - <sup>54</sup> Loevinsohn B, Guerrero E, Gregorio S. Improving primary health care through systematic supervision: a controlled field trial. *Health Policy and Planning* 1995; **10**: 144-53.
  - <sup>55</sup> Bexell A, Lwando E, von Hofsten B, Tembo S, Eriksson B, Diwan VK. Improving drug use through continuing education: a randomized controlled trial in Zambia. *Journal of Clinical Epidemiology* 1996; **49**: 355-7.
  - <sup>56</sup> Ofori-Adjei D, Arhinful DK. Effect of training on the clinical management of malaria by medical assistants in Ghana. *Social Science and Medicine* 1996; **42**: 1169-76.
  - <sup>57</sup> Ross-Degnan D, Soumerai S, Goel PK et al. The impact of face to face educational outreach on diarrhea treatment in pharmacies. *Health Policy and Planning* 1996; **11**: 308-18.
  - <sup>58</sup> Kelley HH, Thibaut JW. Group problem solving. In *The Handbook of Social Psychology*. 2nd edition. Vol. 4. New York: Oxford University Press.
  - <sup>59</sup> Mittman BS, Tonesk X, Jacobson PD. Implementing clinical practice guidelines: social influence strategies and practitioner behavior change. *Quality Review Bulletin* 1992; **18**: 413-22.
  - <sup>60</sup> Hadiyono JP, Suryawati S, Danu SS, Sunartono, Santoso B. Interactional group discussion: results of a controlled trial using a behavioral intervention to reduce the use of injections in public health facilities. *Social Science and Medicine* 1996; **42**: 1185. Available on-line at [http://www.who.ch/programmes/dap/icium/posters/2D2\\_TXTF.html](http://www.who.ch/programmes/dap/icium/posters/2D2_TXTF.html)
  - <sup>61</sup> Gutierrez G, Guisafre H, Bronfman M, Walsh J, Martinez H, Munoz O. Changing physician prescribing patterns: evaluation of an educational strategy for acute diarrhea in Mexico City. *Medical Care* 1994; **32**: 436-46.
  - <sup>62</sup> Guisafre H, Martinez H, Reyes H et al. From research to public health interventions. I. Impact of an educational strategy for physicians to improve treatment practices of common diseases. *Archives of Medical Research* 1995; **26** Spec No: S31-9.
  - <sup>63</sup> Suryawati S, Santoso B. Self-learning for self medication: an alternative to improve the rational use of OTCs. Paper presented at ICIUM conference, Chang Mai, Thailand, April 1997. Available on-line at [http://www.who.ch/programmes/dap/icium/posters/3B3\\_TXTF.html](http://www.who.ch/programmes/dap/icium/posters/3B3_TXTF.html)
  - <sup>64</sup> Kafle KKK and members of INRUD Nepal. Intervention test of training and supervision on prescribing and dispensing practices. Report to the RPM Project, Kathmandu, Nepal.
  - <sup>65</sup> Sia IC, Valerio J. The effects of an intervention on the drug selling behavior of sarisari (variety) store keepers in some villages in the Philippines. Presentation at ICIUM meeting. Available on-line at [http://www.who.ch/programmes/dap/icium/posters/3C4\\_TXTF.html](http://www.who.ch/programmes/dap/icium/posters/3C4_TXTF.html)
  - <sup>66</sup> Fresle DA, Wolfheim C. *Public education in rational drug use: a global survey*. WHO/DAP/97.5. Geneva: World Health Organization. 1997.
  - <sup>67</sup> WHO. *Ethical criteria for drug promotion*. Geneva: World Health Organization. 1988.
  - <sup>68</sup> WHO. *Public-private roles in the pharmaceutical sector: Implications for equitable access and rational use*. Health economics and Drugs DAP Series No. 5. Action Programme on Essential Drugs. Geneva: World Health Organization. 1997.
  - <sup>69</sup> Hongsamoot D, Kajorntam Y, Pradamook P. How effective is the surveillance in ensuring the appropriate distribution of, and patient's accessibility to drugs: The case for steroid tablets. Presentation at ICIUM, Chang Mai. 1997.
  - <sup>70</sup> Laing R. Pharmaceutical management at the central and local levels. In: Kolehmainen-Aitken RL (ed.). *Myths and realities about the decentralization of health systems*. Boston, MA: Management Sciences for Health. 1999.
  - <sup>71</sup> Holloway K, Gautam BR. The effects of different charging mechanisms on rational drug use in Eastern rural Nepal. Presentation at ICIUM, Chang Mai. 1997. Available on-line at [http://www.who.ch/programmes/dap/icium/posters/4e2\\_Text.html](http://www.who.ch/programmes/dap/icium/posters/4e2_Text.html)
  - <sup>72</sup> Campos-Outcalt D, Kewa K, Thomason J. Decentralization of health services in Western Highlands Province, Papua New Guinea: An attempt to administer health service at the subdistrict level. *Social Science and Medicine* 1995; **40**: 1091-8.
  - <sup>73</sup> Brudon-Jakobowicz P, Rainhorn J-D, Reich MR. *Indicators for monitoring national drug policies*. WHO/DAP. Geneva: World Health Organization. 1994.
  - <sup>74</sup> Management Sciences for Health/Rational Pharmaceutical Project. *Rapid Pharmaceutical Management Assessment: An indicator-based approach*. Washington DC: Management Sciences for Health. 1995.

## Acknowledgements

Support for this paper was provided by the World Health Organization Action Programme on Essential Drugs, Boston University, the International Network for Rational Use of Drugs, the Danish International Development Agency, and the Applied Research on Child Health Project.

## Biographies

Richard Laing teaches international public health at Boston University School of Public Health. He has a long-standing interest in improving drug use in developing countries based on his prior experience in the Zimbabwe Essential Drugs Programme (ZEDAP) and as past coordinator for the International Network for the Rational Use of Drugs (INRUD).

Hans Hogerzeil is a public health physician who has worked as a mission doctor in India and Ghana. He joined the Action Programme on Essential Drugs at WHO in 1985. Over the years he has been adviser on essential drugs policies to the governments of India, Indonesia, Kenya, South Africa, Sudan and Zimbabwe and many other developing countries. He has also led research and development activities related to pharmaceutical donations and training of medical students. Currently he coordinates WHO's activities in drug policy development, access to essential drugs, and promoting rational drug use.

Dennis Ross-Degnan is an assistant Professor in the Department of Ambulatory Care and Prevention of Harvard Medical School and Harvard Pilgrim Health Care, and the coordinator for the Harvard Support Group of the International Network for the Rational Use of Drugs. He publishes widely on pharmaceutical policy and behaviour change interventions.

*Correspondence:* Dr Richard Laing, Dept of International Health, Boston University School of Public Health, 715 Albany Street, T4W Boston, MA 02118, USA. Email: [richardl@bu.edu](mailto:richardl@bu.edu)

# 18

## **MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

# Impact of the HIV epidemic on the spread of other diseases: the case of tuberculosis

Enrico Girardi<sup>a</sup>, Mario C. Raviglione<sup>b</sup>, Giorgio Antonucci<sup>a</sup>,  
Peter Godfrey-Faussett<sup>c</sup> and Giuseppe Ippolito<sup>a</sup>

AIDS 2000, 14 (suppl 3):S47-S56

Keywords: HIV infection, AIDS, opportunistic infections, tuberculosis, epidemiology, prevention

## Introduction

The spread of the AIDS epidemic resulted in the emergence of a new population of immunosuppressed individuals, larger than any previous such population. As could be easily anticipated, this, in turn, had a significant impact on the spread and natural history of other diseases, which either require or are enhanced by a severe impairment of cell-mediated immunity. However, the extent and the public health implications of the interaction between HIV infection and other diseases vary greatly. Some opportunistic diseases, such as *Pneumocystis carinii* pneumonia or *Mycobacterium avium-intracellulare* complex infection, that were extremely rare before the AIDS epidemic became quite common in the past two decades [1,2]. However, these common HIV-related conditions pose no threats to the general population. Some forms of cancers, such as non-Hodgkin lymphomas (NHL), also increased in incidence in some population groups in the past two decades, and this finding may be attributed, at least in part, to the spread of HIV infection, which is clearly associated with an increased risk of developing this tumour [3]. However, there is no epidemiologic relation between the incidence of NHL among HIV-infected persons and the risk of NHL for non-HIV-infected persons. A more complex relationship exists between HIV infection and some other sexually transmitted diseases [4]. The sexually transmitted infections, particularly those causing genital ulcers, may increase susceptibility to HIV infection that, in

turn, may prolong or increase the infectiousness of individuals with sexually transmitted infections.

However, the interaction between HIV and tuberculosis has several unique features. First, tuberculous infection is highly prevalent; approximately one-third of the world population was estimated to be infected with *Mycobacterium tuberculosis* in 1997 [5]. In some settings, there is a considerable overlap between the population infected with HIV and that infected with *M. tuberculosis*. For instance, in developing countries, or among those who have recently moved from them, the prevalence of tuberculous infection among young adults, who are at greatest risk of HIV infection, is often greater than 50%. The regions with the highest seroprevalence of HIV in the general community already have high prevalences of tuberculous infection. In industrialized settings, there may also be particular populations with common risk factors for infection with both HIV and tuberculosis such as homelessness or intravenous drug use. Second, tuberculosis is the only HIV-associated respiratory infection that can readily be transmitted via the respiratory route among persons with HIV infection and, from them, to non-HIV-infected persons. Third, the huge burden of HIV-associated tuberculosis has made it more difficult for national tuberculosis programmes in developing countries to achieve or maintain high detection and cure rates, resulting in an increasing transmission of tuberculosis infection [6]. Finally, HIV infection is one of the major factors contributing to

From the <sup>a</sup>Centro di Riferimento AIDS — Servizio di Epidemiologia delle Malattie Infettive, IRCCS L. Spallanzani, Rome, Italy, <sup>b</sup>Programme on Communicable Diseases, World Health Organization, Geneva, Switzerland, and the <sup>c</sup>Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London, UK.

Sponsorship: E.G., G.A. and G.I. were financially supported by Ministero della Sanità-Progetto AIDS, and Fondi per la Ricerca Corrente degli IRCCS.

Correspondence to Dr Giuseppe Ippolito, Centro di Riferimento AIDS — Servizio di Epidemiologia delle Malattie Infettive, IRCCS L. Spallanzani, Via Portuense, 292-00149 Roma, Italy. Tel: +39 65 594 223; fax: +39 65 594 224; e-mail: craids@tiscalinet.it

**Table 1.** Incidence of tuberculosis in persons infected with HIV who did not receive preventive therapy, by tuberculin and other delayed-type hypersensitivity skin test status.

			Tuberculosis incidence per 100 person years					
Country	Study period	Number of persons studied	PPD+	PPD-, anergic	PPD-, not anergic	PPD-, anergy not assessed	Total	Ref.
<b>Observational studies</b>								
United States	1985-1988	215	7.9	-	-	0.3	2.1	[10]
Zaire	1987-1989	249	-	-	-	-	3.1	[11]
United States	1988-1990	93	9.7	6.6	-	-	7.7	[12]
Rwanda	1988-1990	401	5.5	-	-	2.1	2.4	[13]
Spain	1989-1991	290	10.4	12.4	5.4	-	9.1	[14]
Spain	1989-1992	348	16.2	2.6	0	-	-	[15]
Italy	1993-1994	2666	4.5	2.9	0.3	-	2.2	[16]
United States	1988-1994	1037	4.5	0.7	0.2	-	0.7	[17]
<b>Clinical trials*</b>								
Haiti	1986-1991	70	10	-	-	5.7	7.5	[18]
Uganda	1993-1995	895	3.4	3	-	-	-	[19]
Kenya	1992-1994	342	8	-	-	2.7	3.8	[20]
Zambia	1994-1996	394	9.8	-	-	3.5	4.9	[21]
United States	1991-1996	257	-	0.9	-	-	0.9	[22]

\*Data from control groups in clinical trials of tuberculosis preventive therapy are reported. PPD, purified protein derivative.

the resurgence of tuberculosis in sub-Saharan African countries affected by HIV, due to both the high risk of developing active tuberculosis in HIV-infected persons and the increased risk of tuberculous infection from them to non-HIV-infected persons.

### Transmission dynamics of tuberculosis

The impact of the HIV epidemic on tuberculosis can be better understood if one considers the intrinsic transmission dynamics of tuberculosis in the population. According to a basic model of this transmission [7,8], at any given time point in the population, there is a proportion of persons latently infected with *M. tuberculosis*. In any given time interval, a fraction of these persons will progress to overt disease, thus infecting susceptible persons in the population. A proportion (5%, see later) of persons with newly acquired infection progresses rapidly (within 1-2 years) to clinical disease, thus causing additional cases of infection. On the other hand, the large majority of infected persons enter the pool of latently infected individuals in the population. The main parameters governing this dynamic are: (i) the progression rate to active tuberculosis among latently infected persons; (ii) the number of new infections originating from an active case (the infectiousness of tuberculosis patients); and (iii) the proportion of persons who rapidly progress to overt disease among those newly infected. Any condition that may modify the natural equilibrium of these parameters will ultimately affect the magnitude of the epidemic. The impact of such

a condition on the tuberculosis epidemic will also depend upon its prevalence in the population, and specifically among persons with latent infection and among those exposed to infectious cases. We will briefly review how HIV infection acts as an important condition capable of modifying these parameters.

### Progression rate of latent tuberculosis infection

The risk of developing active tuberculosis among persons with latent *M. tuberculosis* infection, but who do not have HIV infection, has been estimated to be no greater than 10% in their entire lifetime [9]. This is in sharp contrast with results of longitudinal studies on tuberculin-positive HIV-infected persons [10-17] and with data from control groups of patients in clinical trials of tuberculosis preventive therapy [18-22]. Although these studies have been conducted in different geographical areas and in different populations, their results are rather consistent, and most of these studies show incidences of tuberculosis ranging from 5 to 10% per year of observation (Table 1). Moreover, the risk of re-activation among HIV-infected persons appears to be correlated with the level of immunosuppression. In a cohort study from Italy [16], the annual incidence of tuberculosis among tuberculin-positive HIV-infected persons was 2.59 per 100 person-years among those with a CD4 cell count above 350/ $\mu$ l, 6.54 among those with CD4 cell counts between 200 and 350/ $\mu$ l, and 13.3 among persons with CD4 cell counts less than 200/ $\mu$ l.

### Infectiousness of tuberculosis patients

The source of transmission of tuberculosis infection is patients with pulmonary tuberculosis. It has been

Table 2 Infectiousness of HIV-infected patients with pulmonary tuberculosis (TB) compared with non-HIV-infected patients.

Country	Study period	Contacts of HIV-positive tuberculosis patients			Contacts of HIV-negative tuberculosis patients			Ref.
		n	% with TB	% PPD+	n	% with TB	% PPD+	
Florida, USA	1985-1986	54	NA	35	44	NA	44	[28]
Burundi	1985-1986	48	12.5*	NA	28	0	NA	[29]
Kenya	1989-1990	102	7.8	61	255	5.1	58	[30]
Zaire	1989-1990	521	NA	60	692	NA	63	[31]
Florida, USA	1985-1989	1095	NA	30.4†	2158	NA	42	[32]
Zambia	1989	207	4	52†	141	3	71	[33]
Spain	1990-1993	456	7.9*	NA	624	3.8	NA	[34]
Uganda	NA	319	NA	79	380	NA	79	[35]
Dominican Republic	1994-1995	153	5	61†	551	6	76	[36]

\*Significantly higher ( $P < 0.05$ ) compared with contacts of HIV patients. †Significantly lower ( $P < 0.05$ ) compared with contacts of HIV patients. PPD, purified protein derivative; NA, not assessed.

clearly shown that, among them, those with a sputum smear positive for acid fast bacilli are much more likely to transmit the infection [23]. A recent study has attempted to quantify the relative infectiousness of sputum-smear-positive and sputum-smear-negative patients using DNA fingerprinting analysis of mycobacterial isolates from patients with pulmonary tuberculosis in San Francisco, CA, USA [24]. This study shows that, although transmission from sputum-smear-negative patients is not at all uncommon, the probability of acquiring tuberculosis infection from a sputum-smear-negative patient is about one-fifth that from a sputum-positive patient. A series of studies compared the proportion of sputum-smear-positive patients between HIV-infected and non-infected tuberculosis patients [25]. Almost all of these studies found a lower proportion of sputum-smear-positive patients among those with HIV infection. Severe immunosuppression may be associated with a high bacillary load in the lung tissue of HIV-infected patients with pulmonary tuberculosis [26]. However, HIV-infected patients may be less likely to mount a granulomatous response to *M. tuberculosis*, and may therefore not produce cavitation and not excrete large numbers of bacilli from the lung [25]. On the other hand, it has been suggested that the diagnosis of tuberculosis may be more often delayed in HIV-infected patients because unusual clinical features lead the doctor to take longer to reach a diagnosis [27]. The resulting delay in the initiation of antituberculous therapy may lead to a longer period of infectiousness. Observational studies that analysed the infectiousness of HIV-infected patients compared with those non-infected [28-36] provided conflicting results (Table 2). In a small study from Burundi [29], six cases of tuberculosis were found among 48 household contacts of HIV-infected patients with pulmonary tuberculosis, while no case was observed among 28 among household contacts of non-HIV-infected

tuberculosis patients. A study from Spain showed similar results [34], while two other studies found a similar proportion of tuberculosis cases among household contacts of tuberculosis cases with and without HIV infection [30,33]. A major limitation of these studies is their cross-sectional design, which made it difficult to ascertain if the case that is diagnosed first (index cases) is really the source of infection for cases diagnosed as a results of contact investigation (secondary cases). Studies assessing tuberculous infection, rather than secondary cases of active disease, among contacts of tuberculosis patients found that the proportion of tuberculin-positive persons was very similar [28,30,31,35] or significantly lower [32,33] among contacts of HIV-infected patients with tuberculosis compared with contacts of non-HIV-infected patients. Again, most of these studies were cross-sectional. However, a recent study from Santo Domingo, Dominican Republic, also assessed tuberculin conversion rates among household contacts of tuberculosis patients [36]. In this study, conversion to a positive tuberculin test was significantly less common among contacts of HIV-infected tuberculosis patients compared with contacts of non-HIV-infected patients (24% versus 35%). Taken together, available data does not provide evidence that HIV infection may enhance infectiousness of individual patients with tuberculosis.

The probability for a person with active tuberculosis to infect susceptible individuals is also a function of the length of time for which this person remains infectious. This, in turn, depends on the rapidity of case detection and initiation of appropriate treatment. At population level, a decrease in the fraction of tuberculosis patients effectively treated will lead to an increased circulation of *M. tuberculosis* [37]. Available evidence does not suggest that tuberculosis treatment is significantly less effective in HIV-infected persons,

**Table 3.** Attack rate of active tuberculosis among HIV/AIDS patients exposed to infectious tuberculosis in institutional settings

Country	Study period	Setting	Multi-drug resistance	Attack rate (%)	Reference
Italy	1989	Hospital ward	No	39	[42]
California, USA	1989	Residential facility	No	37	[43]
New York, USA	1989-1990	Hospital ward	Yes	9	[44]
Puerto Rico, USA	1989	Hospital ward	No	17	[45]
New York, USA	1990	Hospital ward	Yes	22	[46]
Italy	1992-1994	Hospital ward	Yes	29	[47]

although the relapse rate may be somewhat higher among HIV-infected persons [38]. However, the increase of the global number of tuberculosis cases linked to the HIV epidemics may have led, at least in some areas, to a reduction in the overall effectiveness of tuberculosis treatment programmes. In sub-Saharan African countries, a two- to fourfold rise in notification rates, largely attributable to HIV epidemics, has been recorded in the past decade [6]. This has resulted in an increasing demand for anti-tuberculosis drugs, laboratory supply and equipment, and, ultimately, in a tremendously increased workload for health workers. This occurred in a context of declining economies and reduced health care expenditure. Eventually, the crisis faced by many national tuberculosis programmes led to a general reduction in the ability of these programmes to identify and treat tuberculosis patients. Indeed, in many sub-Saharan African countries, less than one-half of patients with sputum-smear-positive pulmonary tuberculosis are detected and, in most, the cure rate does not exceed 70% [39]. A similar phenomenon may also have occurred in some parts of the industrialized world. In New York City, tuberculosis incidence rates increased by almost 40% between 1985 and 1989, and HIV infection, together with worsening social conditions, had a major contribution to this resurgence at a time when most treatment facilities for tuberculosis patients had been dismantled. As a result, treatment completion rates as low as 11% were recorded in New York City in 1989 [40].

#### Progression of recently acquired tuberculosis infection

The risk of developing active tuberculosis is higher during the first 2 years following primary infection. According to current estimates, based on longitudinal studies of HIV-seronegative tuberculin converters, 5% of those acquiring tuberculosis infection present with active disease within 2 years [23,41]. Scarce data are available on clinical progression of HIV-infected persons who convert to tuberculin positivity. In a cohort study from Italy [16], three out of 13 HIV-infected persons who became tuberculin-positive and did not receive preventive therapy developed tuberculosis within 1 year from skin test conversion, while in the United States an incidence

of 5.4 per 100 person years was recorded among 21 HIV-infected tuberculin converters [17]. Estimates of the risk among more severely immunosuppressed patients may be derived from studies on HIV-infected patients exposed to tuberculosis in institutional settings [42-47], in which most patients had symptomatic HIV infection or AIDS (Table 3). An incidence as high as 35 per 100 person-years was reported among patients exposed to infectious tuberculosis in a hospital unit for HIV-infected patients [46]. Attack rates ranging from 9 to 39% have been reported among HIV-infected patients during institutional outbreaks of tuberculosis due to both multidrug-resistant and susceptible strains, with an incubation period ranging from 1 to 6 months. These figures should be regarded as minimum estimates of the rate of rapid progression of a recently acquired infection, since it cannot be assumed that all those exposed were actually infected. Nonetheless, they clearly demonstrate a striking increase of this risk, especially among those with a more severe immunosuppression.

#### Re-activation versus new infection

Data from prospective studies consistently show that the incidence of tuberculosis among HIV-infected persons is higher among those who are tuberculin-positive. The occurrence of tuberculosis in a tuberculin-positive person does not necessarily imply re-activation of a latent infection, and purified protein derivative (PPD) negativity cannot rule out previous tuberculosis infection, since HIV-induced immunosuppression greatly increases the 'false negativity' rate of the tuberculin skin test [48]. Nevertheless, available evidence strongly suggests that a person infected with HIV has a greater probability of developing active tuberculosis if he/she has been infected by *M. tuberculosis* in the past. However, this does not imply that re-activation of a latent infection is the predominant mechanism responsible for HIV-associated tuberculosis at population level.

This issue has been addressed during the past decade using a new molecular tool, DNA fingerprinting analysis of insertion element IS6110 of the genome

**Table 4.** Results of DNA fingerprinting studies of *Mycobacterium tuberculosis* strains isolated for HIV-infected and non-HIV-infected tuberculosis patients.

Country, region	Study period	Clustered strains/total (%)			Reference
		HIV-positive patients	Non-HIV-positive patients	Total	
USA, San Francisco	1991-1992	75/121 (62)*†	117/352 (33)	191/473 (40)	[51]
USA, New York	1989-1992	26/46 (56)*	13/58 (24)	39/104 (35)	[52]
Spain, Seville	1993-1995	40/86 (47)*	13/41 (32)	67/175 (38)	[55]
France, Paris	1995	9/31 (29)	86/241 (36)	95/272 (35)	[56]
Netherlands	1993-1997	90/181 (50)	1883/4087 (46)	1971/4266 (46)	[57]
Brasil, Sao Paulo	1995-1997	58/151 (38)*	35/142 (25)	93/293 (32)	[58]
Namibia, Windhoek	1995-1996	33/73 (45)	90/190 (47)	123/263 (47)	[59]

For each study, the number and the proportion of *M. tuberculosis* strains with a DNA fingerprinting identical to at least another strain (clustered strains) are reported for HIV-infected tuberculosis patients, non-HIV-infected tuberculosis patients and for the entire study population. \* Proportion of strains included in clusters significantly ( $P < 0.05$ ) higher among HIV-infected patients compared with non-HIV-infected patients. † Only patients with AIDS.

of *M. tuberculosis*. When this tool is applied to community-based studies, patients infected with strains that have an identical DNA fingerprint are considered part of a cluster, and all patients included in a cluster but one (the source case) are considered to have tuberculosis due to recent transmission of the infection. The validity of this assumption, however, may vary according to the timeframe and migration within the population in which the study is performed and to the completeness of sampling of tuberculosis cases studied [49,50]. The first studies conducted with these methods [51,52] found a high proportion of cases due to recent transmission in two metropolitan areas in the United States (between one-third and one-quarter) and showed that over one-half of tuberculosis cases among HIV-infected or AIDS patients were in those with recently acquired infections. These findings were unexpected since, at the time, it was commonly held that the overwhelming majority of cases in low tuberculosis incidence countries could be attributed to re-activation of latent tuberculosis infection [53]. However, when these studies were conducted, the tuberculosis incidence rate was high, over 50 cases per 100 000 population both in San Francisco and in New York City [54]. Subsequent studies [55-59], summarized in Table 4, reported an overall similar proportion of cases due to recent infection. However, some of these studies did not find significant differences in the proportion of cases in the cluster among HIV-infected patients compared with other tuberculosis patients [56,57,59]. Taken together, these findings suggest that, during the past decade, at least one-third of HIV-associated tuberculosis cases could be attributed to recent infection, and that the proportion of cases among HIV-infected persons that are recently infected usually reflect, and sometimes magnify, tuberculosis transmission in a given population.

