

INFO PACKAGE FOR DOCTORS

FEEDBACK FORM

1. Is the Info Pack useful?

Yes No

If No, why? give reasons.

2. Would you like to get the Info pack regularly?

Yes No

3. What type of Information would you like to get?

- | | |
|----|----|
| 1. | 4. |
| 2. | 5. |
| 3. | 6. |

4. Do you have any other suggestion to improve the pack?

5. Please provide a few addresses of Doctors who could benefit by this package

Signature :

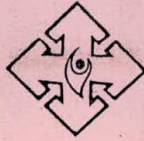
Date:

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Speciality :

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Phone/Fax/E-mail



September, 1997

INTRODUCTION TO DOCTORS FORUM

The idea of forming a DOCTORS FORUM in VHAAT is gaining momentum since 1996.

The purpose of the doctors Forum is to build up an active network of socially conscious Doctors, who are open to new ideas in Health Care to come together to share ideas and experiences.

VHAAT would like to build up and support a professional group of Doctors who could think and act alternatively to provide rational Health Care, where people are given prime importance. Special emphasis would be given to the area of preventive and promotive Public Health care.

Doctors Forum is planning to take up the following initiatives:

- ❖ To provide a platform for the Doctors to share their views regarding their profession and the burning health issues of the country.
- ❖ To send Information Packages for Doctors as a part of continuing medical education especially for doctors working in remote areas.
- ❖ To debate and discuss about various health policies and technologies emerging in India and provide alternate suggestions.
- ❖ To collaborate with the existing network like IMA, CMAI, MJC, etc. and work together for a common cause.

In short, Doctors Forum is a proactive and futuristic group for Doctors who could be in the forefront to take up health issues and find solutions to public health problems in India.

As a first step we are sending you the first INFO PACKAGE FOR DOCTORS as a part of continuing medical education.

Kindly fill in the feedback form and send your comments and suggestions.

Thanking you in anticipation.

VHAAT Friends

To Drs VB/CMAI/ARS/SPT for information
We should send them materials for
inclusion in the Doctor Forum
despatches

920

3/10/97

CM
7/1/97

RN
15/10

19/11

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“INFO PACKAGE FOR DOCTORS”

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THE SCOURGE OF HEPATITIS B

The occurrence of Jaundice has been known for centuries but it is only in this century that the various causes of jaundice have been described. The rapid strides in medical technology have led to elucidation of the various types of jaundice. Previously we used to classify jaundice into two categories - medical jaundice and surgical jaundice, the former implying a medical cause for the jaundice which required no surgical treatment and the later implying the need for some surgical intervention for relieving the jaundice. The commonest cause of medical jaundice is viral hepatitis. The term has two facets a) viral implying that it is caused by a virus and b) hepatitis implying that there is inflammation of the liver. Viral hepatitis can be either acute or chronic. Acute means a process which is recent and chronic implies that the hepatitis is more than 6 months duration. Although a variety of viruses may cause a hepatitis like illness, five well characterized hepatotropic viruses, A to E, are the most important causes of acute and chronic viral hepatitis. These five viruses can be divided into two major groups. The first group consists of viruses that are feco-orally transmitted and don't cause chronic hepatitis i.e Hepatitis A & E, and the second group consists of those viruses that are transmitted through blood and can cause chronic hepatitis i.e Hepatitis B, C and D.

The hepatitis B virus (HBV) is a DNA virus that predominantly affects the liver, leading to inflammation and cell death; in the long term, some patients develop scarring of the liver (cirrhosis) and, less frequently, liver cancer. The spectrum of HBV infection ranges from acute hepatitis, anicteric hepatitis, fulminant hepatitis, a hepatitis with a predominantly cholestatic picture, to chronic liver disease with minimal acute manifestations. The danger of HBV lies in the last presentation as the patient is unaware that he/she is infected with HBV and may unknowingly transmit it to others. A few decades later the patient may develop chronic liver diseases cirrhosis or hepatocellular carcinoma. HBV shares its transmission routes with the HIV (the virus that causes AIDS). However, it is one

hundred times as infectious as HIV. Its potential to cause liver cancer has led to its recognition as the second most important carcinogen (cancer-causing agent), after tobacco. Several hundred million are infected worldwide and these are the main reservoir of HBV infection. The predominant mode of transmission is parenteral i.e by infected blood transfusions, contaminated syringes and needles and unsterile instruments used for surgery. Other modes of transmission are perinatal and sexual. Inapparent parenteral routes of transmission like use of shared razors and toothbrushes, and contaminated needles used for acupuncture, ear-piercing and tattooing are also known.

An estimated 400 million persons worldwide are known to be chronic carriers. One in ten of these is in India, making this country the second largest pool of the virus. The 40 million - 50 million Indians who carry this virus form approximately 4% - 5% of the general population. Various estimates place the number of infected newborns who will become carriers at 1,50,000 - 4,50,000 annually.

SPECIAL PROBLEMS IN INDIA

The enormity of the problem in India is indicated by the above available data. Other factors may compound or aggravate the situation.

Probably the most important among these is the HIV. With an estimated 2 million carriers of the HIV already in this country, India is slated to become the largest pool of HIV in the world by the turn of the century. It is well known that persons immunosuppressed by HIV infection are more susceptible to other infections. Since HIV and HBV share transmission routes, high-risk populations will also be common to the viruses. Data exists to show a symbiotic relationship between these viruses; the effect of HIV infection on the progress of HBV infection is not likely to be favourable, though admittedly data are still

lacking.

Coinfection or superinfection by the other hepatitis viruses (A,C,D,E,G) all of which are common in India - on a liver already diseased by HBV can be further detrimental. Data on such multiple infections with HBV and the C and D viruses are already available and are a cause for concern.

The effect of poor nutrition and alcoholism on HBV liver diseases is not clear yet, though the latter is an established liver toxin. Administration of antitubercular drugs - many of which are known to damage the liver - can also aggravate the condition. It is of course, common knowledge that tuberculosis is widespread in this country.

Finally, ignorance and poverty among the population make it difficult to implement barrier habits. It is believed that 30% - 50% of the blood banks in the country do not routinely test for the HBV; most of them are also dependent on paid 'professional' donors for their supply of blood. This forms a major source of infection especially amongst the ignorant who frequent these blood banks to obtain blood on payment, out of a mistaken fear among relatives that donating blood is harmful to physical (including sexual) and mental well-being. Unfortunately the same populace is also likely to request blood transfusion as a 'tonic'.

Preventive Measures

General Measures

Education : The single most important measure initially is promotion of awareness and dissemination of information. This should be addressed both to the general public as well as to high-risk groups.

Barrier precautions : Among healthcare workers and emergency care providers (firemen, ambulance personnel) at all levels, and especially at the earlier levels in the hierarchy where contact is more likely (labour staff, primary healthcare workers, technical staff, student and staff nurses, medical, dental and paramedical students, resident doctors) the use of hand gloves should be made mandatory at all times when in contact with biological specimens.

The concept of "universal precautions" requires that all human blood and certain body fluids be treated as potentially infectious for HIV, HBV and other blood-borne pathogens, and maximum precautions be taken at all times when in contact with such tissue.

Hands should be washed with soap and water immediately after removal of gloves or other protective coverings ; if handwashing is not possible, an appropriate antiseptic cleanser may be used, and handwashing done as soon as possible. Any body surface that has come in contact with potentially infectious material should be washed with soap and water, or flushed with water as appropriate.

A particular concern in India is the reuse of razor blades by haircutters. It is advisable for the customer to carry his/her own blade; alternatively, it must be ensured that these sharps are either disposed off or are adequately sterilised before reuse.

Disposable / Sterilisable equipment :

All inexpensive equipment and accessories in use in healthcare settings should ideally be disposable. When such items are marked as sterilisable and reusable, the manufacturers' guidelines for sterilisation should be adhered to. Expensive multiple-use items (e.g. endoscopes, ventilators, humidifiers) should be thoroughly cleansed mechanically and sterilised as per the manufacturer's guidelines, before reuse.

Blood Banking Practices :

Blood banks should be allowed to operate in this country only if registered with central or state-level regulatory authorities, who in turn should enforce a phased replacement of professional donors by voluntary donors, use of disposable items for all collection, transport, testing, storage, and transfusion purposes, testing of all collected blood for HBV/HIV, and preferably the hepatitis C virus, use of sensitive third-generation tests for markers of the above viruses.

In addition to the above measures, medical professionals should be educated on the judicious use of transfusion of blood and its products.

Vaccination :

Currently there are two types of hepatitis B vaccines available around the world i.e the first generation "plasma derived" inactivated HBV vaccines and the second generation "genetically engineered or recombinant" HBV vaccines. In the US and in most parts of Europe the recombinant HBV vaccines have replaced the plasma derived HBV vaccines.

The plasma derived have been widely used and have been shown to be safe and effective but there is an unfounded fear about the transmission of viruses as these are derived from the blood of a person suffering from HBV. These vaccines have a long production cycle, require persons having HBV infection and hence their supply may be limited. The level of antibody persistence may vary with the vaccine and the dose administered. Recombinant DNA techniques have been used for expressing hepatitis B surface antigen and core antigen in prokaryotic cells. These vaccines are totally synthetic and don't require the use of blood or blood products. The recombinant vaccine, consists of the purified antigen absorbed onto an adjuvant, usually alum. Recombinant yeast hepatitis B vaccines have undergone extensive evaluation by clinical trials. The results indicated that this vaccine is safe, antigenic and free from side effects (apart from minor local reactions in a proportion of recipients). The immunogenicity is similar to that of the plasma-derived vaccine. Recombinant yeast hepatitis B vaccines are now being used in many countries. The advantages of the recombinant vaccine is the unlimited supply, as no blood products are involved and a shorter production cycle.

The recombinant vaccine currently available commercially in India is administered as 20-microgram doses (10 micrograms in newborns and children) at 0, 1 and 6 months. Dose recommendations for the plasma-derived vaccines vary from 3 micrograms to 20 micrograms at 0,1, and 2 months or 0, 1 and 6 months. Double the above doses is

recommended for immunocompromised individuals (e.g in AIDS, and for patients with chronic kidney failure undergoing dialysis); a fourth dose is also recommended.

Who should be vaccinated ?

The immediate aim should be to vaccinate high-risk groups. At the community level, this includes healthcare workers, emergency-care providers, and commercial sex workers. It should be the responsibility of employers to provide free vaccination to all healthcare workers and emergency care providers. Such vaccination should be provided preferably at entry into training or employment. Catch-up vaccination of senior personnel should be done in a phased manner.

At the individual level, patients needing multiple transfusions of blood or its products (haemophiliacs, thalassaemics etc.); those undergoing elective surgery or dialysis; newborns of mothers known to harbor HBV; sexual partners of HBV carriers and intimate contacts of patients with acute hepatitis B; inmates of institutions (mental homes, old-age homes, handicapped-persons homes, prisons); and individuals with high-risk behaviour (intravenous drug addicts, alcoholics, homosexuals, promiscuous individuals) should be recommended vaccination.

All newborns should be vaccinated by introducing this vaccine into the Expanded Programme of Immunisation. The World Health Organisation has recommended that this be done by the year 1997; over 80 countries have already done so. The Indian Academy of Pediatrics and the Indian Association for Study of the Liver have endorsed this approach.

Experience in countries in South-East Asia has shown this results in a remarkable reduction not only in the HBV carrier rate but also in the prevalence of liver cancer, within a few years.

WHO ANNOUNCES INFLUENZA VACCINE FORMULA FOR 1996/1997

A new composition of the influenza vaccine for the 1996 - 1997 season has been announced by an international experts meeting at the World Health Organization (WHO) headquarters in Geneva. Scientists are constantly challenged to identify major newly emerging strains of influenza viruses, so that effective vaccines can be formulated in time. Compared to last year's recommendations for the vaccine, one of the three influenza vaccine components has been changed.

Every February, the influenza experts advise the national health authorities and pharmaceutical companies on the composition of the virus strains that should be used to produce vaccines for the next influenza season.

Influenza causes epidemics worldwide every year. WHO strongly advises the use of vaccine as a sound preventive measure against this potentially fatal disease. Special attention should be paid to vaccinate the elderly, individuals with immunodeficiency, sufferers of chronic diseases of the heart or lungs as well as diabetes.

For the adult population one dose of inactivated vaccine should be adequate. However, previously unimmunized children in these categories should receive two doses of vaccine, with an interval between doses of at least four weeks.

"The degree of protection conferred by influenza vaccines varies depending on the age and immune status of the vaccine recipient", explains Dr Daniel Lavanchy, in charge of WHO's influenza programme. "We believe that up to 80 per cent of recipients will be protected against disease when there is a good match between the vaccine and circulating strains. The severity of illness and the frequency of serious complications is reduced among the remaining 20 per cent".

The latest formula recommended by WHO is:

- an A/Wuhan/359/95(H3N2)-like strain
- an A/Singapore/6/86(H1N1)-like strain
- a B/Beijing/184/93-like strain.

This differs from last year's composition in that the first of these strains replaces an A/Johannesburg/33/94(H3N2)-like strain.

As in previous years, the specific viruses used in vaccine manufacturing in each country will need to be approved by the national control authorities.



The WHO programme on influenza surveillance and control was established in 1948. Today, it involves 109 WHO-recognized National Institutes on Influenza in 79 countries, and three WHO Collaborating Centres for Reference and Research on Influenza at the Centers for Disease Control and Prevention (Atlanta, USA), the National Institute for Medical Research

(London, UK), and CSL (Parkville, Australia). This fully operational network helps WHO to monitor influenza activity in all regions of the world and ensures that WHO receives information needed to select the new variants of influenza viruses which will be used to produce influenza vaccines for the next influenza season.

There are three main antigenic types of influenza viruses currently circulating among humans, all of which have a remarkable capacity to change their characteristics from year to year. These are known as A(H1N1), A(H3N2) and B. Vaccines are, therefore, composed of two strains of type A and one of type B. With new strains continuously emerging, scientists and pharmaceutical industry face an annual challenge to produce modified vaccines which will be effective against the latest dominant strains.

Epidemics of influenza were reported between October 1995 and February 1996 in many countries in Europe, North America, and Asia. After few reports in October 1995, influenza activity increased in November and reached a peak in December and, in some countries, in January 1996. By February, influenza had declined in most countries. Influenza A viruses have been widespread and caused moderate to severe epidemics affecting mainly children and young adults. European countries and China reported predominantly influenza A(H3N2) while influenza A(H1N1) caused epidemics in Canada, Japan and most regions of the United States of America.

The first outbreaks of influenza A(H3N2) were reported in boarding schools in England in September and October 1995. The disease spread in the United Kingdom and appeared in other European countries during November and December, causing epidemics across most of Europe (Belarus, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Latvia, the Netherlands, Norway; Slovak Republic, Spain, Sweden and the United Kingdom), Madagascar and the USA. Outbreaks of influenza A(H3N2) started in Beijing towards the end of December and spread to six provinces in China during January. Isolates of influenza A(H3N2) virus were also reported in Canada, Europe (Belgium, Iceland, Ireland, Italy, Poland, Portugal, the Russian Federation, Switzerland) as well as in Asia (Guam, Hong Kong, Japan, Singapore) and Oceania (Australia and New Zealand).

Influenza A(H1N1) caused a widespread epidemic in Japan in December 1995, and was the predominant virus in North America (Canada and the USA) and parts of Europe (Belgium, southern France, and Switzerland). These viruses were also detected elsewhere in Asia (China, Hong Kong, Israel, Thailand) and Europe (Finland, Germany, Italy, Latvia, the Netherlands, Poland, Romania, the Russian Federation, Sweden and the UK).

Sporadic cases of influenza B have been reported in North America (Canada and the USA), in Asia (China, Hong Kong, Israel, Japan and Singapore) and in Europe (Belarus, Bulgaria, Finland, France, Germany, Hungary, the Netherlands, Poland, Romania, the Russian Federation, Sweden, Switzerland and the UK). A few isolates in Oceania (Australia and New Zealand) have also been reported.

"The WHO influenza surveillance network together with the influenza vaccine manufacturers ensure that effective vaccines are available to the public in time to provide protection against each season's influenza epidemic", says Dr Nancy J. Cox, Director of the WHO Collaborating Centre for Reference and Research on Influenza in Atlanta, USA. "This joint endeavour represents a very successful collaboration between the public and private sectors, in the interests of public health".

LEGISLATION

IMPORTANT INFORMATION FOR PRESCRIBERS

As per a recent Supreme Court ruling, doctors of modern medicine registered under Indian Medical Council Act are permitted to prescribe ONLY allopathic medicines. Prescription or administration of non-allopathic drugs (such as Ayurvedic, Unani, Siddha or Homoeopathic) shall render such doctors liable to prosecution under both civil and criminal laws resulting in cancellation of registration and/or heavy fine and/or imprisonment. Doctors of modern medicine prescribing non-allopathic drugs are liable to be considered as "quacks" *per se* without further evidence or argument.

Full text of the Supreme Court judgement and the opinion of lawyers from a leading firm of advocates can be obtained from MIMS by sending a self-addressed, stamped (Rs. 2) envelope of the size of 24 cm x 16 cm.

MIMS INDIA

Oct. '96.

— Editor

**FORMATION OF IMA SERVICE DOCTOR'S WING
AND IMA WOMEN DOCTORS' WING.**

The Central Working Committee at its meeting held in New Delhi on 25th-26th November, 1995, approved the formation of IMA Women Doctors' Wing and IMA Service Doctor's Wing and also accepted in principle the basic structure of the Constitution of these Wing. It also decided that these Wings will become operative from the date on which their membership reaches 1,000. This was approved by the Central Council at its meeting held at Bhubnesawar on 27th-28th December, 1995.

The eligibility conditions and rates of subscription and admission fees of the two Wings are as under:-

IMA Women Doctor's Wing

Eligibility : Any Women Life Member of IMA may be enrolled as Life Member of IMA Women Docotor's Wing.

Admission Fee: Rs. 30/- per member.

Life Membership Subscription Rs. 450/- per member.

A State Wing of Women Doctors' will be formed on-enrolment of a minimum of 50 members of the Wing.

IMA Service Doctor's Wing

Eligibility : A Life Member of IMA engaged in any type of service may be admitted as Life Member of IMA Service Doctor's Wing.

Admission Fee : Rs. 30/- per member

Life Membership Subscription: Rs. 450/- per member.

A State Wing will be formed on enrollment of a minimum of 50 members of the Wing.

All State and Local Branches Secretaries are requested to start enrollment of members of these two Wings. Membership Application forms may be obtained from IMA Head Quarter.

The Doctor's Dilemma — Socio-Ethical Issues Related to AIDS

Whether we like it or not, the pandemic of AIDS has reached India, and according to postulation, the epidemic peak with explosive outbreaks of HIV positivity is yet to occur. In the medical profession are we ready to face the challenge ?

The uniqueness of HIV arises mainly out of its four characteristics.

First, handling a HIV positive patient entails a certain amount of physical risk of being contaminated. *Second*, the long clinical latency means that anybody could be seropositive without showing any signs and symptoms.

Third, because HIV is also sexually transmitted, there is a prevalent attitude of attaching a stigma of "loose moral" to the infected.

