Ref: CHC: 4.5/98 17th September, 1998

Dr. D.V. Saldhana,
Chairman,
National Blood Transfusion Council,
Ministry of Health,
Nirman Bhavan,
New Delhi

Dear Dr. Saldhana,

Sub: Blood Bank - draft rules (15th December 1997)

We are happy that the Rules for Blood Banking are being reconsidered. We have the following suggestions:

1. Unbanked Directed Blood Transfusion

There is great need for blood as a life-saving measure in villages where there may not be recognized blood banks. The only way to save lives (e.g., in rupture of tuboid pregnancy) is to give blood made available by relatives and volunteers. Valuable time will be lost, leading to irreversible shock if the relatives/friends have to go to recognized blood banks in the cities/towns, collect blood after the necessary tests and transfer the blood. It is therefore suggested taht we recognize the life-saving role of Unbanked Directed Blood Transfusion to be carried out by a registered medical practitioner in emergencies and in situations where delay can threaten life.

2. Space for Blood Bank

We must have enough space for the proper functioning of blood banks but it need not be lavish.

In India, many of the "blood banks" are mainly blood collection and storage banks, without component separation/preparation, except possibly separation of plasma and cells. The requirements for such banks will be less than those where components are separated/prepared.

In the ordinary blood banks, there is no need for:

i. separate rooms for group serology and infectious diseases serology; one room would suffice;
ii. airconditioning being made mandatory; it may be prefered;

iii. insisting on 150 sq.m. space. About half that space is ample to carry out all the articles of our blood bank (without separation/preparation of components). Insisting on too much space increases the capital expenditure and expenses on upkeep. It must be insisted that the place (including floor, walls, furniture, etc.) must be kept scrupulously clean.

3. Blood component production centres

The requirements for the component separation/production centres will be larger.

The supervisory person should be a graduate in Medicine with further training in Blood Banking and components separation/production of at least one year in a recognized institution, with all the necessary facilities.

4. Deferment of blood donation in case of haemorrhage or illness

It is a sensible idea to defer blood donation in cases of blood loss. Where there is blood loss of moderate severity, at least 120 days (4 months) must intervene. This will ensure safety to the donor. Similar consideration should apply in cases of illness also.

5. Voluntary Blood Donation

We must take all steps to root out commercialization of blood transfusion. Buying (professional donors) and selling blood (commercial blood banks) should be stopped.

6. Blood Donation Camps

Voluntary agencies, who can get the services of recognized blood banks, should be encouraged to conduct blood donation camps. This will especially be useful in educational institutions (colleges), factories, police camps and various other places.

Yours sincerely,

C M Francis

Dr. C.M. Francis,
Community Health Cell.

14-9-[redacted]

Dear Ravi,

I agree with most of the suggestions and especially

(1) Unbanked Directed Blood Transfusion to be done in the villages, as part of an emergency measure (Should there be Registered Village Transfusion Centres?).

(2) No need for separate rooms for group serology and infections diseases serology

(3) No need for airconditioning being mandatory; it may be preferred.

(4) There is no need for 150 sq M space. A space of about 70 sq M is more than ample. At St. Martha's Hospital, we provided in the new building 80 sq M. Where there is no component production, 70 sq M will be sufficient

(5) For blood component production, the supervisory person should be a graduate in Medicine with further training in Blood Banking and component production of at least one year in a recognized institution having the facilities.

The period of deferment should not be reduced. Where there is blood loss of a moderate severity, at least 120 days (4 months) must intervene.

(7) Printing MRP ? We should go allout for voluntary donation. The charges should cover only the overheads and cost of the tests. But, this may not happen for some time.

I have not seen the "draft rules" of the Drugs and Cosmetics (Amendment) Rules, 1997 published by GOI

C. M. Francis
14/9/98

To Dr CMP →

Dear Sir. 12/9/98

Arcot had requested me during my last visit to get CHCs Pune to participation in the issue of 'elitist' standards being recommended for Blood Banks. I had told him that you had been concerned about this already and had considered some alternatives in your work on Quality Standards. Alternative He would like you to critically look at the enclosed literature and

1) Send a response to DGHS - Blood Bank unit as CHC participation in the dialogue

2) Send him any comments or different opinion or suggestions on the Lok Vidnyan Sanghatana's recommendations and letter.