### The global picture: a widening gap between the poor and the rich

#### Tuberculosis/HIV in resource-poor countries

The World Health Organization (WHO) has recently published new estimates of the global burden of tuberculosis [5]. The global picture of tuberculosis/HIV co-infection has also been reassessed. In 1997, it was estimated that 8% of new tuberculosis cases, or 640 000 cases, occurred in HIV-infected persons and, in the same year, more than 10 million people (approximately 2% of the world population) were living with double infection. Most of the burden of tuberculosis/HIV co-infection remains concentrated in sub-Saharan African countries, where the two infections are highly prevalent: in this region, 32% of tuberculosis patients are estimated to be HIV-infected and the overall prevalence of dual infection is above 10%. These figures, however, are only one indicator of the impact of HIV, as they do not reflect the additional tuberculosis cases arising from the overall increase in risk of infection linked to HIV-associated tuberculosis cases. Although the latest global estimates are not strictly comparable with previous ones [60], due to methodological differences, the global number of cases attributable to HIV infection could have at least doubled during the past decade (Table 5). As the vast majority of the 320 000 HIV-associated tuberculosis cases in 1997, in excess to those estimated for 1990, occurred in sub-Saharan Africa, the overall tuberculosis incidence in this area increased by approximately 35% between 1990 and 1997. However, cases among HIV-infected persons account for only 50% of this increase. This observation may reflect, at least in part, the likely contribution of HIV-associated tuberculosis to increased trans-

Table 5. Estimated tuberculosis incidence and number of cases in HIV-infected persons in 1990 and 1997 by region.

Region	1990			1997		
	Total tuberculosis cases	Rate*	Tuberculosis cases in HIV-positive persons (%)	Total tuberculosis cases	Rate*	Tuberculosis cases in HIV-positive persons (%)
South-east Asia	3 106 000	237	66 000 (2)	2 948 000	202	64 000 (2)
Western Pacific†	1 839 000	136	19 000 (1)	1 924 000	129	9000 (0.5)
Africa	992 000	191	194 000 (19)	1 586 000	259	515 000 (32)
Eastern Mediterranean	641 000	165	9000 (1)	615 000	129	16 000 (3)
Americas‡	569 000	127	20 000 (3)	390 000	79	22 000 (6)
Eastern Europe§	194 000	47	1000 (0.5)	360 000	74	2000 (0.5)
Industrialized countries¶	196 000	23	6000 (3)	140 000	16	12 000 (8)
Total	7 537 000	143	315 000 (4)	7 962 000	136	640 000 (8)

Data from [5,60]; different methods were used to produce estimates for 1990 and 1997. \*Crude incidence rate per 100 000 population. †Includes all countries of the Western Pacific Region of the World Health Organization (WHO), except Japan, Australia and New Zealand. ‡Includes all countries of the American Region of the WHO, except the United States and Canada. § Includes Eastern European countries, and states of the former USSR. ¶ Includes Western European countries, Japan, Australia, New Zealand, the United States and Canada.

mission in the general population. This effect has also been recently demonstrated in a study from Kenya [61]. In that country, the annual risk of infection, estimated through tuberculin surveys in school-children, increased sharply between 1986 and 1996 in districts with a 50% HIV prevalence among tuberculosis patients and an increase in notification rates dating from the early 1990s, but not in other districts.

Other regions are suffering from the co-epidemic. For example, in India, where 44% of the population is estimated to be infected with *M. tuberculosis* [5], HIV seroprevalence among tuberculosis cases has been steadily increasing during the past decade [62]. It has been estimated that, in 1997, India was the country with the highest number of co-infected individuals, accounting for almost one-fifth of the global number. Alarming, in countries of the former Soviet Union, tuberculosis incidence rates increased in the past decade due largely to deteriorating socio-economic conditions [63]. This is also the time when the HIV epidemic began to spread [64]. Although the incidence of HIV-associated tuberculosis is still low in this area, the potential for a significant increase clearly exists.

#### Tuberculosis/HIV in high-resource countries

In the industrialized countries, the impact of HIV-associated tuberculosis, which may have increased during the first half of the past decade, seems to have levelled off or decreased in more recent years. The United States has been heavily hit by the tuberculosis/HIV epidemic. The number of tuberculosis cases increased regularly in 1985–1990, and 28 000 cases of tuberculosis were reported in excess to what was expected from the historical trends [65]. It was estimated that at least 30% of the excess cases could be directly attributed to the HIV epidemic [66]. Since

1992, however, the number of reported cases started to decrease and, compared with 1992, a 31% decrease in incidence of tuberculosis has been observed in 1998. In this context, the decrease of HIV-associated tuberculosis was even more pronounced. The proportion of tuberculosis cases with HIV infection between 1993–1994 and 1997 decreased from 15 to 10% among persons of all ages, and from 29 to 21% among those aged 15–44 years [67]. This downward trend appears to reflect primarily the intensification of control measures, including those specifically targeted to HIV-infected persons. In New York City, the incidence of tuberculosis in HIV-infected persons decreased by more than 20% between 1992 and 1994, when several new measures were adopted to improve control [68]. The number of tuberculosis patients receiving directly observed therapy increased from 100 to 1300, and strict tuberculosis control measures, including high-technology tools such as negative pressure isolation facilities, were implemented to prevent tuberculosis transmission in institutional settings. These interventions may have produced a substantial decrease of transmission of *M. tuberculosis* and, thus, of the risk of developing tuberculosis as a result of recently acquired infection. In Baltimore, widespread use of preventive therapy, which may effectively prevent progression to active tuberculosis in those who are latently infected [69], led to a dramatic reduction of the incidence of tuberculosis among HIV-infected intravenous drug users [70]. In San Francisco, starting from 1991, several interventions were intensified, including improvement of contact investigation, expanded use of directly observed treatment and of preventive therapy for HIV-infected persons, and improvement of control measures in hospitals and other institutional settings [71]. The overall tuberculosis incidence rate dropped from 46.0 to 29.8

per 100 000 population between 1991 and 1997, and an even larger reduction was observed among HIV-infected persons (from 491.8 to 65.6 per 100 000). Interestingly, the decrease of incidence among HIV-infected persons was not constant over this 7-year period. In fact, incidence decreased by 5–15% each year between 1991 and 1996, while an 80% decrease (from 295.1 to 65.6 per 100 000 HIV-infected persons) was recorded between 1996 and 1997. This observation is consistent with the hypothesis that the use of new combination antiretroviral therapies may have also contributed to the decline of HIV-associated tuberculosis. In the United States, data from a sentinel surveillance project show, among HIV-infected persons, a more than twofold decrease in incidence of tuberculosis from 1992 to 1997 [72]. Analysis of data on the use of antiretrovirals by persons included in this project shows that the risk of tuberculosis was reduced by 80% in persons on highly active antiretroviral therapy (HAART) and by 40% in persons on other antiretroviral therapies, compared with those who received no antiretrovirals [73]. Similar results are reported in a cohort study from Italy in which patients who took dual combination therapy had an 80% reduction in risk of tuberculosis, while the risk of tuberculosis in those on triple combination therapy was reduced by 91% compared with patients who did not receive combination therapy [74].

In summary, available evidence suggests that the recent decline of HIV-associated tuberculosis in the United States, and most likely in other industrialized countries, has not been influenced by a single public health measure, but rather by the implementation of several, at times expensive, tuberculosis control interventions and, possibly, by novel therapeutic interventions on HIV disease.

### Novel approaches for tuberculosis control in high HIV prevalence settings

What is the relevance of this experience for developing countries with a high prevalence of HIV infection? Directly observed treatment, short course is the tuberculosis control strategy advocated by the WHO. Based on five core elements [75], it emphasizes government commitment, diagnosis based on bacteriological evidence among symptomatic patients, standardized short-course chemotherapy administered under direct supervision, an effective drug supply system, and an information system allowing reporting of cases and monitoring of treatment outcomes. This strategy, which has been shown to be highly effective in the most diverse settings [76,77], however, seems unlikely to succeed, alone, in controlling tuberculosis in areas where HIV is highly prevalent, although it may prevent the emergence of drug resistance [78].

In developing countries, especially in sub-Saharan Africa, the large majority of people living with HIV are not aware of their infection. In most instances, the lack of any possible benefit from testing, such as non-existent options for treatment, is the reason for choosing not to be tested. However, the number of people who choose to find out their HIV status is increasing, partly because of greater awareness of the need to plan the future and partly because of the introduction of medical interventions such as those to prevent mother-to-child transmission of HIV [79]. A completely new set of interventions addressing the tuberculosis/HIV problem is therefore needed that takes into account recent changes in the epidemiology of tuberculosis and that harnesses the considerable community capacity to support people living with HIV. Such a core set would aim to: (i) reduce transmission of *M. tuberculosis* by improving case-finding and treatment; (ii) reduce reactivation of *M. tuberculosis* by establishing preventive therapy services; and (iii) reduce transmission of HIV by enhancing behavioural change through counselling and testing services, condom promotion and providing better management of sexually transmitted infections.

The WHO has developed the concept of operational integration of tuberculosis and HIV/AIDS control programme activities within the 'ProTest' initiative. The ultimate goal of the initiative is to reduce the burden of the combined tuberculosis and HIV epidemics. Towards this aim, voluntary counselling and testing offers an entry point into a wide range of possible interventions. First, those who discover that they are not infected with HIV have a strong motive to ensure that they remain so, which can be translated into behavioural change by appropriate counselling. Second, in those who have no symptoms but are HIV infected, counselling aims to prevent transmission of HIV as well as to offer psycho-social support to the individual. Tuberculosis preventive therapy is most feasible in this group, since exclusion of active tuberculosis is less difficult. Third, in those who already have symptoms of early HIV disease, the challenge is to detect active cases of tuberculosis early and treat them effectively. Not only will early case detection prevent ongoing transmission of tuberculosis, it will also slow the progression of the HIV infection. This may be achieved by developing more active case-finding services for people known to be HIV-seropositive using community workers and primary health care services. Algorithms for the integrated management of respiratory symptoms need to be incorporated into training for those who support people living with HIV. Social mobilization, counselling and education have to be used to encourage people to seek care early for possible tuberculosis symptoms. Case holding will be improved by liaison with home-based care services. Fourth, the possibility to provide prophylaxis against

common bacterial or protozoal pathogens, such as the pneumococci, salmonellae or isospora, during tuberculosis treatment and beyond may need to be explored [80]. This cheap co-trimoxazole-based intervention, if confirmed to be effective, may prolong life among severely ill patients with HIV-related active tuberculosis. If this was implemented and worked well, it would pave the way to systematic and careful introduction of other more potent interventions, such as HAART. Finally, those with advanced HIV disease, many of whom are house-bound, may be unable to visit their local clinic for supervision of tuberculosis treatment and management of their HIV-related illnesses. Thus, full use of community- and home-based care organizations, where they exist, should be considered to ensure that proper tuberculosis care and control are delivered.

## Conclusions

The AIDS epidemic has a major impact on the epidemiologic dynamics of tuberculosis and highlights the many weaknesses of tuberculosis control both in industrialized and in developing countries. The experience accumulated in the past decade in industrialized countries shows that the HIV/tuberculosis epidemic can be brought under control by interventions that reduce the risk of progression to overt tuberculosis infection (i.e. preventive therapy) and the probability of becoming infected with *M. tuberculosis* (i.e. case finding and adequate treatment, prevention of transmission in institutional settings). Eventually, the widespread use of HAART for treating HIV disease may have also contributed to the reduction of incidence of HIV-associated tuberculosis in high-resource countries. However, the long-term effect of HAART on the risk of developing tuberculosis remains to be determined and the impact of the use of HAART on the tuberculosis/HIV epidemic in different populations should be quantified.

The tuberculosis/HIV epidemic appears to still be on the rise in countries where HIV is highly prevalent and innovative solutions are needed to achieve an effective control in these countries. Interventions that proved effective in industrialized countries should also be considered in resource-poor countries, but carefully designed pilot projects are needed to verify their feasibility and effectiveness in countries with limited resources and a high prevalence of HIV infection.

## References

- Inderlied CB. *Mycobacteria*. In *Infectious Diseases*. Edited by Armstrong D, Cohen J. London: Mosby; 1999:8.22.1-8.22.30.
- Hughes WT. Current issues in the epidemiology, transmission, and reactivation of *Pneumocystis carinii*. *Semin Respir Infect* 1998; 13:283-288.
- IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Human immunodeficiency viruses and human T-cell lymphotropic viruses. IARC Monographs on the Evaluation of Carcinogenic Risk to Humans, Vol. 67. Lyon, France: IARC; 1996:88-103.
- Borezin N. HIV and other sexually transmitted diseases. In *AIDS in the World*. Edited by Mann J, Tarantola DJM, Netter TW. Cambridge, MA: Harvard University Press; 1992:113-164.
- Dye C, Scheele S, Dolin P, Pathania V, Ravignione MC. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *JAMA* 1999; 282:677-686.
- Raviglione MC, Harries AD, Msisika R, Wilkinson D, Nunn P. Tuberculosis and HIV: current status in Africa. *AIDS* 1997; 11(suppl B):S115-S123.
- Blower SM, McLean AR, Porco TC, et al. The intrinsic transmission dynamics of tuberculosis epidemics. *Nat Med* 1995; 1:815-821.
- Blower SM, Small PM, Hopewell PC. Control strategies for tuberculosis epidemics: new models for an old problem. *Science* 1996; 273:497-500.
- Sutherland I. Recent studies in the epidemiology of tuberculosis, based on the risk of being infected with tubercle bacilli. *Adv Tuberc Res* 1976; 19:1-63.
- Selwyn PA, Hartel D, Lewis VA, et al. A prospective study of the risk of tuberculosis among intravenous drug users with human immunodeficiency virus infection. *N Engl J Med* 1989; 320:545-550.
- Viles Braun M, Badi N, Rieder RW, et al. A retrospective cohort study of the risk of tuberculosis among women of childbearing age with HIV infection in Zaire. *Am Rev Respir Dis* 1991; 143:501-504.
- Selwyn PA, Sckell BM, Alcibas P, et al. High risk of active tuberculosis in HIV-infected drug users with cutaneous anergy. *JAMA* 1992; 268:504-509.
- Allen S, Batungwanayo J, Kerlikowske K, et al. Two-year incidence of tuberculosis in cohorts of HIV-infected and uninfected urban Rwandan women. *Am Rev Respir Dis* 1992; 146:1439-1444.
- Moreno S, Baraia-Etxaburu J, Bouza E, et al. Risk for developing tuberculosis among anergic patients infected with HIV. *Ann Intern Med* 1993; 119:194-198.
- Guelar A, Gatell JM, Verdejo J, et al. A prospective study of the risk of tuberculosis among HIV-infected patients. *AIDS* 1993; 7:1345-1349.
- Antonucci G, Girardi E, Ravignione MC, Ippolito G, for the Gruppo Italiano di Studio Tubercolosi ed AIDS. Risk factors for tuberculosis in HIV-infected subjects: a prospective cohort study. *JAMA* 1995; 274:143-148.
- Markowitz N, Hansen NI, Hopewell PC, et al. Incidence of tuberculosis in the United States among HIV-infected persons. *Ann Intern Med* 1997; 126:123-132.
- Pape JW, Jean SS, Ho JL, Hafner A, Johnson WD. Effect of isoniazid prophylaxis on incidence of active tuberculosis and progression of HIV infection. *Lancet* 1993; 342:268-272.
- Whalen CC, Johnson JL, Okwera A, et al. A trial of three regimens to prevent tuberculosis in Ugandan adults with the human immunodeficiency virus. *N Engl J Med* 1997; 337:801-808.
- Hawken M, Meme HK, Elliott LC, et al. Isoniazid preventive therapy for tuberculosis in HIV-1 infected adults: results of a controlled trial. *AIDS* 1997; 11:875-882.
- Mwinga A, Hosp M, Godfrey-Fausset P, et al. Twice weekly tuberculosis preventive therapy in HIV infection in Zambia. *AIDS* 1998; 12:2447-2457.
- Gordin FM, Matts JP, Miller C, et al. A controlled trial of isoniazid in persons with anergy and human immunodeficiency virus infection who are at high risk for tuberculosis. *N Engl J Med* 1997; 337:315-320.
- Sivblo K. Epidemiology of tuberculosis. *R Netherlands Tuberc Assoc Selected Papers* 1991; 24:1-129.
- Behr MA, Warren SA, Salamon H, et al. Transmission of *Mycobacterium tuberculosis* from patients smear-negative for acid-fast bacilli. *Lancet* 1999; 353:444-449.
- Doenhoff MJ. Granulomatous inflammation and the transmission of infection: schistosomiasis — and TB too? *Immunol Today* 1998; 19:462-467.

26. Di Perri G, Cazzadori A, Vento S, et al. Comparative histopathological study of pulmonary tuberculosis in human immunodeficiency virus-infected and non-infected patients. *Tuberc Lung Dis* 1996; 77:244-249.
27. Kramer F, Modilevsky T, Waliany AR, et al. Delayed diagnosis of tuberculosis in patients with human immunodeficiency virus infection. *Am J Med* 1990; 89:451-456.
28. Pilchenik AE, Burr J, Suarez M, Fertel D, Gonzalez G, Moas C. Human T-cell lymphotropic virus-III (HTLV-III) seropositivity and related disease among 71 consecutive patients in whom tuberculosis was diagnosed. A prospective study. *Am Rev Respir Dis* 1987; 135:875-879.
29. Standaert B, Niragira F, Kalende P, et al. The association of tuberculosis and HIV-1 infection in Burundi. *AIDS Res Hum Retroviruses* 1989; 5:247-251.
30. Nunn P, Nyamwaya I, Gicheha C, et al. The effect of human immunodeficiency virus type-1 on the infectiousness of tuberculosis. *Tuberc Lung Dis* 1994; 75:25-32.
31. Klausner JD, Ryder RW, Baende E, et al. *Mycobacterium tuberculosis* in household contacts of human immunodeficiency virus type-1-seropositive patients with active pulmonary tuberculosis in Kinshasa, Zaire. *J Infect Dis* 1993; 168:106-111.
32. Cauthen GM, Dooley SV, Onorato IM, et al. Transmission of *Mycobacterium tuberculosis* from tuberculosis patients with human immunodeficiency virus infection or AIDS. *Am J Epidemiol* 1996; 144:69-77.
33. Elliot A, Hayes RJ, Halwandi B, et al. The impact of HIV-1 on infectiousness of pulmonary tuberculosis: a community study in Zambia. *AIDS* 1993; 7:981-987.
34. Cayla JA, Garcia de Olalla P, Galdós-Tangüis H, et al. The influence of intravenous drug use and HIV infection in the transmission of tuberculosis. *AIDS* 1996; 10:95-100.
35. Guwatudde D, Nakeeto MK, Musoke P, et al. The impact of HIV-1 on transmission of tuberculosis in Ugandan households. 12th International Conference on AIDS, Geneva, June 1998 [abstract 608/13258].
36. Espinal MA, Perez EN, Baéz J, et al. Infectiousness of *Mycobacterium tuberculosis* in HIV-1-infected patients with tuberculosis: a prospective study. *Lancet* 2000; 355:275-280.
37. Brewer TF, Heymann J, Colditz GA, et al. Evaluation of tuberculosis control policies using computer simulation. *JAMA* 1996; 276:1898-1903.
38. Centers for Disease Control and Prevention. Prevention and treatment of tuberculosis among patients infected with human immunodeficiency virus: principles of therapy and revised recommendations. *MMWR* 1998; 47(RR-20):1-52.
39. World Health Organization. Global tuberculosis control. *WHO Report 2000. WHO/CDS/TB/2000.275*. Geneva: World Health Organization.
40. Brudney K, Dobkin J. Resurgent tuberculosis in New York City. Human immunodeficiency virus, homelessness, and the decline of tuberculosis control programs. *Am Rev Respir Dis* 1991; 144:745-749.
41. Comstock GW. Epidemiology of tuberculosis. *Am Rev Respir Dis* 1982; 125:1-16.
42. Di Perri G, Cruciani M, Danzi MC, et al. Nosocomial epidemic of active tuberculosis among HIV-infected patients. *Lancet* 1989; ii:1502-1504.
43. Daley CL, Small PM, Schecter GF, et al. An outbreak of tuberculosis with accelerated progression among persons infected with the human immunodeficiency virus. An analysis using restriction-fragment-length polymorphism. *N Engl J Med* 1992; 326:231-235.
44. Edlin BR, Tokars JJ, Grieco MH, et al. An outbreak of multidrug resistant tuberculosis among hospitalized patients with the acquired immunodeficiency syndrome. *N Engl J Med* 1992; 326:1514-1521.
45. Dooley SV, Villarino ME, Lawrence M, et al. Nosocomial transmission of tuberculosis in a hospital unit for HIV infected patients. *JAMA* 1992; 267:2632-2635.
46. Coronado VC, Beck-Sague CM, Hutton MD, et al. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons with human immunodeficiency virus infection in an urban hospital: epidemiologic and restriction fragment length polymorphism analysis. *J Infect Dis* 1993; 168:1052-1055.
47. Moro ML, Errante I, Intuso A, et al. Effectiveness of infection control measures in controlling a nosocomial outbreak of multidrug-resistant tuberculosis among HIV-infected patients in Italy. *Int J Tuberc Lung Dis* 2000; 4:61-68.
48. Huebner RE, Villarino ME, Snider DE. Tuberculin skin testing and the HIV epidemic. *JAMA* 1992; 267:409-410.
49. Godfrey-Fausch P. Interpretation of cluster studies of tuberculosis. *Lancet* 1999; 353:427-428.
50. Glynn JR, Vynnycky E, Fine PE. Influence of sampling on estimates of clustering and recent transmission of *Mycobacterium tuberculosis* derived from DNA fingerprinting techniques. *Am J Epidemiol* 1999; 149:366-371.
51. Small PM, Hopewell PC, Singh SP, et al. The epidemiology of tuberculosis in San Francisco. A population-based study using conventional and molecular methods. *N Engl J Med* 1994; 330:1703-1709.
52. Alland D, Kalkut GE, Moss AR, et al. Transmission of tuberculosis in New York City. An analysis by DNA fingerprinting and conventional epidemiologic methods. *N Engl J Med* 1994; 330:1710-1716.
53. Hamburg MA, Frieden TR. Tuberculosis transmission in 1990s. *N Engl J Med* 1994; 330:1750-1751.
54. Centers for Disease Control and Prevention. *Reported Tuberculosis Rate in the United States, 1993*. Atlanta: US Department of Health and Human Services, Public Health Service, CDC, October 1994.
55. H Safi, J Aznar, JC Palomares. Molecular epidemiology of *Mycobacterium tuberculosis* strains isolated during a 3-year period (1993 to 1995) in Seville, Spain. *J Clin Microbiol* 1997; 35:2472-2476.
56. Gutierrez MC, Vincent V, Aubert D, et al. Molecular fingerprinting of *Mycobacterium tuberculosis* and risk factors for tuberculosis transmission in Paris, France, and surrounding area. *J Clin Microbiol* 1997; 36:486-492.
57. van Soolingen D, Borgdorff MW, de Haas PEW, et al. Molecular epidemiology of tuberculosis in the Netherlands: a nationwide study from 1993 through 1997. *J Infect Dis* 1999; 180:726-736.
58. Ferrazzoli L, Palaci M, Marques LR, et al. Transmission of tuberculosis in an endemic urban setting in Brazil. *Int J Tuberc Lung Dis* 2000; 4:18-25.
59. Haas WH, Engelmann G, Amthor B, et al. Transmission dynamics of tuberculosis in a high-incidence country: prospective analysis by PCR DNA fingerprinting. *J Clin Microbiol* 1999; 37:3975-3979.
60. Dolin PJ, Ravigliione MC, Kochi A. Global incidence and mortality during 1990-2000. *Bull WHO* 1994; 72:213-220.
61. Odhiambo JA, Borgdorff MW, Kiambi FM, et al. Tuberculosis and HIV epidemic: increasing annual risk of tuberculosis infection in Kenya, 1986-1996. *Am J Public Health* 1999; 89:1078-1082.
62. Solomon S, Anuradha S, Rajasekaran S. Trend of HIV infection in patients with pulmonary tuberculosis in India. *Tuberc Lung Dis* 1995; 76:17-19.
63. Zalesky R, Abdullajev F, Khechinashvili G, et al. Tuberculosis control in the Caucasus — successes and constraints in DOTS implementation. *Int J Tuberc Lung Dis* 1999; 3:394-401.
64. United Nations Programme on HIV/AIDS and World Health Organization. *Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization AIDS epidemic update: December 1999*. Geneva: UNAIDS/WHO; 1999.
65. Jereb JA, Kelly GD, Dooley SW, Cauthen GM, Snider DE. Tuberculosis morbidity in the United States: final data 1990. *MMWR* 1991; 40:23-27.
66. Bloom BR, Murray CL. Tuberculosis. Commentary on a reemerging killer. *Science* 1992; 257:1055-1064.
67. Centers for Disease Control and Prevention. *Progress toward elimination of tuberculosis — United States 1998*. *MMWR* 1999; 48:732-736.
68. Frieden TR, Fujiwara PI, Washko RM, Hamburg MA. Tuberculosis in New York City — turning the tide. *N Engl J Med* 1995; 333:229-233.
69. Bucher HC, Griffith LE, Guyatt GH, et al. Isoniazid prophylaxis in HIV infection: a meta-analysis of randomized controlled trials. *AIDS* 1999; 13:501-507.
70. Graham NMH, Galai N, Nelson KE, et al. Effect of isoniazid chemoprophylaxis on HIV-related mycobacterial disease. *Arch Intern Med* 1996; 156:889-894.
71. Jasmer RM, Hahn JA, Small PM, et al. A molecular epidemiologic analysis of tuberculosis trends in San Francisco, 1991-1997. *Ann Intern Med* 1999; 130:971-978.

72. Jones JL, Hanson DL, Dworkin MS, *et al.* Surveillance for AIDS-defining opportunistic illnesses, 1992-1997. *MMWR* 1999, 48:1-22.
73. Jones JL, Hanson DL, Dworkin MS, DeCock KM. HIV associated TB in the era of HAART. 1999 *National HIV Prevention Conference*. Atlanta, GA, August-September 1999 [abstract 164].
74. Girardi E, Antonucci G, Vanacore P, *et al.* Impact of combination antiretroviral therapy on the risk of tuberculosis among persons with HIV infection. *Seventh Conference on Retroviruses and Opportunistic Infections*. San Francisco, CA, January-February 2000 [abstract 255].
75. Raviglione MC, Dye C, Schmidt S, Kochi A, for the WHO Global Surveillance and Monitoring Project. Assessment of worldwide tuberculosis control. *Lancet* 1997, 350:624-629.
76. China Tuberculosis Control Collaboration. Results of directly observed short-course chemotherapy in 112 842 Chinese patients with smear-positive tuberculosis. *Lancet* 1996, 347:358-362.
77. Harries AD, Nyong'Onya Mbewe L, Salaniponi FML, *et al.* Tuberculosis programme changes and treatment outcomes in patients with smear-positive pulmonary tuberculosis in Blantyre, Malawi. *Lancet* 1996, 347:807-809.
78. De Cock KM, Chaisson RE. Will DOTS do it? A reappraisal of tuberculosis control in countries with high rates of HIV infection. *Int J Tuberc Lung Dis* 1999, 3:457-465.
79. World Health Organization/Global Tuberculosis Programme and UNAIDS. Preventive therapy against tuberculosis in people living with HIV. Policy statement. *Weekly Epidemiol Rec* 1999, 74:385-397.
80. Wiktor SZ, Sassan-Morokro M, Grant AD, *et al.* Efficacy of trimethoprim-sulphamethoxazole prophylaxis to decrease morbidity and mortality in HIV-1-infected patients with tuberculosis in Abidjan, Côte d'Ivoire: a randomised controlled trial. *Lancet* 1999, 353:1469-1475.