Fourth, as yet there is no cure for AIDS, and all HIV positives have so far been seen eventually to die due to AIDS or its complications.

The fear of physical risk and social contamination virtually stigmatises a HIV positive into a social outcast. What inevitably follows is discrimination—a HIV positive is denied his/her basic rights—the right to live (in a community) and work and what is important in the present context—right to be treated.

• • •

Relating to the AIDS menace, the medical profession has to come up with answers to a lot of questions not only technical but also social and ethical. Let us look into the issues more closely.

1. *As in other biomedical investigations, a doctor cannot ask for HIV testing (e.g. ELISA) without the consent of the patient — voluntary and informed. Moreover, because of the consequences of and discrimination associated with AIDS, pretest counselling is mandatory. Given our busy practice, are we prepared/tuned to do this ?*
2. *How to confirm the diagnosis? ELISA for HIV can be false positive, particularly among "low risk" people.*
3. *To avoid the risk of contamination can a surgeon or a gynaecologist routinely perform preoperative HIV testing? What happens if the patient withholds consent? What to do during an emergency surgery ?*
4. *Can a doctor refuse to operate or perform any invasive procedure on a seropositive patient ?*
5. *Has a doctor the right to thrust a moral judgement on a patient (and his/her behaviour) and then decide his/her professional attitudes accordingly?*
6. *How does a doctor arrange the follow up and treatment of HIV positive/AIDS cases?*
7. *How to trace the source/route of transmission in a specific case, in order to prevent further transmission from the same source ?*
8. *Except under a few circumstances a doctor is professionally bound to maintain absolute confidentiality about a patient and his/her condition. Should it be followed in case of HIV positives?*

Should the doctor inform the spouse about the patient's seropositive status ? Nondisclosure may spread the disease and may infect the spouse.

However, disclosure may break the family and ruin the patient. How to prevent the social catastrophe arising out of disclosure ?
9. *Should a HIV positive denied social and working rights ? What follows is, if a doctor becomes seropositive should he/she be debarred from handling patients ?*
10. *How to prevent iatrogenic AIDS ? How can a doctor raise the demand individually and collectively — of ensuring aseptic procedures in medical practice ?*

Obiter dicta

- Absolute quarantine of all HIV positives has been tried in different parts of the world. But this has failed to contain the epidemic. Testing all persons for HIV is theoretically possible but logistically impossible in a country like India. Even testing all persons belonging to so called high risk groups is virtually not possible.
- Large multi-institutional studies have indicated that the risk of HIV transmission following skin puncture from a needle or other sharp object that was contaminated with blood from a person with documented HIV infection is approximately 0.3%. The risk of a similar type of exposure to hepatitis B is 20 to 30%.
- The above mentioned risk, however small becomes a potential threat in Indian conditions. In most hospitals and pathological laboratories here, medical personnel draw blood without wearing gloves and blood spillage and skin puncture are common occurrences. Anaesthesiologists almost never use gloves. Dentists all over the country usually perform all outdoor dental procedures without wearing gloves.
- Nosocomial HIV infection is a reality. In a reported incident in Soviet union 152 neonates were infected through use of contaminated syringes and needles. This is of particular concern in the Indian situation. Disposable syringes and needles are not only in short supply in most hospitals, these are often reused after washing or boiling. There is generally a casual approach to sterilisation procedures except in the operation theaters. (Consider the daily morning activity in the wards when almost all patients have their blood samples taken.)
- HIV infected persons have relatively greater number of viruses in their blood during two stages – the initial post infection viraemic stage and much later during the symptomatic stage. During the initial phase of infection lasting for an average of 2 weeks (and a maximum of 8 weeks) the HIV infected is seronegative. What follows is at this time though the person is ELISA negative, he/she can transmit infection.
- In a hospital set up or even in a private clinic, unless specifically informed, a doctor may have no idea as to which of his/her patients belong to the high risk groups. High risk groups are those who are involved in high risk behaviour (sex workers, clients of sex workers, intravenous drug users) and those who are being repeatedly treated with blood or blood products (haemophilia or thalassaemia patients).
- The risk of HIV transmission from an infected doctor to his/her patient is extremely small. Large multi-institutional studies have put the risk of acquiring HIV infection from a doctor or a dentist during an exposure prone procedure at 1/1000000, which is 1/10th the risk that a given unit of screened blood is HIV positive and 1/100th the risk of dying from general anaesthesia.

The number of HIV infected in this country is steadily increasing. What happens doctor, if the next patient in your clinic is HIV positive ?

What happens if the patient declares that he is HIV positive ? Would you examine the patient or would you refer him to some other doctor ?

What happens if the patient does not declare or is himself unaware that he is HIV positive. Is your system of patient handling such that you yourself would not be contaminated and would not transmit the infection to your other patients ?

If you are a professionally active doctor, you can hardly avoid handling a HIV positive. **What is most needed is a predetermined approach—scientific, ethical, humane and bold.**

The AIDS pandemic has shown its capacity to evolve and permeate all sectors of society. It is useless to think that my patients cannot be HIV positive, as they are all good and respectable people. **Complacency, indifference, denial and a "business as usual" attitude threaten the success of the struggle against AIDS.**

It is obvious that neither does screening exclude all HIV positive nor is screening feasible in all situations. **What is feasible is strict adherence to standard procedures of asepsis in medical practice – irrespective of who your patients are. This is the only tenable method of avoiding the transmission to your other patients.** There is no need to shun away the HIV positives if you adhere to the norms of asepsis.

• • •

Today in India, there are media reports off and on of discrimination against HIV positive – in the community and also in the health care set ups. But the HIV positives and AIDS patients are being treated the world over in general hospitals, private clinics and in intensive care units. Why is the situation different in India ?

Such avoidance reaction have occurred all over the world. But many doctors have also engaged

in their fight against AIDS. Ultimately in the end we all have to adapt to the situation of providing optimal health care to the HIV positives and AIDS patients without discrimination and with due protection of their rights and dignities. The quicker we reach the stage the better.

We must remind ourselves of the paradoxical situation that if discrimination persists, not only will people not volunteer for HIV testing, but will also hide their HIV status.

Discrimination arises out of misinformation and ignorance. But that is not all. The relation between knowledge and behaviour is far more complex. But knowledge and awareness is the primary prerequisite for behaviour modification. What follows is that our first task is to know about HIV and its transmission. Only then can we take up the challenge to fight the epidemic.

In the fight against AIDS doctors are speaking in the language of human rights and dignity. Measures to protect human rights will not of themselves guarantee an effective AIDS programme, but denial of human rights is clearly incompatible with effective AIDS prevention and control.

Today, it is important to realise that social solidarity has now become a public health goal, on which the survival of entire societies may depend.

— Carballo & Bayer

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Asish Kumar Kundu

Declaration of Standing Committee of Doctors of the EC

The Standing Committee of Doctors of the European Community (EC) adopted the following Declaration concerning the practice of medicine within the Community at its Plenary Assembly Session held in Nuremberg in November 1967 (Charter of Nuremberg (original in French)). The text is as published in *The Handbook of Policy Statements 1959-1982*, Standing Committee of Doctors of the EC.

1. Every man must be free to choose his doctor. Every man must be guaranteed that whatever a doctor's obligations vis-a-vis society, whatever he confides to his doctor and to those assisting him will remain secret.

Every man must have a guarantee that the doctor he consults is morally and technically totally independent and that he has free choice of therapy.

Human life from its beginning and the human person in its integrity, both material and spiritual, must be the object of total respect.

Guarantees of these rights for patients imply a health policy resulting from firm agreement between those responsible to the state and the organised medical profession.

2. The aim common to the health policy of states and medical practice is to protect the health of all its citizens.

It is the duty of states to take all precautions to ensure all social classes - without discrimination - have access to all the medical care they require. Every man has the right to obtain from the social institutions and the medical corps the help he needs to preserve, develop or recover his health: he has an obligation to contribute materially and morally to these objectives.

Economic expansion finds one of its principal human justifications in the advancement of resources allocated to health; the medical profession intends to do all in its power to increase, at equal costs, the human and social effectiveness of medicine.

3. The unusual necessary contact between the doctor and his patient take account of the fact that these two partners belong to one community, a condition of all health and social policy. But there must be reciprocal confidence between the patient and his doctor based on the certitude that in his treatment the doctor holds in the highest esteem and has consciously consecrated all his knowledge to the service of the human person. No matter what his method of practice or remuneration the doctor must have access to the existing resources necessary for medical intervention; he must have free choice of decision bearing in mind the interests of his patient and the concrete possibilities offered by the advancements of science and medical techniques.

Doctors must be free to organise their practice together in a manner complying with the technical and social need of the profession, on condition that moral and technical independence be respected and the personal responsibility of each practitioner maintained.

4. Whatever is method of practice the medical profession is one. These methods are complementary. They derive from the same deontology although they may be submitted to different organisation conditions. Respect for moral laws and for the basic principles of medical practice is assured by independent institutions, emanating from the medical corps and invested, particularly under the highest judicial processes in the country, with disciplinary and judicial power.

Every doctor has a moral obligation to actively participate in his professional organisation. Through this organisation he participates in the elaboration of the country's health policy. Members of the profession can and must fight for respect of basic principles in the practice of medicine, on condition that the rights of the patient are safeguarded.

5. Hospital equipment must be within the compass of its specific mission in the service of the whole population. Its establishment is the result of a planned policy in which the public powers and the organised profession participate, allocating to public power and private initiative fuller distribution of health establishments. It comprises a variety of establishments, graded and co-ordinated among themselves, meeting the task or several tasks given to it: prevention, care, rehabilitation, teaching, research.... The professional independence of the hospital doctor must be guaranteed by unquestionable criteria of nomination and a statute assuring him stability of function, economic independence and social protection.

'Technical progress, the basis of our industrial civilisation and economic expansion which is its fruit have for their natural end especially thanks to a health policy, to bring about full physical and spiritual development of man, of all men'.

[Rowe AJ et al: *Philosophy & Practice of Medical Ethics*. London: British Medical Association 1988.]

50 facts from the '96 Regional Health Report

10 countries make up the WHO South-East Asia Region (SEAR) -- Bangladesh, Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka and Thailand.

Population & Socioeconomic Situation

About 1.4 billion people live in the WHO South-East Asia Region. The 10 Member States comprise 25% of the world's population and only 5% of the world's land area.

Over the past 15 years the Region's population has grown by 367 million and is expected to increase by another 380 million during the next 15 years.

Population growth rates of most SEAR countries have declined since 1980-85. Three countries - Indonesia, Sri Lanka and Thailand have annual growth rates lower than the world's growth rate of 1.57% (1990-95).

The number of people living in urban areas has increased from almost 229 million in 1980 to 389 million in 1995, and is expected to reach 460 million by the year 2000 and 641 million by the year 2010.

The average annual urban population growth rate (1990-95) is highest in Nepal at 7.07% and lowest in Sri Lanka at 2.20%. The Region contains four megacities - Mumbai, Calcutta and Delhi in India and Jakarta in Indonesia.

In 1995 there were a higher proportion of children aged 0-14 years living in the SEAR countries as compared with the rest of the world; but lower proportions in the adult (15-64 years) and elders (65 years and more). This trend is likely to continue until 2010. The number of elders in the Region is expected to increase by 10.6 million during 1995-2000, putting a greater pressure on the health-care and welfare system.

Most countries showed a steady GNP growth rate during 1992-94. The gross national product (GNP) per capita in the Region ranges from a low of US\$170 in Bhutan to a high of US\$2110 in Thailand (1993). India, Indonesia and Thailand are included among twelve major developing economies. The amounts spent on health differ among countries. As a percentage of total income (in terms of GDP), expenditures range from 2% to 6% including both government and private expenditures.

Data on burden of poverty in 1990 were available for six SEAR countries (Bangladesh, India,

Indonesia, Nepal, Sri Lanka and Thailand) which represented 95% of the total SEAR population and included 507 million people in poverty - whose income or expenditure level was below the amount considered necessary to afford a minimum, nutritionally adequate diet plus essential non-food requirements. Poverty is also widespread in some other SEAR countries.

Literacy rates in 1995 ranged from 40.9% and 14% for males and females respectively in Nepal, to 100% for both sexes in DPR Korea. Nepal, Bangladesh, Bhutan and India have the lowest female literacy levels of between 14% and 38% respectively. Countries with higher female literacy tend to have lower infant mortality.

Countries with low fertility have a higher human development index (HDI) and gender-related development index (GDI). Only one SEAR country (Thailand) has HDI or GDI above 0.8, putting it in a higher human development category. Much progress remains to be made in gender equality in almost every country of the Region. Efforts are to be made so that women are able to participate in political decision-making, to increase their access to professional opportunities, and improve their earning power.

Births, Deaths and Life Expectancy

Since the 1970s, the crude birth rates in the Region declined as a result of population control and family planning efforts. They now range from a low of 19.4 in Thailand to a high of 41.6 in the Maldives. The world average is 25 per 1000 population.

Women had fewer children in the past five years than before as seen from the decline in the total fertility rate (TFR) for the Region.

50 facts from the Regional Health Report '96

During 1990-95, the TFRs ranged from 2.10 children in Thailand to 6.80 children in the Maldives per woman in the reproductive age group of 15-49.

12 Life expectancy at birth showed an increase for all SEAR countries. During 1990-95 it was below 60 in Bangladesh, Bhutan, Myanmar and Nepal; it was between 60 and 69 years in India, Indonesia, Maldives and Thailand and was 70 years or above in DPR Korea and Sri Lanka.

13 There has been a significant, steady decline in the crude death rate in the Region, now ranging from 5.3 per 1000 population in DPR Korea to 13.3 in Nepal. These rates must, however, be viewed with caution as death registration systems in most countries remain inadequate.

14 The infant mortality rate (IMR) declined in all countries, but Bangladesh, Bhutan, India, Indonesia, Myanmar and Nepal still have unacceptably high rates of 70 deaths or above during the first year of life per 1000 live births. DPR Korea, Sri Lanka and Thailand have IMRs below or around 30 per 1000 live births.

Morbidity and Mortality

Communicable Diseases

15 Almost 7 million people in SEAR countries die each year from infectious diseases alone. Infectious diseases are the leading cause of death worldwide, killing at least 17 million people annually.

16 Approximately 1.4 million children under five die each year

from acute respiratory infections (ARIs) accounting for more than 30% of deaths in under-fives. Pneumonia is the leading cause taking 90% of this total. Deaths due to pneumonia could be significantly reduced by the use of standard case management as recommended by WHO ARI Control Programme.

17 Tuberculosis still kills more adults than any other single infectious disease - an estimated 1.2 million people in the Region will have died during 1995. 80% of these deaths are in the most productive age group 15-59 years, thus affecting socioeconomic development of countries. The most effective way to stop the spread of tuberculosis is by curing it and the best curative method known is *directly observed treatment short course* (DOTS).

18 TB/HIV co-infection is present in many patients - by 2000 it is estimated to increase to nearly 20% of all TB cases. The proportion of TB deaths attributable to HIV in the Region will also increase from 2% in 1990 to 14% by 2000.

19 The total number of the leprosy-afflicted in the Region is more than two-thirds of the global leprosy cases. Four countries - Bangladesh, India, Indonesia and Myanmar are among the top five countries accounting for four-fifths of the global case load. Yet multi-drug therapy (MDT) has proven so successful that it is expected to eliminate leprosy as a public health problem by 2000.

20 The Region has achieved a high level of immunizing children under one year against the six immunizable diseases - diphtheria,

pertussis, tetanus, tuberculosis, poliomyelitis and measles. By the year 2000, ninety per cent of women in the child-bearing age will have been immunized against tetanus.

21 The Region has demonstrated dramatic acceleration of polio eradication activities, particularly with the implementation of national immunization days in seven SEAR countries. Health experts are confident that they will be able to eradicate poliomyelitis through effective universal immunization and adequate epidemiological surveillance.

22 A 70% reduction in the number of reported diphtheria and whooping cough cases has been achieved as a result of the 90% immunization coverage.

23 The total number of measles deaths in the Region has decreased by about 87% and the number of reported cases has fallen by about 67% as a result of about 80% immunization coverage.

24 Five SEAR countries (Bhutan, DPR Korea, Maldives, Sri Lanka and Thailand) have achieved the target of no more than one neonatal tetanus case per 1000 live births.

25 The pandemic of HIV/AIDS has spread rapidly during the last few years in the South-East Asia Region. It is estimated that by the end of the century, 8 to 10 million men, women and children are likely to become infected with HIV accounting for over 25% of the global cumulative infections. The spread of AIDS/HIV is particularly significant in India, Myanmar and Thailand.

26 The total number of curable, sexually transmitted diseases (STDs) in the South-East Asia Region were 150 million cases in 1995.

27 Each year, approximately 14 million people are infected with the hepatitis B virus, and it is estimated that there are 80 million carriers, i.e.

50 facts from the Regional Health Report '96

more than 5% of the total population.

28 Diarrhoeal diseases continue to account for about 25% of under-five mortality in the Region, viz. over one million children die each year from diarrhoea. 90% of these deaths are preventable.

29 Malaria still dominates the disease pattern in the Region with 1.2 billion people living in malarious areas, and at risk. The overall malaria situation in the Region has remained static over the last twelve years - with reported cases ranging between 2.5 and 3.1 million, and reported deaths between 5000 and 7500. The estimated numbers of malaria cases and deaths are much higher. The emergence of drug-resistant malaria and its rapid spread are posing a major threat to the Region, and putting severe pressures on the countries' scarce resources.

30 Dengue and dengue haemorrhagic fever continues to persist in several countries - an estimated 400,000 cases with 8000 deaths were reported in the Region during 1995. Tetravalent live attenuated dengue vaccine has been developed in Thailand, with support from WHO, and clinical trials of this vaccine in children are under way. This is the first time a developing country has successfully carried out the development of a vaccine for human use.

31 In India alone, there are an estimated 45 million microfilaria carriers and 19 million people in the Region are suffering from filarial diseases, and approximately 500 million people are at risk.

32 During 1995 there were an estimated 21,000 cases of Japanese encephalitis with 4000 deaths in the Region. In the same year, the number of meningococcal meningitis cases was estimated to be 20,000 with 5000 deaths.

33 At present, approximately 110 million people in the Region are at risk of contracting visceral leishmaniasis (kala-azar). Major endemic foci have been reported in border areas between India, Bangladesh and Nepal. A dramatic decline in kala-azar cases and deaths is reported in India since 1994.

34 No plague cases have been reported in the recent past from Bangladesh, Bhutan, DPR Korea or the Maldives. But natural foci of plague exist in India, Indonesia, Myanmar and probably in Nepal. The reappearance of human plague in India in 1994 after 27 years caused much concern, necessitating regular serological tests of rodents for predictive surveillance and laboratory diagnosis of plague in the Region.

Non-communicable diseases

35 In India alone, nearly 800,000 persons die from ischaemic heart disease and more than 600,000 from stroke each year. A health survey in New Delhi showed that every tenth person aged 35-64 years suffers from ischaemic heart disease, and every fourth person has high blood pressure.