We could discuss this with others in the team if required.

Thanks Ravi

LOK VIDNYAN SANGHATANA
HEALTH COMMITTEE

759 / 97, D, Shanti Bhuvan,
Prabhat Rd. Lane No. 2, Pune-411 004
Telephone No : 373173 (off)
Contact Nos. : 341230, 436981, 334816

2.9.98

Dear friend,

Greetings from Pune !

Some of us in Pune (myself, Dr Ashok Kale of NMO, Dr. S.V. Gore of Sevadham Trust) and Dr R.R. Tongaonkar of Dondaicha, Dhule district, have been lobbying against some of elitist, anti-people existing rules and the new draft rules related to blood banking. Enclosed herewith is a consensus note that emerged out of a discussion of various experts, convened by the health-committee of the Lok-Vidnyan Sanghatana. This note gives an idea about the issue. I hope, you would broadly agree with this note.

This is to request you to send a letter to Dr. D.V. Saldhana, Chairman, National Blood Transfusion Council, Ministry of Health, Nirman Bhawan, New Delhi, pointing out that the proposed draft rules would further drprive the rural poor from access to blood, by making the blood or its components unnecessarily more costly and even physically more inaccesible.

You may demd the following :-

1) Make Unbanked Directed Blood Transfusion to be done in registered Village Blood Transfusion Centres, legally valid.
2) Scrap the requirement of (a) separate rooms for group serology, and infectious diseases serology. (b) air-conditioning the bleding room and the laboratory, (c) A space of a minimum 150 Sq.metres, (d) A full time post-graduate medical person to superwise blood component manufacturing.

RN
12/9
To Dr CMF for needful →

could we file these in a policy resource file on blood banking
TN

3) Change on scientific basis, the period of deferement of blood donation in case of certain illness/condition of donors.

4) Make it mandatory for blood banks to print Maximum Retail Price of the blood on the blood-bag.

You may mention that you endorse/agree with the Lok-Vidnyan note as published in the July-August issue of BODHI.

I am sure, you would certainly find time out of your busy schedule to send such a letter to Dr. Saldhana. If many many rural health-organizations oppose these new draft rules, it is only then that there will be some change.

Please do send me a copy of your letter to Dr. Saldhana. Last week, there was news in all papers that NGOs, people's Organization should send their comments to Dr. Saldhana within two months. By the time this letter reaches you, almost a month would have already gone.

With best wishes and regards,

Thanking you,

Sincerely yours,

A. Phadke

Enc: as above.

(ANANT PHADKE).

Draft Rules for Blood Banks - Suggested Modifications

The Health - Committee of the Lok-Vidnyan Sanghatana is a sub-committee of doctors of the Lok-Vidnyan Sanghatana, a registered body. The Health Committee works for public interest. It discussed in a specially convened meeting on 27th January 1998, the "draft rules" of the Drugs and Cosmetics (Amendment) Rules, 1997, as published in the Extra Ordinary Gazette, of the Central Government of India, dated 15th December 1997. Different experts - surgeons, obstetricians, physicians, paediatricians, dermatologists, haematologists blood-transfusion officers, community health experts, pathologists and other doctors participated in this meeting.

The overall opinion of this group of experts about these draft rules was that some of the provisions in these rules would unnecessarily increase the cost of the blood with hardly any increase in its quality and that some of the important issues in the blood-transfusion sector have not been dealt with at all. We deal below, with the latter aspect first.

1. ISSUES MISSING IN THE DRAFT RULES

1.1 - **Unbanked Directed Blood Transfusion (UDBT)**

1.11 - UDBT - a safe procedure - UDBT involves, first selecting an appropriate donor of a compatible blood group, carrying out mandatory screening tests (for malaria, syphilis, HIV, Hepatitis - B) on the donor as well as major and minor cross-matching and then to transfuse his/her blood to the patient, without storing it in a blood bank.

UDBT is as safe as giving banked blood and was widely practised. After the advent of blood banks, it has become out of fashion especially in cities, partly because it is an easier option for a city-based surgeon/physician, as the whole responsibility about safety of the blood is taken over by the blood banks. But rural surgeons, obstetricians, physicians have continued to practice UDBT. However, with the onset of HIV-epidemic, UDBT had stopped, partly because single test kits for HIV-tests were not available in the early nineties and partly due to official disapproval. Now single test kits for HIV-test are available and yet the official disapproval for UDBT continues.