**19**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

## Under-diagnosis of smear-positive pulmonary tuberculosis in Nairobi, Kenya

M. P. Hawken,<sup>\*\*</sup> D. W. Muhindi,<sup>†</sup> J. M. Chakaya,<sup>\*</sup> S. M. Bhatt,<sup>‡</sup> L. W. Ng'ang'a,<sup>\*</sup> J. D. H. Porter<sup>†</sup>

<sup>\*</sup> Centre for Respiratory Diseases Research, Kenya Medical Research Institute (KEMRI), Nairobi, Kenya;

<sup>†</sup> Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London, UK;

<sup>‡</sup> Department of Medicine, University of Nairobi, Nairobi, Kenya

### SUMMARY

**SETTING:** Nairobi City Council Chest Clinic, Nairobi, Kenya.

**OBJECTIVE:** To determine if under-reading of sputum smears is a contributing factor in the disproportionate increase in smear-negative tuberculosis in Nairobi, Kenya.

**METHODOLOGY:** Between October 1997 and November 1998, patients fulfilling the local programme definition of smear-negative presumed pulmonary tuberculosis were enrolled in the study. Two further sputum specimens were collected for examination in a research laboratory by fluorescence microscopy.

**RESULTS:** Of 163 adult subjects enrolled, 55% were seropositive for the human immunodeficiency virus type 1 (HIV-1). One hundred subjects had had two pre-study sputum smears assessed before recruitment and produced two further sputum specimens for re-examination in the research laboratory; of these 19 (19%) were

sputum smear-positive on re-examination and a further seven (7%) became smear-positive on second re-examination.

**CONCLUSIONS:** Of those patients with smear-negative presumed pulmonary tuberculosis by the local programme definition, 26% were smear-positive when re-examined carefully with two repeat sputum smears. This suggests that the high rates of smear-negative tuberculosis being seen may in part be due to under-reading. This is probably as a result of the overwhelming burden of tuberculosis leading to over rapid and inaccurate sputum examination. Retraining of existing technicians and training of more technicians is likely to reduce under-reading and increase the yield of smear-positive tuberculosis. This finding also stresses the need for regular quality assurance.

**KEY WORDS:** smear-negative; tuberculosis; HIV; low-income countries; Africa

AN INCREASE in the annual number of notifications of all types of tuberculosis (TB) has been seen in many low-income countries with high TB and human immunodeficiency virus (HIV) prevalence, and is attributed primarily to the predisposing effect of HIV on TB.<sup>1</sup> Associated with this increase in all types of TB, the rate of increase in smear-negative TB has been greater than that of smear-positive TB in several low-income countries.<sup>2,3</sup> For example, in Kenya,<sup>4,5</sup> the case notification rate for all types of TB was 52 per 100 000 population in 1987 and had risen to 171/100 000 in 1998. The annual increase has risen dramatically over this period to levels of 10–20% per annum in the last four years. In 1987 the ratio of smear-negative to smear-positive cases (exclusive of extra-pulmonary cases) was 0.6, while in 1998 this ratio had risen to 0.7.

There are several technical reasons that may give rise to a false negative sputum examination. These include inadequate sputum collection procedures,

inadequate storage of sputum specimens and stained smears, failure to select suitable sputum particles for smear preparation, inadequate preparation of smears or staining of slides and inadequate examination of the smear. In addition to technical laboratory-related factors, the altered pathology in HIV-associated TB may also be contributing to the increase of the proportion of smear-negative TB, for two reasons. The mean concentration of bacilli in the sputum of HIV-infected patients is reported to be lower than in HIV-negative patients,<sup>6</sup> with a consequent decrease in the sensitivity of the sputum smear examination.<sup>7,8</sup> This decreased sensitivity of the sputum smear in HIV-associated TB may be producing a genuine increase in the number of smear-negative TB cases. There is also a decreased specificity of the chest radiograph.<sup>9</sup> As sputum culture is not routinely performed in Kenya, diagnosis of suspects with negative sputum smears is based on the interpretation of the chest radiograph. Because of the decreased specificity of the

chest radiograph in HIV-associated TB, other HIV-associated pathology such as bacterial or fungal pneumonitides may be being labelled as smear-negative TB. Finally, the sheer increase in the number of patients requiring screening for TB brought about by HIV may be leading to more rapid and inadequate smear examinations, or in some cases technicians may be limiting examination to one or two of several specimens from each patient.

This study was part of a larger study to examine the validity of the programme definition of smear-negative presumed pulmonary TB. We report here on the first part of the study, where patients with a programme definition of smear-negative presumed pulmonary TB had two further sputum specimens examined by fluorescence microscopy in a research laboratory. Our objective was to determine if under-reading of sputum smears is a contributing factor in the disproportionate increase in smear-negative TB in Nairobi, Kenya.

## METHODS

### *Study population*

Patients were recruited from the Nairobi City Council Chest Clinic, the main government out-patient clinic for the screening of patients with suspected TB. Patients are referred by government health facilities, private practitioners and non-governmental health facilities. Patients were screened by one of two permanent clinical officers. The definition of smear-negative presumed pulmonary TB as defined by the World Health Organization (WHO) and accepted by the Kenya National Leprosy and Tuberculosis Programme is: cough >3 weeks, three sputum smears negative for acid-fast bacilli (AFB), a pulmonary infiltrate on chest radiograph and no response to broad spectrum antibiotics after 7 days.<sup>10</sup> Two negative smears only are accepted in the case of severely ill patients.

Although the WHO definition requires three negative sputum specimens for a diagnosis of presumed smear-negative pulmonary TB, in practice this policy was not adhered to by the health workers. In practice, two or at times one negative smear was accepted by the health workers as a means to expedite the diagnostic process to cope with the increase in numbers of TB suspects. Original sputum examinations were done by light microscope examination of Ziehl-Neelsen stained smears at either government TB laboratories or private laboratories in Nairobi.

From November 1997 to October 1998, 10 162 suspects were screened for TB at the Nairobi City Council Chest Clinic; 1104 patients were registered as smear-negative presumed pulmonary TB and 2702 were registered as smear-positive TB. Of the 1104 patients registered as smear-negative presumed pulmonary TB, 430 were screened on 3 days a week by the study team and enrolled in the study if they met the following criteria: age >17 years, registered as

smear-negative presumed pulmonary TB, resident in Nairobi and gave informed consent. Reasons for non-enrolment in the study were: declined to be in the study (147, 55.1%), declined HIV testing (6, 2.2%), aged <18 or >50 (45, 16.9%), unable to give informed consent (6, 2.2%), past history of TB or current treatment for TB (33, 12.4%), non-resident in Nairobi (17, 6.4%), pregnancy (6, 2.2%), and milary pattern on chest radiograph (7, 2.6%). The age and sex ratio of those patients who declined was similar to that of those included in the study.

One hundred and sixty-three subjects (98 male and 65 female) were enrolled in the study; 55% (81/163) were HIV-1 positive. One hundred and twenty-three patients produced a further two specimens for examination in our laboratory, 20 produced one repeat sputum only, and 20 failed to produce a repeat sputum. Further analysis is on the 123 patients who produced two further sputum specimens for re-examination. The mean age of the subjects was 30.9 years (SD 7.5, median 30 years, range 18–49). The male to female ratio was 1.5:1.

### *Mycobacteriology*

Sputum fluorescence microscopy was performed by the Centre for Microbiology laboratory, Kenya Medical Research Institute (KEMRI), by standard methods.<sup>11</sup> Positive smears were classified as 1+ (1–9 AFB/100 fields), 2+ (10–100 AFB/100 fields and 3+ (1–10 AFB/field in at least 50 fields).<sup>12</sup>

### *HIV serology*

Serum was tested for HIV antibodies using a rapid immunoassay (DETECT-HIV, Biochem ImmunoSystems Inc, Montreal, Canada) after pre-test counselling and informed consent. Those testing positive were confirmed with a second, more specific immunoassay (Recombigen Biotech, Galway, Ireland).

### *Ethical permission*

Ethical permission was obtained from the KEMRI/National Ethical Research Committee, Nairobi, and the Ethics Committee, London School of Hygiene and Tropical Medicine.

### *Statistical analysis*

Data were recorded on standard forms and then stored in the data storage package Fox Pro. Data were analysed using the SAS statistical package (SAS Institute, Cary, NC). Standard parametric and non-parametric statistical methods were used as appropriate.

## RESULTS

The results of repeat sputum examination in the research laboratory are shown in the Table. Of the 123 patients assessed, 100 patients had had two pre-study sputum smears examined and 23 (19%) had

Table Patients with a positive repeat sputum smear

	Two pre-study sputum smears (n=100)	One pre-study sputum smear (n=23)
1st repeat sputum smear positive	19	4
2nd repeat sputum smear positive	7	1
	26 (26%)	5 (22%)

only one sputum specimen examined. In 19 (19%) of the 100 patients with two negative pre-study smear results, the first repeat smear examined in the research laboratory showed a positive result. Seven more patients showed positive after examination of a second sputum specimen. In total, 26% of initially smear-negative patients proved smear-positive in either one of two subsequent repeat examinations. The degree of positivity was: 19  $\times$  1+, 4  $\times$  2+, and 3  $\times$  3+. The mean number of days was 19.1 (14.3) and 18.3 (17.1) days from the first pre-study smear to the last study smear, respectively, in those who had a positive study smear and those who remained consistently negative ( $P = 0.8$ ). Of the 23 patients who had had only one sputum smear examined before recruitment, the first repeat smear showed positive in four (17%) and the second repeat smear showed positive in one (5%). Sixty-seven per cent (67%) of the pre-study smears were examined in a government laboratory and 32% were examined by private laboratories. There was no significant difference between the proportions of positive smears reported by government or private laboratories ( $P = 0.47$ ).

## DISCUSSION

This study found that a significant number of cases (26%) registered as smear-negative TB were in fact smear-positive when re-examined carefully with two repeat sputum smears. Based on figures from serial smear examinations, we would have expected to detect a further 4% of cases from a third smear.<sup>13-15</sup> Despite using the more sensitive technique of fluorescence microscopy as compared to the Zeihl-Neelsen method,<sup>15-17</sup> we believe 19% on first re-examination is greatly in excess of what would be expected. Ideally we should have examined the original smears, but this was not possible. We cannot exclude the possibility of smear-negative cases becoming positive with time. However, this explanation is unlikely as there was no significant difference in the mean time between the first pre-study smear and the last study smear in those who showed positive and in those who did not. Likewise, we cannot exclude the possibility of the high false negative rate being due to delay in specimens reaching the laboratory or inappropriate sputum collection. However, it is most likely that this difference reflects under-reading of the smear at the time of sputum microscopy. This under-reading is most

likely a result of the overwhelming burden of TB suspects requiring screening, leading to over rapid and inaccurate sputum examination.

There are several reasons why it is important to identify the smear-positive patient and to begin treatment as soon as possible. First, patients with a negative smear may not be diagnosed at all, as the final diagnosis will be based on the chest radiograph and the clinician may decide that the patient does not have TB. Secondly, smear-positive cases misclassified as smear-negative will go on to have an unnecessary chest radiograph and a course of broad-spectrum antibiotics, introducing a delay in starting treatment. This delay is likely to lead to increased morbidity and mortality. It also introduces an additional cost for both the patient and the programme. In a situation where the TB burden is likely to continue to rise and resources are already limited, programmes cannot afford this additional expense. In addition, during the period while start of treatment is delayed, the smear-positive patient will continue to infect more contacts.

Re-training of existing technicians and training of more technicians is likely to reduce this under-reading and increase the yield of smear-positive TB. Regular quality assurance is also necessary to monitor the quality of a programme's diagnostic service.

In this study, 19% of suspects of TB were registered by medical staff as smear-negative TB after only one sputum smear examination. Several studies<sup>13-15</sup> suggest that there is little increased yield from a third sputum smear but that a second smear has a sufficiently increased yield to be worth doing. Reinforcement of the importance of adhering to the programme definition criteria is therefore a training priority.

## Acknowledgements

We would like to thank the medical and nursing staff of the Nairobi City Council Chest Clinic and the Department for International Development, UK, and KEMRI for supporting the study. We would also like to thank the Director of KEMRI for permission to publish.

## References

- 1 Dolin P J, Raviglione M C, Kochi A. Global tuberculosis incidence and mortality during 1990-2000. *Bull World Health Organ* 1994; 72: 213-220.
- 2 Harries A D, Maher D, Nunn P. An approach to the problems of diagnosing and treating adult smear-negative pulmonary tuberculosis in high-HIV-prevalence settings in Sub-Saharan Africa. *Bull World Health Organ* 1998; 76: 651-662.
- 3 Graf P. Tuberculosis control in high-prevalence countries. In: Davis P D O, ed. *Clinical Tuberculosis*. London: Chapman & Hall, 1994: p 337.
- 4 National Leprosy & Tuberculosis Programme Annual Report 1987. Nairobi, Kenya: Kenya Ministry of Health, 1987.
- 5 National Leprosy & Tuberculosis Programme Annual Report 1998. Nairobi, Kenya: Kenya Ministry of Health, 1998.
- 6 Brindle R J, Nunn P P, Githui W, Allen B W, Gathua S, Waiyaki P. Quantitative bacillary response to treatment in HIV-associated pulmonary tuberculosis. *Am Rev Respir Dis* 1993; 147: 958-961.
- 7 Elliott A M, Namaambo K, Allen B W, et al. Negative sputum

- smear results in HIV-positive patients with pulmonary tuberculosis in Lusaka, Zambia. *Tubercle Lung Dis* 1993; 74: 191-194.
- 8 Long R, Scalchini M, Manfreda J, Jean-Baptiste M, Hershfield E. The impact of HIV on the usefulness of sputum smears for the diagnosis of tuberculosis. *Am J Public Health* 1991; 81: 1326-1328.
  - 9 Harries A D. The association between HIV and tuberculosis in the developing world. In: Davis P D O, ed. *Clinical Tuberculosis*. London: Chapman & Hall, 1994: pp 241-264.
  - 10 *Treatment of Tuberculosis. Guidelines for National Programmes*, 2nd ed. Geneva: WHO, 1997.
  - 11 Collins C, Grange J, Yates M. *Organisation and practice in tuberculosis bacteriology*. London, UK: Butterworth, 1985.
  - 12 Rieder H L, Chonde T M, Myking H, et al. National Tuberculosis Reference Laboratory/National Laboratory Network. Minimal requirements, role and operation in low-income countries. Paris: IUATLD, 1998.
  - 13 Harries A D, Kameya A, Subramanyam V R, Salaniponi F M. Sputum smears for the diagnosis of smear-positive pulmonary tuberculosis. *Lancet* 1996; 347: 834-835.
  - 14 Rieder H L, Arnadottir Th, Tardencilla Gutierrez A A, et al. Evaluation of a standardized recording tool for sputum smear microscopy for acid-fast bacilli under routine conditions in low income countries. *Int J Tuberc Lung Dis* 1997; 1: 339-345.
  - 15 Ipuge Y A I, Rieder H L, Enarson D A. The yield of acid-fast bacilli from serial smears in routine microscopy laboratories in rural Tanzania. *Trans Roy Soc Trop Med Hygiene* 1996; 90: 258-261.
  - 16 Ba F, Rieder H L. A comparison of fluorescence microscopy with the Ziehl-Neelsen technique in the examination of sputum for acid-fast bacilli. *Int J Tuberc Lung Dis* 1999; 3: 1101-1105.
  - 17 Githui W, Kirui F, Juana E S, Obwana D O, Mwai J, Kwamanga D. A comparative study on the reliability of fluorescence microscopy and Ziehl-Neelsen method in the diagnosis of pulmonary tuberculosis. *East Afr Med J* 1993; 70: 263-266.

## R É S U M É

**CADRE:** Centre de pneumologie de la ville de Nairobi, Kenya.

**OBJECTIF:** Déterminer dans quelle mesure une insuffisance de lecture des frottis d'expectorations est un facteur qui contribue à l'augmentation disproportionnée de la tuberculose à bacilloscopie négative à Nairobi, Kenya.

**METHODOLOGIE:** Entre octobre 1997 et novembre 1998, on a introduit dans l'étude les patients répondant à la définition de présomption de tuberculose pulmonaire à bacilloscopie négative définie par le programme local. Deux échantillons complémentaires d'expectoration ont été recueillis pour examen par microscopie à fluorescence dans un laboratoire de recherche.

**RÉSULTATS:** On a enrôlé 163 sujets adultes dont 55% étaient séropositifs pour le virus de l'immunodéficience humaine type 1 (VIH-1). Chez 100 sujets, l'on disposait de deux frottis d'expectoration examinés préalablement à leur admission dans l'étude. Les patients ont fourni deux échantillons complémentaires d'expectoration pour un nouvel examen au laboratoire de recherche.

Parmi ceux-ci, 19 (19%) se sont avérés avoir une bacilloscopie positive lors du premier réexamen et sept (7%) l'eurent lors du deuxième réexamen.

**CONCLUSIONS:** Parmi les patients avec présomption de tuberculose pulmonaire à bacilloscopie négative selon la définition du programme local, 26% s'avèrent positifs à l'examen direct lors d'un réexamen soigneux comportant deux frottis d'expectoration. Ceci suggère que les taux élevés de tuberculose à bacilloscopie négative actuellement observés peuvent être dus partiellement à une déficience de la lecture. Ceci résulte probablement du fardeau accablant de la tuberculose qui entraîne des examens d'expectoration trop rapides et imprécis. La formation continue des techniciens existants et la formation d'un plus grand nombre de techniciens sont susceptibles de réduire cette insuffisance des lectures et d'augmenter la récolte des tuberculoses à bacilloscopie positive. Cette observation souligne également la nécessité d'un contrôle de qualité régulier.

## R E S U M E N

**MARCO DE REFERENCIA:** Clínica del Tórax, Ciudad de Nairobi, Kenia.

**OBJETIVO:** Determinar si la mala lectura del examen de esputos es un factor que contribuye al aumento desproporcionado de la tuberculosis con esputo negativo en Nairobi, Kenia.

**METODOLOGÍA:** Entre octubre de 1997 y noviembre de 1998 se incorporaron a este estudio los pacientes que el programa local definía como pacientes tuberculosos con esputo negativo. Se analizaron dos muestras de esputos complementarias por microscopia fluorescente en un laboratorio de investigación.

**RESULTADOS:** Se incorporaron 163 sujetos adultos. El 55% de ellos eran VIH-1 positivos. Cien sujetos habían tenido dos análisis de esputos previos al estudio y se efectuaron otros dos estudios de esputos en el laboratorio de investigación. De ellos, 19 (19%) tenían esputos

positivos en un primer nuevo examen y siete (7%) fueron positivos en un segundo examen.

**CONCLUSIONES:** El 26% de los pacientes con presunta tuberculosis pulmonar con esputo negativo, según la definición del programa local, resultaron con esputo positivo al ser re-examinados con dos nuevos análisis de esputos. Esto sugiere que las tasas elevadas de tuberculosis con esputo negativo deben ser debidas, en parte, a una mala lectura. Esto es probablemente el resultado de un recargo de enfermos tuberculosos que lleva a un examen de esputos demasiado rápido e impreciso. Es probable que el mejor entrenamiento de los técnicos existentes y el aporte de otros nuevos pueda reducir los errores de la lectura y aumentar el número de tuberculosis con esputo positivo. Estos hallazgos también refuerzan la necesidad de un mejor control de calidad de los resultados.

**20**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

WHO/CDS/TB/99.269  
Original: English  
Distr: General

# **GUIDELINES FOR THE PREVENTION OF TUBERCULOSIS IN HEALTH CARE FACILITIES IN RESOURCE-LIMITED SETTINGS**

*Writing committee:*

**REUBEN GRANICH, NANCY J. BINKIN,  
WILLIAM R. JARVIS AND PATRICIA M. SIMONE**

*Centers for Disease Control and Prevention  
Atlanta, United States of America*

**HANS L. RIEDER**

*International Union Against Tuberculosis  
and Lung Disease  
Paris, France*

**MARCOS A. ESPINAL AND JACOB KUMARESAN**

*Communicable Diseases Programme  
World Health Organization  
Geneva, Switzerland*

**Medical Mission Institute  
Health Services and HIV/AIDS  
Salvatorstr. 22  
D-97074 Würzburg, Germany**



**World Health Organization  
1999**

## CONTENTS

Executive Summary .....	5
Glossary and Abbreviations .....	7
Introduction .....	11
1. Pathogenesis and Transmission of TB .....	13
1.1 Review of transmission and pathogenesis of <i>Mycobacterium tuberculosis</i> .....	13
1.2 Factors affecting the risk of <i>Mycobacterium tuberculosis</i> infection .....	13
1.3 Risk of disease following infection .....	15
2. Risk of Nosocomial Transmission of <i>Mycobacterium tuberculosis</i> to Health Care Workers in Resource-limited Countries .....	17
2.1 Documentation of nosocomial risk .....	17
2.2 Who is at risk? .....	17
2.3 Conclusion .....	18
3. An Introduction to Infection Control Strategies .....	21
3.1 Infection control strategies .....	21
3.2 Administrative (managerial) controls .....	21
3.3 Environmental control measures .....	21
3.4 Personal respiratory protection .....	22
4. Administrative Control Measures .....	23
4.1 Administrative (managerial) control measures .....	23
4.2 District level .....	23
4.3 Referral level .....	28
4.4 Special areas and topics .....	32
5. Environmental Control Measures .....	37
5.1 General comments .....	37
5.2 Environmental controls .....	37
5.3 Ventilation patterns .....	37
5.4 Methods to maximize natural ventilation .....	38
5.5 Mechanical ventilation .....	40
5.6 Monitoring of ventilation and ventilation systems .....	41
5.7 Special areas .....	41
5.8 Ultraviolet germicidal irradiation .....	42
5.9 HEPA filtration .....	43
6. Personal Respiratory Protection .....	45
6.1 The role of respiratory protection .....	45
6.2 The role of surgical masks and respirators .....	45

## CONTENTS

7. Laboratory Safety .....	49
7.1 Laboratory safety .....	49
7.2 AFB Smear preparation .....	49
7.3 Preparation of liquid suspensions of <i>Mycobacterium tuberculosis</i> .....	49
7.4 Biosafety Cabinets .....	49
7.5 Personal respiratory devices in the laboratory .....	50

## EXECUTIVE SUMMARY

Presently, disease caused by *Mycobacterium tuberculosis* (*M. tuberculosis*) is the leading cause of mortality among adults in the world. Populations in resource-limited settings account for nearly 95% of *M. tuberculosis* infections, with the global burden due to infection of *M. tuberculosis* being approximately 1.1 billion people. In 1998, WHO reported an estimated two million deaths due to tuberculosis (TB).

The WHO strategy to control TB, Directly Observed Treatment, Short-Course Chemotherapy (DOTS), can cure nearly all cases of TB. One of the foundations of DOTS is the administration of standard short-course chemotherapy (SCC) under direct observation to TB patients via health care workers (HCWs). Recent studies performed in developing countries have shown that HCWs caring for infectious TB patients are at increased risk of *M. tuberculosis* infection and disease.

HCWs are essential in the fight against TB and they should be protected. Given the integral nature of HCWs in managing active cases and in preventing further transmission of *M. tuberculosis*, the World Health Organization (WHO) presents these guidelines to provide Member States with limited resources, with inexpensive and effective control strategies for prevention of *M. tuberculosis* transmission in HCWs. These guidelines serve not only to prevent patient-to-HCW transmission, but also to prevent patient-to-patient transmission.

These guidelines provide discussion and recommendations for the district and referral level (thus accounting for the wide variety of health care facilities) based upon three levels of infection control: administrative, environmental, and personal respiratory protection. The first priority in infection control is the use of administrative control measures to prevent the generation of infectious droplet nuclei, thereby reducing the exposure of the HCWs and patients to *M. tuberculosis*. Measures at the referral and district level include development of an Infection Control Plan, HCW training, patient education, sputum collection, triage and evaluation of suspect TB patients in outpatient settings, and reduction of exposure in the laboratory. Additional measures such as isolation of patients with multidrug-resistant TB (MDR-TB) and other isolation policies apply specifically to referral level facilities.

The second priority is environmental control methods that are used to reduce the concentration of droplet nuclei in the air in high-risk areas. Environmental control methods range from inexpensive methods such as maximising natural ventilation and mechanical ventilation, to more costly methods such as ultraviolet germicidal irradiation and HEPA filtration. Environmental control methods should not be used in absence of, or as a replacement for, administrative control measures.

The third priority is to protect HCWs, via personal respiratory protection, from inhaling infectious droplets. Surgical masks prevent the spread of microorganisms from the wearer but do not provide protection to the wearer. Respirators provide protection to the wearer from inhaling infectious droplet nuclei. Respirators are expensive and they should be reserved for high-risk referral hospital settings.

## EXECUTIVE SUMMARY

Personal respiratory protection alone will not provide adequate protection for the HCW from infection of *M. tuberculosis*.

HCWs are vital resources in the fight against TB. These guidelines provide cost-effective interventions that can be directly implemented (or modified) within a facility at the district or referral level in any resource-limited setting. Efforts should be made to execute such control strategies to prevent nosocomial transmission of *M. tuberculosis*. Such measures serve not only to conserve resources in terms of direct costs due to treatment of HCWs and indirect costs in terms of loss of HCWs specialising in the management of TB patients, but also in reducing the burden due to tuberculosis.