36 The most common neoplasms in India are cancers of the breast, uterine cervix, lip, oral cavity and pharynx. In Thailand, liver cancer is the most frequent malignancy among males (8000

new cases every year) and lung cancer is second in rank (4700 cases). These two cancers account for 44% of all new malignancies in men. In women, cervical cancer is the most frequent (5600 cases annually) followed by liver cancer (3500), breast cancer (3300) and lung cancer (2600). These four cancers account for 52% of all malignancies in women.

37 Diabetes mellitus has a prevalence of about 2% in rural populations, but a prevalence of 3% and more in urban areas suggests that urbanization and affluent lifestyles could aggravate the risk of disease.

38 It is estimated that between 4 and 5 million persons in India are afflicted by a variety of severe mental disorders at any given time. However, facilities and support for the care of the afflicted are far from being sufficient.

39 Smoking is attributed to be one of the main causes of cancers, cardiovascular diseases and respiratory ailments. Every 10 seconds, somewhere in the world, tobacco causes another death. It has been established, beyond any doubt, that death rates for smokers are two-to-three times higher than for non-smokers of all ages.

Other causes of Death and Morbidity

40 Accidents and injuries constitute 9 - 10% of the total mortality in India - with road accidents accounting for the maximum number of deaths.

41 Some 585,000 maternal deaths occur globally every year. About 99% of these happen in developing countries and 235,000 (40% of the total number) in SEAR countries. A vast majority of these lives could be saved with simple available skills and local technologies. Effective family

50 facts from the Regional Health Report '96

planning, good antenatal care and attendance of a trained midwife during delivery are some of the crucial factors which could significantly lower maternal mortality.

42 Protein-energy malnutrition and the three micronutrient deficiencies of iodine, vitamin A and iron are the main burdens of undernutrition in the South-East Asia Region.

43 The SEAR Region is home to almost one-third of the world's blind persons. Much of this blindness is avoidable and curable. Cataract accounts for nearly 70% of the total blindness affecting 8 million persons.

44 Threats to health and development from deteriorating environmental conditions affect everyone. The World Health Organization's Health and Environment Initiative aims at mobilizing the national health authorities to sensitize other sectors such as environment, agriculture, and municipalities to include protection of health and environment as part of their development plans. To address urban environmental issues, the WHO Healthy Cities Initiative strives to promote healthy living conditions in urban areas with local governments as key partners.

Health-Care Infrastructure, Approaches and Resources

45 There are currently 42,774 health centres of various categories and 164,337 subcentres operating in SEAR countries providing a

range of outpatient and inpatient services, and serving as first referral points. In addition, more than 746,914 outreach sites, managed by the community with technical support from health centre staff, have been established at the community level in SEAR countries.

46 The WHO Regional Office has successfully assisted Member States in developing national drug policies with a focus on the availability of essential drugs for primary health care. WHO collaboration in the Region has resulted in the establishment of appropriate national drug policies and programmes which focus on the issues of rational use, availability, accessibility and affordability of essential drugs as well as on their quality, safety and efficacy.

47 Many questions related to the balance and relevance of human resources still remain unresolved. Newer problems of imbalances in the types of health personnel and their geographical distribution are also emerging, and these need to be addressed with care and urgency. Considering the fact that human resources for health (HRH) utilizes up to 70% of health budgets, some of these problems lead to very costly imbalances. A significant emerging factor which contributes to the imbalance of HRH in the Region is the increased competition between the public and private sectors.

The Challenges Ahead

48 In 1978, health for all (HFA) by the year 2000 seemed a reasonably-paced, achievable proposition. But now, with only three years left before the turn of the century, many of the HFA goals still seem rather distant for the 10 countries of the South-East Asia Region. The challenges that lie ahead call for political commitment, community involvement, and a multi-sectoral approach to health. A combination of these three factors could well mean a healthier future for South-East Asia.

49 Sustainability is one of the major challenges that governments will have to face as the countries move into the 21st century. Much of the success of health programmes is due to investment in terms of financial and human resources by countries, WHO, other UN agencies and bilateral donors. SEAR countries will have to meet the challenge of sustaining such programmes on their own. Only through vigorous programme implementation will a significant impact be made on the disease situation.

50 Population growth will be accompanied by rapid urbanization in developing countries. The urban population in SEAR is expected to reach 43% of the total by 2020. Countries will have to pay serious attention to the needs of urban infrastructure - sanitation, safe drinking water, housing and public transport - as well as to the increase in demand for health services. Providing accessible and acceptable family planning services will make a significant contribution to the health of the population as a whole.



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The National Law School – NOVIB Project on the Implementation of Socio-Economic Rights

Status and Implementation of the Right to Health in the State of Karnataka: A Report

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Towards a definition of the right to health

The conceptualisation of rights of individuals has been predominantly based on the social and political institutions of the time, throughout history. Changes in society brought about by the development of liberal humanist ideas and democratic political practices, led to a gradual conceptualisation of rights for all human beings. Beginning with the magna carta, the Declaration of Independence of the United States of America (1776) and the Declaration of the Rights of the Man in France (1789), Liberty, justice, equality and human dignity became the essential attributes of rights of human beings.

The modern concept of human rights, universal and inalienable, emerged from a conjunction of moral, legal and political perspectives, defining the rights which must be possessed by all human beings, equally, embodied in the Universal Declaration of Human Rights, 1948. The Universal Declaration of Human Rights, has in modern times, become the primary instrument which defines and protects rights which must be guaranteed to every human being, one of the most critical aspects of this conceptualisation of human rights being the capacity of all individuals to assert these rights.

Therefore, any analysis on implementation of human rights must proceed at two distinct levels. One, whether the rights are available and possessed by all human beings. And second, whether the human beings have the actual capacity to assert these rights which have been theoretically made available to them.

Subsequent to the Universal Declaration of Human Rights, in 1966, the United Nations adopted two major Covenants, one defining civil and political rights¹ and the other, economic, social and cultural rights². Both Covenants came into force in 1976. The popular consensus on the division of the two sets of rights is that it is linked to a political division of the role of state in the society. While civil and political rights are rights held against everyone else, economic and social rights impose duties on governments.

Although the international human rights system has its own limitations, it remains a framework--one of the few--within which we may attempt to address the issues of definition, injustice and abuse of human rights and fundamental freedoms

¹The International Covenant on Civil and Political Rights (ICCPR).

²International Covenant on Economic, Social and Cultural Rights (ICESCR).

by governments at the global level. The discussion on human rights also provides a focus for many of the moral and philosophical dilemmas we face in contemporary society, and the process of determining norms which can be applied to all human beings so that they may live with integrity and respect is one which challenges us today in the face of the disintegration of many social and political institutions.

With this background on human rights, it is essential to locate a framework within which to view the individual's right to health.

Right to Health in the Universal Declaration of Human Rights, 1948

The provision pertaining to right to health is contained in Article 25 of the Universal Declaration of Human Rights, which states as under.

Article 25

- (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or lack of livelihood in circumstances beyond his control.
- (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Right to health as in the International Covenant on Economic, Social and Cultural Rights, 1976.

The International Covenant on Economic, Social and Cultural rights, in its Article 12, recognises right to health as:

Article 12:

- (1) the State Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
- (2) The steps to be taken by the State Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:
 - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
 - (b) The improvement of all aspects of environmental and industrial hygiene;

- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The World Health Organisation and Right to health

According to the World Health Organisation, *health* is a

"state of complete physical, mental and social well-being and not merely the absence of disease or deformity".

This definition can be said to be the embodiment of the concerns of all human rights instruments of the century, recognising that *health is fundamentally a function of the every society.*

From the foregoing International provisions, and the Who definition, it becomes possible to define an individual's right to health as his right to a complete physical, mental and social well-being and not just a right to curative services.

This Right to Health is no doubt a right belonging to the category of social and economic rights, and therefore, this definition of the World Health Organisation envisages active participation and responsibility of the state in ensuring that health is a part of *the overall development process of the nation*³

The role of the state in ensuring the right to health

The Declaration of Alma Ata, and various other doctrines that have been built up by member states through the World Health Organisation and other international agencies embody a number of fundamental principles for health development. Among these are⁴:

1. The responsibilities of governments for the health of the people
2. The right and duty of people individually and collectively to participate in the development of their health;

³Formulating Strategies for Health for all by the year 2000, World Health Organisation, Geneva, 1979, Pg.11

⁴ Formulating Strategies for Health for all by the year 2000, World Health Organisation, Geneva, 1979, Pg.11

3. The duty of the governments and the health professions to provide the public with relevant information on health matters so that people can assume responsibility for their own health;
4. Individual, community and national self-determination and self-reliance in health matters;
5. The interdependence of individuals, communities and countries based on their common concern for health;
6. More equitable distribution of health resources within and among countries, including their preferential allocation to those in greatest social need so that the health system adequately covers all the population;
7. Emphasis on preventive measures well-integrated with curative, rehabilitative and environmental measures;
8. The pursuit of relevant bio-medical and health services research and the speedy application of research findings;
9. The application of appropriate technology through well-defined health programmes integrated into a country wide health system, based on primary health care and incorporating the above concepts;
10. The social orientation of health workers of all categories to serve people and their technical training to provide people with the service planned for them.

The Alma Ata Declaration, further states that atleast the following should be included in the primary health care:

- Education concerning primary health problems and the methods of preventing and controlling them;
- Promotion of food supply and proper nutrition;
- An adequate supply of safe water and basic sanitation;
- Maternal and child health care, including family planning;
- Immunisation against the major infectious disease;
- Prevention and control of locally endemic diseases;
- Appropriate treatment of common diseases and injuries; and ,
- Provision of essential drugs.

To achieve this goal of Health for all by 2000, the role of the state is crucial in the context of ensuring basic health standards.

The World Health Organisation Document on 'Formulating Strategies for health for all by the year 2000'⁵, lays down certain referral guidelines for formulating national policies, strategies and plans of action in order to achieve successfully the goal of Health for All by 2000. A perusal of the same in the light of those adopted by us in this regard, may shed light on the aspects over-looked and may also help assessing our present position.

To sum up the major points, a national plan of action has to be:

- A inter-sectoral master plan, including the action to be taken in all sectors involved, to give effect to the policy. It indicates what has to be done, who has to do it, during what time frame, and with what resources. It is a framework leading to more detailed programming, budgeting, implementation and evaluation.
- Each country has to develop its health policy as part of overall socio-economic development policies, in the light of its own problems and possibilities, particular circumstances, social and economic structures, and political and administrative mechanisms.
- Primary health care forms an integral part of the country's health system, of which it is the central function and main agent for delivering health care. It is also an integral part of the overall social and economic development of the community. For primary health care to succeed, it will require the support of the rest of the health system and of other social and economic health sectors concerned.
- The introduction of strengthening of the development processed needed to attain health for all, will require unequivocal political commitment. It will most likely have to be set in motion by political decisions by the government as a whole, permeating all sectors, at all levels throughout the country and not merely by the ministry of health or the health sector alone.
- The overall social goal of health for all has to be broken down into more concrete social policies aimed at improvement of the quality of life and maximum health benefits for all. If the gap between the "haves" and the "have nots" is to be reduced within and among countries, there will be a need in most countries to formulate and put into effect concrete measures for equitable distribution of

⁵ WHO, Geneva, 1979.

resources. In many countries, this will imply the preferential allocation of health resources to those in greatest social need as an absolute priority, as a step towards attaining total population coverage.

- || Measures have to be taken to ensure free and enlightened community participation, so that notwithstanding the overall responsibilities of the governments for the health of their people, individuals, families, and communities assume greater responsibility for their own health and welfare, including self care. This participation is not only desirable, it is a social, economic and technical necessity.

- || In developing health strategies, each country will have to take into account its cultural and social patterns and its political system.

The W.H.O also recognises that, most countries are dealing with all these aspects of planning, but not in a systematic and inter-related manner. The initiation of a more systematic process may start with any of the above-mentioned steps, subsequently leading to the remaining step being carried out in a systematic and interrelated manner. Thus, there could be many possible entry points to the country health programming process.

The National health Policy, 1983

As a signatory of the Alma Ata Declaration in 1978, the Government of India is committed to taking steps to provide Health For All by 2000 AD. In 1983, the National Health Policy which aims at achieving this goal by 2000 AD, laid down the specific goals to be achieved by the year 2000 AD as:

1. Reduction of infant mortality rate from the present level of 125(in 1978) to below 60 in 2000 AD.
2. To raise the expectancy of life at birth from the present level of 52 years to 64 by the year 2000AD.
3. To reduce the crude birth rate from the present level of 32 per 100 population to 21 per 1000 by the year 2000 AD.
4. To reduce the crude death rate from the present level of 12 per 1000 population to 9 by the year 2000 AD.
5. To achieve a net reproduction rate of one by the year 2000AD.

The National Health Policy lays down specific goals to be realised by 1985, 1990 and 2000, such that by the year 2000, the above mentioned could be achieved. In 1983, this Policy was evolved by the Ministry of Health and Family welfare and approved by the parliament, and it was sought to be implemented through the sixth and seventh five year plan and the 20 Point Programme.

According to National Planning, the health sector has been divided into the following sectors for the purpose of planning:

1. Water Supply and Sanitation
2. Control of Communicable Diseases
3. Medical Education Training and Research
4. Medical Care, including, hospitals, dispensaries and primary health centres
5. Public Health Services
6. Family Planning
7. Indigenous Systems of Medicine

Since the inception of the National health policy,, the Central Government has evolved various Programmes throughout which the agenda of the policy was sought to be achieved. The agenda of the health department in each state is basically to implement the Central Programmes in addition to the State Programmes and activities in the health sector. Most of these schemes are with the aim to ensure the

availability of adequate infrastructure and medical and para-medical man power such that goals of health care as envisaged in the national health policy can be realised.

The Department of Health and Family Welfare Services in the State of Karnataka and the provision of health services

The main objective of the Department of Health and Family Welfare Services is to provide comprehensive health care services to the people of the state, by way of implementation of various national and state health programmes of public health importance, through its network of various types of Health and Medical Institutions.

Organisational Hierarchy⁶

The Director of Health and Family Welfare Services is the Head of the Department, and is responsible to provide the Health Care Services to the community by way of implementing various National and State Health Programmes in the state.

The Directorate of Health & Family Welfare Services is located in the State Head Quarters which has got Director, Health and Family Welfare Services as the Head of the Department and Co-shared by the Director, Health Education and Training.

Within the state of Karnataka, Primary Health Centres are established at the rate of one for a population of 30,000 in plain and Maidan areas and 20,000 in the Hilly and Tribal areas. By strengthening Primary Health Centres, Health Care delivery activities in the areas as per the Government of India pattern is adopted. Primary Health Centres provide Primary Health Care in the areas to the net-work of sub-centres and other Para Medical Staff. Primary Health care includes preventive services, Curative Services, Environmental sanitation, Health Education, Family Welfare Services and recording of vital statistics. Various National Health Programmes which are in force from time to time are also implementing through the network of Primary Health Centres.

Furthermore, one out of every four Primary Health Centres is generally upgraded into Community Health Centre, which contain curative services in addition to preventive services.

⁶ Status Report(1990-1995) of the Department of Health and Family Welfare Services, State of Karnataka.

30/10

In addition to Primary Health Centres, Community Health Centres and District Hospitals, there are General Hospitals and Civil Hospitals in different parts of the State

Sub-Centres are also established at the rate of one each for a population block of 5000 in the Plain and Maidan areas and 3000 in hilly, Tribal and inaccessible and remote areas. Each Sub-centre is managed by Female Health Worker who covers comprehensive Health Care activities in the areas allotted with a due priority to the Maternal and Child Health Care and Family Welfare activities. She is assisted by a Male Health worker who covers the population of the sub-centre in the matters relating to Health Care activities, with a priority in the Malaria Eradication and communicable diseases control programme.

In addition to Community Health Centres and Primary Health Centres, the Primary Health Units are also providing Curative and Preventive services. Gradually, these Primary Health Units are upgraded as Primary Health Centres in phased manner to extend their field activities to cover the area by providing additional infrastructure.

In the difficult and inaccessible areas, Mobile Dispensaries are also provided especially in the Forest areas, Tribal areas and remote areas.

Status And Implementation of Right to health in the State of Karnataka: The Report

The report on the Status and Implementation of Right to health in the State of Karnataka, as the name itself suggests, consists of two major parts. The first part is to define and identify what actually are the components of an individual's right to health, and then, with those defined components of a right to health, an analysis proceeds as to whether within our state of Karnataka, such a right to health exists.

The definition of a Right to Health

One major setback experienced by the author at the beginning of this report was the definition of the right to health itself. It was felt that without really understanding and attempting to define the ambit of an individual's right to health, it is not possible to analyse the implementation of the right within a meaningful framework.

Therefore, the first half of the report completely focuses on attempting to define a right to health. Starting from the Universal declaration of Human Rights, to the International Covenant on Economic, Social and Cultural rights, to the Alma Ata Declaration and the international goal of Health for all by 2000 and the various WHO guidelines for member states, a broader perspective of a right to health as can be derived from all relevant international instruments has been presented.

With this background, the analysis proceeds to the National Health Policy of 1983 in order to cull out the components of the right to health which have been recognised at the governmental level. For a comprehensive understanding of how the National health Policy envisages as an individual's right to health, the Policy has been analysed in depth keeping the history of development of a health policy at the Central level.

The analysis moves on to directive principle of state policy on the duty of the state towards health and an overview of all the major central and State laws which deal with the health standards, and the cases decided at the Supreme Court and the High Court of Karnataka on issues of health.

With the help of all the above, the first part of the report tries to precisely arrive at what actually constitutes a 'right' to health, and within what confines this right should operate.

The implementation of right to health within the State of Karnataka

With the definition of a right to health mainly from the National Health Policy, and supported by the provisions of other laws and judicial decisions in the first part, the second part of the report is an analysis of the implementation of this right within the state of Karnataka.

This part presents the Programmes and Schemes of the State of during the past 20 years and their implementation, with the levels of progress achieved. The main strength of the report is that the analysis of working of the Department of the health and Family Welfare Services and the progress in the past twenty years has been completely supplemented by the State Government Reports of the Department of Health and family Welfare.

With these statistics on the working and the organisational hierarchy of the Department of Health and Family Welfare Services, the main focus of the report is on *whether today, is right to health an integral part of our overall developmental process? If not, what lies ahead to achieve this?*

Since this is the main focus of the report, to emphasise the fact that health is an overall function of the society and cannot be a service provided in isolation, two clear case studies are presented:

1. The status and problem of street children in Bangalore with an analysis of its causative factors and a comparison of the reality with the agenda of the Karnataka State Plan of Action for the Child (which was a plan starting in 1990, with set objectives to be achieved by the year 2000). This is an attempt to discuss and assess the objective of the state goal in the case of "children in difficult circumstances" as set out by the state plan in the 1990, and the position today, to clearly emphasise the link between health and other policies at the central/ state level. This analysis derives its basis from the work done by four students of the National Law School on the topic of Street Children in the past nine months, specifically, street children operating around Cubbon Park area of Bangalore, where the author of this report was one of them.
2. Another analysis on the point is the health and environmental problems caused by aquaculture (or Shrimp Farming). Shrimp Farming is presently one of the most lucrative activities on the coastal areas in Karnataka, Tamil Nadu and Andhra Pradesh, and is a steady foreign exchange source for the Government. The work done by the Third Law Reform group of the National Law School reveals that shrimp farming has severe public health repercussions.