1.12 - Advantages of UDBT-

UDBT has several advantages over banked blood -

i) It avoids the metabolic problems caused by storage of blood e.g. (hyper kalemia, depletion of 2-3 DPG levels and hence oxygen carrying capacity) as well as avoids depletion of platelets and coagulation factors, which are necessary in certain cases.
ii) It makes blood available to the patient at the earliest; saves precious human power, time (up to 6-8 hours) travel-costs, loss of wages for the relative who has to go to the city to fetch blood.

iii) It avoids commercial donors. Though commercial donors have been banned, if a villager is asked by the blood-bank to bring a replacement donor, the villager would resort to the commercial donor hovering around the blood bank, as s/he has no friends, relatives in the alien city, to give replacement donation. UDBT would avoid this scenario and would be one of the chief measures to stop commercial blood donation.

1.13 - Blood Transfusion Centres for UDBT -

Given the safety and the advantages of UDBT, it should be explicitly legalized and controlled. We propose the following -

There should be a section in the Drugs and Cosmetics (Amendment) Rules 1977, on UDBT. This section should lay down the requirements and the procedure to be complied with for setting up of Unbanked Directed Blood Transfusion Centres (UDBTCs).

There is a precedence of legal Medical Termination of Pregnancy Centres (MTP-centres) under certain conditions.

The hospital applying for UDBT registration should have a qualified doctor who is also trained / has the experience of working as a Blood Transfusion Officer in recongnised Blood banks for say a month, so that s/he has sufficient experience in matching and cross-matching of blood and the aseptic precautions needed for collecting blood.

The UDBTC need not have its own laboratory to do the mandatory screening test on the donor. But a qualified pathologist's test-report, done within say 48 hours prior to blood-transfusion certifying that the tests for all the 4 blood-borne, infectious diseases are negative must be given. The report should also specify the haemoglobin level and blood group of the donor. This report should be mandatory.

The UDBTC should be required to keep record in an approved format specifying name, age, sex, address, and results of the blood-tests etc. This record should be available for inspection by the concerned officials.

2. Testing the donor's blood before bleeding -

Under the existing protocol, a donor's blood sufficient for blood transfusion is collected and then the mandatory screening tests are done on a sample from this collected blood. If any of the tests turns out to be positive, this blood is naturally rejected. But in the process, the drawn blood is wasted. A better option would be to test the donor's blood first and bleed him/her only if all the tests are negative. This would avoid unnecessary wastage of blood. The donor must be tested within a week preferably within 48 hours prior to bleeding, so that the chances of the donor getting infected within these two to seven days are minimal. It may be pointed out that testing any way is not fool - proof, especially in view of the 'Window Period' and there is no point in wasting blood in the pursuit of the unattainable mirage of zero-risk blood.

We, therefore, propose that the following be inserted as clause 1 in section K, in the draft-rules titled 'Testing of Whole Blood'.

1 Mandatory screening tests to detect common blood-borne infectious diseases and tests for Hb-level, blood-group of the donor may be conducted within a week and preferably within 48 hours before bleeding the donor..The donor should be bled if his/her blood is found suitable after these tests.

Existing sub-clause 1,2,3 in section K in the draft-rules would become sub-clause 2,3,4 respectively.

It may be pointed out that the existing rules focus attention exclusively on the on the product, i.e. the blood stored in the pack. By allowing the tests to be done on the donor's blood before collecting it in the pack, safety or responsibility is not compromised. If the basic aim of making rules is achieved, flexibility must be allowed and a blinkerd view should be avoided.

3. Honouring the Blood Donation Cards -

Blood donation cards given to voluntary donors are honoured only by the same institution and not by others. The donor later on may require blood in some other area or institution and feels frustrated when s/he can not get blood when needed, even after having donated blood earlier, in many cases several times. This dampens the tendency to donate blood regularly and people prefer to donate only when a specific need arises in their family or against friends.

There is absolutely no rationale for not honoring the donor - cards of other blood banks, since the blood bank doesn't incur any loss in doing so. All the expenses of testing and banking are borne by the patient. The blood-bank gets blood free and hence does not incur any loss by honouring the donor-card of any other blood bank.