**21**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

# Participating in God's Salvation Activities in the World

## A Shift in the Understanding of Mission

Bate  
klob

The criticism of the missionary practice of the Western churches in the second half of the 20<sup>th</sup> century gave the impetus for a change in the theology of missions. The Protestant churches developed the *Missio Dei* approach in the sixties. The different understandings of this model precipitated the ecumenical-evangelical controversy. The "Lausanne Covenant" (1974) represents the evangelical position while the document "Mission and Evangelism" represents the ecumenical position. The Second Vatican Council developed the interpretation of missions within the Roman Catholic Church in the apostolic epistle "Evangelii nuntiandi" (1975) and in the encyclical "Redemptoris Missio" (1990). The changes in the understanding of missions decisively influence the relationship between Christianity and other religions and impact inter-religious dialogue and the notion of remote cultures.

### 1 Introduction

The term "missions" denotes the organized activities and efforts of spreading the Christian faith and has only been used since the 17th century. With this meaning, this term lacks an exact equivalent in the Greek language of the New Testament.<sup>1</sup>

Even though the New Testament lacks a conception of missions as an organized missionary work in a foreign country, it nevertheless provides the essential conceptions for such work. God sends Jesus and gives him a mission. Jesus then gathers people whom he sends out with a mission. He commands, "Go therefore, make disciples of all nations" (Mt 28:19) and "You will be my witnesses" (Acts 1,8; cf. Lk 24,48) and "As the Father sent me, so am I sending you" (Jn 20,21).

For Jesus, both the gathering of people and the sending them out with a mission intrinsically belong together. The mission of the disciples and our mission as Christians extend and continue the mission Jesus fulfilled for his Father. The term "missions" describes the historically based and concrete fulfillment of the commission Jesus asked us to accomplish.<sup>2</sup>

Today, the term "missions" evokes uneasiness in many people, and for some "missions" has even become an emotive word. Very often, the term "missions" is avoided in the names of some study groups, journals, or institutions. The contemporary diverse criticism of missions is, however, principally directed neither against the missionary character of Christianity nor against Christians themselves but against the form or paradigm of missions that has character-

<sup>1</sup> Amstutz, *Kirche* 12; Pesch, *Voraussetzungen* 12-14

<sup>2</sup> Cf.: Bürkle, *Missionstheologie* 20

ized the image of missions during the past centuries. Specifically, this criticism focuses on the "practice of Western missions in the past and in the present."<sup>3</sup> Some accuse Western missions of being a one-way street that reflects the "white man's arrogance"<sup>4</sup> and "a kind of triumphalist expansion of the Church."<sup>5</sup> These critics identify Christian missions with the colonialism of the past<sup>6</sup> and accuse such missions of being allied with colonial expansion and oppression and of destroying indigenous cultures, social structures, and religions and of creating an alienated church as well.<sup>7</sup>

Such criticism compel Christians to rethink their practice of missions and to develop a new understanding of Christian missions.

Rethinking missions is the subject of the present essay. Section 2 discusses the ecumenical and the evangelical analysis of the understanding of missions. Section 3 describes missions within the Roman-Catholic Church. Section 4 describes some consequences of the understanding of missions, and section 5 summarizes the development of the understanding of missions and describes the position of DIFAEM in this discussion.

## **2 The Understanding of Missions in the Ecumenical-Evangelical Discussion**

### **2.1 The Initial Situation: Different Objectives of Missions**

At the beginning of the 20<sup>th</sup> century, the various Protestant groups espoused different objectives of missions:

Anglo-Saxon Protestant missions sought to establish the Kingdom of God while German Protestant missions, influenced by Pietism, primarily aimed at the conversion and salvation of individuals.

For a significant number of German missionaries, however, the purpose of missions was to expand the Christian church. They referred to Gustav Warneck's definition of missions: "We understand Christian mission as the efforts of Christians worldwide to establish and organize the Christian church among non-Christians."<sup>8</sup>

Even though they espoused different missionary objectives, all these various groups nevertheless understood missions as "foreign missions," i.e., the efforts of Western churches to spread Christianity in non-Christian countries.

### **2.2 New Approaches in the Understanding of Missions**

#### **2.2.1 From Western Missions to Worldwide Missions**

The modern ecumenical movement, which was initiated during the Edinburgh Conference on World Mission in 1910 demonstrated the need to transform the un-

<sup>3</sup> Collet, *Missionsverständnis* 26

<sup>4</sup> Bürkle, *Missionstheologie* 29

<sup>5</sup> See: Collet, *Missionsverständnis* 27

<sup>6</sup> Ibid. 28

<sup>7</sup> Ibid. 34

<sup>8</sup> See: Hering, *Missionsverständnis* 21

derstanding of Christian missions. This conference assumed the superiority of the Western Christian world over the rest of the world and marked the "climax of triumphant world mission."<sup>9</sup>

The succeeding conferences of the International Mission Council (IMR) are also called World Mission Conferences and took place in Jerusalem in 1928, in Tambaran (India) in 1938, and in Whitby in 1947.

These conferences mark the transformation from "western missions" to "world missions." This transformation resulted from the two world wars, which shook the self-confidence of the west, as well as from the secularism that increasingly spread across the Western world. This secularism erased the distinction between "mission countries" and "Christian countries," a distinction that had been so important to Christian missions since the 17<sup>th</sup> century. This transformation also resulted from the increasing strength of mission churches that objected to the title "offspring churches" and demanded more independence from the "mother churches." Participants of the Whitby Conference of the IMR no longer spoke of "mother churches" and "offspring churches" but of "partners of obedience."<sup>10</sup>

At the first plenary assembly of the World Council of Churches in Amsterdam (1948), the participants refused to differentiate any longer between inner and outer missions because the missionary activity in Christian countries did not differ in principle from non-Christian countries.<sup>11</sup> Participants of

the IMR conference in Willingen in 1952 reached a similar conclusion. This transformation from western missions to world missions refocused the conversation about missions around the conception of missions to the continents. The mission conference in Mexico City in 1963 articulated this new conception as the churches' moving toward the world in six continents.<sup>12</sup>

### 2.2.2 Missions as *Missio Dei*

The missions work of the western churches in the first half of the 20th century had been severely criticized. The climax of this criticism was the expulsion of all Christian missionaries from China in 1949. These events necessitated a radical change in the conception of missions. The defining question was how to justify Christian missions. Participants in the world mission conference in Willingen in 1952 addressed the topic "The Missionary Commitment of the Church." Discussion of this topic precipitated a "copernican change in the meaning of mission"<sup>13</sup> and justified the *Missio Dei* approach.

The two theologians Karl Barth and Johannes Christiaan Hoekendijk laid the theoretical foundation for the *Missio Dei* approach.

For Barth, revelation means self-revelation. God is for him the only one who really acts in the process of revelation. In relation to missionary work, Barth's conception of revelation means that God is the only one who is active. So, God's nature is at one and the same time both revealing and missionary. According to this understanding, the

<sup>9</sup> Was heißt Mission? 14

<sup>10</sup> Cf.: Werner, Mission 62f

<sup>11</sup> Üffing, Kirche 22

<sup>12</sup> Hering, Missionsverständnis 86

<sup>13</sup> Werner, Mission 66

human task is to give testimony, and God uses humans for God's purpose in the process of missionary work.<sup>14</sup>

Hoekendijk was the first secretary on questions related to evangelization in the study department of the World Council of Churches (1949-1952). At the conference in Willingen, he warned against missions strictly in terms of the church and pleaded for the avoidance of the conception of the church and the beginning and end of missionary work.<sup>15</sup> According to Hoekendijk, the aim of all missionary work is not to fill the world with churches but to confront the world with the demand for God's kingdom.<sup>16</sup> The ideas advanced by Barth and Hoekendijk formed the basic foundation for the *Missio Dei* approach to missions.

According to the *Missio Dei* approach to missions, God sends Son and Spirit and thus opens Godself to the world. The legitimation for missions flows from the essence of God. God is the one who sends, and each human's sending (sender) participates in the divine sending. In order to carry out God's sending plan, God makes use of people, especially the church. So, missions is not simply an activity of the church. Missions is part of the church's essence and also characterizes each individual Christian.

According to the *Missio Dei* approach, missions is located no longer in soteriology (missions to save souls) or in ecclesiology (missions to plant churches) but in the Trinitarian understanding of God. This theo-

logical understanding of missions means that missions is part of the essence of God in that God is a missionary God. This understanding of missions as part of the *Missio Dei* defends Christian missions against those who question their legitimacy.<sup>17</sup>

The *Missio Dei* approach demonstrates that the church's essence is missionary. Thus, missions cannot be basically questioned. The church "does not take part" in missions, it "is" missions. The term *Missio Dei* was quickly accepted after the conference at Willingen and became a generally accepted part of discussions about missions.

Two different models explaining how God's sending could be effected quickly arose.

Georg E. Vicedom advocates the first model. This model is based on the history of salvation and holds that God sends Jesus Christ into the world as the true missionary and that the church continues Jesus' mission. This model sharply differentiates the history of the world from the history of salvation. The history of the world is irrelevant; the only history that matters is salvation history. According to this model, God sent Jesus to rescue the church from a corrupt world that is perishing.<sup>18</sup>

J. Chr. Hoekendijk advocates the second model. This model is based on the history of promise and conceives of the *Missio Dei* much more inclusively than the first model. According to this second model, God's will to heal (cf. 1Tim 2,4) and the Christ event has already brought healing to all creation and to all human beings. God sent Christ

14 Bosch, *Mission* 390. Wrogemann, *Mission* 89-104

15 Bockmühl, *Missionstheologie* 14-16; Werner, *Mission* 63-66

16 Grundmann, *Welt* 132

17 Ahrens, „*Mission*“ 123

18 Cf.: Vicedom, *Missio Dei* 70-72

not only to rescue the church but the entire world as well. This model abolishes the dichotomy created by the first model between the history of the world and the history of salvation.<sup>19</sup>

Since the 1960s, Protestants have vigorously discussed these two models and become divided over the issue of which model is preferable.

The **evangelicals** are primarily influenced by the history of salvation model. For them, redemption is only possible through the conversion to Christ, and the world outside Christianity is unredeemable. The gospel is the highest authority, and orthodoxy, the vertical dimension of faith, is stressed. Missions is first of all a propagation of the gospel and does not aim to change the structures of the world.<sup>20</sup>

The **ecumenicals** in contrast are primarily influenced by the history of promise model. Because of their conviction that God has saved the whole world through Christ and that God desires the healing of the world within history, they stress the horizontal dimension of missions as the humanization of the world. Neither the evangelicals nor the ecumenicals denies that the vertical and the horizontal dimensions of missions belong together. However, evangelicals admonish the ecumenicals not to replace eternal salvation with secular welfare. Conversely, the ecumenicals warn the evangelicals not to neglect social ethics by focusing only on eternal salvation.<sup>21</sup>

### 2.3 The WCC Studies about "The Missionary Structure of the Community"

At the third plenary assembly of the World Council of Churches in New Delhi in 1961, the IMR was integrated into the WCC. This organizational shift emphasized what had become apparent through the approach of the *Missio Dei*. In essence, church and missions belong together since the church as a whole is missionary.

Under the direction of Jochen Margull, a study project addressing "The Missionary Structure of the Community" was begun in New Delhi in 1962 to characterize the missionary character of the church. Margull was influenced by Hoekendijk and his history of promise model of missions. There was a wide interest in this study and several international working groups were established to facilitate its completion.

In 1965, Margull published the workbook "Mission as Structural Principle." In 1967, the WCC then publicized the final reports of the West European and North American work groups in a publication entitled "Church for Others and Church for the World Struggling to Find Structures for Missionary Communities."

These two publications have several points in common. First, history and the world as a whole are under the influence of the *Missio Dei*. The direction of movement is God—World—Church.<sup>22</sup>

19 Cf. Frieling, Weg 273; Holthaus, Mission 42; Werner, Mission 67

20 Frieling, Weg 276f

21 Ibidem 276f

22 Cf. Kirche für andere 16

Second, the world is considered positively. The church and the world are not confrontational enemies, but the church is "part of the world loved by God and to which he reveals his love."<sup>23</sup>

Third, conversion in the traditional view means to turn away from the world, but now conversion means "to turn to the world in hope."<sup>24</sup>

Fourth, the aim of missions is not above all growth of the church in quantitative terms, but missions is understood in messianic terms as the aim to preach and embody the liberating acting of God (the Gospel) in reconstructing the kingdom while offering "peace and salvation."<sup>25</sup> The notions of "shalom" and "humanization" in the sense of a liberation of true humanity are introduced into the discussion about the aim of missions.<sup>26</sup> The notion of shalom emphasizes that salvation and welfare belong together. Thus, isolationism and retreat from the world is excluded from Christian missions.<sup>27</sup> With this conception of the aim of the church, these publications justify Bonhoeffer's programmatic statement that "church is only church when it is there for the other".<sup>28</sup>

Finally, not only pastors and professional missionaries but also lay people are responsible for Christian missions. "It is indeed the lay man who is qualified to be the missionary of our time."<sup>29</sup>

These studies published by Margull and the WCC represent a turning point in the comprehension of Christian missions from the history of salvation model to the history of promise model.

## 2.4 The Ecumenical-Evangelical Controversy

### 2.4.1 "Look, I Have Been Creating Everything Anew – The Plenary Assembly of the World Council of Churches in Uppsala in 1968

The interpretation of missions as outlined in the WCC study of "The Missionary Structure of the Community" had a decisive influence on the fourth WCC plenary assembly, which was held in Uppsala in 1968 under the banner "Look, I Have Been Creating Everything Anew."

At this conference, the document "Renewal of the Mission" caused violent discussions, and the conflict between ecumenicals and evangelicals became apparent to a broader public for the first time. This document envisions "an anthropological change in the interpretation of missions" due to the confession that Christ is the "true" or the "new man." This document mentions shalom and humanization of society as missionary aims in accordance with the structural study.<sup>30</sup> Missions should open itself to the world. The formulation "the world determines the order of the day" has become commonplace since Uppsala. The world is the place where the credibility and significance of the Gospel is revealed.<sup>31</sup>

<sup>30</sup> Werner, Mission 111

<sup>31</sup> Grundmann, Welt 132

<sup>23</sup> Ibid. 14

<sup>24</sup> Ibid. 14

<sup>25</sup> Hoekendijk in: Mission als Strukturprinzip 33

<sup>26</sup> See: Kirche für andere 17.89

<sup>27</sup> Werner, Mission 97

<sup>28</sup> Ibid. 94

<sup>29</sup> Kirche für andere 28

In Uppsala, John Stott, speaker of the evangelicals within the Church of England, represented the evangelical position. He thought that the WCC was so anxious about physical hunger that it did not take the spiritual hunger of humanity into consideration.

After the conference, the missionary theologian Peter Beyerhaus formulated the evangelical criticism on Uppsala in his book "Humanization – Only Hope in the World?" He stated, "There has been a fundamental ecumenic-evangelical confrontation before and after Uppsala."<sup>32</sup>

#### 2.4.2 Missions as Liberation:

##### The Missionary Conference in Bangkok in 1973

The 1960s were characterized by optimism in technical and scientific progress and confidence in improving the world situation by human efforts. In the 1970s, this positive view of the world was subdued because of increasing social conflicts and crises.

This background shaped the world mission conference in Bangkok in 1973. The theme of this conference was "Salvation of the World Today." This conference is important for the understanding of missions because an "integrative comprehension of salvation" was developed. This integration was mainly elaborated in a document entitled "Salvation and Justice."

In this document, the integrative comprehension of salvation is formulated as follows: "We think that salvation means re-

newal of life-development of true humanity in the fullness of God (Col. 2,9). It is salvation of the soul and of the body, of the individual and the society, of mankind and the 'sighing creature' (Rom 8,19). ... We must overcome in our thoughts the splitting between soul and body, man and society and mankind and creation. That is why we consider the fight for economic justice, political freedom and cultural renewal as elements for a complete liberation of the world in the name of God."<sup>33</sup>

Whereas humanization had been a leit-motif in previous meetings of the WCC, salvation as well as missions was at the center of discussion in Bangkok. The integrative meaning of salvation marked "the beginning of a social hermeneutics of salvation" (H. J. Margull) and consequently led to a change in the interpretation of missions. The trend was towards missions as empowerment to liberation.<sup>34</sup>

This trend related to the Latin American theology of liberation that was so important in the Roman Catholic Church at that time.

Evangelicals seriously criticized this view of salvation elaborated in Bangkok. The most important representative of the evangelicals in Bangkok was Peter Beyerhaus. In reflecting of the conference, he stated that the understanding of salvation and missions was not informed by biblical but by syncretistic and socio-political notions.<sup>35</sup> The difference between evangelicals and ecumenicals had become more obvious and seemed to be irrec-

<sup>32</sup> Beyerhaus, *Humanisierung* 46ff

<sup>33</sup> See: Werner, *Mission* 200

<sup>34</sup> Werner, *Mission* 201

<sup>35</sup> Hering, *Missionsverständnis* 123

oncilable for some people. A representative of the WCC remarked at that time, "You are either evangelical or a friend of the WCC."<sup>36</sup>

## 2.5 The Lausanne Covenant (1974)

After the conference in Bangkok, many evangelical missionary groups kept their distance from the WCC and its interpretation of missions. The evangelical movement gained in strength under the influence of such powerful speakers as Billy Graham, John Stott and Donald McGavran.

Following several evangelical congresses, about three thousand evangelicals from over 150 countries met in Lausanne in 1974 for a congress about world evangelization. This congress was initiated by Billy Graham, and its theme was "Let the Earth Hear His Voice." The result of this congress is the "Lausanne Covenant," which became the most important document for the understanding of missions in the evangelical movement.

The "Lausanne Covenant" consists of fifteen items, but only items five and six are relevant for the present essay.

Item 5 recognizes the social responsibility of Christians and reads, "We ... express penitence ... for having sometimes regarded evangelism and social concern as mutually exclusive. Although reconciliation with other people is not reconciliation with God, nor is social action evangelism, nor is political liberation salvation, nevertheless, we affirm that evangelism and socio-political involvement are both part of our Christian duty. For both are necessary expressions of our doctrines of God and man, our

love for our neighbour and our obedience to Jesus Christ."

Item 6 emphasizes the priority of evangelization in its formulation, "In the Church's mission of sacrificial service evangelism is primary." This item also affirms, "World evangelization requires the whole Church to take the whole gospel to the whole world."

Preference for the term "evangelism" over the term "missions" in the Lausanne Covenant raises the question of the relationship between evangelism and missions. John Stott answered this question by stating that the term "mission" is used in a larger sense and includes evangelism in the sense of propagation but that evangelism cannot be identified with propagation.<sup>37</sup> Earlier at Uppsala, Stott already articulated this larger understanding of missions when he said, "Mission is equal to propagation plus service." Thus, the evangelical movement confirmed that social and political commitment is a genuine Christian task of evangelism and recognized missions as a more comprehensive endeavor than evangelization. The vertical and horizontal dimensions of missions belong together even though the priority is given to evangelization.<sup>38</sup>

## 2.6 The Larger Interpretation of Missions: The Fifth Plenary – Assembly of the World Council of Churches in Nairobi in 1975

The Lausanne Covenant brought evangelicals and the WCC back together again so that at the fifth plenary assembly in Nairobi, evangelicals and ecumenicals were conversing once again.

<sup>36</sup> See: Hering, *Missionsverständnis* 125

<sup>37</sup> *Ibid.* 129

<sup>38</sup> Cf.: Hering, *Missionsverständnis* 127–130; Sautter, *Heilsgeschichte* 246–250

The broader understanding of missions or the "comprehensive understanding" was expressed by Bishop Mortimer Arias in a speech in Nairobi. He stated:

"True evangelism is comprehensive: all the Gospel for all mankind and man as a whole. The recipient of evangelism is man in his wholeness: in his individuality and sociality, in body and spirit, in time and timelessness. That is the reason why we reject all attempts of the present and the past to divide man and attempts to reduce the Gospel to a single dimension and attempts to divide man who is the image of God. We reject the opinion that evangelization means only to save souls and is an exclusive search for a better hereafter for each individual, because it is not sufficient in the biblical sense. Neither do we accept that the Gospel is simply reduced to a programme of service and social development or to a simple tool of socio-political concepts (Mt 9,35-38; Lk 4,18-19; Acts 16,31; 1Tim 4,6-10; 2Tim 1,10)."<sup>39</sup>

John Stott as a representative of the evangelicals completely accepted Bishop Arias' statement.

## **2.7 Mission from the Perspective of the Periphery: The Missionary Conference in Melbourne in 1980**

The missionary conference in Melbourne in 1980 adopted the theme "Your Kingdom Come." This conference had to consider several developments on the world scene. The disparity between industrial nations and third world nations had increased and

the dialogue between them had fallen silent.<sup>40</sup>

In this global context, the contribution of missions to the creation and maintenance of dominant power constellations became increasingly apparent.<sup>41</sup>

These developments of the world scene had important consequences for the conference in Melbourne, which transformed the motto of the 1960s "Church for Others" into an ecclesiological programme. This conference concluded:

"The Church of Jesus Christ must be a church of the poor (and not simply a church for the poor)."<sup>42</sup>

Missions should happen from the "perspective of the periphery" – the powerful mission on the top should be changed to the mission practice from the bottom.<sup>43</sup>

In Christological terms, the understanding of missions changes in Melbourne from a *theologia gloriae* that stresses the image of an elevated and triumphant Christ to a *theologia crucis* oriented toward the earthly life and death of Jesus and stressing the identification of both God and Jesus with the poor, with those who suffer, and with those who are condemned and helpless and powerless.<sup>44</sup>

In its understanding of missions, the conference in Melbourne naturally referred

<sup>39</sup> See: Hering, *Missionsverständnis* 5

<sup>40</sup> Werner, *Mission* 128-130

<sup>41</sup> *Ibid.* 129

<sup>42</sup> *Ibid.* 130

<sup>43</sup> *Ibid.* 225

<sup>44</sup> *Ibid.* 131f

frequently to the Latin American liberation theology.

## **2.8 Mission and Evangelism –**

### **An Ecumenical Affirmation (1982)**

In 1976, one year after the plenary assembly of the WCC in Nairobi, the central committee of the WCC instructed the Commission for World Mission and Evangelization (CWME) to draft a declaration about missions and evangelism. All member churches of the WCC were asked to explain the essence of their missionary work. On the basis of these statements, the CWME drafted an ecumenical declaration and presented it in 1981 to the central committee, which passed it in 1982. This first official declaration of the WCC with regard to the interpretation of missions reflects the contributions of the churches as well as the results of the assemblies in Nairobi and Melbourne.

The document "Mission and Evangelism" (ME) was broadly accepted by the ecumenical movement. Currently, this document is the most important statement about the understanding of missions within the ecumenical movement.

This document refers to Jn 20,21 and Acts 1,8 and justifies the missionary character of the church in the sense of the *Missio Dei* approach by confessing, "The church has as one constitutive mark its being apostolic, its being sent into the world" (paragraphs 7-8). For that reason, the proclamation of the Gospel includes solidarity with the poor.

ME expressively emphasizes both the vertical and the horizontal dimensions of the Gospel by declaring, "The spiritual Gospel and the material Gospel were in Jesus one Gospel" (paragraph 33). The aim

of missions is conversion (paragraphs 10-13) as well as "the multiplication of local congregations in every human community" (paragraph 25). ME stresses "mission in six continents," the statement of the missionary conference in Mexico City, and explains, "Everywhere the churches are in missionary situations" (paragraph 37).

ME bridges the gap between ecumenicals and evangelicals. The long period of polarization had come to an end.

In the 1990s, some member churches of the WCC expressed their wish to develop a new declaration about missions and evangelization that would not replace ME but continue it.<sup>45</sup> An initial consultation for a new declaration of missions gathered in San Salvador in 1996.<sup>46</sup> Before the plenary assembly of the WCC occurred in 1998 in Harare, a draft for a complementary declaration was completed but not presented to all the member churches and councillors of the WCC before the assembly. This procedure and the criticism of the draft declaration by some members were the reasons why this declaration did not find acceptance. Hence, ME continues to form the basis for the understanding of missions in the WCC.<sup>47</sup>

## **2.9 The Trinitarian Approach to the**

### **Missio Dei: Canberra 1991**

Before and after the WCC plenary assembly in Canberra in 1991, the interpretation of *Missio Dei* was discussed again with regard to the inter-religious dialogue (see 4.2). The theme of the Canberra Meeting

<sup>45</sup> Linn, Vollversammlung 187

<sup>46</sup> Zu einer Hoffnung berufen 60

<sup>47</sup> Linn, Vollversammlung 186-189

was "A New Interpretation of the Prerequisites of the Missio Dei with Regard to the Trinitarian Theology."

In this meeting, the model of the history of promise was extended beyond the Christological and ecclesiological understanding of Missio Dei to a pneumatological understanding. Arising from Trinitarian theology, the underlying question was formulated before Canberra as follows: "The question is whether the Father is the only source of the spirit or together with his Son. If the latter is the case, then the flowing of the Spirit is limited to Christian channels and more particularly to the church. The rest of humankind can only experience the Spirit through the intervention of the church. If the former is the case, then the starting point from which the spirit blows freely through the oikoumene is more vast and comprises the neighbours of the other faiths as well."<sup>48</sup>

In the pneumatological understanding of missions, the missions of the church consequently cannot be "God's only mission." Missions then is only part of the worldwide mission of the Lord's Spirit who has the freedom to influence other religions in movements and communities outside the church.<sup>49</sup>

Great expectations flowed from the WCC plenary assembly at Canberra. Some people hoped that concentrating on the theme "Come, Holy Spirit – Renewing All Creation" would bring the complete Trinitarian perspective of church and missions into vogue and open a new chapter of ecumenical history.<sup>50</sup>

These expectations were not realized, however, and full realization of the Trinitarian theology in the Missio Dei approach is part of the future work of missions theology.

## **2.10 The Declaration of the Lutheran World Federation: God's Mission as Common Task – A Contribution of the LWF to the Understanding of Missions (1988)**

The LWF's declaration will not be presented in its entirety. Instead, relevant statements are excerpted that focus on some significant aspects of missions theology.