With the above two case studies, the last chapter of the report draws attention on the need to re-think health in light of the components of the right to health, the inter-relation between health and other policy actions, especially in the light of international developments and national obligations in the form of structural adjustment programmes, India's obligation to grant process patents to pharmaceutical products in the Trade-Related Aspects of Intellectual property Rights and the availability and prices of drugs in the future and issues of equity in provision of health services with the state of Karnataka and between states in the country.

We obviously have several achievements to our credit such as reduction in mortality rates or increase in expectancy of life at birth; the expansion of medical research and education; the expansion of the health care services including especially the establishment of the Primary Health Centres; the excellence of our specialised institutions; the control of communicable diseases like malaria, small pox, plague and cholera; the provision of MCH services on a larger scale; the family planning programmes, and the investment of far greater funds than at any time in the past. These achievements make us proud and give us greater confidence to think and plan the road ahead.

But there are some greater failures on which the focus has to be shifted in order to decide our way ahead. It has not so far been possible to integrate health with overall development. This seems to be the major lacuna in our approach to health services within the country. That is, we are still far away from the stage when health could be considered as a major agenda in every policy decision of the Government. Until and unless we reach this stage, we seem to be creating/ enhancing the health problems of the people on one hand and providing services through primary, secondary and tertiary care centres on the other hand. This is a sheer waste of resources.

(Note: A Table of Contents of the final report has been appended to provide for a better overview.)

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A BACKGROUND PAPER FOR WORKSHOP ON SOCIO-ECONOMIC RIGHTS

A PROJECT OF THE NATIONAL LAW SCHOOL OF INDIA UNDER SUPPORT FROM NOVIB

AUGUST, 1998

INTRODUCTION

This is a project on implementation of certain social and economic rights. The rights chosen are of education, health, work and environment. The location for study is Southern India comprising the four States of Kerala, Karnataka, Tamil Nadu and Andhra Pradesh. The object of the project is to know the present status of implementation of these rights in the region and to find out how the level of implementation can be improved through the processes of law and government. In short, it is a study on social justice, a study aimed on mechanisms for delivery of social justice particularly to the poorer sections of society who feel endangered by the policies of economic liberalisation and structural adjustment.

The project extending to nearly 3 years is part of the extension services of the National Law School of India University, Bangalore. The first part of the project which is to conclude by August 1998 consists of four State-wise Task Forces looking at what has been happening in their respective States during the last five decades and presenting a Status Report on each of the four Rights in a specially-convened workshop of experts including Government representatives and NGOs. This paper expects to provide a proper context to the deliberations, raising issues and concerns relevant to the project in the various sessions of the workshop.

Are Socio-Economic Rights, Rights at all?

In Law, certain individual needs or interests get recognized as a 'right', only when they cast corresponding duties on those obliged to honour such needs, and when a mechanism is provided for enforcement of such duties for violation of which certain remedies are made available to the interest-holder.

According to the above proposition, all needs or interests, however basic it may appear to be need not be recognized and/or protected by Law. If Law recognizes a need but does not protect it by way of stipulating duties and providing reliefs if violated, such need cannot claim to have the status of a legal right. It may be a conditional entitlement or discretionary benefit which require further legal action to assume the status of a "right". To the beneficiary of such entitlements, there is no legal remedy enforceable through courts and his getting the said benefit depends on the disposition and good sense of those who command the resources and wield public power. However, once it is legally protected (legal duties are prescribed and legal sanctions attached) certain legal

consequences follow to the advantage of the intended beneficiaries. The Government is obliged to honour the same by creating institutions, allocating resources, providing equal access and undertaking accountability for its non-performance. This duty on the part of the Government is a self-imposed one when they agree to extend the services under a law which they themselves have enacted. Such a legal right can assume still greater protection in the realm of rights jurisprudence if it is elevated as a Fundamental Right protected under the Constitution. In such a situation the citizen need not entirely depend on Government initiative for the fulfilment. There is no further legislation ordinarily required for accessing Fundamental Right; the Government cannot excuse itself from honouring such a right on the plea that there are not enough resources available or they do not form part of their priorities.

Thus, from the citizen's point of view, a basic need or interest is best protected if it is a Constitutionally guaranteed Fundamental Right; the second best situation is when it is part of the statutes and has been articulated in terms of content, conditions of eligibility, scope of remedies if denied, system of administration for accessing the rights etc.; the third situation of course less beneficial, is when the need or interest is acknowledged by policy instruments evolved by the Government with commitments to progressively implement programmes directed towards its realisation by the beneficiaries. It is difficult to consider such a promised benefit as a right or even as an entitlement as its availability is based on purely executive priorities and discretion which may change with the change of Government or of policies. The worst situation is where the need or interest remains only in public discourse or political rhetoric awaiting articulation or attention of policy planners and power-brokers. It is then in the domain of politics and not of law where political action, rather than legal action, is more important.

What does the Project/Workshop Seek to Accomplish?

The purpose of the Project on Socio-Economic Rights is to find out where we stand in respect of the basic need for education, health, employment (work) and clean environment. There has been international treaties on each of these basic rights. India ratified most of them and assumed obligations to protect these basic needs of people. The Constitution of India put them as part of Directive Principles of State Policy and commanded the State to treat them as "fundamental in the governance of the country". The Government at the Centre and in the States have in varying degrees legislated upon these basic needs promising some benefits and entitlements, the quality and level of services determined by policies and resources which the Government of the day thought appropriate. After four decades of planned development, the Government adopted the policy of liberalisation of the economy which meant that the citizen has to live with market forces with lesser dependence on Governments. Given the fact that 50% of India's humanity are still living below the poverty line, that over 40% of people are still illiterate, that there is growing unemployment and under-employment particularly among the youth, that there is not even potable drinking water available to half of rural India, and that the ecological balance is increasingly disturbed by the so-called development,

there is widespread apprehension of the quality of life that Indians will be forced to live in the coming years. Looking around, people find that the language of rights is used widely to take care of basic needs of people every where. As if to re-assure them in their belief, the Supreme Court of India in recent times, by a process of liberal interpretation of the "Right to Life" under Article-21 declared that the right guaranteed is the right not for vegetable existence, but a life with dignity. Thus, it was clarified by the Court, that right to life does include right to education, right to health, right to work and right to a clean environment.

The people now want to access these rights and ask as to where they should go, what they can get and how much of it as part of basic human rights. Admittedly, the theory of socio-economic rights has not developed enough to provide satisfactory norms and standards for dispensing judicial reliefs in individual cases. The correlative duties seem to rest not only in the Government but on individuals themselves and on society as well. It is this dilemma which this project aims to address by looking at the existing nature and scope of these rights and inquiring into how they can be enriched by Governmental or Non-governmental initiatives.

Mechanisms for Enforcement of Socio-Economic Rights

Every right stipulates corresponding duties on others. In the case of basic human rights, the duties are vested in the State and State agencies. The implementation of duties and consequent protection of rights are organized both through conventional mechanisms of Government and through some modern institutional arrangements. Among the conventional mechanisms are the following:

- (a) The Legislative Assemblies through enabling legislations and appropriation of budgetary resources;
- (b) The Executive Departments of Government through actual delivery of services or providing conditions therefor; and
- (c) The Courts through adjudication of disputes thereon.

These are all State institutions which have limitations in respect of access, reach and remedies. Therefore, in recent times a variety of new mechanisms have been developed in liberal democracies which play varying roles in protection and promotion of human rights. Among them are the following:

- (a) The media including a free press through monitoring, reporting and building public opinion;
- (b) Legal aid and public interest litigation;
- (c) Non-Government organizations, trade unions, political parties through mobilising and lobbying efforts;

- (d) Reporting and compliance mechanisms of International Human Rights Law under United Nations;
- (e) Ombudsman-like watch dog bodies like Lok Ayuktha, Women's Commission, SC/ST Commission, Minorities Commission, Back Classes Commission, etc.;
- (f) Human Rights Commissions.

With such a range and variety of implementation and supporting mechanisms, no one can argue that socio-economic rights are not rights because they are not enforced or enforceable. However, if one considers only judicially enforceable rights are real rights, there can be doubt about the status of rights like education, health, employment and environment.

Courts usually act when violations are complained before it. Socio-economic rights warrant affirmative action rather than violation on the part of State. When can one explain that one's right to health is violated? One's right to work is violated? It is indeed difficult to be precise. If so, courts cannot act or give remedies. Perhaps, legislatures can or governments can provide reliefs. Does it mean that socio-economic rights are suitable for enforcement more through legislative and administrative processes, rather than judicial processes? To be able to articulate the content of socio-economic rights, one needs inputs from economists, sociologists, political scientists, medical, agricultural and industrial specialists and a host of other experts apart from lawyers. Then process of litigation of accessing rights is inadequate to absorb these extraneous inputs for balanced decision-making of individual entitlements. These difficulties become evident in the rather convoluted efforts of the Supreme Court in reading the right to education in Article 21 dealing with right to personal liberty. Nevertheless, the judiciary did take the struggle on board and made an honest effort within the parameters of the judicial process to put education, health, work and environment in the bill of rights.

From the limited experience of litigating these rights in Constitutional Courts on the basis that they are integral to life and liberty, what have we achieved? Is the position of the average citizen any way better than what was before in terms of enjoying the so called rights of education, health, etc.? If citizens continue to knock at the doors of Supreme Court and High Courts, can they access these rights? What do they complain? When do they establish violation on the part of the State? What relief should they be asking? Given the fact that approaching the highest court of the land every time a violation occurs is not a practical proposition for the majority of Indian humanity, are there other strategies for better accessing socio-economic rights? If ultimately courts need to be used, what would a lawyer be seeking to establish in a cause of action? It is this jurisprudence which this project is aiming to gather and build upon.

UNDP's Human Development Index has sought to measure the progress in the realisation of socio-economic rights by evolving certain "indicators" or bench marks for identifying the core content of these rights. It is questionable whether these indicators

can be universally applicable, given the diversities in quality of life and standard of living. Even if some indicators can help, there are difficulties in gathering acceptable data and agreeable method of analysis for drawing conclusions. Nonetheless, in the search for the core content of socio-economic rights, certain 'indicators' are indeed useful.

The prevalence of certain human rights postulates or principles such as non-discrimination, the right to information, equity in land holding, democratic participation in governance, gender equality and parity in economic levels of living are said to be of assistance in determining the prospects for realisation of socio-economic rights. Analysis of Government policies, public expenditure patterns, reports of expert committees and professional bodies as well as agreements entered into between Governments and international financial institutions should give further material for drawing conclusions on the realisation of socio-economic rights. A suggestion recently made in this regard is to seek for every major project involving substantial public expenditure a "human rights impact statement" analysing the nature and extent of adverse effects of the proposed activity. The story of the Narmada Dam agitation suggests possibilities in this regard for human rights protection.

The discussion above helps to re-examine the mechanisms and their relevance to the contemporary situation in India. Poverty, illiteracy, unemployment and disease are still the lot of a large number of Indians. For them, all the talk of human rights make little sense even after 50 years of Democratic Governments. The Constitution proclaims social justice in eloquent terms. International Human Rights instruments are ratified by India promising realisation of these rights by every section of Indian humanity. Political parties swear in the name of social justice. The courts expand the scope of Fundamental Rights and issue directions to the Governments for making basic rights accessible to all. Despite all these and more, free compulsory primary education is not available to India's 100 million children many of whom work in farms and factories. "Health for all" is a distant dream and all types of diseases take their toll regularly. Half of rural India drink polluted water and succumb to water-borne diseases. There is increasing unemployment and occasional famine conditions at least in some parts of the country. What does the future hold out to these millions of citizens? More rights may not mean more justice. The question is of accessibility, accountability and responsiveness. Can Law, Politics and Administration provide the answer?

Some Issues for Discussion

1. Are socio-economic rights merely aspirations to aim at on a future date? Are they just policies yet to mature into rights?
2. Does a policy become a right by judicial interpretation or extension of already existing rights? Is judicial enforceability a condition precedent for legal rights?
3. From the citizen's point of view, what difference does it make if education,

health, work and environment remain at the level of-

- (a) policies and declarations,
- (b) laws and regulations, or
- (c) part of Constitutional bill of rights.

4. How does one know whether a "basic human need" has got the status of a legal right? With reference to any of the four needs (education, work, health, environment) please give minimum indicators which can qualify the said need to be recognized as a legal right.
5. What are the constraints in the existing situations which inhibit the availability of socio-economic rights to all sections of the people? Is it possible to expect the realisation of the rights in the foreseeable future? What steps are required for the above purpose?

Dr. N.R. MADHAVA MENON

Chlormezanone

BANNED IN EUROPE
on sale in India

Chlormezanone, a centrally acting muscle relaxant with minor anxiolytic properties has been withdrawn from the French market in October 1996.

This withdrawal followed a European pharmaco-vigilance survey conducted between January 1988 and May 1995, into the association of chlormezanone with toxic epidermal necrolysis.

Toxic epidermal necrolysis is the most serious cutaneous drug reaction and may be fatal. Onset is generally acute and is characterised by epidermal necrosis with a minimal dermal inflammatory process.

The survey identified 153 cases of toxic epidermal necrolysis. All these cases occurred during normal conditions of use.

In the *British National Formulary*, (BNF) chlormezanone is classified as an anxiolytic. It is indicated for short

term use in anxiety or insomnia and for muscle spasm. The BNF then goes on to state that the clinical efficiency of chlormezanone as a muscle relaxant is not well established, although it is often included in compound analgesic preparations.

The severity of the drug reactions when weighed against the limited therapeutic value of the compound could not justify its continued manufacture and the product has been withdrawn.

In India, chlormezanone continues to be available. According to the Jan-March 97 issue of *Drug Today* there are nine preparations containing chlormezanone available.

These preparations are given in the table below.

Reference:

Prescribe International
February 1997, Volume 6, no 27 and
Drug Today, Lorina Publications
January-March 1997

Preparations containing Chlormezanone

Dicron-C (Kamron)	Diclofenac Sod. 50mg, Paracetamol 325mg, Chlormezanone 100mg.
Dolobak (Brown & Burk)	Paracetamol 450mg, Chlormezanone 100mg.
Electrogesic (SOPL)	Diclofenac Sod. 50mg, Acetaminophen 325mg, Chlormezanone 100mg.
Ibuflamar-MX (INDOCO)	Ibuprofen 400mg, Paracetamol 300mg, Chlormezanone 250mg.
Myospas (Win medicare)	Chlormezanone 100mg, Paracetamol 450mg.
Ontac Forte (Elder)	Diclofenac Sod. 50mg, Paracetamol 325mg, Chlormezanone 100mg.
Powergesic (Jenburkt)	Diclofenac Sod. 50mg, Paracetamol 325mg, Chlormezanone 100mg.
Prestifen-MR (Synthiko)	Ibuprofen 400mg, Acetaminophen 325mg, Chlormezanone 100mg.
Systafam (Systopic)	Chlormezanone 100mg, Acetaminophen 500mg, Diclofenac Sod. 50mg.

Drugs Today

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Drugs Today



Issue 15
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An Update on Rational Drug Use

Mefloquine is now available in India but is recommended only for the treatment of drug resistant malaria.

Mefloquine : use with caution

Mefloquine, a 4 - quinoline methanol compound chemically related to quinine is now available in India. Marketed under the trade name *Mefliam* by Cipla, it is available as tablets containing 250mg of mefloquine.

Action

Mefloquine is a potent, long acting blood schizonticide active against malaria parasites resistant to chloroquine, sulfonamide/pyrimethamine combinations and other 4 - aminoquinolines. As it is very slowly eliminated (plasma half life 10 to 40 days), a single weekly dose of 250mg provides effective prophylaxis. In uncomplicated malaria a single dose of 15mg/kg body weight is usually adequate.

Indications for use in India

In India mefloquine is recommended only as a second line drug in the treatment of malaria. It should ideally be used only for the treatment of chloroquine resistant malaria and not as a prophylactic or for the treatment of uncomplicated malaria.

Mefloquine has been available since 1984 and some 16 million doses of this drug have been taken, often in combination with sulfadoxine/pyrimethamine. Despite this extensive usage, reservations about using mefloquine, especially as a prophylactic persist.

This review of the adverse effects is compiled from western sources, where mefloquine has been used for prophylaxis and treatment. As a result the adverse events encountered under both treatment regimens have been documented.

Frequent adverse events

Almost one in every five persons who takes mefloquine prophylactically notices some dizziness, nausea, vomiting, diarrhoea, or abdominal pain. These symptoms are generally mild and resolve without specific treatment, but may be severe. These events may be dose dependent. The incidence of vomiting, which can prejudice the outcome of treatment, is reported to be some three times higher among children given mefloquine at 25mg/kg rather than the more common dose of 15mg/kg.

Neuropsychiatric adverse events

Over a ten-year period starting in 1985 more than 1500 neuropsychiatric adverse events, associated with mefloquine were reported. The most common were affective disorders, anxiety disorders, hallucinations and sleep disturbances. A few instances of

continued on page 2

Adverse events

- Gastro-intestinal — nausea, vomiting, diarrhoea or abdominal pain.
- Neuropsychiatric — dizziness, affective disorders, anxiety disorders, hallucinations and sleep disturbances are common. Overt psychosis, toxic encephalopathy and convulsions have been reported.
- Cardiovascular — bradycardia and sinus arrhythmia. ECG changes, when used with related anti malarial drugs.

continued from page 1

overt psychosis, toxic encephalopathy and convulsions have also been reported. Patients at highest risk are those with a history of neurological or psychiatric illness. One-third of all convulsions reported occurred in patients with a personal or family history of such events.

In the larger doses used for treating malaria, mefloquine is associated with a yet higher incidence of neuropsychiatric events. Among patients retreated with a second dose of mefloquine within one month, the overall incidence of adverse events has been estimated to rise some sevenfold and the risk may also be increased by concomitant use of quinine. These adverse events developed more rapidly among retreated patients. Three-quarters were noted within three days; few occurred with a latency of more than 10 days, and most had remitted fully within three weeks.

Effects on performance

Transient dizziness is a common complaint among patients who have taken mefloquine. A single dose of 25mg/kg is reported to have caused light headedness in each of seven volunteer subjects, and severe incapacity for several days in four of them.

Use in pregnancy and nursing mothers

WHO currently advises that mefloquine may be given safely during the second and third trimesters of pregnancy both for prophylaxis and treatment. The organisation recommends that prophylactic use should be avoided during the first trimester, and that

Adverse effects are:

- *dose related*
- *increased on retreatment*
- *frequently seen, when combined with quinine or chloroquine.*

its use during this period for treating malaria should be based on a risk-benefit analysis. Mefloquine can reasonably be prescribed to protect non-pregnant women of childbearing potential, but pregnancy should be avoided for at least three months subsequent to the last dose. However, in the case of an unplanned pregnancy, exposure to mefloquine is not regarded as an indication for termination.

There is no evidence that the small amounts of mefloquine excreted into breast milk constitute a risk to breast-fed infants.