We therefore propose that these should be a clause in the draft rules making it mandatory for blood banks to honour the donor-cards of other blood-banks. (This will be of course subject to the availability of suitable blood in the bank at that time.)

4) EXEMPTION FOR AUTOLOGOUS BLOOD TRANSFUSION (ABT)

ABT is the safest mode of blood transfusion and is the most preferred mode whenever feasible for planned surgery. In section 122-EA, in para a, autologaus blood transfusion has been defined. But no reference has been made through out the draft rules. In case of ABT, there is no need to conduct any tests on the blood since the patient's own blood is to be transfused back to the patient. This exemption should be specifically granted in section K of Part XII B of the draft-rules. Similarly, in section M, titled 'Labels', a para should be added.

In case of autologous blood transfusion, the label need not contain the group or the results of screening tests since these tests are unnecessary in such instance. The label shall contain the classification 'Autologous Blood Donor.'

2) MODIFICATIONS NEEDED IN THE DRAFT - RULES -

In the interests of the patients and of public health, we feel that the following modifications are required in the draft - rules -

2.1- Part XII B, subsection B, titled - Accommodation for a blood bank -

A total of 150 sq. metres' space stipulated in this sub-section is excessive. This unnecessarily increases the overheads without enhancing quality. Good quality blood banks were operating with lesser space.

Two separate rooms for blood group serology and for testing for blood-transmissible diseases, is quite unnecessary. Similarly, for smaller blood banks with a turnover of say less than a thousand bottles per year, a separate stores-cum record room is not needed.

2.12 - This section B specifies that the bleeding room and the laboratory should be air-conditioned. This would unnecessarily increase the cost of the blood without enhancing the quality.

This section should specify that entry to the bleeding room and the laboratory should be highly restricted & it should have self-closing doors, and that they should be assiduously kept clean by daily wet mopping of the floor and tables and weekly cleaning of the walls and the top.

Experience shows that this much precaution is sufficient. Reagents etc. can be stored in a fridge and there is no need to air-condition the whole laboratory for that purpose. (A.C. temp. is in any case means higher than 2 to 8^0 c)

2.2 - Deferment of blood donation -

In section H, the table titled 'Deferment of blood donation' specifies conditions afflicting the donor, for which blood-donation should be defered for the safety of the donor or the recipient. Some of the restrictions specified in the table are unnecessary and hence unnecessarily reduce the already limited pool of voluntary donors in India.

The table below gives our suggestions along with the rationale, about changes needed in the draft - rules.

Deferment of blood donations - modifications suggested

No.	Condition	Period of deferment as per draft-rules	Modifications suggested with rationale
1.	Abortions	6 months	6 weeks. The average blood loss is 100 to 200 ml. In any case a person can loose blood up to 300 ml every 3 months without risk.
2.	Minor surgery	3 months	No restriction needed. There is hardly any blood-loss in minor surgery.
3.	Major surgery	6 months	6-12 weeks. Effects of surgical trauma are overcome within this period.
4.	Typhoid	6 months after recovering	12 weeks after the attack. There is no rationale for deferment after full recovery.
5.	Breast feeding	6 months after delivery	6 weeks after the delivery. The mother fully recovers from the stress of delivery. The stress of breast-feeding is no scientific bar on blood-donation.

2.3 - **Tests to be conducted on the donor's blood** -

Under section K of the draft-rules, tests for only HIV- I, HIV - II antibodies and for HBs Ag have been mentioned. This is welcome since tests for malarial parasite and for VDRL have been found to be of no practical value. Malarial parasite is extremly difficult to detect and both malarial parasite and spirochaetes die within 48 - 72 hours of stored blood. VDRL can act as a surogate indicator of sexually transmitted disease including HIV and may be retained. However, in the section L - ('Records') in para 2, the master record includes these two tests. This inconsistency should be corrected by deleting at least the test for malaria from this para.

These two tests should be mandatory in case of UDBT since malarial parasites and spirochaetes in fresh blood can cause infection in the recipient.

2.4 - **Blood Donation Camps** -

In section II of Part XII, B, the draft rules specify that only designated Regional Blood Transfusion Centres or Indian Red cross banks or licensed Government blood banks can organise blood-donation-camps. We propose that any blood bank approved by the government and which complies with the requirements of holding a blood donation camp

as specified in this section II, should be allowed to hold blood-donation-camps. These is no reason why a recognised bank should not held a blood-donation-camp.