In the first chapter entitled "Theological Statements to Mission from a Lutheran Point-of-View," the Missio Dei is the starting point. "God is a God of mission. The sending of his Son and the Holy Spirit into the world was the highest expression of the Godly missionary effect" (1.1). The declaration refers expressly to the Trinity. "The mission of God is considered in this document with relation to the term Trinity. ... The radius of the Godly mission cannot be understood by man" (1.2). "The mission of the Church is deduced from God's own mission. God's own mission is larger than the mission of the Church" (1.3).

The primary aim of mission is conversion "to convert all peoples to disciples" (1.3). In 4.1.6, mission is described holistically, "All the ecclesiastical propagation must express the wholeness of mission by unifying word and deed. ... The word without deeds corresponding to it falsifies the word itself. On the other hand, when the deed is not accompanied by the word, there is the danger to lapse into pure humanity."

48 Werner, Mission 425

49 Ibid. 426

50 Ibid. 445

Other parts of the declaration emphasize the importance of social action. "An integral part of mission ... is to work for freedom and justice" (1.3). Missions must face challenges caused by poverty, and the churches must be "present there where the poor are" for reasons of credibility" (3.4.5). Christologically, missions is oriented towards Jesus Christ, who became human and died on the cross. Missions has to propagate the crucified Christ, and therefore "triumphalism is in contradiction to God's own mission" (4.1.10).

There is significant agreement in the understanding of missions in the Lutheran World Federation and in the document Mission and Evangelism of the WCC. An important difference, however, is that the *Missio Dei* approach is interpreted in ME christologically but in the LWF declaration theologically with special emphasis on Trinitarian theology.<sup>51</sup>

### 3 The Understanding of Missions in the Roman Catholic Church

Section 3 of this essay presents the development of the understanding of missions in the Roman Catholic Church by discussing educational missions texts beginning with the Second Vatican Council from 1962 to 1965 and later.

#### 3.1 Tendencies in Missions Theology before the Second Vatican Council

At the beginning of the 20th century, two different tendencies were present in the Roman Catholic understanding of missions.

J. Schmidlin founded the Munster school and emphasized the soteriological center of missions. For him, missions means evangelization with the aim of saving souls and of converting people.

In contrast, P. Charles of the Leuven School placed ecclesiology at the center of missions. For him, the aim of missions is the *plantatio ecclesiae*, which means that the Church is "implanted" among non-Christians by establishing the institutions of the Church.

#### 3.2 The Missions Theology of the Second Vatican Council

The Second Vatican Council specifically addressed the missionary activity of the Church in a decree called "Ad gentes." Other decrees, however, also contain important statements about the understanding of missions, especially the dogmatic constitution "Lumen gentium." In these documents, the ecclesiology of the Church forms the basis for the understanding of missions.

The church is no longer exclusively considered as a hierarchical institution but as a sacramental reality. "The Church, in Christ, is in the nature of sacrament -- a sign and instrument, that is, of communion with God and of unity among all men" (LG 1).

The sacramentality of the Church is interpreted in two ways. On the one hand, Church is a sign for the relationship to God and the unity of humankind. On the other hand, Church is an instrument that has a responsibility toward the world.<sup>52</sup>

<sup>51</sup> Cf.: Holthaus, Mission 42f

<sup>52</sup> Rahner, Konzilskompendium 106

The missionary character of the Church is a constitutive component of the church as a sacramental reality. The missionary character of the Church is explicitly exposed in the mission decree of the Second Vatican Council. "The pilgrim Church is missionary by her very nature, since it is from the mission of the Son and the mission of the Holy Spirit that she draws her origin, in accordance with the decree of God the Father" (AG 2). The basis of the Church's missionary character is Trinitarian. Before the Council, the Church was the sender, but after it the Church is the one sent from God into the world.<sup>53</sup> The parallels to the *Missio Dei* approach are apparent.

Since the Council describes the Church as "God's people" (LG 9-17), every baptized person participates in the mission of the Church. Each Christian is a missionary and has to fulfill her or his task of being sent (cf. LG 17; AG 35.36).<sup>54</sup>

Important for the Council's understanding of missions are also the elevation of the churches in each country and the teaching of the bishops' collegiality. The Church consists of different national churches (cf. LG 23), and the bishops are authorized to be the leaders of their national churches. The Western or "mother Church" is no longer the head of the "offspring churches." On the contrary, the churches form a brotherly community. Karl Rahner says, "The Second Vatican Council and its first trial to find itself may be considered as the first official self-achievement of the Church as world church."<sup>55</sup>

This understanding breaks open ecclesiastical centralism but leaves unclear how the primacy of the Papacy can be combined with this plurality of the Church.<sup>56</sup>

According to the Council, the task of missions are "Preaching the Gospel and planting the Church among peoples or groups who do not yet believe in Christ" (AG 6). By stating the aim of missions this way, the Council tries to synthesize the two tendencies in missions theology before this decisive Council occurred.

The targets of missions are "peoples and communities," and thus missionary activity is described geographically, sociologically, and anthropologically.<sup>57</sup> This view corresponds to the comprehension of "mission in six continents" espoused by the missionary conference in Mexico City in 1963.

Rahner speaks in this context of a "planetary diaspora" and means that there are no longer so-called "Christian countries."<sup>58</sup>

A further new understanding of missions marks the conciliar confession to God's general salvation that encompasses the non-Christian world. "The Savior wills all men to be saved (cf. 1 Tim 2,4). Those who, through no fault of their own, do not know the Gospel of Christ or his Church, but who nevertheless seek God with a sincere heart, and, moved by grace, try in their actions to do his will as they know it through the dictates of their conscience — those too may achieve eternal salvation" (LG 16; cf. AG 7). God's influence is also outside the church,

53 Glazik, *Mission* 157.

54 Üffing, *Kirche*, 32; cf. also LG 17; AG 35f.

55 Üffing, *Kirche* 20f.

56 Cf. Collet, *Missionverständnis* 116f.

57 Üffing, *Kirche* 33f.

58 Collet, *Missionsverständnis* 63 (note 27).

and God offers salvation to all humans. This understanding is very similar to the salvation history model of the *Missio Dei* approach.

### 3.3 The Development of the Roman Catholic Understanding of Mission after the Second Vatican Council

#### 3.3.1 The Apostolic Letter

“*Evangelii nuntiandi*” (1975)

The understanding of missions is continued in Pope Paul VI's apostolic letter “*Evangelii nuntiandi*” (EN).

According to EN, “evangelizing” is “the essential mission of the Church” (EN 14). The Church evangelizes in the succession of Jesus, who was sent by the Lord (EN 6,7). Here missions is not grounded in Trinitarian theology as at the Council (AG 2) but in the historical Jesus.

EN defines “evangelizing” as “bringing the Good News into all the strata of humanity, and through its influence transforming humanity from within and making it new” (EN 18). Thus, EN defines “evangelizing” in terms “of proclaiming Christ to those who do not know him” (EN 17).

The aim of evangelization is qualitatively an inner change and quantitatively “preaching the gospel in ever wider geographical areas or to greater numbers of people” (EN 19). At several places (EN 8,9,34) EN mentions the propagation of God's kingdom with regard to the continents and clearly stresses liberation theology. The targets for evangelization are not only non-Christians but also “baptized people, who do not practice” (EN 21). So EN envisions a global situation of missions.

Significantly, EN addresses the relationship between propagation and social action. This question can be seen in connection with the development of the ecumenical movement. EN refers to social action by using terms such as “development” and “liberation.” EN 31 reads, “Between evangelization and human advancement—development and liberation—there are in fact profound links.” Both aspects should be taken into account. On the one hand, the mission of the Church may not be limited by an anthropocentric refusal to consider the religious dimension of the human being, his or her “openness to the absolute, even the divine Absolute” (EN 33) or by replacing the “proclamation of the kingdom by the proclamation of forms of human liberation” (EN 34). In this context, EN speaks of the “primacy of the spiritual vocation” (EN 34). On the other hand, mission should not be reduced “in a religious way” since “it must envisage the whole man, in all his aspects” (EN 33). “The Church is ... not willing to restrict her mission only to the religious field and dissociate herself from man's temporal problems” (EN 34).

So, EN develops a broader understanding of missions and searches for a balance between the vertical and the horizontal dimensions of missions.<sup>59</sup>

#### 3.3.2 The Encyclical Letter

“*Redemptoris Missio*” (1990)

Twenty-five years after the end of the Second Vatican Council and fifteen years after the publication of “*Evangelii nuntiandi*,” Pope John Paul II published the encyclical letter “*Redemptoris missio*” (RM). Its theme is the continued validity of missions.

59 Cf. to EN: Collet, *Missionsverständnis* 124-132; Müller, *Missionstheologie* 37f

Admitting that "missionary activity specifically directed 'to the nations' (ad gentes) appears to be waning," the encyclical letter emphasizes the "urgency of missionary evangelization" (RM 2). Missionary activity should "push forward to new frontiers" (RM 30). RM describes the following tendencies in the Roman Catholic understanding of missions.

RM generally has a positive view of missions and recognizes the shift from western missions to world missions. Nevertheless, it reintroduces some old inequities with statements such as the following: "To say that the whole Church is missionary does not exclude the existence of a specific mission ad gentes, just as saying that all Catholics must be missionaries not only does not exclude, but actually requires that there be persons who have a specific vocation to be 'life-long missionaries ad gentes'" (RM 34). This statement alludes to the old geographic view of missions and assigns a position of prominence to the Western Church that was avoided in the Second Vatican Council.<sup>60</sup>

According to RM, the goal of missions is both to convert the lost and "to found Christian communities and develop churches to their full maturity" (RM 48). Faith in Christ is understood as "directed to Man's Freedom" (RM 6), but it is emphasized that "there is one mediator between God and men, the man Jesus Christ" (RM 5) and "that the Church is the only way of salvation and that she alone possesses the fullness of the means of salvation" (RM 55). Such statements make the inter-religious dialogue difficult.<sup>61</sup>

60 Cf. Collet, *„Redemptoris Missio“* 163; Waldenfels, *Ekklesiologie* 181f  
61 Cf. Evers, *Dialog*

RM also comments on the relationship between evangelization and social obligations. It attaches special importance to the danger of reducing salvation and missions to the social dimension alone. "There are ideas about salvation and mission which can be called 'anthropocentric' in the reductive sense of the word, inasmuch as they are focussed on man's earthly needs. In this view, the kingdom tends to become something completely human and secularized; what counts are programs and struggles for a liberation which is socio-economic, political and even cultural, but within a horizon that is closed to the transcendent. ... The kingdom of God, however, 'is not of this world ... is not from the world.'" (Jn 18,36; RM 17).

By rejecting the limitation of salvation to the horizontal dimension, RM distances itself from the Latin American liberation theology. At the same time, RM stresses that "action on behalf of integral development and liberation from all forms of oppression is most urgently needed" (RM 58). Thus, it refuses to limit salvation to the vertical dimension.<sup>62</sup> RM narrows somewhat the understanding of missions as a worldwide mission and retreats from the broad understanding of missions that envisions every land and people in need of missionary activity.<sup>63</sup>

### 3.4 Karl Rahner's Theory of the "Anonymous Christ" and Its Effect on the Understanding of Missions

Karl Rahner's theory of the anonymous Christ is of great importance for the understanding of missions in the Roman Catholic Church. His theory has two presuppositions.

62 Cf. Collet, *„Redemptoris Missio“* 171-174  
63 *Ibid.* 174f

First, Rahner favors an anthropology that sees human beings as a unity of spirit and matter. He supposes that a human in his or her spirituality has always been related to God, the absolute being. Rahner states, "Man is spirit, that means he lives his life in a permanent stretching to the absolute, in an openness for God." "He is man simply because of the fact that he has always been on the way to God, whether he knows it explicitly or not, whether he wants it or not, because he is always the unending openness of the finiteness for God."<sup>64</sup> The human orientation to God is always there regardless if a human realizes it or not. Humans always have to do with God when they meet their own fellow humans and in their encounter with their surroundings in general.

Second, Rahner stresses the general salvation will of God as a second presupposition for his theory (cf. 1Tim 2,4). God desires healing for all people and offers it to everyone.

The theory of the anonymous Christ holds that a person who has never been confronted with the Christian verbal revelation is able to believe. Such a person is not a Christian in an explicit and confessing manner but in an implicit anonymous way. According to Rahner, persons are believers when they affirm themselves, when they follow their conscience, when they practice faith, hope and love.<sup>65</sup>

It is important to know that an anonymous Christian is exhorted to become explicitly and consciously a Christian when he

is confronted with the Christian message. Being an anonymous and confessing Christian cannot be considered as two equivalent forms of being a Christian. Being an anonymous Christian leads to becoming a confessing Christian. According to Rahner's theory, non-Christian religions can be legitimate ways of salvation for humans.

Several critics of Rahner's theory stress that it undermines the missionary efforts of the Church. Why should a person become an explicit Christian when that person can find God's blessing as an anonymous Christian?<sup>66</sup> These criticisms assume that Rahner considers Christianity as well as non-Christian religions as equivalent ways of salvation. He does not, however, and holds that Christian missions has an important task since it aims at the transformation of an implicit Christian into an explicit Christian. Rahner thinks his theory provides a basis for missions. Missions can only be effective when there is a sensibility for the Christian message, and this sensibility is an inner orientation to God. Thus, Rahner's theory of the anonymous Christ is important for understanding Christian missions.<sup>67</sup>

## 4 Materialization

### 4.1 The Relationship between Christianity and the Non-Christian Religions

Everyone who attempts to understand missions encounters the question of how to define the relationship between Christianity and other religions. Three different models explaining the possible relationships have

64 Rahner, Hörer 86

65 Cf.: Bernhardt, Absolutheitsanspruch 174-187; Jäger, Heilsmöglichkeit 161-217; Sievernich, Aktualität 196

66 Cf. Bernhardt, Absolutheitsanspruch 195

67 Sievernich, Aktualität 196; cf.: Rahner, Schriften VI 485-488

way, a new unity and community is created, not only within the culture in question but also in the church as a whole."<sup>80</sup>

Evangelization or missions always happens – and this is what Crollius' definition clarifies – within cultural ideology and is a mutual event. Leonardo Boff says, "The Gospel shows itself in the guise of a particular culture."<sup>81</sup> The Christian faith finds its expression in the culture of a people without opening itself to the cultural forms of thinking and living; enculturation occurs in the "tension of proximity and distance of the Gospel to the cultures."<sup>82</sup>

These different understandings of enculturation are important for the Roman Catholic as well as the Protestant theology of missions at the beginning of the third millennium. The starting point for the apostolic letter "Evangelii nuntiandi" and the encyclical "Redemptoris Missio" is enculturation. For example, RM 54 reads,

"Through enculturation the Church makes the Gospel incarnate in different cultures and at the same time introduces peoples, together with their cultures, into her own community. She transmits to them her own values, at the same time taking the good elements that already exist in them and renewing them from within."

With regard to ecumenical missionary theology, the relationship between the Gospel and culture have been talked about

repeatedly.<sup>83</sup> This theme was the main topic on the agenda of the 11th World Mission Conference in Salvador da Bahia in 1996. The theme of this conference was "Destined for One Hope – The Gospel in Different Cultures." The message sounding from this conference was "We sincerely hope that this last mission conference in this century has made plain that the Gospel must remain itself if it wants to bear fruit and at the same time it must be part of a culture or rooted in it."<sup>84</sup>

## 5 Summary

In his book *"Transforming Mission. Paradigm Shifts in Theology of Mission"*, David Bosch presents the shift in the understanding of missions in the history of theology. He speaks of a "*post-modern paradigm*" of the theology of missions. The present essay has addressed this paradigmatic change that has occurred and continues to occur in the understanding of missions both in the Protestant and Roman Catholic churches. This section of this essay summarizes the points investigated and clarifies the areas of conflict in which discussions of missions take place.<sup>85</sup>

1. Christian missions is no longer understood ecclesiocentrically as an activity starting from the churches to save souls and found churches. Missions is anchored in the doctrine of trinity and is a characteristic of God, who is a sending God. God sends the Son and the Holy Spirit, and **missions is founded in the Missio Dei**. All human mission is part of

80 Üffing, Kirche 235

81 Reliprax 14

82 Ibid.

83 Cf.: Werner, Mission 265-381

84 Zu einer Hoffnung berufen 115

85 Cf.: Bosch, Mission 349-351; Gensichen, Akzente 113; Werner, Mission 44-47

the *Missio Dei*, and every Christian has a missionary task. The *Missio Dei* approach was and is understood in various ways.

**Two models** may be distinguished:

- The **history of salvation model** affirms that God sends Jesus and the sending of Jesus continues in the sending of the church. The histories of the world and of salvation are two different and separate things. Salvation is given to the unredeemed world through the church.

- The **history of promise model** interprets the *Missio Dei* approach in a broader sense. It affirms that God has saved the whole world through Christ and that God's mission exceeds the borders of the visible church. This model lays the foundation for a Christian's being directed towards the world. An extension of this model to Trinitarian theology leads to a pneumatological understanding of missions. God's Spirit starts directly from the Father and not only through the mediation of the Son. That is why God's Spirit also has an effect not only inside the church but also outside the church as well. The extent of the influence of God's spirit and as such of God's mission is larger than the extent of the Christian church.

A tension between the two understandings of the *Missio Dei* caused the **ecumenical-evangelical controversy** with regard to the understanding of missions. This controversy is fueled by the **tension between the vertical and horizontal dimensions of missions** that distinguishes between word and deed, between the preaching of the Gospel and Christian social service, between testimony and service, between orthodoxy and orthopraxy, and between church and world. Both the vertical and horizontal

dimensions are essential for an integrative, holistic understanding of missions, but the controversy over and the discussions about these two dimensions has by no means come to an end.

Klaus Schaefer relates evangelization and church social service when he says: "When we distinguish between evangelization and church social service, these two dimensions of the mission of the church in the world may not be considered separately. Missionary preaching is – to quote David J. Bosch – the 'heart' of mission, but evangelization and church social service are related to one another and will continue to be related. They compliment one another; they correct one another; they are a credible testimony of the church being part of God's mission by means of this unsolvable interplay; and which is directed to the salvation of the whole creation. ... The most important thing about this unsolvable interplay is that the credibility of the church's acting is at stake."<sup>86</sup>

2. In the seventies, solidarity with the poor became very important. In the eighties, the poor are no longer considered as recipients or objects of missions but the true bearers of missions as subjects. This change corresponds to the shift in the paradigm of **missions from the perspective of missions in the center to missions in the periphery**.

3. Recognizing the tension between missions and culture, Christians have finally accepted the cultural identity of non-Western peoples and churches. Missions is no longer a "cultural mission" but an **encul-**

<sup>86</sup> Schaefer, *Mission* 271

**turation** of the Gospel. This development results in a "cultural polycentral structure of the world church."

4. The issue of the **relationship between Christianity and other religions** is controversial. Three basic models illustrate this controversy:

- The model of **exclusivism** illustrates that "among all religions only Christianity possesses the perception of God or His revelation in the sense of salvation."

- The model of **inclusivism** holds that "among all religions Christianity does not possess the only perception of God or His revelation in the sense of healing. But the difference is that Christianity possesses it in a form superior to all other religions."

- The model of **pluralism** communicates that "among all religions, Christianity does not exclusively possess the perception of God and His revelation in the sense of salvation. The understanding of God and His revelation are, even in their relatively highest form, part of other religions besides Christianity."

5. Three models help explain the various possibilities of the relationship between missions and the dialogue of Christianity with other religions:

- The model of **polarity** recognizes no relationship between Christian missions and dialogue with other religions.

- The model of **subordination** presents dialogue merely as an instrument to attain the conversion of those of other faiths.

- The model of **complementarity** presents dialogue with other religions as an important aspect of missions. According to this model, missions and dialogue influence and correct one another. In the dialogue,

one's own identity becomes comprehensible in the listening and speaking with the other. The aim of dialogue is finding the truth by a reciprocal process of learning.

## 6 Conclusion

This essay has briefly described the shift in the understanding of missions in the 20<sup>th</sup> century. It has attempted to explore the various and complex issues involved in understanding missions. In responding to these issues, Christians should realize they are part of the *Missio Dei*, of God's own mission.

Christian missions means participating in God's salvation activities in the world.

## Bibliography:

Ahrens, Th.:

„Mission“ und „missionarisch“ – eine Standortbestimmung. In: E. Jaschinski (Hrsg.), *Das Evangelium und die anderen Botschaften. Situation und Perspektiven des christlichen Glaubens in Deutschland*, Netetal 1997

Amstutz, J.:

*Kirche der Völker. Skizze einer Theorie der Mission.* (QD 57) Freiburg 1972

Berneburg, E.:

*Das Verhältnis von Verkündigung und sozialer Aktion in der evangelikalen Missionstheorie – Unter besonderer Berücksichtigung der Lausanner Bewegung für Weltevangelsingelisation (1974-1989).* Wuppertal 1997

Bernhardt, R.:

*Der Absolutheitsanspruch des Christentums. Von der Aufklärung bis zur Pluralis-*

tischen Religionstheologie. Gütersloh 1990

Beyerhaus, P.:

Humanisierung – einzige Hoffnung der Welt? Bad Salzuflen 1970

Bockmühl, K.:

Die neuere Missionstheologie. Eine Erinnerung an die Aufgabe der Kirche. Stuttgart 1964

Bosch, D.J.:

Transforming Mission. Paradigm Shifts in Theology of Mission. New York 1991

Bürkle, H.:

Missionstheologie. Stuttgart 1979

Collet, G.:

Das Missionsverständnis der Kirche in der gegenwärtigen Diskussion. (TTS 24) Mainz 1984

ders.:

Zu neuen Ufern aufbrechen? „Redemptoris Missio“ aus missionstheologischer Perspektive. In: ZMR 75 (1991) 161-175

Evers, G.:

Interreligiöser Dialog und Mission nach der Enzyklika „Redemptoris Missio“. In: ZMR 75 (1991) 191-209

Frieling, R.:

Der Weg des ökumenischen Gedankens. Eine Ökumenekunde. (Zugänge zur Kirchengeschichte Bd. 10), Göttingen 1992

Gensichen, H.-W.:

Akzente und Problemstellungen in der gegenwärtigen evangelischen Missionstheologie. In: ZMR 70 (1986) 112-127

Glazik, J.:

Mission – der stets größere Auftrag. Gesammelte Vorträge und Aufsätze von Josef Glazik MSC. Aachen 1979

Grundmann, Chr.:

Die Welt als Horizont – Vision, Illusion und Irritation christlicher Mission. In: ZMR 80 (1986), 129-144

Hering, W.:

Das Missionsverständnis in der ökumenisch-evangelikalen Auseinandersetzung – ein innerprotestantisches Problem. (Studia Instituti Missiologici Societatis Verbi Divini Nr 25), St. Augustin 1980

Holthaus, S., Müller, K.W., (Hrsg.):

Die Mission der Theologie. FS für Hans Kasdorf zum 70. Geburtstag, Bonn 1998

Jäger, N.:

Die Heilsmöglichkeit der Nichtchristen und die Notwendigkeit der Mission. Das Zweite Vatikanische Konzil auf dem Hintergrund der Theologiegeschichte. Münster 1975

Lehman-Habeck, M.:

Evangelisation im umfassenden Sinne. Eine ÖRK-Position. In: Evangelische Mission, Jahrbuch 1984, Hamburg 1984, S. 25-34

Linn, G.:

Die achte Vollversammlung des ÖRK in Harare und das Thema Mission. Eindrücke und Überlegungen, in: ÖR 48 (1999), Heft 2, S.181-189

Metz, J.B.:

Im Aufbruch zu einer kulturell polyzentrischen Weltkirche. In: ZMR 70 (1986), 140-153

Margull, H. J. (Hg.):

Mission als Strukturprinzip. Ein Arbeitsbuch zur Frage missionarischer Gemeinden. ÖRK, Genf 1965

Müller, K.:

Missionstheologie. Eine Einführung von Karl Müller, Mit Beiträgen von H.-W. Gensichen und H. Rzepkowski, Berlin 1985

Müller, K., Ustorf, W. (Hrsg.):

Einleitung in die Missionsgeschichte. Tradition, Situation und Dynamik des Christentums, Stuttgart-Berlin-Köln 1995

n.n.

Was heißt Mission? Grundlagen und neue Aspekte einer Theologie der Mission, Dokumentation eines Seminars in Bossey, Genf vom 4.-9. September 1989 (Weltmission heute Nr. 8) Hamburg 1990

ÖRK: Die Kirche für andere und die Kirche für die Welt im Ringen um Strukturen missionarischer Gemeinden. Schlußberichte der Westeuropäischen Arbeitsgruppe und der Nordamerikanischen Arbeitsgruppe des Referates für Fragen der Verkündigung, ÖRK, Genf 1967

Pesch, R.:

Voraussetzungen und Anfänge der urchristlichen Mission. In: Kertelge, K. (Hrsg.), Mission im Neuen Testament, (QD 93), Freiburg 1983, S. 11-70

Peter, A.: Von einem ekklesiozentrischen zu einem soteriozentrischen Missionsverständnis. In: Peter, A. (Hrsg.), Christlicher Glaube in multireligiöser Gesellschaft. Erfahrungen – Theologische Reflexionen – Missionarische Perspektiven. (Neue Zeitschrift für Missionswissenschaft), Immensee 1996, S. 383-401

Piepkke, J.G.