Cardiovascular events

Bradycardia and sinus arrhythmia is estimated to occur in some two-thirds of patients treated with

P. falciparum resistance to chloroquine

Resistance to chloroquine was first reported in India in 1973. This was identified in North East India and since then has been spreading. Unfortunately, the areas where resistance to chloroquine has been identified have not been mapped, nor has a criteria for identifying chloroquine resistant malaria been publicised. As a result second line drugs are often used to treat uncomplicated malaria.

There is a very real danger that Mefloquine will be used indiscriminately in the treatment of malaria. While it has been recommended that mefloquine be dispensed only through hospitals our lax supervisory mechanisms have ensured that it is freely available.

Mefloquine is a useful drug but it must be used only when required. In India the only indication for the use of mefloquine is severe falciparum malaria or drug resistant malaria.

Criteria for suspecting drug resistance

The diagnosis of malaria rests on the demonstration of the parasite in peripheral blood smears.

Both thin and thick blood smears should be examined. The parasitemia is expressed as the number of parasitised erythrocytes in 100 cells and then converted to the number of parasitised erythrocytes per microliter.

Drug resistance should be suspected and treatment modified if the parasitemia does not fall below 25 per cent of the admission value, 48 hours after starting treatment or has not cleared by seven days.

mefloquine. Administration of 250mg mefloquine weekly for 4 weeks has not been shown to induce changes in either the blood pressure or the electrocardiogram of volunteers. However, both electrocardiographic abnormalities and convulsions have been reported when mefloquine is given together with the related antimalarial compounds, quinine, quinidine and chloroquine.

These findings have aroused concern that mefloquine and other antimalarials might interact adversely with cardioactive drugs including anti-arrhythmic agents and calcium channel blockers, and possibly with antihistamines, tricyclic antidepressants and phenothiazines. However, cumulative experience has been reassuring to the extent that co-medication with such drugs is no longer contraindicated.

Excerpted from:
WHO Drug Information
vol 10, no. 2, 1996

Resistant organisms

Some strains of *S. pneumoniae* & *H. influenzae* are now resistant to commonly used antibiotics.

Infections by *S. pneumoniae* and *H. influenzae* are known to cause substantial morbidity and mortality in infants and children world wide. There are reports that suggests that these two bacteriae cause about 50 per cent of all ospitalised pneumonia and about 20-40 per cent of all pyogenic meningitis in the community.

The IndiaCLEN Invasive Bacterial Infection Surveillance (IBIS) study is an ongoing multicentre project in India. The study is conducted in teaching hospitals from the southern, central and northern states in India.

Materials and methods

The study is a prospective hospital based, multicentre surveillance of all invasive pneumococcal and *H influenzae* diseases in six centers in India. The study was initiated in October 93 and is currently in progress at hospitals in Vellore, New Delhi, Lucknow, Nagpur, Madras and Trivandrum.

Microbiology procedures

From all prospectively recruited patients 5ml or at least 2ml of blood from children were cultured along

with specimens of other sterile body fluids as indicated for isolation of *S.pneumoniae* or *H.influenzae*.

Antimicrobial susceptibility testing

Antimicrobial susceptibility testing for *S. Pneumoniae* and *H. Influenzae* was performed using the disk diffusion method. The antimicrobials tested included Penicillin, Cephotaxime, Chloramphenicol, Erythromycin, Cotrimoxazole for *S.pneumoniae* and Ampicillin, Chloramphenicol, Cotrimoxazole and Cephotaxime for *H. Influenzae*.

Status of the IBIS Study

A total of 3600 cultures at the six INCLEN centres have been collected during the initial two years of IBIS. The common penumococcal serotype identified were type 1,4,5,6,16 & 19. Types 1 to 5; account for more than 25 per cent of infections in India. IBIS has shown that *H. influenzae* is the most common cause of childhood bacterial meningitis in India causing 30-40 per cent of culture positive cases and is associated with 20 per cent mortality. Also interesting to note is the lack of resistance to penicillin among the first 157 pneumococcal isolates. However the data from 1996 (3rd year) shows that there are a few emerging strains of pneumococci that show resistance to penicillin.

Resistant pneumococcal strains		
	Chloro.	Cotrimox.
Delhi	40%	80%
Nagpur	53%	71%
Vellore	10%	30%

Regional differences in antibiotic resistance

The IBIS study has shown that common invasive *S.pneumoniae* and *H. Influenzae* show significant resistance to chloramphenicol and cotrimoxazole.(see below)

Strains with resistance to		
	Chloro.	Cotrimox.
<i>S.pneumoniae</i>	23%	48%
<i>H.influenzae</i>	61%	42%

It is noted that there is a wide variation in the proportion of resistant pneumococcal strains from different centers.

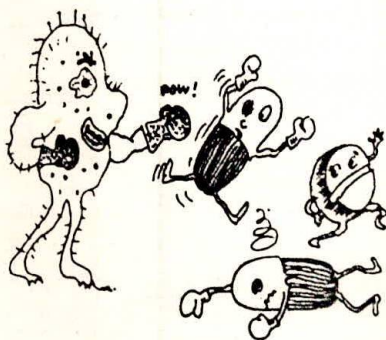
This variation could possibly be attributed to the prior use of antibiotics in these regions.

Excerpted from:
 "Epidemiology of infections due to *S.pneumoniae* and *H. influenzae* in India"
 IndiaCLEN Multicentre Study
 Invasive Bacterial Infection Surveillance (IBIS) Study Group

It is difficult to make a recommendation, on the basis of the IBIS study, regarding the drug of choice in Acute Respiratory Infections (ARI). The WHO recommendations are correct but need to be qualified

- In ARI when the child is not very sick, cotrimoxazole may be given but requires follow up.
- In ARI when the child is quite sick, amoxicillin is a better choice.
- In a very sick child, requiring hospitalisation the choice would be I.V. penicillin along with injection gentamycin.

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Manoj Kurian

ALERT!

Terfenadine

and other antihistamines may cause arrhythmias.

In February 1997 the French medicines agency decided to suspend all preparations of terfenadine for one year. This followed an increase in the risk-benefit ratio, based on a French pharmacovigilance survey showing new cases of cardiac arrhythmias

Long-established cardiotoxicity

The risk of cardiac arrhythmias such as torsades de pointes* on terfenadine was identified in the late 1980s, first in cases of overdose, then after concomitant treatment with systemic ketoconazole. Deaths on terfenadine have since been reported.

Terfenadine is almost completely converted by the liver into an active metabolite. In patients with severe liver disease or taking drugs inhibiting the metabolism of terfenadine, its plasma levels can increase sufficiently to disturb ventricular repolarisation and cause severe arrhythmias. Since 1992, severe liver failure was a contraindication to terfenadine administration, and combining terfenadine with several enzyme inhibitors was contraindicated or advised against. These enzyme inhibitors included some antifungal drugs (systemic ketoconazole) and some macrolide antibiotics (erythromycin).

Provisional conclusions

The decision to take terfenadine off the market was fully justified. This drug was used for symptomatic

treatment of only mild conditions, yet carried a risk of life-threatening adverse effects; in addition, other antihistamines appear to be safer. Unfortunately the withdrawal of terfenadine leaves a number of problems unsolved.

Astemizole carries the same risk of cardiac effects as terfenadine, and is therefore not an acceptable alternative. Loratadine might also induce cardiac arrhythmias and sudden death. Cetirizine seems to be the non sedative antihistamine with the lowest risk of this type of adverse effect.

An in-depth reassessment of the risk-benefit ratios of all members of this class is clearly necessary, bearing in mind that they are used for mild conditions.

Recommendations

Pending the results of further studies, we make the following recommendations: do not trivialise the prescription and dispensing the antihistamines, even if those drugs are claimed to be 'modern' and 'risk-free'. Follow the recommended doses and watch out for situations increasing the risk of overdose and/or drug interactions (liver failure, heart failure, polypharmacy etc.) Bear in mind that the effects of these drugs have rarely been studied in children.

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*Torsades de pointes is a type of ventricular tachycardia characterised by QRS complexes with cyclical variations in amplitude and duration, oscillating around the baseline and preceded by QT prolongation. Torsades de pointes usually induce malaise and syncope, but can sometimes cause ventricular fibrillation and cardiac arrest.

Paracetamol

Popular Brands Rate Low

Our laboratory tested 18 brands of paracetamol, of which 9 failed — alarming for a drug most of us buy without consulting a doctor. What's more, widely sold brands like *Calpol*, *Crocin* and *Metacin* were found at the bottom of our quality chart.

Little Bunty was groaning in pain and fever. It was late in the night, and his mother was hesitant to ring up the doctor. So she decided to give him a tablet to reduce the fever. The clock ticked on, but the fever persisted. Until the next morning, when the doctor changed the brand.

Maybe, in this Test Report, Bunty's mother will find an answer to her puzzle of that night.

Many of us may have wondered why a paracetamol we buy, often without consulting a doctor, and whose safety is taken for granted, works at times, and at times does not. No wonder, 9 out of the 18 paracetamol brands we tested failed to meet the Indian Pharmacopoeia (IP) specifications.

Calpol, a multinational brand with the largest market share (see Appendix III) and national brands like *Crocin* and *Metacin* could only get low ratings, indicating poor quality control. Their large market share may perhaps be attributed to their large advertising budgets, and not to their superior quality.

WHAT IS PARACETAMOL ?

Calpol, *Crocin*, *Metacin*, etc. are familiar brands, indispensable in every home. The generic name of the drug in these brands is 'paracetamol'. Paracetamol, in other words, relieves pain and fever and is taken also for relief from headache, toothache, rheumatic pain, flu, sore throat, earache, and such others. Paracetamol in different dosages is recommended for infants, children and adults. For adults it comes in tablet form, and for children in both tablet and liquid forms.

We usually don't consult a doctor for minor ailments.

Since paracetamol is available without prescription, drug quality is a very critical factor.

WHAT WE TESTED

We tested 18 brands of paracetamol (national and regional as well as generic tablets) bought locally from medical shops in Ahmedabad. On the basis of a national market share information and our own survey, we went for a



KEY FINDINGS

Out of 18 brands of paracetamol tested, only 9 met all the specifications required by IP. This is disturbing in the case of an OTC drug whose "purity, safety and efficacy" are taken for granted.

Pyrigesic, a national brand from Calcutta with one per cent market share, topped our quality ratings with an overall score of 77 per cent. It was moderately priced at 31 paise per tablet. **Calpol**, a brand with the highest market share of 6.5 per cent, just met the minimum requirement of 95 per cent in assay. It hovered on the borderline with 95.73 per cent. National brands like **Crocin** and **Metacin** were found at the bottom of our overall ratings table. This is indeed an eye-opener as these three brands have captured the largest chunk of the market.

Yet another revelation is that two local generic products, **Paracetamol** of **Manish Pharmaceutical Works** (71%) and **Paracetamol** of **Jay-Navy Pharmaceuticals** (55%) have scored over some of the more popular national brands such as **Crocin** (50%) and **Metacin** (43%) in terms of quality and price. They were cheaper at 23

paise and 20 paise respectively per tablet, compared to 31 paise of the branded.

Fifty per cent failure of the tested brands may speak volumes about the aspect of quality control in our country. Seven of them — one national brand, **Pacimol**, and 6 generic products — failed in the dissolution test. This is an important parameter which simulates the actual release of the drug in our body.

Four of these generic products could not meet the requirements for uniformity of weight. Two of them, **Paracetamol** of **Jay Formulation**, **Ahmedabad**, and **Paracetamol** of **Infinitive Pharmaceutical**, **Disa**, also failed in the disintegration test.

Our study indicates that the generic products display considerable inconsistency. While two of them, **Paracetamol** from **Manish Pharmaceutical Works** and **Jay-Navy Pharmaceuticals**, could reflect a good GMP, the rest eight could not.

representative selection of both the branded and generic forms of the drug. (See Appendix II)

Seven of them are national brands : **Calpol**, **Crocin**, **Metacin**, **Pyrigesic**, **Pacimol**, **Dolo - 650** and **Malidens**. One local brand, **Demol**, was also tested. The rest 10 market samples are generic paracetamol tablets manufactured in Gujarat, four of which are sold in bulk (1000 tablets in a pack).

We took up paracetamol for testing because of our concern for the safety of a widely-used OTC drug. More so in the case of bulk drugs. Doctors in their private practice often dispense drugs to patients. They generally go in for bulk packs as they are cheaper compared to the branded ones. Hospitals and public health centres also buy in bulk. While some bulk products are of good quality and can be relied upon, some others are not. Our test findings supported this. While **Paracetamol** from **Manish Pharmaceutical Works** and **Jay-Navy Pharmaceuticals** passed, **Paracetamol** from **Supharma Laboratories** and **Mercury Laboratories** failed in some parameters. We hope that the Food and Drug Administration (FDA) effectively monitors the production and sale of these bulk formulations to prevent substandard drugs from reaching the patients.



All brands were tested against the specifications and procedures of the Indian Pharmacopoeia (IP). We also used the US Pharmacopoeia (USP) specifications to analyse the product's quality against the benchmark of international standards.

Paracetamol Content or Assay

The only active ingredient in a paracetamol tablet is the chemical paracetamol. IP standards require that the actual paracetamol content or assay in a tablet should fall within the range of 95-105 per cent of the amount claimed on the label.

Assay value denotes the percentage of actual paracetamol drug present in the tablet, as against the quantity claimed on the label. This information is vital in evaluating the effect of a tablet on a patient. So assay has the highest weightage in our overall rating.

All brands passed in this test. Surprisingly, **Calpol** gave a borderline result of 95.73 per cent in assay, against a minimum requirement of 95 per cent.

Disintegration

After it is consumed orally, a tablet must break into small granules in order to release the drug it contains. If it does not break into smaller pieces, it will not be absorbed in the circulating blood to effect a cure. The disintegration test makes sure that the tablet breaks within 15 minutes, as specified in the Pharmacopoeia. Two generic products, **Paracetamol** from **Jay Formulation** and **Paracetamol** from **Infinitive Pharmaceutical**, failed in this parameter. They took as long as 25 and 40 minutes respectively to break down.

This means that if you take these particular formulations, they will have a very delayed effect. The earlier a tablet breaks, the faster the drug is available to your body.

For this test, a disintegration apparatus which simulates the process in the body, is used. This helps in recording the time taken by a tablet to disintegrate (break down).

Among the brands that passed, a wide range of disintegration time from a mere 40 seconds to a long 9 min.45 seconds was observed. The longest time to disintegrate was taken by *Pyrigesic* (9 min. 45 sec.) of *East India Pharmaceuticals*, followed by *Crocin* (5 min. 40 sec.). *Metacin*, *Malidens* and *Paracetamol* (*Jay-Navy*) disintegrated in just about a minute and a few seconds.

Dissolution

11 brands indicated a good dissolution percentage. This test specifies that the paracetamol dissolved in a dissolution medium should not be less than 85 per cent of the labelled amount in 30 minutes.

The best dissolution percentage was given by *Pyrigesic* of *East India Pharmaceutical Works* (99.5%), followed by *Paracetamol* of *Supharma Laboratories* (98.6%) and *Manish Pharmaceutical Works* (97.5%), two bulk products. But *Metacin* was found to have only 85.4 per cent which is just close to the required minimum of 85 per cent.

Generic *Paracetamol* from *Infinitive Pharmaceutical* and *Jay Formulation* performed poorly with an extremely low

release of 10.7 per cent and 12.5 per cent respectively.

Dissolution is a critical parameter in determining the performance and defining the quality of tablets and capsules. It measures the release of a drug into the gastro-intestinal fluid and is an essential first step in drug availability to the body. Dissolution, therefore, has been considered an important parameter in our rating. Though earlier dissolution was only a parameter in USP, it has now been incorporated in the revised 1996 edition of IP.

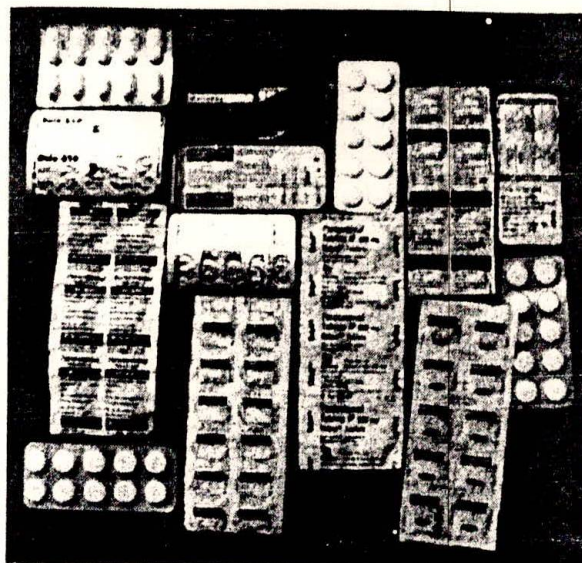
Weight

Of the 18 brands tested for weight, 14 met the IP standards of uniformity (95% - 105%). But four generic paracetamol produced by *Lennecc Remedies*, *Mercury Laboratories*, *Jay Formulation* and *Supharma Laboratories* failed to conform to the standards.

Demol gave a marginally lower standard of 94.75 - 105.03 per cent in the test. This indicates that the manufacturer has chosen to comply with the lower specifications in IP.

BORDERLINE CASES

From our test findings on both 'Ampicillin capsules' and 'Paracetamol tablets', it appears that quite a few manufacturers comply marginally with the statutory provisions, merely to satisfy the minimum legal requirements. These 'borderline cases' may turn out to be less effective than those with better quality. They may also take more time to bring relief. And, in turn, the consumer may not get good value for his money.



A few brands in the market

A glaring example is *Calpol*, which gave a low reading of only 95.73 per cent in assay, against a minimum standard of 95 per cent. In dissolution too, only 89.3 per cent of the drug could dissolve in 30 minutes, against a minimum requirement of 85 per cent. Compare this with the 99.5 per cent dissolution rate of *Pyrigesic*.

Crocin and *Malidens* also hovered on the borderline with a percentage of 96.93 and 96.31 in assay.

Metacin, a widely - used national brand with only 85.4 per cent dissolution rate and the bulk *Paracetamol* from *Jay-Navy* with 86.9 per cent were the other borderline cases in dissolution. They also gave borderline results in weight, along with bulk *Paracetamol* from *Manish*.

A generic product, *Paracetamol* (*Infinitive*) could give only 96.9 per cent in assay, and *Demol*, a local brand, recorded a lower weight percentage of 94.75 - 105.03 against the

Disintegration vs Dissolution

Disintegration only determines whether the tablet breaks into granules or not.

Dissolution gives information on the actual release of the drug content from the tablet.

Paracetamol Tablets

specification of 95 - 105 per cent.

VALUE FOR MONEY

We compared the test results of each paracetamol brand coupled with its cost per tablet. We wanted to find out if higher cost provides better quality. But once more we found that the costliest brand need not be the best. (Our test findings on Ampicillin also confirmed this - see our Jan-Feb '97 issue). A generic product, *Paracetamol* of *Manish Pharmaceutical Works*, coming second in our performance rating with a creditable score of 71 per cent, also turned out to be cheaper with 23 paise per tablet. The cheapest was also a generic *Paracetamol* from *Jay-Navy Pharmaceuticals* (20 paise), with a good rating of 55 per cent. *Pyrigesic* which came out of the test with the best showing of 77 per cent was reasonably rated at 31 paise per tablet along with the other national brands like *Calpol*, *Crocine* and *Metacin*. The costliest tablet at 49 paise was *Paracetamol* of *Shreechem Laboratories* which had failed in the dissolution test (see Table).