2.5 - **Training of the personnel in charge of Blood Component Manufacturing** -

Part XII C, subsection C, gives qualification required for directing and supervising manufacture of blood components; The provision of One year's working experience in the manufacture of blood products/ plasma fractionation is quite necessary. But in the next para, the draft-rules specify that such a person should have a post - graduate degree in medicine / microbiology / pathology etc. In our view, these post-graduate qualifications do not directly enable the person to handle the manufacture of blood-components and a special training is required for it. An MBBS doctor from a recognised university has sufficient broad based knowledge to enable him/her to learn directing, supervising blood component manufacture, by undergoing a year's training / working experience.

The requirement that at least one of the supervising personnel should be a full-time employee is also superfluous. Blood-banks with limited output do not require a full-time medical director / supervisor for blood-component manufacture. We therefore, propose the following stipulation - "The blood-component manufacturing must take place under the direct, personal supervision, guidance of the personnel in charge." If the volume of work is more, this would mean a full-time job for the supervisory person.

2.6 - **Maximum Retail Price (MRP) on the blood pack - label** -

Subsection I in part XII C deals with labelling of the blood-pack. It does not mention the need to mention MRP on the blood-pack. Such mention should be mandatory.

Legally, stored blood / blood component is a manufactured drug and hence its label should mention MRP as in the case of all other drugs. Such mention is necessary as a blood pack is today sold at varying prices from Rs. 300 to Rs. 1800 per pack! When MRP is printed, the blood-bank will have to justify the MRP with the ministry of chemicals and fertilizers. This would stop the exploitation of the needy, helpless patients.

3. CONCLUSION

The draft rules for blood- banks as specified in the extra-ordinary gazette, of 15th December 1997, need the above modifications so that safe blood and blood-components would be available to ordinary Indians at reasonable rates. In absence of these modifications, blood would unnecessarily become mere costly, beyond the reach of most Indians.

It is hoped, that due, serious consideration would be given to the above suggestions. We would be happy to provide further clarifications to the points made above.

❖❖❖

1

URGENT

Date : 4th Aug.2001

Dear Colleagues,

You are aware of our fight for making available safe Blood wherever & whenever required. Unfortunately our demand to legalise 'Unbanked Directed Blood Transfusion (UDBT) has been turned down by the Government & National Blood Transfusion Council, but because of our efforts, the Government has at least started thinking to meet the peripheral Blood demands & has come out with the idea of 'Satellite Blood Transfusion Centre' & now published the 'Draft Rules' to amend the Blood Banking Rules.

We have to take objections or suggestions to these 'Draft Rules' which should reach Delhi Before 16th Aug. 2001.

Therefore you have to hurry up and send on your 'Letter Head' the suggestions & objections to Delhi.

I am enclosing the proposed Draft Rules & a general outline of objections & suggestions.

You may modify, add or subtract any of the matter.

On the face of it the Draft Rules appear acceptable in toto, but I have been given the Confidential information that most of the policy makers want that these centres should be run only by Government Agencies, this will deprive most of us working in shall private hospitals getting these centres & therefore the urgent need to send our objections.

Please send the letter to concerned authorities with copies to relevant people immediately.

Thanking you,

Your sincerely,

Dr. R. R. Tongaonkar.
President, Association of Rural Surgeons of India,
Dr. Tongaonkar Hospital, Dondaicha, Dist - Dhule
Pin code - 425 408. Maharashtra

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics(Amendment Rules 2001.

(2) They shall be published in the Official Gazette.

2. In the Drug and Cosmetics Rules, 1945, in Schedule K, after serial number 5A and entries relating thereto the following shall be inserted namely :-