(Hrsg.): Evangelium und Kultur. Christliche Verkündigung und Gesellschaft im heutigen Mitteleuropa. Nettetal 1995

Reliprax (Religionspädagogik von der Praxis für die Praxis, Unterrichtsentwürfe – Arbeitsblätter – Bilder – Hintergrundmaterialien), Mission? – Mission!, 7 (1998)

Sautter, G.:

Heilsgeschichte und Mission. Zum Verständnis der Heilsgeschichte in der Missionstheologie. Am Beispiel der Weltmissionskonferenzen und der ökumenischen Weltkirchenkonferenzen bis 1975 und der evangelikalen Erklärungen von Wheaton, Frankfurt, Berlin und Lausanne. Gießen 1985

Schmidt-Leukel, P.:

Die religionstheologischen Grundmodelle. Exklusivismus, Inklusivismus, Pluralismus. In: Peter, A. (Hrsg.), Christlicher Glaube in multireligiöser Gesellschaft. Erfahrungen – Theologische Reflexionen – Missionarische Perspektiven. (Neue Zeitschrift für Missionswissenschaft), Immensee 1996, S. 227-237

Schoen, U.:

Dialog. In: K. Müller, Th. Sundermeier, Lexikon missionstheologischer Grundbegriffe, Berlin 1987, S. 65-68

Sievernich, M.:

Die Aktualität der Mission nach Karl Rahner. In: Missionswissenschaftliches Institut Missio e.V. (Hrsg.), Ein Glaube in vielen Kulturen. Theologische und soziopastorale Perspektiven für ein neues Miteinander von Kirche und Gesellschaft in der einen Welt. Frankfurt 1996, S. 186-204

Sundermeier, Th.:

Theologie der Mission. In: K. Müller, Th. Sundermeier, Lexikon missionstheologischer Grundbegriffe. Berlin 1987, S. 470-495

Üffing, M.:

Die deutsche Kirche und Mission. Konsequenzen aus dem nachkonziliaren Missionsverständnis für die deutsche Kirche. Nettetal 1994

Vicedom, G.:

Missio Dei. Einführung in eine Theologie der Mission. München 1958

Werner, D.:

Mission für das Leben – Mission im Kontext. Ökumenische Perspektiven missionarischer Präsenz in der Diskussion des ÖRK 1961-1991. Mit einem Geleitwort von Gerhard Linn/CWWME. (Ökumenische Studien Bd. 3), Rothenburg 1993

Wietzke, J. (Hg.):

Mission erklärt. Ökumenische Dokumente von 1972-1992. Theologische Kommission des Evangelischen Missionswerkes Hamburg, Leipzig 1993

Wrogemann, H.:

Mission und Religion in der Systematischen Theologie der Gegenwart. Das Missionsverständnis deutschsprachiger protestantischer Dogmatiker im 20. Jahrhundert. Göttingen 1997

Schäfer, K. (Hg.):

Zu einer Hoffnung berufen. Das Evangelium in verschiedenen Kulturen. Berichtsband zur 11. Konferenz für Weltmission und Evangelisation in Salvador da Bahia 1996. Evangelischen Missionswerks in Deutschland, Frankfurt 1999

**22**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**



## WHAT DOES QUALITY MEAN TO LAY PEOPLE? COMMUNITY PERCEPTIONS OF PRIMARY HEALTH CARE SERVICES IN GUINEA

SLIM HADDAD,<sup>1</sup>\* PIERRE FOURNIER,<sup>1</sup> NIMÀ MACHOUF<sup>1</sup> and  
FASSINET YATARA<sup>2</sup>

<sup>1</sup>Université de Montréal, Groupe de Recherche Interdisciplinaire en Santé, Pavillon Marguerite  
d'Youville, C.P. 6128, Succursale A, Montréal, Que., Canada H3C 3J7 and <sup>2</sup>UNICEF, Conakry Local  
Office, Conakry, Republic of Guinea

**Abstract**—The success of strategies to revitalize primary health care services such as those advocated by the Bamako Initiative requires a response adapted to the expectations of the population, especially in terms of quality. The goal of this study, conducted in two rural communities in Guinea, was to identify, characterize, and classify the criteria that the public uses to judge the quality of primary health care (PHC) services. This study included 180 participants in 21 focus group discussions. Forty-four main criteria were identified. These criteria vary depending on the respondents' sex and age, and their ability to access primary health care services. Some of the criteria correspond to those used by health care providers, while others do not. The general public places considerable emphasis on outcomes, but little emphasis on preventive services. The users appear very sensitive to aspects of the interpersonal relations they have with professionals and the technical quality of the care provided. A taxonomy of perceived quality is developed, which includes the following five categories: (1) technical competence of the health care personnel; (2) interpersonal relations between the patients and care providers; (3) availability and adequacy of resources and services; (4) accessibility and (5) effectiveness of care. It is a major challenge to refocus on quality in the development of health care services. This will require considerable changes for which training may be an effective, but certainly not a sufficient means. Promoting professionalism and changing the relations between public authorities and the general public are the only means of improving the quality of health care services as well as user perception. © 1998 Elsevier Science Ltd. All rights reserved

**Key words**—quality of health services, community perceptions, primary health care services, focus group discussions, developing countries, Bamako Initiative

### INTRODUCTION

Until recently, little attention had been paid to the quality of primary health care services (PHC) in developing countries (Sauerborn *et al.*, 1989; Forsberg *et al.*, 1992; Haddad and Fournier, 1995). This lack of interest can be explained by the priority that has long been placed on improving availability of services in contexts where there have been enormous needs that have rarely been met. It can also be explained by the attitude of authorities responsible for health care who have felt that evaluating and ensuring quality were luxuries reserved for developed countries (Thomason and Edwards, 1991) since PHC services, which do not rely heavily on advanced technologies, had less need for quality standards (Roemer and Montoya-Aguilar, 1989). Some (Bruce, 1990) also suggest that "confusion surrounding the meanings of the term *quality*" have

slowed progress in the field (in particular in the area of family planning).

Nevertheless, interest in the quality of health care services in developing countries appears to be on the rise. There has been an increase in the number of actions aimed at maintaining acceptable standards of quality (Thomason and Edwards, 1991) and of studies concerning the assurance and evaluation of quality. This trend undoubtedly translates the concerns raised by the implementation of strategies to improve the continuity and effectiveness of PHC services. It is also the consequence of the repeated observation of strong links between the quality of services and use of these services. In fact, perceived quality is one of the principal determining factors of utilization (Mwabu, 1986; Sauerborn *et al.*, 1989; Hotchkiss, 1993; Gilson *et al.*, 1994; Haddad and Fournier, 1995), and non-utilization of services — a major issue in several developing countries — is often traced to a perceived lack of quality (Abu-Zaid and Dann, 1985; Mwabu, 1986;

\*Author for correspondence.

Berman *et al.*, 1987; Vogel, 1988; Waddington and Enyimaew, 1989).

Most often, evaluation studies deal with quality according to one of the following two perspectives: the "technocratic" perspective of health care professionals, or less frequently, that of the communities (Wouters, 1991). In both cases, the notion of quality carries a favorable connotation, conforming to the common meaning of the term and evoking a set of virtuous or worthy attributes. Studies based on the technocratic perspective are relatively frequent and convey the representations of health care professionals\*. Most often, and in a more or less explicit fashion, they rely on a normative definition of quality: services are judged to be of good quality as soon as they reach defined standards (Rocmer and Montoya-Aguilar, 1989; Thomason and Edwards, 1991; Forsberg *et al.*, 1992). In the second perspective, the recipients of PHC services play a central role in the definition and assessment of quality. For example, Jain *et al.* (1992) considers that "A program of high quality is one that is client oriented and aims to help individuals achieve their...intentions or goals". Donabedian (1980) believes that user satisfaction "can be regarded as the patient's judgement on the quality and the goodness of care", while other authors consider that quality requires an appropriate response to consumers' expectations (Van Campen *et al.*, 1995).

The evaluation of the quality perceived by the public is justified in the desire to meet users' expectations, thereby contributing to "the process of democratization of health care services". (Calnan, 1988b). It also draws legitimacy in practical considerations since the viability of the health resources appears to be closely linked to the perceptions that communities have of the quality of the services they offer.

There have been relatively few works published with the specific objective of identifying the criteria that communities apply to judge primary health care services in developing countries. In a rapid appraisal of urban consumer preferences about health services in Fiji, criteria related to the art of care emerged as the foremost issue, followed by availability of drugs and personnel, physical environment, technical quality, accessibility and in-patient food (Attah and Plange, 1993). In Zaïre, a study on the qualities that should be found among health workers showed that women valued interpersonal qualities (respect, patience, courtesy, atten-

tiveness, friendliness and straightforwardness), technical qualities and to a lesser extent, integrity (Haddad and Fournier, 1995). When they were asked about the two best qualities a nurse should have, the majority mentioned a relational component first and a technical component second. Thus, women's judgement on the quality of care may be largely based on their perception of the health providers' conduct. Studies conducted in various settings and with various population groups support this observation (Calnan, 1988a; Bruce, 1990; Lohr *et al.*, 1991; Vera, 1993).

Additional information on women's views of the quality of PHC services are reported in a recent Tanzanian study in which 250 women were invited to discuss their previous experiences with public, private and traditional providers (Atkinson and Ngenda, 1996). From the comments on public services, the authors deduced a classification of perceived quality involving six dimensions: (1) conduct of health staff; (2) technical care, including outcome; (3) convenience of the health facility; (4) organization of the health care; (5) drugs (prescription, availability) and (6) structural aspects, including staffing.

These studies provide interesting information on the criteria that communities may use to judge the quality of PHC services. However, additional studies that are specifically designed to address this question would add to our knowledge of these perceptions. Since communities are not homogenous in their definition of quality and most of the previous studies in developing countries focus on specific, somewhat non-representative groups, these studies do not necessarily provide an exhaustive view of the perceptions which can prevail in a community. As research conducted in the West suggests, perceived quality may vary among members of different socio-economic groups (Calnan, 1988a; Roberge *et al.*, 1996) and may be influenced by the social, organizational and technological context in which the health services are delivered (Lohr and Thier, 1988; Palmer, 1991; Ellis and Whittington, 1993). We also lack a detailed taxonomy of perceived quality which could act as a framework for the construction of tools to measure this component of care in conformity with the dominant representations of the users.

This study has been designed to address these needs. Its objective is to take a broad and systematic approach to identifying the perceptions of quality of PHC services in an African rural context and to develop a reference framework for perceived quality. As part of an operational research program in Guinea, this is the first in a series of surveys which have been developed to better document lay people's perceptions of the quality of PHC services and the determinants of their utilization.

\*For example, (Pust and Burell, 1986; WHO, 1989; Engelkes, 1990; Garner *et al.*, 1990; Lewis *et al.*, 1991; Nicholas *et al.*, 1991; Peters and Becker, 1991; Thomason and Edwards, 1991; Bryce *et al.*, 1992; Kaufman *et al.*, 1992; Askew *et al.*, 1993; Kipp *et al.*, 1994; Satia *et al.*, 1994; World Health Organization, 1990).

Table 1. Number of FG according to composition and location (presence/absence of PHC services in the village)

	Women		Men	
	PHC available	PHC not available	PHC available	PHC not available
Younger adults	2	2	3	1
Older adults	1	4	3	5
Sub-total	3	6	6	6
Total by sex	9		12	
Grand total	21			

## BACKGROUND

There has been a recent large-scale reorganization of the PHC system in Guinea. The PEV/SSP/ME\* program, inspired by the Bamako Initiative and supported by UNICEF, allowed for improvement of close to 300 health care centers (Levy-Bruhl *et al.*, 1994; Unicef, 1994). The majority of these centers have been renovated and their staff was trained. They are administered by management committees, they offer curative and preventive services, and they are funded through a cost recovery system ensuring availability of essential drugs.

The study was conducted in two sub-prefectures in Lower Guinea located approximately one and a half hours from the capital, Conakry. Their county seats, Wonkifong and Maférinyah, are about twenty kilometers from one another. The majority of the population is Susu; the habitat is rural or semi-urban and agriculture provides most of the local resources (cassava and some cash crops such as pineapple). A rural health center is located in each county seat. In some villages, health posts assume some of the caseload for these centers.

## METHODS

The approach chosen is suited to the exploratory and resolutely empirical aspect of this study. It was carried out without prior modelization or taxonomy of the notion of quality and in so far as possible, it tried not to let the preconceptions of the team members color the respondents' viewpoints.

The method uses focus group discussions (FGDs), an approach based on open discussion on pre-identified themes, with a variable number of participants gathered around a moderator. Unlike some techniques, that of FGDs places more emphasis on the interaction between the participants and the emergence of good group dynamics than on the exchanges between the participants and the group moderators (Morgan, 1988; Simard, 1989). This is the preferred method when the approach is exploratory, whether the goal is to document opinions or points of view, and the researchers want to avoid a situation where the content of the messages

expressed is influenced by their own preconceptions (Morgan, 1988).

The constitution of the groups, their execution, as well as the gathering and handling of the information were carefully prepared taking into account the specific nature of the local cultural features and the themes dealt with (especially their particularly abstract character). Special attention was paid to the development of a technique which calls for the moderators to participate in a discreet, non-directive manner and to maintain as neutral an attitude as possible. They were recruited from outside of the health care system, on the basis of their experience. Most of them were sociologists and they were highly involved in preparing the study. A one-week seminar, followed by three experimental FGDs, gave them the opportunity to refine the method and put the finishing touches on their training.

The focus group discussions were conducted in villages selected at random from lists of administrative districts and sectors in each of the two sub-prefectures involved. The moderators were paired, and each pair led one or two FGDs in each village. The groups were composed to ensure good group dynamics and production of optimal information: homogeneity of the groups in terms of age and sex and exclusion of leaders and those holding any form of authority. The debates lasted an average of 48 min (30–76'). They were recorded, taking into account that the local climate and situation dictated a certain degree of discretion (possible natural reticence and the imminence of elections). Twenty-one focus group discussions, including eight composed of women, were conducted in eleven villages (Table 1). In eight of the FGDs, the participants were "young adults", while "older adults" participated in thirteen others. Nine FGDs were conducted in areas with a health resource (health center or post).

The moderators produced and translated the transcripts of the FGDs the day they were held. The national trainers supervised the manual transcriptions, with the goal being to reproduce the participants' words as accurately as possible (an average of one working day per transcript). They were then entered into a computer, using the Microsoft Word software package (Microsoft, 1991). The data processing used both manual and computer procedures adapted to the qualitative character of the information, with the goal of pre-

\*Programme élargi de vaccination / Soins de santé primaire / Médicaments Essentiels — Expanded program of Immunization / Primary health care/ Essential drugs.

Table 2. Number of groups in which the particula

Item	All n =						
<b>Components related to structure</b>							
1 availability of drugs							
2 accessibility of the facility							
3 availability of "good" drugs							
4 presence of "good" doctors							
5 conditions of buildings and rooms							
6 presence of "doctors"							
7 availability of hospital beds							
8 delivery of services not conditional upon prior payment							
9 cleanliness of rooms							
10 availability of diagnostic equipment (devices)	7						
11 availability and quality of running water	7						
12 drugs and services free	6						
13 availability, state of washrooms	5	1					
14 availability of roads, bridges and electricity	5	1					
15 availability of in-patient food, quality of meals	4	2					
<b>Components related to process: technical aspects</b>							
16 overall patient care	18	7	11				
17 caring for and treating patients well	13	5	8				
18 good clinical examination	15	6	9	7			
19 dispensing drugs	14	5	9	5			
20 dispensing "good drugs"	13	7	6	6			
21 personnel doing their jobs well	12	5	7	4	8		
22 making a good diagnosis	11	3	8	4	7		
23 appropriate prescription	10	3	7	4	6	6	
24 use of diagnostic equipment	8	3	5	2	6	1	
25 appropriate referral	7	1	6	2	5	4	
26 follow-up, continuity, monitoring patient during his stay	6	2	4	3	3	1	5
27 prescription of drugs	5	1	4	2	3	2	3
28 administration of injections	5	3	2	1	4	0	5
29 questioning of patient	5	0	5	2	3	3	2
30 drugs dispensed rapidly	4	0	4	3	1	2	2
31 recognizing one's limits	2	0	2	0	2	2	0
32 giving advice (how to take the drugs)	2	1	1	1	1	2	0
33 appropriate care (treatment: bandages, injections)	2	1	1	0	2	0	2
<b>Components related to process: behavioral and interpersonal aspects</b>							
34 overall reception	18	7	11	8	10	8	10
35 compassion, support	12	5	7	3	9	6	6
36 access to doctor on arrival	12	5	7	5	7	4	8
37 interest, attention paid	12	4	8	5	7	5	7
38 kindness, politeness, respect	10	3	7	3	7	4	6
39 waiting time	7	3	4	2	5	1	6
40 devotion, willingness to serve, being at the patient's disposal	5	3	2	0	5	1	4
41 information concerning the nature of the illness	4	0	4	0	4	1	3
42 doctor and staff human, not haughty	3	0	3	1	2	2	1
<b>Components related to outcomes</b>							
43 recovery, cure	19	7	12	6	13	8	11
44 rapid recovery, rapid cure	7	1	6	4	3	3	4

Availability of drugs (attribute mentioned in 19 FGDs) or good drugs (14 FGDs)

By all appearances, drugs are considered a key element in the care process: "a patient can never be cured without drugs" and "if drugs are not on hand, death will come". Regardless of the health resource used, the availability of drugs is of prime importance: "when drugs are available, I can rest easy", "when you're sick, all you want is some medication, no matter where it comes from — here, there, the hospital, or the healer". The "good doctor" is "the one who has drugs" and "if we have drugs, we are cured, and we are satisfied with the doctor and his care". There cannot be a good "hospital" unless drugs are available there: "you don't go to the hospital just because its a hospital, you go for the drugs". Availability of drugs often takes precedence over the other attributes of quality: "I don't care whether the hospital looks nice,

has a fresh coat of paint or not...what I care about is the drugs, no matter where I see my doctor". To give us a better understanding of the importance of having drugs in the "hospital" a participant drew a comparison with our visit: "When you came to see us, we gave you a present: you got a place to stay, you were hungry, so we gave you something to eat and then you were happy. After the meal, you were cured (of your hunger). At the hospital, its the same thing".

It is not enough for drugs to be available. It is also important for the health resource to have the "right drug", i.e. the one which will enable the patient to recover. This additional condition appears in 14 of the 21 groups and translates the concern that communities have about access to adequate drugs. "If I go to the hospital and I can't have the drug that can cure me, I don't like that hospital". "Can you imagine a good doctor without

serving the entire content of the transcripts. This involved five steps: (1) locating key exchanges, (2) computer file transfer, (3) coding of expressions, (4) validation and (5) production of matrices recording the results and analysis.

The locating involved several sub-steps: first, the researchers carefully read the transcripts and excluded exchanges that resulted from a suggestive intervention from the group leaders\*. The locating involved marking the exchanges likely to convey the meanings conferred on quality services†. The text of the 664 exchanges identified in this way was then transferred to the data base in a qualitative data processing software designed by the team using the FileMakerPro software package (Claris, 1990). The coding of expressions consisted in: (1) compiling the list of criteria of quality mentioned in the 21 FGDs; (2) assigning a distinct code to each of these criteria and (3) identifying and entering the "criteria-codes" associated with the 664 transcripts. Forty-four criteria were identified, referring to aspects as varied as the reception extended to the patient, the availability of drugs, health outcomes, etc. The validation process focused on the three preceding steps. The purpose of the validation was to test the adequacy of the key exchange location and the criteria-codes by submitting the transcripts from two FGDs to two independent experts‡. This led to adjustments in the formulation of the criteria identified.

The matrices of the results allowed the researchers to evaluate the informative content of each of the groups and to compare the information produced according to the characteristics of the groups. The analysis focused on the content and the recurrence of the different criteria identified; the degree of recurrence of a key message can be considered as the expression of the importance attached to it (Simard, 1989).

## RESULTS

To facilitate the analysis, the 44 criteria of quality identified were first divided into 3 categories, using

\*For example, the answer to a question like "Should the doctor be competent?" was not used if the notion of a doctor's competence was raised by the group leader rather than by a participant.

†The locating was based on a conservative approach and only those exchanges in which the participants defined what they understood by good service, a good doctor or a good drug were used, as well as those in which they expressed specific expectations in terms of quality.

‡One was chosen for his knowledge of the field of quality of health care services; the other, for his knowledge of the local scene, and the Susu language and culture.

§In the local context, the word "hospital" refers to a health care facility and more specifically to a health center. In the same manner, all health care professionals are called "doctor".

Donabedian's classification — structure, process, outcome — which has the dual advantage of being widely accepted and easily understood (Donabedian, 1980). Fifteen criteria refer to structural components, with those relating to availability of resources in health facilities being mentioned far more frequently than any others. There were almost twice as many process criteria. Of these 27 attributes, two have an overall character, in that they deal with the general process of care: the fact of taking good care of the patients, of taking an interest in them and their problems (a criteria mentioned in 18 FGDs) and the fact of caring for them, offering them good care, good treatment (a criteria mentioned in 13 FGDs). Among the remaining items, 16 refer to what are generally termed the technical components of care (Donabedian, 1980). They deal mainly with the diagnostic and therapeutic competence of the professionals as well as with the dispensing of drugs. Nine items deal with the conduct of health care providers and interpersonal relations between patients and professionals. Lastly, two criteria have to do with health outcomes, and one of these, "recovery or cure", was mentioned in almost all of the groups. The full list of these 44 criteria, as well as their occurrence in each type of group, is found in Table 2. Seventeen are mentioned in more than half of the groups, with eight being mentioned in more than two thirds.

### *Recovery (attribute mentioned in 19 FGDs)*

Recovery is one of the most important criteria used to judge quality of services: "I just want to be cured" is an expression commonly heard. A "hospital"§ is judged first for its effectiveness: "people will be talking about it for a long time — they'll say that its thanks to the hospital that such and such a person didn't die; the hospital is really working...its because of similar actions that people have confidence in the hospital", "if you go to the hospital and you are not cured, you will not be happy". It seems that expected effectiveness is the main determining factor for resorting to treatment: "I go to the practitioner who can cure me so that I can get well again", or "wherever they can cure me is the best hospital for me".

Similarly, the quality of the drugs and the physicians is determined by their effectiveness: "A good drug is one that, once it gets into your body, helps you get well again". The good doctor is "the one who solves your health problem". "If the patient gets well again, the person will be happy and the doctors who cared for him will be happy also because they were able to help a sick person get well". "If a doctor succeeds in saving a patient from death...he can be proud of himself because he gave that person his life back again...the doctor who is successful in treating you will be highly regarded among his peers".

Table 2. Number of groups in which the particular criteria is mentioned

Item	All n = 21	Women n = 9	Men n = 12	Young n = 8	Older n = 13	With PHC n = 9	Without PHC n = 12
Components related to structure							
1 availability of drugs	19	7	12	7	12	8	11
2 accessibility of the facility	17	6	11	5	12	6	11
3 availability of "good" drugs	14	7	7	5	9	6	8
4 presence of "good" doctors	12	5	7	5	7	4	8
5 conditions of buildings and rooms	12	5	7	2	10	3	9
6 presence of "doctors"	10	5	5	3	7	4	6
7 availability of hospital beds	9	3	6	2	7	2	7
8 delivery of services not conditional upon prior payment	8	2	6	1	7	3	5
9 cleanliness of rooms	8	4	4	3	5	3	5
10 availability of diagnostic equipment (devices)	7	3	4	2	5	3	4
11 availability and quality of running water	7	3	4	1	6	3	4
12 drugs and services free	6	3	3	2	4	1	5
13 availability, state of washrooms	5	1	4	1	4	1	4
14 availability of roads, bridges and electricity	5	1	4	1	4	2	3
15 availability of in-patient food, quality of meals	4	2	2	1	3	1	3
Components related to process: technical aspects							
16 overall patient care	18	7	11	7	11	8	10
17 caring for and treating patients well	13	5	8	4	9	6	7
18 good clinical examination	15	6	9	7	8	5	10
19 dispensing drugs	14	5	9	5	9	4	10
20 dispensing "goods drugs"	13	7	6	6	7	4	9
21 personnel doing their jobs well	12	5	7	4	8	5	7
22 making a good diagnosis	11	3	8	4	7	5	6
23 appropriate prescription	10	3	7	4	6	6	4
24 use of diagnostic equipment	8	3	5	2	6	1	7
25 appropriate referral	7	1	6	2	5	4	3
26 follow-up, continuity, monitoring patient during his stay	6	2	4	3	3	1	5
27 prescription of drugs	5	1	4	2	3	2	3
28 administration of injections	5	3	2	1	4	0	5
29 questioning of patient	5	0	5	2	3	3	2
30 drugs dispensed rapidly	4	0	4	3	1	2	2
31 recognizing one's limits	2	0	2	0	2	2	0
32 giving advice (how to take the drugs)	2	1	1	1	1	2	0
33 appropriate care (treatment: bandages, injections)	2	1	1	0	2	0	2
Components related to process: behavioral and interpersonal aspects							
34 overall reception	18	7	11	8	10	8	10
35 compassion, support	12	5	7	3	9	6	6
36 access to doctor on arrival	12	5	7	5	7	4	8
37 interest, attention paid	12	4	8	5	7	5	7
38 kindness, politeness, respect	10	3	7	3	7	4	6
39 waiting time	7	3	4	2	5	1	6
40 devotion, willingness to serve, being at the patient's disposal	5	3	2	0	5	1	4
41 information concerning the nature of the illness	4	0	4	0	4	1	3
42 doctor and staff human, not haughty	3	0	3	1	2	2	1
Components related to outcomes							
43 recovery, cure	19	7	12	6	13	8	11
44 rapid recovery, rapid cure	7	1	6	4	3	3	4

*Availability of drugs (attribute mentioned in 19 FGDs) or good drugs (14 FGDs)*

By all appearances, drugs are considered a key element in the care process: "a patient can never be cured without drugs" and "if drugs are not on hand, death will come". Regardless of the health resource used, the availability of drugs is of prime importance: "when drugs are available, I can rest easy", "when you're sick, all you want is some medication, no matter where it comes from — here, there, the hospital, or the healer". The "good doctor" is "the one who has drugs" and "if we have drugs, we are cured, and we are satisfied with the doctor and his care". There cannot be a good "hospital" unless drugs are available there: "you don't go to the hospital just because its a hospital, you go for the drugs". Availability of drugs often takes precedence over the other attributes of quality: "I don't care whether the hospital looks nice,

has a fresh coat of paint or not...what I care about is the drugs, no matter where I see my doctor". To give us a better understanding of the importance of having drugs in the "hospital" a participant drew a comparison with our visit: "When you came to see us, we gave you a present: you got a place to stay, you were hungry, so we gave you something to eat and then you were happy. After the meal, you were cured (of your hunger). At the hospital, its the same thing".

It is not enough for drugs to be available. It is also important for the health resource to have the "right drug", i.e. the one which will enable the patient to recover. This additional condition appears in 14 of the 21 groups and translates the concern that communities have about access to adequate drugs. "If I go to the hospital and I can't have the drug that can cure me, I don't like that hospital". "Can you imagine a good doctor without

good drugs?" A good "hospital" is "where you find both good doctors and good drugs".