WEIGHTAGES ASSIGNED

A panel of experts from the pharmacy colleges in Gujarat and pharmaceutical experts laid down the final weightages for each parameter, which helped in rating and ranking the passing brands :

Assay - 36% (because it reveals the actual drug content in the tablet)

Dissolution - 27% (because it indicates the amount of drug that reaches the site of action)

Disintegration - 13.5% (because a drug has to break down before it dissolves)

Uniformity of weight - 13.5% (indicates the actual weight of the tablet)





BRANDS		OVERALL WEIGHTED SCORE				
		Bar chart	Value			
		25	50	75	100	
PASSING BRANDS	NATIONAL	PYRIGESIC East India Pharmaceutical Works, Calcutta			77	
		DOLO - 650 Micro Labs Ltd, Hosur (TN)			60	
		MALIDENS Nicholas Piramal India Ltd, Pithampur, (MP)			51	
		CROCIN Duphar-Interfran Ltd., Mumbai			50	
		METACIN Themis Pharmaceutical, Mumbai			43	
		CALPOL Burroughs Wellcome, Mumbai			38	
	LOCAL	DEMOL Debonair Pharmaceuticals, Ahmedabad			58	
	GENERIC		PARACETAMOL (Bulk) Manish Pharmaceutical Works, Viramgam (Guj)			71
			PARACETAMOL (Bulk) Jay-Navy Pharmaceuticals, Ahmedabad			55
	FAILING BRANDS	NATIONAL	PACIMOL IPCA Laboratories Ltd. Ratlam (MP)			
GENERIC		PARACETAMOL Rajdip Pharmaceuticals, Ahmedabad				
		PARACETAMOL Shreechem Laboratories, Mumbai				
		PARACETAMOL Apollo Pharmaceuticals, Vatva (Guj)				
		PARACETAMOL Infinitive Pharmaceutical, Disa (Guj)				
		PARACETAMOL Lerinecc Remedies, Vapi (Guj)				
		PARACETAMOL (bulk) Supharma Laboratories, Vatva (Guj)				
		PARACETAMOL (bulk) Mercury Laboratories, Vadodara (Guj)				
	PARACETAMOL Jay Formulation, Ahmedabad					
		WEIGHTAGES ASSIGNED ▶		100		
Note : Weightages are indicative of the degree of relative importance between the characteristics tested for.						

Price - 10% (Although price variation is small, a 20-50 paise difference becomes relevant with the varying income-groups in India)

Thus, overall quality in terms of four parameters is assigned 90% weightage, and price is assigned 10% weightage.

Results & Ratings

KEY

			
Passing Brands	Borderline Results	Failing Brands	Failing Parameters

CHARACTERISTICS & WEIGHTED									
PRICE OF A TABLET OF 500 mg		ASSAY LIMIT 95% - 105%		DISINTEGRATION LIMIT MAXIMUM 15 MIN.		DISSOLUTION LIMIT 85% - 100%		UNIFORMITY OF WEIGHT LIMIT 95% - 105%	
PAISE	WEIGHTED SCORE (in %)	PERCENTAGE	WEIGHTED SCORE (in %)	TIME (Min./Sec.)	WEIGHTED SCORE (in %)	PERCENTAGE	WEIGHTED SCORE (in %)	MINI-MAX (in %)	WEIGHTED SCORE (in %)
31	09.7	103.52	30.67	9/45	04.81	99.5	25.87	97.23-102.70	05.56
37	08.1	100.24	18.86	4/25	09.56	93.3	14.80	97.79-101.35	08.86
30	10.0	96.31	04.75	1/00	12.11	95.2	18.20	97.48-103.85	05.51
31	09.7	96.93	06.98	5/40	08.45	94.7	17.28	97.40-102.12	07.18
31	09.7	99.43	15.98	1/30	12.18	85.4	00.70	96.49-102.60	04.48
31	09.7	95.73	02.66	3/00	10.83	89.3	07.67	97.76-102.00	07.51
30	10.0	102.13	25.70	2/35	11.11	91.1	10.85	94.75-105.03	-00.27
23	08.7	101.98	25.13	4/00	09.94	97.5	22.30	96.58-102.24	04.59
20	10.0	102.42	26.71	1/00	12.61	86.9	03.40	96.79-104.03	02.54
38		102.16		1/40		46.2		98.15-101.94	
30		99.86		2/55		18.3		97.70-102.74	
49		99.97		2/45		35.3		97.85-103.34	
38		101.14		2/25		14.7		97.73-103.25	
30		96.90		40/0		10.7		97.73-103.47	
40		100.90		1/30		72.6		90.23-107.50	
18		98.86		0/40		98.6		86.99-114.36	
19		100.70		7/15		91.4		92.43-107.19	
30		101.77		25/0		12.5		92.81-107.32	
10		36		13.5		27		13.5	

HOW THEY RATE

Out of 18 paracetamol brands tested, only 9 conformed to all the parameters provided by IP. Quality-wise, *Pyrigesic* gave an

excellent performance with a score of 77 per cent, followed by *Paracetamol* from *Manish Pharmaceutical Works* (71%). Quite surprisingly, *Crocina* (50%) and *Metacin* (43%) and *Calpol* (38%) came at the

bottom end of the table. These three brands, in spite of adhering to the lower specifications in IP, might be below par in therapeutic effectiveness compared to the rest.

WARNING !

The major risk with Paracetamol is poisoning through overdose, whether accidental or intentional. Overdose causes jaundice, liver failure and death, especially in adults who absorb more than 15 g. of the drug. Overdosing can also be cumulative. It is not recommended for those with liver or kidney problems, or for heavy drinkers.

It is also possible to take too much paracetamol accidentally when you take different medications such as cold remedies and pain killers which may also contain this drug.

If symptoms like diarrhoea, increased sweating, loss of appetite, nausea or vomiting, stomach cramps or pain, swelling or tenderness in the upper abdomen, bloody or black stools, bloody or cloudy urine, fever with or without chills occur, consult your doctor immediately.

Anyone who has taken an overdose needs prompt treatment preferably within 12 hours for possible recovery, even though there may be no visible symptoms.

MANUFACTURERS' VIEWS

Our policy envisages intimating the test results to all the manufacturers, irrespective of whether their brand has passed or failed in our tests. The results are posted to their Registered Offices under registered A.D. The manufacturers receive only the results of their own product without any information on its rating and ranking. They are given a week from the date of receipt to respond.

Lennecc Remedies, manufacturers of generic Paracetamol, cited disparity in weight "due to the mistake of the technical person who is handling the punching section". They assured us of better quality control in future.

Supharma Laboratories, which make generic Paracetamol in bulk that failed in uniformity of weight, stated, "We cannot believe that our tablet does not comply with uniformity of weight". They also clarified that a "few tablets may lose weight due to abrasion during improper transit or bad handling".

We stand by our test results. The testing is conducted strictly as per IP specification and the results are double-checked before finalising.

Mercury Laboratories (bulk) and Jay Formulation, whose generic products failed in uniformity of weight and dissolution, and also in disintegration in the case of the latter, found our test results at variance with their own.

We stand by our test results and

have notified the FDA of our findings.

Shreechem Laboratories, manufacturers of generic Paracetamol, informed us that "the products are manufactured as per IP specifications and the additional test carried out by you is not required".

Debonair Pharma (Demol) wrote back to say that "USP 95 is not binding on us because we are manufacturing as per IP standard".

Nicholas Piramal India Ltd (Malidens), informed us that "we are not surprised that the product also meets dissolution test as specified in the USP because our specification already incorporates this test from the very beginning", though "this is not mandatory with respect to IP specification".

We test products against international standards not to fail them, but to create awareness particularly among the Industry for improvement.

We have been vindicated in our efforts by the incorporation of the dissolution parameter in the revised edition of IP 1996.

East India Pharma, manufacturers of Pyrigesic and Micro Labs (Dolo - 650) evinced a keen interest in our findings and sought detailed information.

Test reports are for consumers: No commercial use and advertising of test results are permitted.

Manufacturers of Calpol, Crocin, Metacin and Paracetamol (Manish

Pharma) did not respond.

No reply was received from the manufacturers of these failed brands, viz. Pacimol (IPCA Lab), Paracetamol

(Rajdip Pharma) and Paracetamol (Apollo Pharma).

NEED FOR ACTION

CERS proposes to

- circulate its findings among doctors, hospitals, government purchase departments and concerned professional associations;
- issue a Press Release on the findings to all sections of the media and consumer groups around the country for wider dissemination of information;
- initiate legal action under the CPA against manufacturers of failing brands;
- demand the recall or withdrawal of unsafe products;
- seek corrective ads on false claims.

We have requested the FDA to initiate suitable action against the erring manufacturers, and to improve the monitoring system, especially with respect to bulk packings. In response we have received an assurance from the Drugs Controller General (India) that the Directorate proposes "to initiate suitable follow-up measures".

FOR MORE INFORMATION

- Methodology of calculations (Appendix I) page 14
- Names and addresses of manufacturers (Appendix II) page 14
- Market share information (Appendix III) page 14

KNOW YOUR DRUGS

ANALGESICS & ANTIPIRETTICS

(Continued from the previous issue)

Side-effects

- 1. Aspirin or Acetyl Salicylic Acid (ASA) : Gastro-intestinal and skin reactions in hypersensitive patients.

Warning

Aspirin can produce abnormal bleeding tendencies in some patients. These may be minor or serious in nature. Alteration (or blackening) of stool colour in patients on long-term aspirin-therapy should be brought to the notice of a doctor immediately.

Aspirin should not be used in children under 12 years of age as it can cause a dangerous condition called Reye's syndrome which can be fatal. Other drugs could be used instead of this.

- 2. Paracetamol : Prolonged use of this drug or overdose can cause liver damage. Except for this, there are no serious side-effects for this drug which is relatively safe for children.
- 3. Ibuprofen : Gastrointestinal discomfort and heartburn, activation of stomach ulcers, hypersensitivity reactions, headache, dizziness and vertigo, pruritus and skin rashes, fluid retention, ringing in the ear, blurred vision, corneal deposits, nausea and prolonged bleeding from wounds
- 4. Indo Methacin : Headache, dizziness, gastro-intestinal ulcers and bleeding, drowsiness and confusion, depression, syncope, thrombocytopenia, hypertension, hyperglycemia, blurred vision, corneal deposits, peripheral neuropathy.
- 5. Diclofenac Sodium : Gastrointestinal discomfort and bleeding, nausea, diarrhoea, hypersensitivity reactions (such as angioedema, asthma, rashes, headache, dizziness, vertigo, tinnitus, fluid retention, reversible acute renal failure in patients with previous renal impairment and chronic renal failure.

- 6. Naproxen : Side-effects as for Ibuprofen
- 7. Piroxicam : Side-effects as for Ibuprofen
- 8. Codeine : Respiratory depression, tolerance, dependance, sedation, dizziness, nausea, constipation, cough suppression, urinary retention.
- 9. Morphine : Same as for Codeine
- 10. Pethidine : Same as for Codeine
- 11. Pentazocine : Same as for Codeine
- 12. Buprenorphine : Same as for Codeine

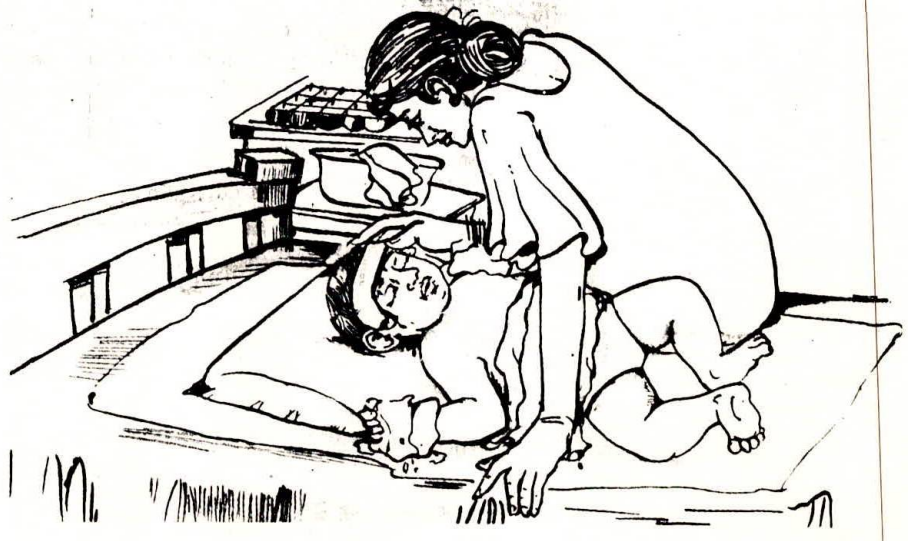
Drug Interactions

- 1. Aspirin or Acetyl Salicylic Acid (ASA) : Interacts with metoclopramide, an antiemetic drug which potentiates the effect of aspirin.
- 2. Paracetamol : Cholestyramine, a drug used in hyperlipidemia causes reduced absorption of paracetamol. Metoclopramide causes potentiation of the effect of paracetamol.

Formulations banned

Note : Fixed dose drug combinations in general are to be avoided in the rational use of drugs.

- 1 Fixed dose combinations of vitamins with anti-inflammatory agents (such as Ibuprofen) and tranquillisers.
- 2 Fixed dose combinations of atropine, analgesics and antipyretics
- 3 Fixed dose combinations of vitamins and analgesics.
- 4 Fixed dose combinations of sedatives/hypnotics/ anxiolytics with analgesics and antipyretics



Recommended dosage schedules

1. Acetyl Salicylic Acid : Adults: 300 - 900 mg every 4 to 6 hours; Children : not recommended
2. Paracetamol : Adults : 500 - 1000 mg, every 6 to 8 hours; children : 1-3 years - 1/2 tsp every 6-8 hours; 3-7 years - 1 to 2 tsp every 6-8 hours; 7-12 years - 2 tsp every 6-8 hours
3. Ibuprofen : Adults : 400 mg, thrice daily after food in the initial phase; 200 mg, twice daily in the maintenance phase. Children : 20 mg / kg day in three divided doses.
4. Indo Methacin : 25-50 mg, orally, twice daily
5. Diclofenac Sodium : Tablets: 25 to 50 mg, thrice daily preferably after food; Injection : deep IM, 50-75 mg once or twice daily for two days; Gel : external application at the site of pain.
6. Naproxen : Tablets : 250 mg, twice daily
7. Piroxicam : Capsules : 20 mg, daily after food in the initial phase, followed by 10-20 mg.
8. Codeine : Tablets : 10 to 60 mg every 6 hours (maximum of 200 mg per day)
9. Morphine : Adults: 8-15 mg im or sc injections 2 mg / min upto 10-15 mg by IV; Children : 0.1 mg / kg by injection
10. Pethidine : Adults : 25-100 mg injection, 25-50 mg IV, Children : 1 mg / kg b w by injection
11. Pentazocine : Oral, 15 to 100 mg / day, injection 30-60 mg per dose injection (may be repeated after 6 hours); IV injection 30 mg.
12. Buprenorphine : Tablets (sublingual): 0.2 mg every 6 to 8 hours; injections 0.3 to 0.6 mg or IV (may be repeated after 6 hours)

Special Precautions

1. Aspirin or Acetyl Salicylic Acid (ASA) : Not to be used in
 - a. Bronchial asthma
 - b. Pregnancy
 - c. Renal impairment
 - d. Hepatic dysfunction
2. Paracetamol : Not to be used in hepatic dysfunction

3. Ibuprofen : Not to be used in
 - a. Pregnancy
 - b. Patients with Acid Peptic disease
4. Indo Methacin : Best avoided in
 - a. Hypertension
 - b. Epilepsy
 - c. Psychiatric disturbance
 - d. Renal disease
 - e. lactation
5. Diclofenac Sodium : To be avoided in patients with active peptic ulceration.
6. Naproxen : Same as for Ibuprofen
7. Piroxicam : Same as for Ibuprofen
8. Codeine
9. Morphine
10. Pethidine
11. Pentazocine
12. Buprenorphine

To be avoided in infants (0-1 year)

These opioid analgesic should be used with caution in patient with

- a. history of drug abuse
- b. decreased respiratory reserve
- c. hypothyroidism
- d. asthma
- e. hepatic impairment
- f. Renal dysfunction

They should be avoided or used with extreme caution in pregnancy and lactation, and in the elderly debilitated patients.

Contra-indications

1. Acetyl Salicylic Acid : Not to be used at all in children below 12 years.
2. Paracetamol : Not to be used in hypersensitive patients
3. Ibuprofen & other non-opioid analgesics : Active peptic ulcer disease and hypersensitivity are contraindications.

Opioid analgesics should be avoided in patients with raised intracranial tension or head injury as they will interfere with respiration, pupillary responses etc which are vital for clinical assessment and diagnosis.

Conclusion

Useful often as relievers of pain and fever, these drugs are the mainstay in symptomatic treatment. The fact remains that in case the symptoms persist inspite of treatment, the root-cause of these symptoms should be sought and specific treatment initiated.

In the next issue
ANTI-ASTHMATIC DRUGS

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D/N

■ WOMEN'S ISSUES

Women at risk

Quinacrine sterilisation, a practice that defies accepted international norms, continues in India.

NALINI VISVANATHAN
MOHAN RAO

OVER the last several months, the issue of chemical sterilisation of women in India with quinacrine has been a matter of controversy (*Frontline*, May 2, 1997). In West Bengal, where Dr. Biral Mullick admits to having sterilised more than 10,000 women over the past two decades, activists of the Ganatantrik Mahila Samiti led by Professor Malini Bhattacharya forced the West Bengal Government to call a halt to the "trials" and initiate an enquiry into Dr. Mullick's practice. In Bangalore, where the Contraceptive and Health Innovation Project (CHIP) of Dr. Pravin Kini and Dr. Sita Bhateja hopes to sterilise 25,000 women over the next two years (having so far sterilised close to a thousand), a coalition of health and women's groups have held demonstrations. On May 2, women's groups held a huge demonstration in New Delhi outside the clinic of Dr. J. K. Jain, former member of Parliament of the Bharatiya Janata Party (BJP) and the kingpin of the network for the conduct of these trials in the country.

The Government of India denies granting approval to quinacrine as an agent for female sterilisation. In Parliament, in response to questions tabled by Dr. Ashok Mitra, Minister of State for Law Ramakant Khalap stated that the Government was aware that the World Health Organisation (WHO) had specifically recommended that pending further studies, trials with quinacrine on human populations be stopped. He said: "Approval for clinical trials of quinacrine pellets has not been granted to any investigator by the Drug Controller General of India." He also stated that "no drug manufacturer has been granted licence to manufacture quinacrine and the drug is not imported." Meanwhile, the Indian Council of Medical Research (ICMR), in published statements, condemned the practice.