Class of Drugs	Extent and Conditions of Exemptions
"5B. Whole Human Blood I.P. and/or its components, stored for transfusion by a First Referal Unit, Community Health Centre, Primary Health Centre and a Hospital	The provision of Chapter IV of the Act and the rules made thereunder which require obtaining of a licence for operation of a blood bank or processing Whole Human Blood for components, subject of the following conditions, namely. 1) The First Referal Unit, Community Health Centre, Primary Health Centre and/or other Hospital shall be approved after satisfying the conditions and facilities through inspection. 2) The captive consumption of Whole Human Blood I.P. or its components in the First Referal Unit, Community Health Centre, Primary Health Centre and/or other Hospital shall not be more than 500 units annually. 3) The Whole Human Blood and/or its components shall be procured only from Government Blood Bank and/or Regional Blood Transfusion Centre licensed for the purpose. 4) The approval shall be valid for a period of two years from the date if issue unless sooner suspended or cancelled and First Referal Unit, Community Health Centre, primary Health Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval. 5) The approval shall be automatically deemed to be cancelled if the licence of the Government blood bank or of the Regional Blood Transfusion Centre from where the Whole Human Blood I.P. or Blood Components procured is cancelled. 6) The First Referal Unit, Community Health Centre, Primary Health Centre and Hospital shall have the following technical staff for storage of Blood or its components :- (a) A trained Medical Officer for proper procurements, storage and matching of blood and/or its components. He/ She shall also be responsible for identifying haemolysed blood

and ensure non-supply of date expired blood or its components.

(b) A blood bank Technician with the qualification and experience as specified in part XII B of Schedule F or persons having experience of not less than two years in a licensed blood bank for blood grouping and cross matching.

7) The First Referal Unit, Community Health Centre, Primary Health centre and Hospital shall have a minimum areas of not less than 10 sq. meters of covered area. It shall well lighted, clean and preferably air-conditioned. Blood bank refrigerators fitted with alarm device and recording thermographs of appropriate capacity shall be provided to store blood units between 4 C to 6 C and if the components are proposed to be stored, specialized equipments as specified in part XII B of Schedule F shall also be provided.

8) The First Referal Unit, Community Health Centre, primary Health Centre and Hospital shall maintain records and registers including details of procurements of Whole Human Blood I.P. and/or blood components, as required under Part XIIB of Schedule F.

9) The First Referal Unit, Community Health Centre, primary Health Centre and Hospital shall store samples of donors blood as well as patients sera for a period of seven days after transfusion".

[No. X-11014/3/2001-DMS & FFA]

DEEPAK GUPTA, Jt. Secy.

Foot Note :- The Principal Rules were published in the Official Gazette vide notification No. F. 28 -10/45-H(I) dated 21-12-1945 and last amended vide G.S.R. 242 (E) dated 3-4-01. The Drugs and Cosmetics Rules, 1945 as amended up to 1-5-1979 is contained in the publication of the Ministry of Health and Family Welfare (Department of Health) containing the Drugs and cosmetics Act. 1940 (PDGHS-61)

Sir, Please also find our some more suggestions which are based on our Country wide studies & detailed study of a District in State of Maharashtra. regarding Satellite Blood Transfusion centres.

A questionnaire was sent to 100 Surgeons/small hospitals working in Rural & peripheral areas all over the country & 40 Doctors working at periphery in District Dhule of Maharashtra were interviewed in October 2000. Out of 100 Rural Surgeons we received answers from 29 surgeons.

We also did detailed study of Dhule District regarding use of Blood at peripheral areas in 1998

The outcome & conclusion from these studies were as under :-

1) Across the country from Jammu & Kashmir to Tamilnadu out of 29 respondents 27 were still collecting Blood themselves by what is know as 'Unbanked Directed Blood Transfusion' (UDBT), So also out of 40 Doctors in Dhule District 39 were doing UDBT.

2) The Satellite Blood Transfusion centre should be placed where UDBT is being practised.

3) It should be given to private Doctors also.

4) All agree that minimum two bottles of each group should be stored at the centre at a given time

5) It should be responsibility of the Govt. or Licensed Blood Bank or Regional B.T.C. to supply the blood to these centres maintaining the cold chain.

6) If the blood is not used in time, it should be taken away by the Licensed Blood Bank or Regional Blood Transfusion centre before its expiry, otherwise it will go waste.

7) This centre should have communication & transport facilities.

The argument that the satellite Blood transfusion centre should be given to 'Private Small Hospital' and where there is a competent 'Doctor' who can use the blood effectively can vary well be exemplified by the following table, which is taken from supplement to our Booklet on 'Unbanked Directed Blood Transfusion'.