*Reception of patients (attribute mentioned in 18 FGDs)*

To a large extent, health care personnel are judged on the manner in which they receive their patients. "The most important thing is the way in which a patient is received and looked after". "The 'good doctor' is someone who receives you very well, he looks at you carefully, greets you, he is very happy with you...he takes an interest in the patient, doesn't neglect him to take care of his relative instead". A good doctor "doesn't mean education alone since that cannot change the way a person acts. There are men who are well educated and behave very badly". Sometimes proper reception of patients is as important as having drugs available: "drugs and proper reception of patients are equal;...if you see that you are getting good drugs, it is because he (the doctor) examined you well and because you found a good person".

Here too, the participants often drew parallels with everyday life to illustrate their points: "When someone comes to your door, first you have to say hello to them". But the need to extend a proper reception is not simply a matter of observing social niceties. A proper reception is first a source of hope because "once you fall ill, you lose all sense and the patient...will be at ease and will have hope that he will get well again". It inspires courage and the manner in which the doctor receives the patient is a source of comfort: "if you go and the doctor receives you well and looks after you, that may be enough". The reception enables the patient to accept a difficult situation and it helps him to overcome the thought that the treatment may fail: "if you receive a patient well and you succeed in treating and curing him, he will be very grateful to you". If the opposite happens, the patient will say: "he did everything to cure me, but didn't succeed, but he was very kind". At this point, the patient will have no regrets, "his condition is in God's hands". The reception extended also compensates for other shortcomings since "even if drugs are not available, at least you have a good impression of the person" and "even if I die it will not be your fault". A proper reception also takes on therapeutic powers. It can "decrease the pain of your illness" and start the recovery process: "just by the way the doctor greets you, he can relieve you..." since "it is not money that cures a patient, but rather the good care of the doctor". Lastly, a proper reception is justified because it has the ability to increase the clientele knowing that once "I come to you and you receive me very well and you give good treatment, I will find lots of patients for you, telling them that its the best hospital".

*Overall care (attribute mentioned in 18 FGDs)*

These are expressions in which the participants raise the matter of "taking care of the patient", "looking after him", or "dealing with his problem". This notion of looking after the patient usually encompasses the steps of the care process which, within the framework of the local representations, contributes greatly to recovery: the reception extended, the examination of the patients, the diagnosis, and then dispensing the appropriate drug. Thus, for example, "looking after the patient" involves the following sequence: "the patient comes in worried, you approach him, prescribe the good drugs for his illness, and you give him the drugs". Thus, it is less a matter of a criterion concerning a specific attribute of quality of services, and more an aggregate enabling the patient to make an overall judgement on the care process. Here too, it is one of the pillars that patients use as the basis of their judgement of the quality of health resources; the good doctor is typically "the one who can look after his patients very well" since "the patient wants someone to take care of him well by helping him to make a full recovery".

*Accessibility of the "hospital" (mentioned in 17 FGDs)*

The question of accessibility to health care centers was systematically raised in the five villages that do not have one. However, the same was true in the other villages, suggesting that proximity to health resources would always be an important criterion for judging them. It should also be noted that the desire expressed in the outlying villages to have bridges and roads actually speaks of the desire to improve accessibility to existing health centers "to stop going to others to get care" and because "its no picnic to carry a sick person on your back for 23 km".

*Good clinical examination (attribute mentioned in 15 FGDs)*

In a context in which performing a clinical examination is not always effective, the communities expect their care providers to conduct a thorough visit with their patients. A good doctor must "take a close look at the patients", "observe them carefully". Of course, this examination enables the doctor to make a good diagnosis and to set in motion the follow-up in a favorable manner "the doctor looks at my sickness so that myself and my child do not die". In addition, it is reassuring: "when you go to the hospital and the doctor walks past you and does not even touch you much, the patient ends up feeling afraid; but if he looks at you and tries to do something for you, then you're happy".

*Dispensing drugs (attribute mentioned in 14 FGDs)*

It is not enough for a "doctor" or a "hospital" to have a drug available. This "doctor" must also dispense the drug to his patients. There was no direct explanation for this distinction between availability and dispensing of drugs in the exchanges during the FGDs. Nevertheless, it is probably related to the experiences of some participants for whom the drugs available in the health centers had not been distributed in a systematic or perfectly transparent manner. Here again, the participants emphasized that it has to be the right drugs — those that cure (the distinction between the two items "dispensing of drug" and "dispensing of the good drug" is one of the characteristics of the process that recurred most frequently. "The person who treats me must not only give me a product, but a product that can cure me. The good doctor gives good drugs", he is the one "who administers the good injections...gives you the good drugs and you are cured".

*Other attributes*

The 44 items cover the main components that enable users to characterize health care or services. Though they focus on the care, not one refers directly to preventive services such as vaccination, prenatal consults, family planning, or health education. Some deserve special attention. Thus, the possibility to defer payment for care was mentioned in 9 FGDs, even though these payment arrangements contravene the rules in force in the health centers. The availability of infrastructures such as roads, bridges or electricity in the villages was mentioned in 5 FGDs, although these are components

that by and large are beyond the scope of the health sector *per se*. Food was mentioned in 4 FGDs even though this is a service which is not offered in the health facilities, as is common throughout Africa. From the point of view of processes, the administration of injections is a criterion of quality mentioned in five groups, whereas the PEV/SSP/ME program is trying to decrease the practice. Aside from the reception extended to the patient, there were many qualifiers mentioned that have to do with interpersonal relations between the patients and caregivers. With the help of the national trainers, they were broken down into three categories according to Susu semantics and local cultural representations: kindness, respect, and compassion. It should also be noted that from the point of view of outcome, good health care services must lead to cure, and if possible, a rapid cure.

*Criteria of quality and composition of groups*

In this section, we compared the criteria expressed in the different groups according to sex, age, and the participants' access to health services. The small number of groups and the resulting lack of statistical strength made it impossible to use inference tests and to generalize the possible differences observed to a general population. The criteria expressed in this sample of groups were not distributed uniformly (see Table 2). Fewer criteria of quality emerge from groups made up of young adults, women and those who had means to access health care services. Of the 44 attributes, on average 16.4 were raised in the groups of women and 21.3 in the groups of men (for a general average of 18.0 items per FGD). These values were 16.9 for the groups of young adults, 20.7 for those of older adults, 17.0

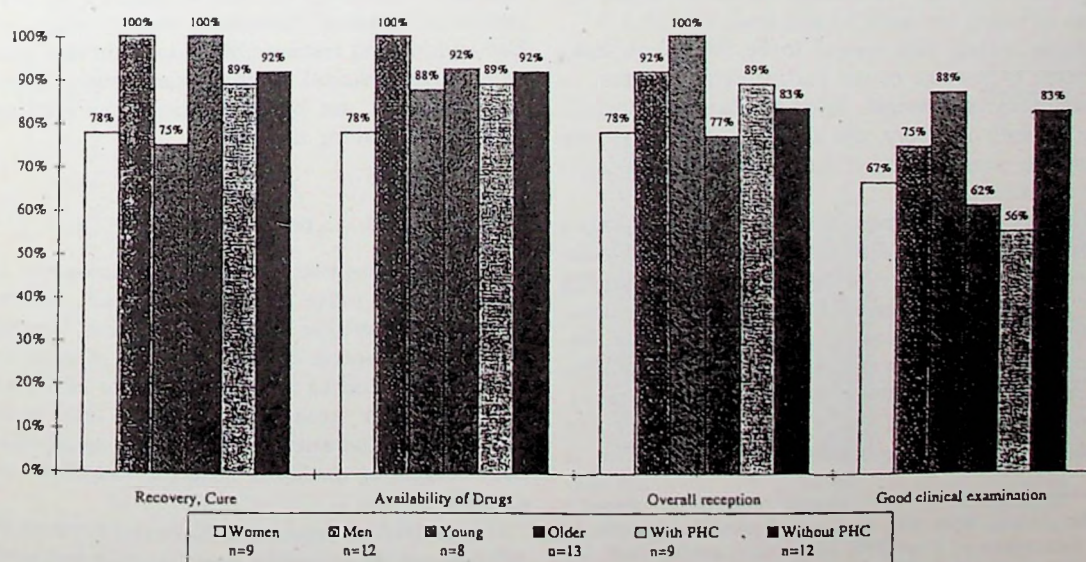


Fig. 1. Major criteria valued in each of the groups: Proportion of groups in which the particular criteria is mentioned.

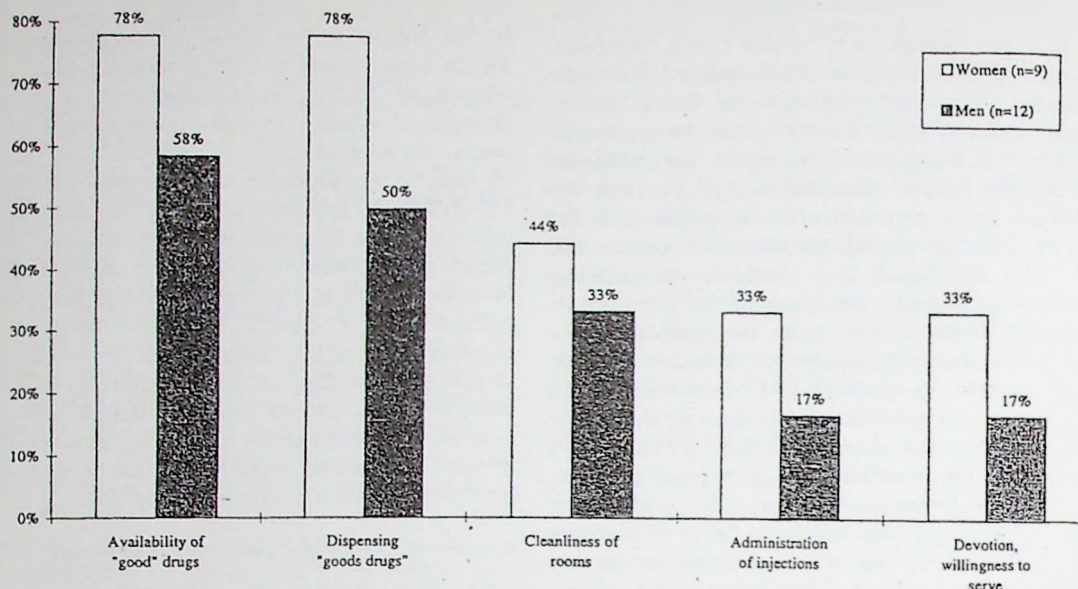


Fig. 2. Criteria valued more by women than men: Proportion of groups in which the particular criteria is mentioned.

for those group discussions that took place in villages that have health resources and 20.9 in those carried out in areas that do not have health resources.

The less productive nature of these groups was confirmed for the different categories of criteria. On average, there were 20% more criteria in the groups of men and the difference was even more marked for the criteria dealing with technical aspects of the processes or health outcomes. As for age, the most significant differences deal with the criteria related to the structure and interpersonal aspects (+53% and +23% for older adults). The criteria of structure were also more frequently mentioned in the villages in which accessibility was lower (+40%).

Some criteria still appear to be important, independent of the age of the participants, their sex, or accessibility of services. In particular these include the patient's recovery, the availability of drugs, the reception extended, and the practice of a clinical examination (see Fig. 1).

On the other hand, there are more contrasts between some of the distributions. The women mentioned the availability of "good drugs", dispensing of "good drugs", cleanliness of the rooms, "administering injections" and in-patient food more frequently than the men did (see Fig. 2). Accessibility, "dispensing drugs", the attention given to patients, good diagnosis, kindness, appropriate prescription and referral, the possibility of resorting to a

deferred payment plan, and rapid cure\* were among the criteria most frequently mentioned by men (see Fig. 3). The older adults clearly placed greater importance† on the accessibility, the physical conditions and state of the rooms and beds for consultation and hospitalization, the possibility of resorting to a deferred payment plan, and the compassion of the staff members (see Fig. 4). They seemed less concerned than the younger adults with speed of recovery as well as a good clinical exam and "dispensing good drugs" (see Fig. 5). Lastly, and logically, the inhabitants with the most limited access to health services were also those who most frequently mentioned the need to ensure good availability of physical (hospitals, rooms, beds) and human (doctors) resources that would in turn guarantee good technical quality (examination, dispensing of drugs, use of diagnostic equipment) and reduction in waiting times.

## DISCUSSION

The study suggests that when communities are called upon to judge the quality of health services, they tend to mobilize a variety of criteria, covering the different aspects of quality. Most of these criteria had been raised within the first five FGDs and one could have reasonably concluded that, in the local context, the essence of the scope of significations concerning quality of health services had been covered.

It is possible to establish a hierarchy between the different criteria of quality based on how frequently they are mentioned. Eight criteria appear to be greatly valued. Most of them relate to the structure (availability of drugs and accessibility of the health

\*This list of items was purposely limited to the criteria that appeared over 50% of the time among men and that were mentioned in at least one third of the 21 FGDs.

†Evaluated according to the same method as in the preceding note.

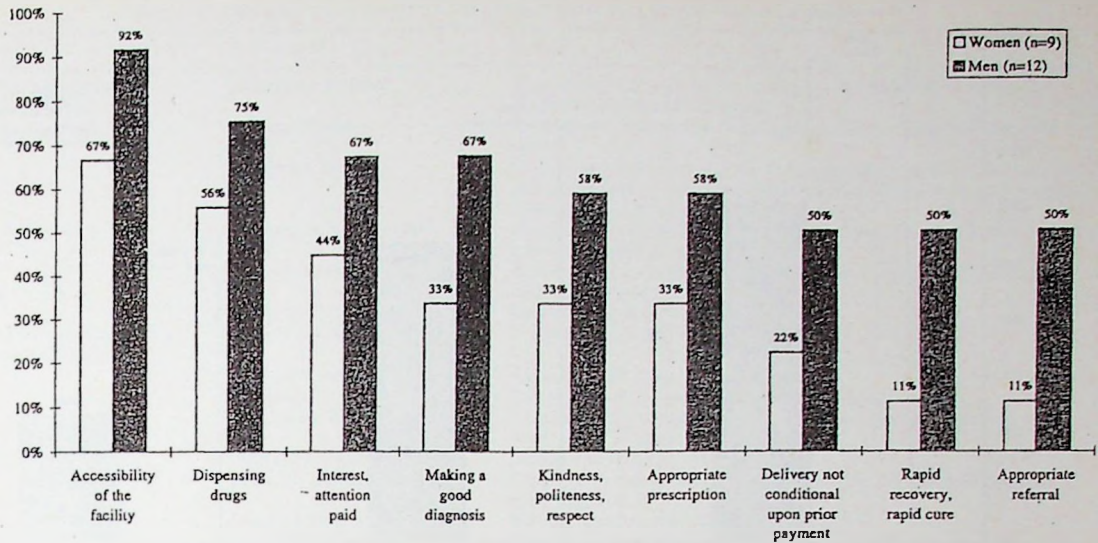


Fig. 3. Criteria valued more by men than women: Proportion of groups in which the particular criteria is mentioned.

facility) or the process of care (reception of patients, overall care, good clinical examination, dispensing drugs and/or good drugs) and are regularly reported in the literature. The eighth criteria, recovery of health, is the most frequently encountered, suggesting that quality of health services is first and foremost to be judged in terms of outcomes. This result is quite interesting given that outcomes are surprisingly rarely mentioned as a distinctive attribute of perceived quality (Atkinson and Ngenda, 1996, include them in the dimension of technical competence and they do not appear in the Attah and Plange, 1993, taxonomy).

The accent placed on the capacity of the services to produce a cure should be placed alongside the fact that the expectations expressed were basically of a curative nature. Unlike what has been observed elsewhere (Gilson *et al.*, 1994), the study participants never spontaneously mentioned preventive services or their complementarity with health care activities, even though these services are highly integrated in the local context. The criteria expressed also do not address the notion of acceptability of the services that has been suggested by some studies, especially in the area of family planning (Bruce, 1990; Kim *et al.*, 1992; Askew *et al.*, 1993).

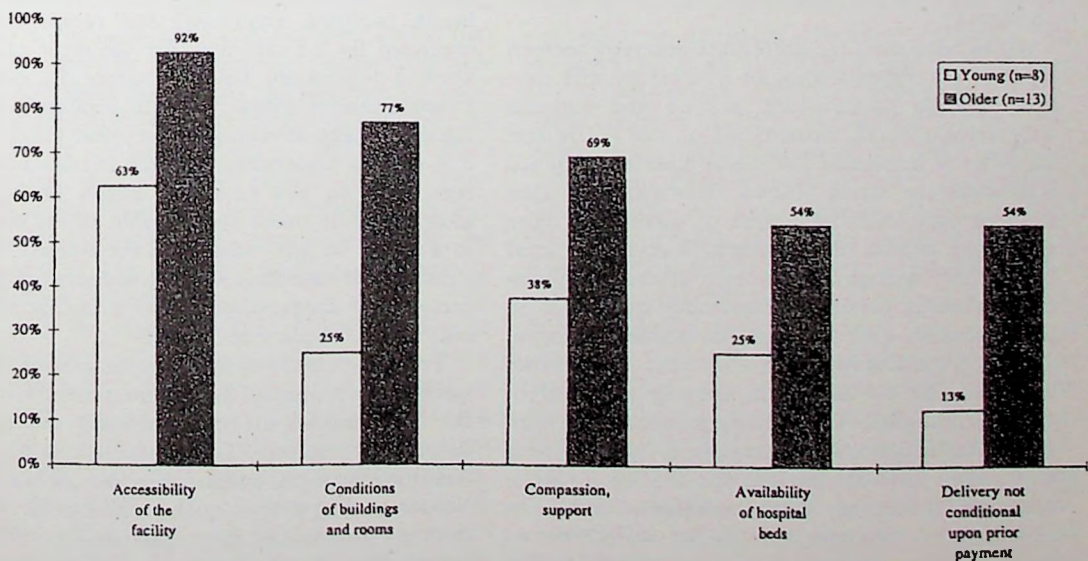


Fig. 4. Criteria valued more by older than younger adults: Proportion of groups in which the particular criteria is mentioned.

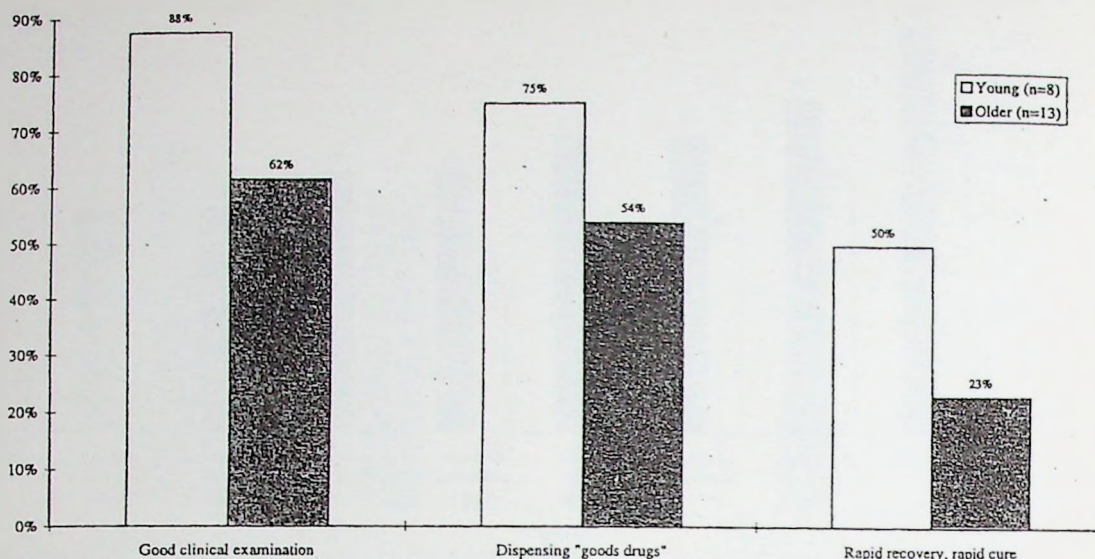


Fig. 5. Criteria valued more by younger than older adults: Proportion of groups in which the particular criteria is mentioned.

It is possible that the moderators did not succeed in leading the participants to express their opinions on this subject. It is also conceivable that in a context in which different medical traditions have coexisted for several decades, the question of acceptability of modern medicine is actually no longer asked. The many exchanges in which the participants stated that they did not care about the type of caregiver, provided that his care was effective, lend credence to this hypothesis. Moreover, the issue of family planning is quite different. It is easy to understand the importance of acceptability in this area, since the professionals and services proposed could easily offend the users' profound convictions (fertility, sexuality).

As we have said, the differences observed between types of participants must be interpreted with caution. Criteria of structure, process and outcome were mentioned in virtually all of the FGDs and the order of importance of the 44 criteria mentioned was relatively stable overall. However, the men seem to base their judgement of quality on more diversified criteria than women. Taking the local context into account, the women are relatively discreet when it comes to expressing themselves in public and we cannot ignore the possibility that in spite of a meticulous preparation, the investigators were not able to succeed in drawing them out of their natural shell. Their strong preoccupation with regard to drugs could be explained by the strong worry they have on "making the trip for nothing" and their concern with cleanliness could be explained by their own familial responsibilities. As far as cure is concerned, they appear more patient than the men, perhaps as they are about other aspects of daily life. The men, who traditionally control the household budget and pay for health

care, are naturally more concerned with the terms and conditions of payment. Lastly, the greater importance expressed by the men with regard to relational aspects is somewhat surprising and could be the consequence of the women holding back, as mentioned above.

The focus group discussions of older adults lasted an average of 15 min longer than those of the young adults and more criteria of quality were expressed during these groups. By virtue of their social status and their experience, the elders clearly felt more at ease when expressing themselves in front of people from outside of their village. Their greater sensitivity concerning the availability of health facilities, equipment and rooms could be explained by the fact that, for the most part, they knew a time when these resources did not exist. Lesser financial resources could explain their willingness to take advantage of payment plans. Lastly, it is easy to understand that the inhabitants of villages that do not have any health facilities and must therefore make considerable efforts to obtain care would be those who place the greatest value on structural components such as accessibility and the presence of drugs, doctors and a facility equipped with hospital beds. (see Table 2).

The results concerning the criteria used to judge quality are supported by previous observations on the determinants of health services utilization in developing countries. Close associations have been described between utilization and people's perceptions regarding overall quality (Ellis *et al.*, 1990), a facility's reputation (Pepperall *et al.*, 1995) and accessibility (Stock, 1983; Tsongo *et al.*, 1993), availability of drugs (Unger *et al.*, 1990; Waddington and Enyimayew, 1990; Litvack and Bodart, 1993; Gilson *et al.*, 1994), payment pro-

Table 3. Classification of lay people's perceptions of the quality of primary health care services

Aspects	Sub-aspects	Criteria
Technical competence	Diagnostic Process	Questioning the patient; Good clinical examination; Use of diagnostic equipment; Good diagnosis
	Decision Process	Appropriate prescription; Appropriate referrals; Recognizing ones limits
	Treatment Process	Dispensing drugs and/or good drugs; Drugs dispensed rapidly, Administration of injections; Giving advice; Good follow-up during patient stay; Appropriate care
Attitudes, conduct	Interpersonal Competence	Reception; Support; Doctor and staff human; Respect, Kindness and patient regarded as equal
	Interest taken in patient	Access to doctors upon arrival; Devotion — Willingness to serve; Information on the nature of the illness
	Integrity	Honesty of personnel
Availability and adequacy of resources and services	Human resources	Presence of doctors and/or good doctors
	Drugs and treatments	Availability of drugs and/or good drugs
	Equipment	Availability of diagnostic equipment (devices)
	Rooms, Buildings	Condition; Cleanliness; Availability of hospital beds, running water, washrooms, in-patient food
Accessibility	Geographic accessibility	Distance to facility
	Financial accessibility	Drugs and services free; Delivery of services not conditional upon prior payment
	Organizational accessibility	Waiting time; Access to doctor upon arrival
Effectiveness	Effectiveness of care	Recovery; Rapid cure

cedures (Haddad and Fournier, 1995) and waiting time (Kloos *et al.*, 1987; Tsongo *et al.*, 1993; Pepperall *et al.*, 1995; Atkinson and Ngenda, 1996). Utilization has also been related to health workers' qualifications (Abosedo, 1984; Berman, 1984; Sauerborn *et al.*, 1989), technical competence (Egunjobi, 1983; Tsongo *et al.*, 1993; Gilson *et al.*, 1994; Haddad and Fournier, 1995), honesty (Bruce, 1990; Gilson *et al.*, 1994; Haddad and Fournier, 1995) and conduct (Bichman *et al.*, 1991; Gilson *et al.*, 1994; Haddad and Fournier, 1995; Pepperall *et al.*, 1995).

Some of the criteria were congruent with those that the health professionals consider, implicitly or explicitly, when they are called upon to judge the quality of PHC services. This was the case for most of the criteria concerning the structure and technical quality of the care. There are, however, others that differ. Contrary to the public, the professionals base their judgements most often on indicators of structure, or even of process, but rarely on measurement of outcome (Wouters, 1991). They also focus mainly on the technical aspects (Bruce, 1990; Gilson *et al.*, 1994; Rees Lewis, 1994) and neither the quality of the reception nor the conduct of the staff are usually among the questionnaires they design and use to measure quality.

Some of the attributes clearly illustrate the gaps that can exist in the representations of the health care authorities and the communities in terms of quality of services. The possibility of obtaining credit plan, for instance, is one of the important criteria used by the public to judge the quality of services. These payment schemes are actually prohibited, since those in charge of the government program feel that they are a sign of poor management and inadequate quality. The availability of injections is another example. As in other countries

(Reeler, 1990), the Guinean population seems highly attracted by the idea of receiving injections and their availability is often seen as a measure of quality. Now, because of the risks brought about by their abusive use, injectable products have been reduced to a minimum on the list of essential drugs and health staffs are strongly urged to use injectable products sparingly.