Despite these efforts, some doctors in the private sector and some non-governmental organisations (NGOs) are con-

tinuing the trials, which defy accepted international norms for the conduct of clinical trials. Indeed, reports indicate that they are spreading. It is in this context that the All India Democratic Women's Association (AIDWA) and the faculty of the Centre of Social Medicine and Community Health of the Jawaharlal Nehru University approached the Supreme Court with a public interest petition seeking an immediate - and enforced - ban on the trials.

THE quinacrine trials raise a host of issues regarding the safety of the particular method of sterilisation, the methodology used in assessing this, and above all the ethical issues concerning the trials that have been raised around the world. The sponsors of these trials, which are said to be going on in 19 Third World countries, are two U.S. doctors: Dr. Elton Kessel and Dr. Stephen Mumford. They are funded by a private foundation and same individuals linked with the Federation for American Immigration Reform, a Washington-based group lobbying for restricted immigration into the U.S.

Kessel and Mumford responded to a number of arguments put forward by their critics when they spoke to the Committee for Women, Population and Environment (CWPE) based at Hampshire College, Massachusetts. However, their response left many questions unanswered.

One major criticism of quinacrine sterilisation pertains to issues of safety. Kessel maintained that risk-benefit assessment, the cornerstone of clinical trials, "favoured the use of quinacrine sterilisation in populations where maternal mortality was high and contraceptive prevalence low." With reference to the WHO's recommendations observing that quinacrine may be cancer-producing and thus warranted further studies, he argued that toxicologists maintain that the duration of exposure is the most critical element when humans are exposed to carcinogenic or mutagenic substances. Laboratory tests indicate that quinacrine causes mutations or changes in cells.

(While all substances that cause such changes are not cancer-causing, conventional scientific norms dictate that they should be excluded before human trials are undertaken.) Kessel also said that while there is a lack of data on the long-term effects of quinacrine, the small number of insertions minimises exposure.

Mumford, on his part, said that quinacrine, as an anti-malarial drug, has been used orally "in higher doses, over a longer period of time, on a larger population" with little deleterious effects.

Similar argument have been put forward by advocates of quinacrine sterilisation in India also. What these arguments miss is that reproductive causes account for only a small proportion of deaths among women in the reproductive age-group in India. Indeed, these causes do not account entirely or even largely for the high maternal mortality rate in the developing countries; the majority of deaths occur owing to diseases of poverty, primarily anaemia, undernutrition and infections and lack of access to health care facilities in the event of complications of pregnancy. Contraception or sterilisation alone thus has an extremely limited role to play in the decline of maternal mortality. If this were indeed the case, countries such as Brazil and Indonesia (the latter has a particularly aggressive family planning programme), which have witnessed remarkable declines in birth rate, should also have experienced declines in the maternal mortality rate. This has not happened.

The argument that quinacrine was used extensively as an anti-malarial drug and that therefore as a sterilising agent it is without danger, is equally specious. Quinacrine was primarily used as an anti-malarial drug only till such time as better alternatives such as chloroquine became available. Further, the extremely high mortality rate for malaria at that time far outweighed the risks due to quinacrine. Unlike the case with malaria then, there are alternative forms of terminal contraception today such as tubectomy for women and vasectomy for men.

Maintaining that sterilisation by the quinacrine method was extremely safe,

Dr. Kessel claimed that there were no deaths in the 40 day period following the insertion of quinacrine in 100,000 women. There are, however, a number of problems with such a facile presentation of data. Included in this huge number are presumably the 31,781 women sterilised in Vietnam between 1989 and 1992. Following WHO recommendations the Vietnamese Government called a halt to the trials.

The New York-based Association for Voluntary Surgical Contraception (AVSC) found serious scientific flaws in the Vietnamese study. The data on side-effects and failure rates, for instance, were not derived from the full sample of women but from much smaller sub-sets

Questions have also been raised about the standard cut-off date of 40 days after surgery being used to determine mortality rates in the case of quinacrine sterilisation. Potentially fatal ectopic pregnancy can occur as long as a woman sterilised with quinacrine is in the reproductive age-group. The use of this cut-off date thus does not constitute a long enough period to assess the mortality risks associated with the method.

WHILE Dr. Kessel said that records are being maintained and that cases are followed up long enough to establish mortality rates, Dr. Mumford acknowledged that they have no resources for follow up. Indeed, Dr. Bhuiyan in

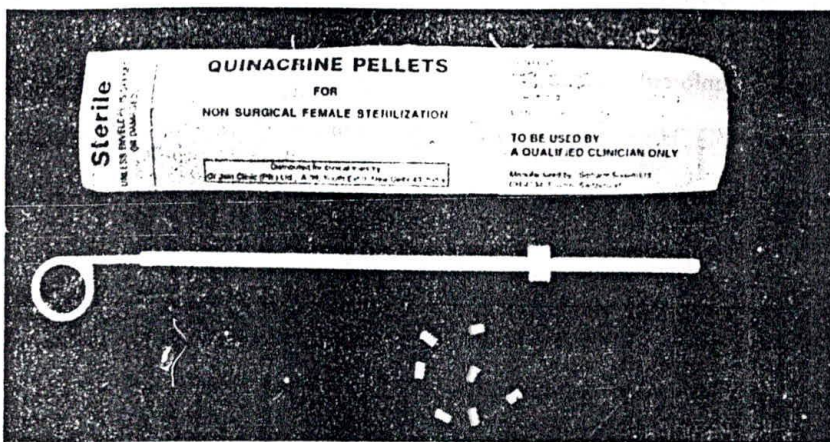
use it as an agent for female sterilisation is baseless. Under the Drugs and Cosmetics Act of India, a new drug is defined to include "a drug already approved... which is now proposed... with new claims, namely, indications, dosage form and route of administration."

The Drug Controller of India has only granted approval for the use of quinacrine in tablet form, orally for the treatment of malaria, giardiasis and amoebiasis. The drug is thus not approved for female sterilisation. It has not received this approval from any authority anywhere in the world, including the U.S. The FDA recently issued a warning on the Internet where quinacrine was being promoted as a method of self-sterilisation. The warning noted that the kit advertised "uses pellets of quinacrine hydrochloride, an unapproved drug which can cause ectopic pregnancies, abnormal pregnancies and permanent damage to a woman's reproductive organs."

Despite the blatantly illegal nature of this practice, some of India's leading doctors continue to take part in this dubious enterprise. At the World Congress of Gynaecology and Obstetrics in Copenhagen in August 1997, a special session on quinacrine sterilisation was organised by Dr. Kessel. It was chaired by Dr. J. K. Jain. Prominent doctors from India making presentations included Dr. Biral Mullick, Dr. Ashi Sarin, Dr. Pravin Kini, Dr. Sita Bhateja and Dr. Ajay Ghosh.

Given the globalised, liberalised nature of the Indian state today, wherein independent institutions of health research established by the state are being systematically undermined, it is not surprising to witness yet another instance of Third World women being subjected to such experiments. Notwithstanding the commitments made at the United Nations Conference on Population and Development in Cairo in 1994 to enhance women's health and reproductive rights, the impunity with which U.S.-based NGOs are violating human rights in countries of the South shows up the need to monitor health systems that have been rendered vulnerable by the incorporation of the Indian economy in the global market. It is ironic indeed that this is being done in the context of neo-liberal rhetoric on reproductive health rights. ■

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Quinacrine pellets and the equipment for their insertion.

among them. The findings from these varying sub-sets of the study population were then extrapolated to the entire sample. For instance, failure rates were calculated based on only a third of the total population. Again it is unclear as to how the ectopic pregnancy rate was calculated: in one province, two out of nine pregnancies were ectopic – a hugely unusual occurrence. Yet, according to the AVSC, "this troubling finding is not mentioned in the analysis of ectopic pregnancies." The AVSC thus maintains that "it is not possible to conclude that quinacrine pellets are a safe and effective non-surgical method of female sterilisation."

In addition, given the fact that a variety of protocols of dosage, number of insertions and adjuvants have been followed, it is not methodologically legitimate to calculate mortality rates from data obtained by diverse and often unspecified methods pooled together. Indeed, it has been revealed that three known deaths due to quinacrine sterilisation were not reported in these findings. This further undermines the credibility of the data.

Bangladesh and Dr. Mullick, in published interviews, admit their failure to follow up cases. Similarly, in Pakistan where women were, according to a participant, "picked off street corners", there were no follow up efforts. It is, therefore, not surprising that the data presented by Kessel are met with scepticism.

Kessel stated that government approval for quinacrine sterilisation is "desirable but not essential" since guidelines from the Food and Drug Administration (FDA) of the U.S. "permitted off-label use (that is, the use of drugs approved for another purpose) under medical supervision." The training literature for quinacrine sterilisation, however, states that one of the advantages of the method is that it "can be provided by many types of trained health care workers, not just doctors." Indeed Dr. Mullick is on record that he has trained "hundreds of health workers" to use quinacrine for sterilisation.

The argument that approval for quinacrine for the treatment of other diseases precludes the need for a licence to

6. CLASSIFICATION OF PRACTICES IN NORMAL BIRTH

This chapter classifies the practices common in the conduct of normal childbirth into four categories, dependent on their usefulness, effectiveness and harmfulness. The classification reflects the views of the Technical Working Group on Normal Birth. Arguments for this classification are not given here; the reader is referred to the preceding chapters, which are the outcome of the reflection and debates of the Working Group, based on the best currently available evidence (numbers of chapters between brackets).

CATEGORY A:

6.1 Practices which are Demonstrably Useful and Should be Encouraged

1. A personal plan determining where and by whom birth will be attended, made with the woman during pregnancy and made known to her husband/partner and, if applicable, to the family (1.3).
2. Risk assessment of pregnancy during prenatal care, reevaluated at each contact with the health system and at the time of the first contact with the caregiver during labour, and throughout labour (1.3).
3. Monitoring the woman's physical and emotional well-being throughout labour and delivery, and at the conclusion of the birth process (2.1).
4. Offering oral fluids during labour and delivery (2.3).
5. Respecting women's informed choice of place of birth (2.4).
6. Providing care in labour and delivery at the most peripheral level where birth is feasible and safe and where the woman feels safe and confident (2.4, 2.5).
7. Respecting the right of women to privacy in the birthing place (2.5).
8. Empathic support by caregivers during labour and birth (2.5).

9. Respecting women's choice of companions during labour and birth (2.5).
10. Giving women as much information and explanation as they desire (2.5).
11. Non-invasive, non-pharmacological methods of pain relief during labour, such as massage and relaxation techniques (2.6).
12. Fetal monitoring with intermittent auscultation (2.7).
13. Single use of disposable materials and appropriate decontamination of reusable materials throughout labour and delivery (2.8).
14. Use of gloves in vaginal examination, during delivery of the baby and in handling the placenta (2.8).
15. Freedom in position and movement throughout labour (3.2).
16. Encouragement of non-supine position in labour (3.2, 4.6).
17. Careful monitoring of the progress of labour, for instance by the use of the WHO partograph (3.4).
18. Prophylactic oxytocin in the third stage of labour in women with a risk of postpartum haemorrhage, or endangered by even a small amount of blood loss (5.2, 5.4).
19. Sterility in the cutting of the cord (5.6).
20. Prevention of hypothermia of the baby (5.6).
21. Early skin-to-skin contact between mother and child and support of the initiation of breast-feeding within 1 hour postpartum in accordance with the WHO guidelines on breast-feeding (5.6).
22. Routine examination of the placenta and the membranes (5.7).

CATEGORY B:

6.2 Practices which are Clearly Harmful or Ineffective and Should be Eliminated

1. Routine use of enema (2.2).
2. Routine use of pubic shaving (2.2).
3. Routine intravenous infusion in labour (2.3).
4. Routine prophylactic insertion of intravenous cannula (2.3).
5. Routine use of the supine position during labour (3.2, 4.6).
6. Rectal examination (3.3).

7. Use of X-ray pelvimetry (3.4).
8. Administration of oxytocics at any time before delivery in such a way that their effect cannot be controlled (3.5).
9. Routine use of lithotomy position with or without stirrups during labour (4.6).
10. Sustained, directed bearing down efforts (Valsalva manoeuvre) during the second stage of labour (4.4).
11. Massaging and stretching the perineum during the second stage of labour (4.7).
12. Use of oral tablets of ergometrine in the third stage of labour to prevent or control haemorrhage (5.2, 5.4).
13. Routine use of parenteral ergometrine in the third stage of labour (5.2).
14. Routine lavage of the uterus after delivery (5.7).
15. Routine revision (manual exploration) of the uterus after delivery (5.7).

CATEGORY C:

6.3 Practices for which Insufficient Evidence Exists to Support a Clear Recommendation and which Should be Used with Caution while Further Research Clarifies the Issue

1. Non-pharmacological methods of pain relief during labour, such as herbs, immersion in water and nerve stimulation (2.6).
2. Routine early amniotomy in the first stage of labour (3.5).
3. Fundal pressure during labour (4.4).
4. Manoeuvres related to protecting the perineum and the management of the fetal head at the moment of birth (4.7).
5. Active manipulation of the fetus at the moment of birth (4.7).
6. Routine oxytocin, controlled cord traction, or combination of the two during the third stage of labour (5.2, 5.3, 5.4).
7. Early clamping of the umbilical cord (5.5).
8. Nipple stimulation to increase uterine contractions during the third stage of labour (5.6).

CATEGORY D:

6.4 Practices which are Frequently Used Inappropriately

1. Restriction of food and fluids during labour (2.3).
2. Pain control by systemic agents (2.6).
3. Pain control by epidural analgesia (2.6).
4. Electronic fetal monitoring (2.7).
5. Wearing masks and sterile gowns during labour attendance (2.8).
6. Repeated or frequent vaginal examinations especially by more than one caregiver (3.3).
7. Oxytocin augmentation (3.5).
8. Routinely moving the labouring woman to a different room at the onset of the second stage (4.2).
9. Bladder catheterization (4.3).
10. Encouraging the woman to push when full dilatation or nearly full dilatation of the cervix has been diagnosed, before the woman feels the urge to bear down herself (4.3).
11. Rigid adherence to a stipulated duration of the second stage of labour, such as 1 hour, if maternal and fetal conditions are good and if there is progress of labour (4.5).
12. Operative delivery (4.5).
13. Liberal or routine use of episiotomy (4.7).
14. Manual exploration of the uterus after delivery (5.7).

✓ Misconceptions in Medical Practice

To demonstrate malaria parasite, blood should be drawn during paroxysms of fever

A notion is prevalent amongst doctors, other health personnel and general public as well, that to demonstrate malaria parasite in peripheral blood smear, sample has to be taken during paroxysm of fever. Doctors and laboratory personnel often insist on it and people take immense trouble at odd hours to arrange for the same.

This is a misconception. In an infected person, malaria parasite in its erythrocytic phase is demonstrable in the peripheral blood smear at any time of the day irrespective of the degree of temperature. Let us recall the life cycle of the parasite.

In humans, the sporozoites introduced in the blood stream by an infected anopheles mosquito develop within 5-12 days into pre-erythrocytic (or tissue) schizonts. At the end of this phase, merozoites produced from tissue schizonts are liberated into the blood stream. Invading the blood stream, they start the erythrocytic phase of development. In the R.B.C. they at first appear as ring shaped trophozoites which later enlarge and assume an irregular or amoeboid shape. Following mitotic division of the nucleus, the organism is known as schizont. After several divisions, daughter cells (merozoites) fill the corpuscle, which ruptures and releases them

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(sporulation) to parasitize other RBCs. Some blood merozoites develop into sexual forms (gametocytes) which restart the man - mosquito - man cycle when ingested by a female anopheles mosquito.

Paroxysms of fever coincide with sporulation and destruction of RBCs. The cause of the fever is thought to be related to release of endogenous pyrogens from injured cells. So it is obvious that when fever has subsided the released merozoites have already invaded other RBCs and will be demonstrable in peripheral blood smear. One need not wait for the paroxysm of fever to demonstrate them. It should be stressed that demonstration of the parasite depends upon the degree of parasitaemia. When it is scanty, meticulous search is the only option, while in heavy parasitaemia it is easily detected.

Peripheral smear may not show the parasite at the first instance. Hence it should be repeated 3 or 4 times at 4-6 hrs interval. Both thick and thin smear should be prepared. It is needless to point out that the technique of taking blood sample and subsequent staining should be correct. Thick films should be examined for at least 5 minutes (corresponding to approximately 100 microscopic fields) while a thin smear must be examined for 15-20 minutes before issuing a negative report. Blood smear should be examined for 2-3 days, in case of a negative report.

A. Mitra

Quality Health Care : A Crying Consumer Need

N.M. Mathew

Medical services have been progressively becoming more and more complex and sophisticated, with the rapid advancements in medical technologies. With the increase in consumer awareness and expectations, health care managers today realize the need for total quality management in health care services, to make it effective, economical and relevant. Health managers need an enabling system to ensure that the people associated with the delivery of health care at different levels, monitor, evaluate and account for their own work and, thereby, provide quality care to patients on an ongoing basis.

Supreme Court Intervention

The Supreme Court judgment of November 13, 1995 bringing medical services in the ambit of Consumer Courts was historic in many respects. It had a great spin-off for the consumer movement, on the positive side, and a strained patient-doctor relationship, on the negative.

This verdict has been an affirmation on the doctors' responsibilities towards health consumers, suggesting a greater need for transparency in matters of investigations, records and charges. Accountability has to be established everywhere, not only in the private sector but also in the the public sector. Even though free medical care remains outside the purview of CPA 1986, there are already established precedents to take care of this aspect, as can be seen from the writ petition (c) No 796 of 1992 in the matter of Paschim Banga Khet Mazdoor Samity & Drs. vs. State of West Bengal, decided on 6-5-1996. In this case, the petitioners filed a case against the State run hospitals for indifference and callous attitude on the part of state medical authorities. They argued that the patient's Fundamental Right under Art. 21 of the Constitution was at stake. The Supreme Court agreed with this view and held that the State had violated the Right to Life and awarded a compensation of Rs 25000 to the petitioners' wife.

The Court ruled that providing adequate medical facilities for the people is an essential part of the obligations undertaken by the government in a welfare state. The medical officers employed therein are duty-bound to extend medical assistance for preserving human life. Failure to do so, amounts to violation of Art. 21.

The most significant aspect of this ruling was the guidelines issued by the Court to avoid occurrence of such incidents in future. These included upgradation of PHCs and intermediate groups of hospitals like the district, sub-division and state hospitals. It directed that serious patients should be

necessarily admitted in hospitals for which a Central Bed Bureau must be established besides setting up of regional casualty or traumatology hospitals. The State government accepted the recommendations in August 1995.

The obligation of the State machinery to provide emergency medical services to the injured to preserve life had already been established in Pt. Paramand Kataria vs. Union of India & Ors. 1989 (4) SCC 286.

Cross-Practice

Cross-practice is one where a person trained in a particular system of medicine adopts treatment methods of another system, in which he/she has no training. This is very dangerous and are detrimental to consumer interests, besides being unethical and illegal. Safety and quality of care are not guaranteed in this process.