♦ Table No. II ♦

Status Of Blood Transfusions Given In Peripheral Areas

Name of Taluka	Population	Blood Transfusions Given		
	in Lac	Government	Semi-Govt	Private
1. Akkalkuva	1.45	0	0	0
2. Akrani	1.08	0	0	0
3. Dhule	7.45	Study not done		
4. Nandurbar	2.80	0	0	795
5. Navapur	2.20	0	0	460
6. Sakri	3.68	0	0	585
7. Shahada	3.23	0	40	212
8. Shindakheda (Dondaicha)	2.94 (0.35)	38 (30)	0 (0)	154 (154)
9. Shirpur	3.06	0	0	118
10. Taloda	1.10	0	0	10
Total	**28.99**	**38**	**40**	**2334**
Total Blood Transfusions at Periphery				**2412**

The Chart gives the distribution of blood used is various peripheral Talukas in our District. In Akkalukuva and Akrani Talukas with combined population of 2.5 Lacs not a single bottle was used. In Taloda Taluka with population of one Lac ten thousand, only 10 bottles were used. In Navapur Taluka with population of 2.5 Lacs not a

single bottle was used in the Navapur Town but - 460 bottles were used in one centre, a Christian Mission Hospital placed in a distant village of Chinchapada. In rest of the Talukas depending on the availability of competent clinicians Blood was used.

The Notable feature was that of the total 2412 bottles used at periphery only 38 were used in Govt. sector, 2334 bottles i.e. 97% blood was used in Private sector even though in each Taluka there is either a Rural or Cottage hospital in Govt. sector. This emphasises the fact that the Utility of Blood depended not on the population or a mere presence of a Government Hospital but on the availability of a competent clinician who could use the blood.

All these facts should be taken in consideration when formulating the Rules & implementing the policies, regarding "Satellite Blood Transfusion Centre".

Subject: [pha-ncc] [Fwd: Fw: Blood Transfusiion Draft Rules.]
Date: Mon, 13 Aug 2001 09:48:06 +0500
From: CEHAT <cehatpun@vsnl.com>
To: pha-ncc@yahoogroups.com, mfriendcircle@yahoogroups.com

Subject: [Fwd: Fw: Blood Transfusiion Draft Rules.]
Date: Sat, 11 Aug 2001 17:30:29 +0530
From: CEHAT <cehatpun@vsnl.com>
To: pha-ncc@yahoogroups.com, mfriendcircle@yahoogroups.com

Dear PHA and mfc members,
I am forwarding a very important letter about the proposed changes in the blood-bank rules. Pl. send it to the Health Secretary on behalf of your organization if you feel involved in the issue.
Sincerely yours,
Anant Phadke

Subject: Fw: Blood Transfusiion Draft Rules.
Date: Tue, 7 Aug 2001 20:51:10 +0530
From: "Dr.R.R.Tongaonkar" <rrtong@sancharnet.in>
To: <ashtekar@bom6.vsnl.net.in>, <cehatpun@pn3.vsnl.net.in>

-----Original Message-----
From: Dr.R.R.Tongaonkar <rrtong@sancharnet.in>
To: dali_f23@yahoo.com <dali_f23@yahoo.com>; drshivde@rediffmail.com <drshivde@rediffmail.com>; drprabhu@sancharnet.in <drprabhu@sancharnet.in>; dalibenu@vsnl.com <dalibenu@vsnl.com>; ashokpkale@rediffmail.com <ashokpkale@rediffmail.com>; shomik@dte.vsnl.net.in <shomik@dte.vsnl.net.in>; masalekar.shriram@rediffmail.com <masalekar.shriram@rediffmail.com>; baif@vsnl.com <baif@vsnl.com>; ibp@pnvsnl.net.in <ibp@pnvsnl.net.in>; dhrutis@im.eth,net <dhrutis@im.eth.net>; frchpune@giaspn01.vsnl.net.in <frchpune@giaspn01.vsnl.net.in>; frchbom@bom2.vsnl.net.in <frchbom@bom2.vsnl.net.in>; zarsol@bom5.vsnl.net.in <zarsol@bom5.vsnl.net.in>; bloodbnk@pn3.vsnl.net.in <bloodbnk@pn3.vsnl.net.in>; ereuben@cclan <ereuben@cclan>; ashtekar@giasbm01.vsnl.net.in <ashtekar@giasbm01.vsnl.net.in>
Date: 05 Aoustos 2001 Pazar 22:02
Subject: Blood Transfusiion Draft Rules.