It would be useful to present the criteria expressed in a way which allows for distinctions to be drawn between the main dimensions covered by the notion of "perceived quality". We attempted to reorder the criteria and include them into a validated — or at least, widely accepted — framework of perceived quality. Unfortunately, this appears to have been an unrealistic expectation. This may be explained in part because such a framework does not exist as previous conceptual (Brooks and Williams, 1975; Vuori, 1982; Bruce, 1990; Palmer, 1991; Donabedian, 1992) or empirical (Calnan, 1988a; Lohr *et al.*, 1991; Attah and Plange, 1993; Wilde *et al.*, 1993; Thomas *et al.*, 1995; Atkinson and Ngenda, 1996) research has led to quite distinct classifications, and in part because the criteria identified in our study encompass most of the components reported in the majority of the field studies we encountered. We then developed our own classification using a mixed approach (conceptual and empirical). It includes five dimensions (see Table 3). Two of them refer to the personnel, two to the health facilities and one to health care outcomes. Each dimension is divided into sub-categories involving a variable number of criteria. Three of the forty-four criteria were not included in the classification. The criterion "presence, availability of roads, bridges and electricity in the village" was not deemed relevant in a classification dealing with the quality of health services. The items "overall patient

care" and "caring for and treating patients well" were judged to be too general and their content is covered in several sub-categories. One criterion — integrity — was added since: (1) private discussions outside of the focus group discussions (with respondents and key informants) suggested that it would be relevant to consider it as a criteria of perceived quality; (2) previous research studies have suggested that this aspect may have a strong influence on people's perception of quality (Bruce, 1990) and on their utilization of public health services (Gilson *et al.*, 1994; Haddad and Fournier, 1995).

Rather than focusing on the components of care, like others (Brooks and Williams, 1975; Vuori, 1982; Bruce, 1990; Donabedian, 1992; Ellis and Whittington, 1993; Atkinson and Ngenda, 1996), this taxonomy focuses on the components of quality (Haddad *et al.*, 1997). It seems, however, to be more detailed and deals more specifically with PHC services than those we have consulted. Although the authors feel this classification is realistic, it is neither comprehensive nor universal and it is possible that the dominant representations of quality and the expectations of the public will be different in another context. Further research would be desirable to test whether it can be generalized.

#### CONCLUSION

The success of strategies to revitalize PHC services such as those advocated by the Bamako Initiative rests largely on their ability to meet the expectations of populations, especially in terms of quality. The evaluation of the quality perceived by the communities thus constitutes an important complement to the evaluations carried out according to the health authorities own approaches. Nevertheless, this requires a good knowledge of the meanings that the notion of quality has for the public as well as the main criteria that users apply when they judge the quality of services.

The diversity of the criteria that communities use to judge quality illustrates the wealth of their representations and the complexity of the notion of quality. To a large extent, communities construct their judgement in relation to the ability of the services provided to improve their health. This is one more argument for the development of methodologies for quality evaluation that are based on outcome indicators.

This research provides valuable indications about the changes that should be made to promote the quality of primary health care services. It illustrates the fact that users are just as sensitive to aspects of the interpersonal relations they have with the professionals as they are to the technical quality of the care provided. They recognize the importance of a good diagnosis, adequate treatments, as well as the need to receive sufficient information on the health problem and the treatments to follow. The judge-

ment people make on consultations that last just a few minutes, as is often the case, that are botched and do not even include a physical examination, can hardly be flattering.

The role of interpersonal relations is very important. As in other studies, the conduct of the health care professionals stands out as a central element of the judgement that users make about health services. Health services must take note that their users want a proper reception and treatment, but their main concern is to be considered globally, as a person with a health problem rather than as a case. Health care workers have to carry the burden of a dual legacy: that of their bio-medical background which, contrary to the traditional treatments that are more anchored in their cultures, tends to focus more on the disease than on the person and that of many professionals who often abuse the authority that has been conferred upon them in the patient-caregiver relationship.

Training may allow for the development or improvement of certain technical or even interpersonal skills. However, this alone will not be sufficient and deeper changes in values will have to be encouraged. Relations between health care professionals and the public are unfortunately often the reflection of those that exist between public powers and the population. Only an effective democratization and good governance will be able to modify the situation significantly.

*Acknowledgements*—The authors extend sincere thanks to their many collaborators from the following partner institutions: the Guinean Ministry of Public Health and Social Affairs, the local UNICEF office, the Mafèrinyah Rural Health Center for Research and Training, Wonkifong Health Project (CECI), Coopération Française. They would also like to thank Christiane Saucier, Raynald Pineault, and Binta Diallo for their contributions to this study and the analysis of the findings and Helene Kaufman for translation of the original manuscript. This study was made possible by a research grant from the Canadian Public Health Association, as part of Phase II of the Canadian International Immunization Program (Canadian International Development Agency).

#### REFERENCES

- Abosede, O. A. (1984) Self medication: An important aspect of primary health care. *Social Science and Medicine* 19(7), 699–703.
- Abu-Zaid, H. A. and Dann, W. M. (1985) Health services utilization and cost in Ismailia, Egypt. *Social Science and Medicine* 21(4), 451–461.
- Askew, I., Tapsoba, P., Ouédraogo, Y., Viadro, C., Bakouan, D. and Sebgo, P. (1993) Quality of care in family planning programmes: A rapid assessment in Burkina Faso. *Health Policy and Planning* 8(1), 19–32.
- Atkinson, S. and Ngenda, L. (1996). *Quality of urban health services: Lusaka, Zambia* (Research Paper Num. 2). UNICEF-Bamako Initiative Operations Research Programme, New York.
- Attah, E. B., and Plange, N. K. (1993). *Quality of health care in relation to cost recovery in Fidji: Focus group study* (Small Applied Research Report Num. 6). Health

- Financing and Sustainability (HFS) Project. Abt Associates Inc., Bethesda, MD.
- Berman, P. A. (1984) Village health workers in Java, Indonesia: Coverage and equity. *Social Science and Medicine* 19(4), 411-422.
- Berman, P. A., Ormond, B. A. and Gani, A. (1987) Treatment use and expenditure on curative care in rural Indonesia. *Health Policy and Planning* 2(4), 289-300.
- Bichman, W., Diesfeld, H. J., Agboton, Y., Gbaguidi, E. A. C. and Simhäuser, U. (1991) District health systems: Users' preferences for services in Benin. *Health Policy and Planning* 6(4), 361-370.
- Brooks, R. H. and Williams, K. N. (1975) Quality in health care for the disadvantaged. *Journal of Community Health* 1, 132-156.
- Bruce, J. (1990) Fundamental elements of the quality of care: A simple framework. *Studies in Family Planning* 21(2), 61-91.
- Bryce, J., Toole, M. J., Waldman, R. J. and Voigt, A. (1992) Assessing the quality of facility-based child survival services. *Health Policy and Planning* 7(2), 155-163.
- Calnan, M. (1988a) Lay evaluation of medicine and medical practice: Report of a pilot study. *International Journal of Health Services* 18(2), 311-322.
- Calnan, M. (1988b) Towards a conceptual framework of lay evaluation of health care. *Social Science and Medicine* 27, 927-933.
- Clarisc Corporation (1990). File Maker Pro Software. Santa Clara, CA.
- Donabedian, A. (1980). *The definition of quality and approaches to its assessment*, Vol. 1. Health Administration Press, Ann Harbor.
- Donabedian, A. (1992). Defining and Measuring the Quality of Health Care. In *Assessing Quality Health Care. Perspectives for Clinicians*, ed. R. P. Wenzel. Williams and Wilkins, Baltimore.
- Egunjobi, L. (1983) Factors influencing choice of hospitals: A case study of the northern part of Oyo State, Nigeria. *Social Science and Medicine* 17(9), 585-589.
- Ellis, R., and Whittington, D. (1993). Quality assurance in health care. In *Quality Assurance Handbook*, ed. R. E. D. Whittington, pp. 1-8. Edward Arnold, London.
- Ellis, R. P., Kirigia, J. M., and Mwabu, G. (1990). *Demographic patterns and health care utilization for a sample of households in South Nyanza, Kenya* (Report).
- Engelkes, E. (1990) Process evaluation in a Colombian primary health care programme. *Health Policy and Planning* 5(4), 327-335.
- Forsberg, B. C., Barros, F. C. and Victoria, C. G. (1992) Developing countries need more quality assurance: How health facility surveys can contribute. *Health Policy and Planning* 2, 193-196.
- Garner, P., Thomason, J. and Donaldson, D. (1990) Quality assessment of health facilities in rural Papua New Guinea. *Health Policy and Planning* 5(1), 49-59.
- Gilson, L., Alilio, M. and Heggenhougen, K. (1994) Community satisfaction with primary health care services: An evaluation undertaken in the Morogoro region of Tanzania. *Social Science and Medicine* 39(6), 767-780.
- Haddad, S. and Fournier, P. (1995) Quality, cost and utilization of health services in developing countries. A longitudinal study in Zaire. *Social Science and Medicine* 40(6), 743-753.
- Haddad, S., Roberge, D. and Pineault, R. (1997) Comprendre la qualité. En reconnaître la complexité. *Ruptures* 4(1), 59-78.
- Hotchkiss, D. (1993). *The role of quality in the demand for health care in Cebu, Philippines* (Small Applied Research Report Num. 12). Health Financing and Sustainability (HFS) Project. Abt Associates Inc., Bethesda, MD.
- Jain, A., Bruce, J. and Mensch, B. (1992) Setting standards of quality in family planning programs. *Studies in Family Planning* 3, 392-395.
- Kaufman, J., Zhirong, Z., Xinjian, Q. and Yang, Z. (1992) The quality of family planning services in rural China. *Studies in Family Planning* 23(2), 73-84.
- Kim, Y. M., Rimon, J., Winnard, K., Corso, C., Mako, I. V., Lawal, S. and Babalola, S. (1992) Improving the quality of service delivery in Nigeria. *Studies in Family Planning* 23(2), 118-127.
- Kipp, W., Kielmann, A. A., Merk, G., and T., R. (1994). Monitoring of primary health care services: An example from Western Uganda. *Health Policy and Planning*, 9(2), 155-160.
- Kloos, H., Etea, A., Degefa, A., Aga, H., Solomon, B., Abera, K., Abegaz, A. and Belemo, G. (1987) Illness and health behaviour in Addis Ababa and rural central Ethiopia. *Social Science and Medicine* 25(9), 1003-1019.
- Levy-Bruhl, D., Soucat, A., Diallo, S., Lamarque, J. P., Ndiaye, J. M., Drame, K., Ossen, R., Dieng, B., Gbedonou, P., Cisse, M., Yarou, M. and Knippenberg, R. (1994) Intégration du PEV aux soins de santé primaires: L'exemple du Bénin et de la Guinée. *Cahiers de Santé* 4, 205-212.
- Lewis, M. A., Sulvetta, M. B. and La Forgia, G. M. (1991) Productivity and quality of public hospital medical staff: A Dominican case study. *International Journal of Health Planning and Management* 6, 287-308.
- Litvack, J. I. and Bodart, C. (1993) User fees plus quality equals improved access to health care: Results of a field experiment in Cameroon. *Social Science and Medicine* 37(3), 369-383.
- Lohr, K. N., Donaldson, M. S. and Walker, A. J. (1991) Medicare: A strategy for quality assurance, III: Beneficiary and physician focus groups. *Quality Review Bulletin* 17, 242-253.
- Lohr, K. N. and Thier, S. O. (1988) Current issues in quality of care. *Health Affairs* 9, 19-22.
- Microsoft Corporation. (1991). Microsoft Word 5.0. Washington.
- Morgan, D. L. (1988). *Focus groups as qualitative research*. Sage, Newbury Park.
- Mwabu, G. M. (1986) Health care decisions at the household level: Results of a rural health survey in Kenya. *Social Science and Medicine* 22(3), 315-319.
- Nicholas, D. D., Heiby, J. R. and Hatzell, T. A. (1991) The quality assurance project: Introducing quality improvement to primary health care in less developing countries. *Quality Assurance in Health Care* 3(3), 147-165.
- Palmer, R. H. (1991). Considerations in defining quality of care. *Striving for Quality in Health Care: An Inquiry into Policy and Practice*, pp. 1-59. Health Administration Press, Ann Harbor.
- Pepperall, J., Garner, P., Foxrushby, J., Moji, N. and Harpham, T. (1995) Hospital or health centre - a comparison of the costs and quality of urban outpatient services in Maseru, Lesotho. *International Journal of Health Planning and Management* 10(1), 59-71.
- Peters, D. H. and Becker, S. (1991) Quality of care assessment of public and private outpatient clinics in Metro Cebu, the Philippines. *International Journal of Health Planning and Management* 6, 273-286.
- Pust, R. E. and Burell, J. M. (1986) Paramedicals' clinical accuracy in 102 cases referred to a provincial hospital. *Tropical Doctor* 16, 38-43.
- Reeler, A. V. (1990) Injections: A fatal attraction? *Social Science and Medicine* 31(10), 1119-1125.
- Rees Lewis, J. (1994) Patient views on quality care in general practice: Literature review. *Social Science and Medicine* 39(5), 655-670.
- Roberge, D., Loiselle, J., Mongrain, J., Lebel, P., Ducharme, F., and Pineault, R. (1996, June). *Qualité*

- des services gériatriques. *La perspective des clientèles*. Paper presented at the 7ème conférence annuelle de l'Association Latine d'Analyse des Systèmes de Santé, Geneva.
- Roemer, M. I., and Montoya-Aguilar, C. (1989). *L'évaluation et l'assurance de la qualité des soins de santé primaires*, ed. World Health Organization, Geneva.
- Satia, J. K., Mavalankar, D. V. and Sharma, B. (1994) Micro-level planning using rapid assessment for primary health care services. *Health Policy and Planning* 9(3), 318-330.
- Sauerborn, R., Ngoutara, A. and Diesfeld, H. J. (1989) Low utilization of community health workers: Results from a household interview survey in Burkina Faso. *Social Science and Medicine* 29(10), 1163-1174.
- Simard, G. (1989). *La méthode du focus group*. Mondia Eds, Laval.
- Stock, R. (1983) Distance and the utilization of health facilities in rural Nigeria. *Social Science and Medicine* 17(9), 563-570.
- Thomas, L. H., MacMillan, J., McColl, E. J.P., Hale, C. and Bond, S. (1995) Obtaining patients' views of nursing care to inform the development of a patient satisfaction scale. *International Journal for Quality in Health Care* 7(2), 153-163.
- Thomason, J. and Edwards, K. (1991) Using indicators to assess quality of hospital services in Papua New Guinea. *International Journal of Health Planning and Management* 6, 309-324.
- Tsongo, B., Willis, C. Y., Deal, D. R., and Wong, H. J. (1993). *Cost recovery and quality of care in the Congo* (Small Applied Research Report Num. 7). Health Financing and Sustainability (HFS) Project. Abt Associates Inc., Bethesda, MD.
- Unger, J. P., Mbaye, A. and Diao, M. (1990) From Bamako to Kolda: A case study of medicines and the financing of district health services. *Health Policy and Planning* 5, 367.
- Unicef. (1994). *Programme quinquennal de coopération 1991-1995 UNICEF-République de Guinée*. (Rapport de la revue à mi-parcours du 14 au 19 février 1994). UNICEF, Conakry, Guinea.
- Van Campen, C., Sixma, H., Friele, R. D., Kerssens, J. J. and Peters, L. (1995) Quality of care and patient satisfaction - A review of measuring instruments. *Medical Care Research and Review* 15(2), 109-133.
- Vera, H. (1993) The client's view of high quality care in Santiago, Chile. *Studies in Family Planning* 24(1), 40-49.
- Vogel, R. J. (1988). *Cost recovery in the health care sector. Selected country studies in West Africa* (Technical Paper Num. 82). World Bank, Washington DC.
- Vuori, H. (1982). *Quality assurance of health services: Concepts and methodology*. WHO Regional Office for Europe, Copenhagen.
- Waddington, C. J. and Enyimayew, K. A. (1989) A price to pay: The impact of user charges in Ashanti-Akin district, Ghana. *International Journal of Health Planning and Management* 4, 17-47.
- Waddington, C. J. and Enyimayew, K. A. (1990) A price to pay, part 2: The impact of user charges in the Volta region of Ghana. *International Journal of Health Planning and Management* 5, 287-312.
- Wilde, B., Starrin, B., Larsson, G. and Larsson, M. (1993) Quality of care from a patient perspective. *Scandinavian Journal of Caring Sciences* 7, 113-120.
- World Health Organization. (1989). *Approaches to evaluation*. Geneva. WHO CDD/TAG/89 5.
- World Health Organization (1990). *Manuel d'enquête auprès des établissements de santé. Prise en charge des cas de diarrhées*, ed. World Health Organization, Geneva.
- Wouters, A. V. (1991) Essential national health research in developing countries: Health-care financing and the quality of care. *International Journal of Health Planning and Management* 6, 253-271.

**23**

**MATERIAL ON HIV/AIDS**

**SENT BY**

**MEDICAL MISSION INSTITUTE**

**UNIT FOR HEALTH SERVICES AND HIV/AIDS**

**SALVATORSTR. 22**

**D-97074 WÜRZBURG**

**GERMANY**

**June 2001**

## Features

- If the blood is not after all needed by the patient, the blood bank stands to gain, providing of course that the blood is fully screened before being given to another patient.
- It is cheaper than pre-deposit autologous blood transfusion.

The major disadvantage of APH is over-dilution. This can be avoided by close monitoring and the use of diuretics.

Contraindications to the procedure exist. These include a haematocrit of less than 30%, sickle cell disease, severe cardiovascular diseases, bleeding disorders, bacteraemia, diabetes mellitus, hypertension, liver diseases etc.

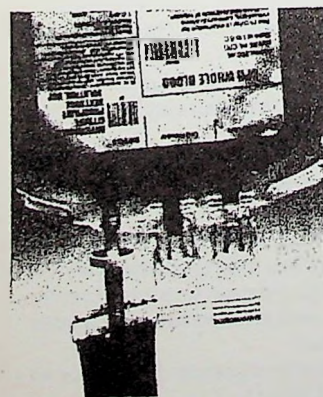
Haemodilution can be an important component of a comprehensive autologous transfusion programme. Such a programme comprises combinations of APH itself, intra-operative blood salvage, post-operative blood salvage, and a pre-deposit autologous programme."

Bruce<sup>1</sup> found that transfusion requirements for 138 aortic reconstructive procedures were minimised through the combined use of haemodilution, autotransfusion and good surgical technique. He also pointed out that autotransfusion was cost-effective.

George, rheumatologist,<sup>10</sup> performs preoperative phlebotomy of 2-3 units of blood prior to performance of reconstructive procedures such as total hip replacement or knee arthroplasty. He practices haemodilution routinely as a policy. Nevertheless, a major reason for underutilisation of autologous service is the failure of surgeons to recommend it to eligible patients. Pearl<sup>11</sup> recommends that autologous blood should be utilised whenever possible, as it does not cause alloimmunisation.

Onwukeme<sup>12</sup> noted that autologous blood might be more useful in tropical Africa because of the high incidence of malarial hepatitis, HIV infection, and the scarcity of voluntary donors. In another study,<sup>13</sup> he found that haemodilution accompanying blood donation of one pint of blood did not affect the values of platelets and leucocytes. This, he explained, was due to the fact that the circulating granulocyte pool is so large that removal of one pint has no significant change on the leucocytes; the same holds true for the platelets. However,

*Preoperative haemodilution can save blood stocks © Photodisc*



the same investigator found that the platelet count did not increase above the upper limit value normal in Africans following surgical trauma.<sup>14</sup>

Africans, especially Nigerians, stand to gain when they participate in autologous blood transfusion programmes, particularly haemodilution. The blood transfusion service in Nigeria is bedevilled by chronic shortage of homologous

blood, as Nigerians are unwilling to donate voluntarily, except when their relatives are involved or where there is financial benefit attached.<sup>15</sup>

Berede et al<sup>16</sup> recommend that, for hospitals with limited blood bank facilities and frequent cancellation of surgeries, the use of APH is the best option. Liaw et al<sup>17</sup> found no morbidity, such as transfusion reaction, infection or reoperation for bleeding, associated with haemodilution. Chandanayingyong et al<sup>18</sup> concluded that haemodilution with gelatin solution is suitable and possibly practical in obtaining sufficient blood for elective surgical patients and is without undesirable side-effects.

Despite the wealth of evidence supporting the use of autologous blood transfusion, there is a poor response rate amongst eligible autologous donors. The answer lies in better education – of patients, physicians and blood bank personnel – on the merits of autologous therapy, particularly haemodilution.

### Experience on the Jos Plateau, Nigeria

A case-control study was conducted at Jos University Teaching Hospital over a 2-year period (October 1996–September 1998).<sup>19</sup> Sample size was 100, and there were also 100 controls. Sample and control patients were matched for age, sex, and preoperative PCV of at least 30%.

In the sample group, prostatectomy and thyroidectomy emerged as the two major procedures most often requiring blood transfusion. Ninety-two per cent of patients had one pint of blood withdrawn and haemodilution was done successfully. No untoward effects were noted.

Patients in the control group had at least two pints of blood transfusion each, with significant reactions to blood transfusion. We therefore conclude that APH can be safely practised in our environment.

Furthermore, in this work it was found that 40% of patients needed no blood transfusion at all after haemodilution, thus saving on blood bank stocks. In the control group only 4% of patients had no blood transfusion at all, indicating homologous blood transfusion consumes and wastes blood. Haemodilution is therefore to be preferred.

### Conclusion and recommendation

It is clear that acute preoperative haemodilution can be done routinely in surgical practice in our environment. No side-effects were noted in our own experience with 100 patients. It is cheap, safe, and is to be preferred to other forms of blood transfusion in elective surgical procedures. Contraindications to the procedure are emergencies, malignancies, or severe sepsis. Patients and their relations, physicians, and blood bank personnel are urged to promote preoperative haemodilution. It is hoped – given the emphasis on cost containment and concern about blood safety coupled with emerging technologies – that wider application of haemodilution will be seen in the next decade.<sup>2</sup>

Please contact the Editor of *Africa Health* for the references to this article.

# Blood transfusion: the case for preoperative haemodilution in adults

*Professor C H Ihezue, Head of Department of Surgery and Dr Aminu Likita, Senior Registrar in General Surgery, Jos University Teaching Hospital, Jos, Nigeria*

Homologous blood transfusion carries a number of hazards, some of which may be immediate – allergy, haemolytic reactions, circulatory overload etc. Delayed hazards are the transmission of diseases such as HIV infection, cytomegalovirus infection, syphilis, serum viral hepatitis, immunosuppression etc.<sup>1,2</sup> The occurrence of these problems has led to a search for alternatives to homologous transfusion. Such alternatives include: directed blood transfusion,<sup>3</sup> use of blood substitute (e.g. perfluorocarbon, modified haemoglobin), and the use of autologous blood.

Autologous blood transfusion (autotransfusion) means collection and subsequent reinfusion of a patient's own blood.<sup>1</sup> It averts some of the complications associated with homologous transfusion. The five different types of autologous transfusion<sup>2</sup> are:

- pre-deposit autologous transfusion
- acute preoperative haemodilution
- intra-operative blood salvage
- post-operative blood salvage
- frozen storage of autologous blood.

These methods are not mutually exclusive and often can be used beneficially together for the patient.

### Acute preoperative haemodilution

This article focuses on acute preoperative haemodilution (APH) – a form of autologous blood transfusion where the patient's blood is removed 48 hours or less before surgery.<sup>4,5</sup> Cell-free solution (crystalloids or colloids) is simultaneously infused to maintain normovolaemia. Surgery is performed with the patient's blood haemodiluted. When haemostasis is secured at the completion of surgery, or sooner if necessary, the patient's blood is reinfused. It is a simple procedure and quite cheap.

### APH in practice

The decision on which patients are suitable is usually taken by the surgeon. The procedure must be fully explained to the patient. Venesection is done in the blood bank or in the theatre at induction of anaesthesia. The blood is collected, under sterile conditions, into a blood bag containing the anticoagulant citrate phosphate dextrose (CPD). Blood is collected from one venous line and blood volume is replaced simultaneously with colloids (e.g. dextran in a ratio 1:1) or crystalloids (e.g. isotonic saline in a ratio 1:3) via a second venous line. The number of units withdrawn is usually one or two but some have withdrawn as much as four.<sup>6</sup> As much as 2000 ml of blood can be obtained and transfused.<sup>7</sup>

The blood packs are clearly labelled and stored in a refrigerator.

Transfusion is done intra-operatively when losses exceed 300 ml and, preferably, when haemostasis has been achieved, or in the immediate post-operative period.<sup>4</sup>

### The case for APH

APH provides fresh red blood cells, platelets, coagulation factors etc. and so reduces the haematocrit, leading to optimal capillary perfusion. It has been demonstrated that APH lowers blood viscosity, and that maximum oxygen delivery to tissues actually occurs at a haematocrit of 30%. This leads to increase in cardiac output and tissue perfusion and, hence, overcompensates for the effects of reduction in red cell concentration and the blood's oxygen-carrying capacity. Generally, red cell losses are less at haematocrit 30%, and anaemic patients bleed less.<sup>8</sup>

These findings have led to wide application of APH in the United States in cardiovascular, vascular, orthopaedic and abdominal surgery. APH is the most widely established method of autologous blood transfusion. It is also the standard practice in many surgical units of the Western-world.<sup>9</sup> The feasibility and safety of the procedure has been demonstrated since the 1970s.<sup>6</sup> It requires no specialised instrumentation and can be carried out in a general hospital that has manpower and facilities for blood transfusion on a routine basis. It has proved useful in all branches of surgery including paediatric surgery.<sup>7</sup>

The Nigerian National Blood Transfusion Service recommended, in 1991, the following patient selection criteria:<sup>4</sup>

- haematocrit must be at least 30%
- surgery is such that blood loss is likely to be greater than 15 ml/kg
- children over 2 years of age can benefit if the blood loss will be more than 10 ml/kg
- patients over 65 years-of-age require individual evaluation.

The advantages of APH are many but may be summarised as follows.

- Decreased requirement for homologous blood. Several studies have shown a decrease of 15–25% in the use of homologous blood.<sup>3</sup>
- The fresh blood from APH, being blood less than 24 hours old, is rich in platelets and coagulation factors. This could lead to improvement in post-operative haemostasis, although such an effect has not yet been demonstrated in practice.
- There are less biochemical changes with fresh blood as compared with banked blood.<sup>3</sup>