Consumers won a major battle against medical malpractices when the Supreme Court came down heavily on this issue in a recent judgment. The SC stated that the person who studies one system of medicine but practices another is a quack and charlatan and guilty of medical negligence.

Here is a case of a Bombay-based Dr Ashwin Patel, a registered homeopath, who treated a patient, Pramod Verma, with allopathy drugs for suspected viral fever. He gave the patient two antibiotics, paracetamol and an injection of a sodium compound for fever and back pain on 4th July 1992. The second antibiotic was for typhoid, even though there was no confirmation of the disease through investigation. The patient became unconscious and died in a nursing home ten days later.

Interestingly the National Commission did not find anything wrong with the way Dr Patel handled the case, not even in his practicing allopathy. The SC overruled the Commission and awarded Rs 3 lack compensation plus Rs 30000 as costs to the petitioner, only because Dr Patel, even when he had exercised reasonable care and skill, had practiced allopathy without being qualified in that system and therefore, he was guilty of negligence per se, which needed no other argument or proof to establish the negligence.

The Court said negligence has many manifestations - it may be active or passive, collateral, continued, criminal, gross, hazardous, willful or reckless, or negligence per se.

The problem of quackery cannot be eliminated by this judgment alone. Lot more coordinated actions are needed to weed out this menace. There is yet another big question as what can be done to those who practice medicine without any training in any system?

Another important legal intervention was made by the Bombay High Court. In a landmark judgment pronounced in January 1996, the Court directed that copies of case papers must be given to the patients on demand by the hospital/doctor. These cannot be denied to them in the guise of being 'confidential'.

Burgeoning Private Sector

The profit motivated private sector is a serious factor to be reckoned with in the health scenario of the country. About 75 per cent of outpatient care is handled by this sector. The cost of health care invariably is high. But many people prefer this sector because of easier accessibility and better attention. It has been found that private doctors prescribe a larger number of drugs compared to government doctors. This has both cost and safety implications. Added to this are the other malpractices of unnecessary investigations, prolonged hospitalizations, unregulated charges, ghost surgeries, referrals with vested interests, promotion of particular brands of drugs for monetary gains and the like.

Intervention by N.H.R.C.

In an interesting turn of event, the National Human Rights Commission (NHRC) has recently decided to take up the task of scrutinizing the functioning of the private sector, having been seriously concerned over the mounting complaints of medical negligence. The Commission will examine the various aspects from the human-rights angle which include the registration of private nursing homes, their grading on the basis of the facilities available, frequent monitoring of these facilities to ensure that they are maintained, framing of regulations and making their violations punishable and, finally, shifting of private hospitals from non-conforming areas if they pose health hazards to the local residents. It will also investigate whether nursing homes employ qualified medical practitioners and have adequate medical infrastructure, blood banking facilities and proper disposal of hospital wastes systems.

Only 120 out of the estimated 1700 private nursing homes in the capital are registered with the Delhi government. The issue of registration of private nursing is pending adjudication in the Delhi High Court.

The Commission decided to take the plunge as a result of the petition filed with the Commission on the death of a 14 year old girl, who was admitted in a west Delhi private hospital with complaints of stomach pain. She died on the operation table soon after being administered spinal anaesthesia. The compensation claimed is Rs 27 lakh. The prestigious Escorts Heart Institute has been sued in another case of a 2 year old girl for alleged negligence and compensation of Rs 20 crore.

Need for Regulation

CPA and other health related legislations would do a great deal to bring discipline in this sector. But there has to be other methods as well to deal with this problem.

One way is to enact/revitalize and enforce the Private Hospital/Nursing Homes Act. Delhi had such an act in 1956. Hopefully, as per assurance from the Delhi Health Minister, this Act will be revived in the near future. This Act is meant to regulate private hospitals and nursing homes by setting up standards for quality, service conditions, personnel, disposal of hospital waste, keeping of hospital records and reporting.

The Bihar Government has already introduced a similar bill. But the NGO hospitals are up in arms against the requirement in the bill, for yearly renewal of license to run the hospital/nursing home for a fee ranging between Rs 10,000 and 150000 depending upon the bed strength and location.

Another major initiative towards better quality health services is the Delhi Govt. programme on promotion of rational drug therapy in its hospitals. This programme has tried to put into practice the concept of essential drugs. The Govt. prepared a list of essential drugs and asked the hospitals to use 80% of their budgets only for these drugs. The remaining 20 per cent was left to the discretion of the hospital to meet the specialized needs. The Govt. seems to have met with some success in this area.

Doctors' Responsibilities

Doctors' responsibilities stems from the fact that they are dealing with human beings who are sick, and not some commodities to be disposed off. The patients are victims of some affliction needing attention which the doctor is duty-bound to offer, out of professional compulsions and out of pure human concern.

There are several measures a conscientious doctor can take to make his/her medical practice purposeful and efficient.

*** Medical Audit**

Medical audit is a method of objective evaluation of the quality of medicare. This is conducted by the service providers themselves (in-house; the treating physicians and the medical administrators) supervised by a peer group. It helps detect deficiencies in the health care service provided, to improve attitude, skill and knowledge of the providers and to ensure collective responsibility and accountability. Medical audit involves audit of structure, process, outcome patient satisfaction, economics and cost. An effective medical audit system for improving health care facilities, should have a performance parameter and should cover health care related laws/consumer laws and medical ethics.

** Rational Drugs*

The campaign towards rational drug therapy should be supported and encouraged at all levels. Governments should be urged to adopt policies on essential drugs, similar to that of the Delhi and Tamil Nadu Governments. States should immediately come out with list of essential drugs, with suitable regional variations to the list recently released by the Central Government.

** Professional Bodies*

Formation of new professional networks or joining with already existing associations like the Medico Friend Circle or other professional bodies should be encouraged among doctors. (VHAI is also in the process of building up a Doctors Forum for the socially conscious and progressive minded doctors).

** Continuing Education*

A system of continuing education for doctors should be streamlined so that they have access to the latest advances in the medical science which will delink them from the influences of drug companies. This process would also require development of effective communication materials for these doctors.

** Legal System*

The legal system needs to be tightened up to properly regulate the services of doctors to urge them to care for the patients as their first priority. The nursing homes act or other similar acts should be enacted in all the states.

** Redressal Support*

Finally, assistance to the victims of medical negligence is of paramount importance. Generally the gullible patient is unable to establish the guilt of the doctor in a court of law, hence the high failure rate. Consumer bodies should elicit support of medical experts to give evidences in the courts in support of the complainants.

"The doctor aims a drug at a disease; sometimes it hits, sometimes misses. The misses are left out of account, the hits treasured up, reckoned and systematized into a science"

- Sri Aurobindo

Source : VHAI

Non-allopathic doctors form the backbone of rural health

H. S. Bawaskar

Introduction

India is a country of villages. Most villagers are illiterate, innocent farmers who are busy round the clock all through the year. They are unaware of medical facilities in or around the village till they fall sick. They do not plan for measures to be taken if and when they are ill, nor do they participate in any medical insurance schemes. They are entirely dependent for medical care on the practitioner in or near their village. They call any person giving drugs and injections 'Doctor'. When facing him, they are interested only in getting well and not in the qualification of the doctor or what '-pathy' he follows.

Health pattern in rural areas

Government Health Service	Location	Private health service
Civil Hospital	District headquarter	Nursing homes Specialists, GPs Visiting specialists Few non-allopaths
Rural hospital or cottage hospital	Taluka headquarter	Nursing homes GPs, surgeon, physician, Few non-allopaths
Primary health centre	Peth	Non-allopaths Occasional MBBS doctor Visiting MBBS doctor
Health visitors Malaria workers SEW, SW centre	Village	Non-allopaths Visiting MBBS doctor
Visiting health worker?	Kond or wadi	Quacks, mantriks, village healer, visiting non-allopath

Villagers usually seek medical help when they are seriously ill or when illness disallows work. The common problems one encounters in villages are acute dysentery, gastroenteritis, malaria, hyperpyrexia, convulsions, hepatitis, bronchopneumonia, fevers, infected scabies, conjunctivitis and bites (snake, scorpion, fox, dog). Of course, one also has to deal with pregnancies and difficulties in labour.

Due to non-availability of public transport, when a person falls sick in the dead of night and is seriously ill (snake bite, scorpion sting, obstructed labour, eclampsia, acute gastroenteritis...) the patient is placed in a wicker basket and carried to the nearest public health centre or to a private practitioner at the taluka headquarters.

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Government health service

Civil Hospital This is located at the district headquarters, is well equipped and has a consultant physician with ancillary staff. Patients are referred there from the primary health centre, cottage or rural hospital, or private nursing homes. The Civil Hospital of Raigadh District is located at one corner of the district headquarters at Alibag. Patients prefer to go to Bombay instead of the Civil Hospital there.

The civil hospital should be sited in a centrally located place, which can easily be approached. As matters stand, the consultant at the civil hospital, its medical officers and others are often busy with their private practices. What little time they do spend at the hospital is often spent in issuing medical certificates, conducting medical board examinations and attending to VIPs.

Cottage and rural hospitals These are located at taluka headquarters and are supposed to possess indoor beds, staff and radiology and laboratory facilities for investigations. These machines are often out of order. Technicians are rarely to be found there. Xray films or chemicals for developing them are usually out of stock. The medical superintendent possesses a postgraduate qualification. Other medical officers are diploma holders. The nursing staff is inadequate.

The environment in and around the hospital is filthy and not conducive to health. Bedside lockers are broken, the mattresses stink, bedsheets soiled and toilets dirty beyond imagination. Few are willing to get admitted to these hospitals. The abjectly poor must, perforce, seek help here and lie on these beds. They are made to feel highly obliged to the staff. The doctors are busy attending calls in private nursing homes. Soon after they join the hospital, they start building their own nursing homes and once these are ready, resign.

Primary health centre This is located at the peth or large village and is intended to cater to the medical needs of a population of fifteen to thirty thousand. Here the conditions can only be compared to those in cow sheds. The centre is spick and span only on the auspicious day of its inaugural by a VIP. The medical officer is rarely available. He may visit just for a few hours to conduct an outpatient clinic. The rest of the time is spent in private practice or 'table practice' (charging patients examined at the centre). When I stopped this practice, I was harassed by all authorities

including the local politician when I compelled these medical officers to work - as they are supposed to - without charging their patients.

These medical officers are supposed to collect data on immunisation, ante-natal care and family planning. Their sincerity and awareness can be judged from the fact that they claim to have inserted more copper-Ts than the number received by the centre. The consequence: population storm.

The only person available at the centre all the time is the humble servant who informs anyone who calls that the doctor is not in. Even victims of snake-bites have to move from centre to centre, ultimately landing up in a nursing home.

The total absence of rational and ethical therapy is especially evident in the case of a pregnant primary teacher who was brought to a government dispensary soon after a dog-bite. The person in charge refused to administer anti-rabies injections for fear of teratogenic consequences. The woman died of rabies. It did not occur to this person that an abnormal foetus can always be identified and terminated but a dead mother cannot be brought to life.

Adivasis, other tribals and all except the most poor shun government services.

Government hospitals serve but two purposes: 1. To register medico-legal cases - who are transferred elsewhere once the first aid has been offered. 2. Stepping stones for their doctors who flourish and soon start their own nursing homes in the same area. Sick government hospitals and clinics have permitted allopaths and non-allopathic medical practitioners to flourish in rural India.

Private health services

Allopathic doctors They crowd in district and taluka headquarters where multi-storied nursing homes mushroom. Radiology, sonography, endoscopy and cardiac monitoring are easily available. The staff watching the cardiac monitor may not be able to identify abnormalities on the oscilloscope or use the defibrillator.

Whilst sophisticated gadgets are freely available, their usage is questionable. A patient with a renal colic will be subjected to plain xrays of the abdomen, intravenous pyelography and sonography. Examination of the urine will be done only after these have been completed. Xrays and ECG are carried out on requests by patients and their families rather than on referral by consultants. Patients move from doctor to doctor. If one consultant advises against an investigation demanded by the patient, they will go next door to a more obliging doctor.

Surgeons claim that there are few patients in rural areas for them to operate upon. They thus add midwifery to

their trade and diagnose obstructed labour that necessitates Caesarian section.

Allopathic doctors are unwilling to move to the villages because of personal or family compulsions. The key factors cited are lack of facilities for the education of their children and paucity of outlets for recreation.

Non-allopathic doctors This group comprises of those who have qualifications such as BAM&S, BHMS, DHB, LCEH, GFAM and those who are registered medical practitioners (RMP), vaidyas professing ayurveda and unani practitioners. They include village healers (mantriks) and quacks. They reside in the villages, participate in all the activities of the community and are available to patients round the clock. They are truly family physicians and villagers repose confidence and trust in them. They treat all acute illnesses with commonly used allopathic drugs, give intravenous fluids and injections. Their poor understanding of the science of modern medicine leads to grave errors as when injecting atropine or digoxin, administering corticosteroids and prescribing chloroquin, quinine and diuretics. Leeches are frequently used.

I must refer to retired vaccinators, malaria workers, operation theatre assistants, wardboys and compounders serving as non-allopathic doctors without any additional training. They prescribe allopathic drugs and give injections to villagers.

Non-allopathic doctors and allopathic therapy

Non-allopathic doctors are sincere and eager to learn allopathy. Let me provide some examples. In the villages where I work, scorpion stings are not uncommon. Many victims died of pulmonary oedema. I was able to reduce mortality from this complication by using prazosin. I have travelled throughout this region and have done my best to spread this knowledge through talks, slides and demonstrations to all doctors, regardless of their background. I later carried out a postal survey¹.

Results of postal survey to assess effects of training on treatment of victims of scorpion-stings

Reporter	Number	Total cases	Systemic involvement	Treatment given	Fatal	Mortality
Physician - MD	7	287	166	Prazosin	2	1.2
MD (Ped)	3	67	33	Prazosin	4	12
MBBS	35	2971	251	Prazosin	5	1.9
Non-allopath	6	197	79	Prazosin	2	2.5
Physician - MD*	2	24	13	Conventional therapy	5	38

*= consultant not aware of the utility of prazosin
Conventional therapy= digoxin, frusemide, atropine, corticosteroids

I found that these non-allopathic doctors were now diagnosing and treating these victims of scorpion stings effectively with a low mortality whilst a postgraduate allopathic doctor was unaware of the use of prazosin and reported a high mortality whilst using conventional therapy.

The second example is from Gadchiroli.² Villagers were trained to record the respiratory rate of children with bronchopneumonia and estimate the severity of the disease. Excellent results were obtained using co-trimoxazole.

The third example is that of an ayurvedic doctor who was trained in the administration of general anaesthesia. From 1978 to 1994 he was the only anaesthetist in Mahad. He provided excellent anaesthesia for patients operated upon by seven surgeons in Mahad, Mangaon, Srivardhan and Poladpur talukas. He was even able to demonstrate the ideal technique for cardiac resuscitation to the cardiologists in the region.

Health care can thus be provided to villagers without a single allopathic doctor. It will be necessary for the authorities to help the non-allopathic doctors. Each of them must be provided training at a functioning civil hospital where instruction on drugs and their usage should be imparted. Special care must be taken to emphasise side effects and complications and caution them against drugs beyond their competence. They should also be made to undergo annual training programmes to update their knowledge. (Such continuing education is equally necessary for allopathic doctors.)

Irrational practices

Farmers and labourers in villages develop an irrational faith in the potency of intravenous injections in the treatment of *vat* (illnesses such as myalgia and paresthesiae supposed to result from imbalance of the four humours). Calcium gluconate is their drug of choice and is routinely administered by allopathic and non-allopathic doctors on demand. The consumption of this drug jumps during the pre-monsoon season and in October when there is a lot of work to be done on the farms.

The treatment of tuberculosis also invites criticism. In many cases a few injections of streptomycin and tablets for a few days is all the patient receives. In clinics run by the government, only patients with positive sputum are given bactericidal treatment.

Patients with severe anaemia are given blood transfusion without determining the cause or continuing long-term medication to prevent recurrence.

The unkindest cut of all is when the terminally ill, brought in gasping, are sent home so that the hospital or

nursing home does not have a death on its premises. At times, lack of transport is used as an excuse by relatives to take such patients or even the corpse home.

Dilemmas consequent to Supreme Court ruling

Confronted with the recent ruling by the Supreme Court disallowing non-allopathic doctors from using allopathic drugs, I am in a quandry.

Suppose a villager suffers severe anginal pain and the only medical attendant in his vicinity is a non-allopathic doctor who has often used nitroglycerine successfully in such patients, should the doctor be allowed to prescribe this drug or not? This question becomes even more relevant when the non-allopathic doctor later learns that a consultant cardiologist has prescribed the same drug in the same dose for his patient.

I have taught non-allopathic doctors to treat the victims of scorpion stings with prazosin. Several lives have been saved thus. Should these doctors now be disallowed to administer this drug in the absence of any other medical attendant?

Conclusion

The Supreme Court decision needs review if the health care system in our villages is not to collapse. There is no dispute over the need to ensure adequate training of non-allopathic doctors with provision for continuing education programmes and certification. We need to ensure that the medical practitioner does not deteriorate into a drug pusher.

Allopathic doctors need to be cautioned against disparaging their non-allopathic colleagues. We are well aware of the fact that most Indian medical colleges are of low standard. Our journals are full of shoddy papers with little or no peer review. The medical profession consisting of allopathic doctors is no more respectable or noble. The practice of medicine has degenerated into commerce.

Whilst the allopath demands huge sums from the patient, the non-allopathic doctor in the village is content with poultry, lemons, coconuts and clothes from his patients. As I ponder these facts, it occurs to me that Mahatma Gandhi would have been greatly saddened at the sight of the educated in the medical profession deceiving the illiterates whilst approaching the 21st century.

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INFO PACK FOR DOCTORS

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Jan. - Mar. '98

INTRODUCTION TO DOCTORS FORUM

Dear Doctor,

The idea of forming a *DOCTORS FORUM* in *VHAI* is gaining momentum since 1996.

The purpose of the *Doctors Forum* is to build up an active network of socially conscious Doctors, who are open to new ideas in Health Care to come together to share ideas and experiences.

VHAI would like to build up and support a professional group of Doctors who could think and act alternatively to provide rational Health Care, where people are given prime importance. Special emphasis would be given to the area of preventive and promotive Public Health care.

Doctors Forum is planning to take up the following initiatives:

- * To provide a platform for the Doctors to share their views regarding their profession and the burning health issues of the country.
- * To send Information Packages for Doctors as a part of continuing medical education especially for Doctors working in remote areas.
- * To debate and discuss about various health policies and technologies emerging in India and provide alternate suggestions.
- * To collaborate with the existing network like *IMA*, *CMAI*, *CHAI* & *MFC* and work together for a common cause.

In short, *Doctors Forum* is a proactive and futuristic group for Doctors who could be in the forefront to take up health issues and find solutions to public health problems in India.

Enclosed is the *INFO PACKAGE FOR DOCTORS*. This is the second package we are sending you as a part of continuing medical education.

Kindly fill in the feedback form and send your comments and suggestions. Please send the addresses of Doctors who would benefit by this package.

Thanking you in anticipation.

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To Drs ARS/RRP/DX/VB/CMF
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