>From Dr.R.R.Tongaonkar,
President,Association of Rural Surgeons of India,
Dondaicha,Dist.Dhule, Maharashtra,425408.

URGENT REQUEST.
Dear Colleagues,
This is an urgent work you have to do regarding the New Draft Rules about 'Satellite Blood Transfusion centres.
Please find attached herewith-
1) My covering Letter,
2)Format of letter you have to send to concerned authorities on your letter-head (and/or letter-heads of other organisations like IMA,Your Association,Rotary or similar clubs or NGOs)
3)Draft Rules Published in the Gazette.
4)Additional information I have sent to Delhi besides the "2)Format of letter"
Please act quickly,Time is very short.
Yours sincerely,
Dr.R.R.Tongaonkar:

RN
13/08

To Dr CMF
Urgently for a response
RN 17/8
(M) 18/8

[pha-ncc] [Fwd: Fw: Blood Transfusiion Draft Rules.]

email attachment for blood.doc	**Name:** email attachment for blood.doc **Type:** Winword File (application/msword) **Encoding:** base64

DIS-17

Safe blood starts with me

Blood saves lives

World Health Organization

International Federation of Red Cross and Red Crescent Societies

FOREWORD

Safe blood starts with me. Blood saves lives

At the beginning of this new millennium, we should like to ask people everywhere to safeguard their health by caring for that precious life source, their blood. Good nutrition, a clean and healthy lifestyle, proper prevention and early treatment of disease all contribute to healthy blood. We should like to emphasize the importance of managing blood properly, at the individual and at the global level.

Joining forces for quality, safety and sustainability

Throughout the world, people have generously given their blood to save the lives of others, and they continue to do so. We thank all blood donors on behalf of those millions of recipients whose lives have been saved through the gift of blood - a unique gift from one person to another, where the donor hardly ever hears a word of thanks from the recipient. We especially express our gratitude to all voluntary, non-remunerated donors who give their blood on a regular basis, thereby providing the strongest foundation for a safe and sustainable blood supply.

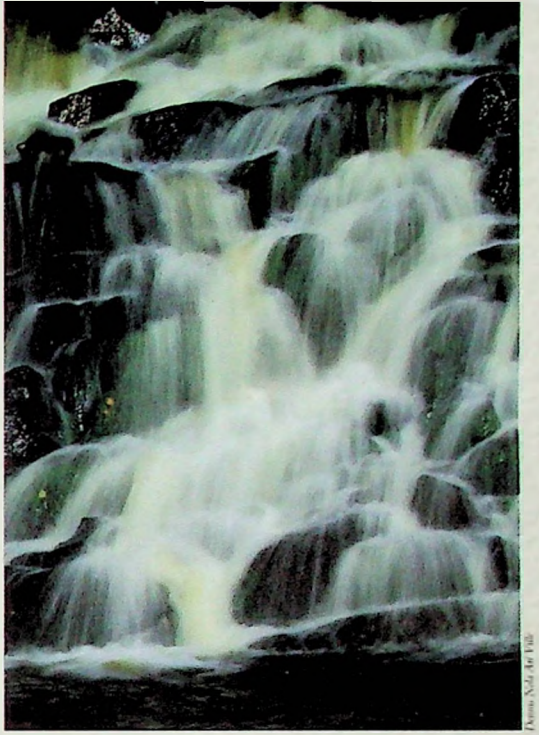
We invite you to reflect on this year's World Health Day slogan, "Safe blood starts with me". The global community shares a common life source: blood. The need for voluntary donors is a permanent requirement - blood is used round the clock, year in year out.

We urge you to think carefully about this slogan, "Safe blood starts with me". Each one of us can apply this maxim to our own lifestyle and thus contribute to a global culture of quality and a continuous improvement in critical health-related areas.

Dr Gro Harlem Brundtland
Director-General
World Health Organization

Mr George Weber
Secretary General
International Federation of Red Cross and Red Crescent Societies

Blood – the fluid of life



The life force in all human beings, regardless of their colour, race or belief, flows through their arteries and veins: it is a red liquid which – depending on whether they are well or ill – bears good and bad tidings. Its various components form a highly developed defence and transport system which gives and saves life.

Blood is a whole world in itself, each component having a specific job – red blood cells transport oxygen throughout the body; plasma transports proteins, including antibodies and clotting factors, and nutrients like glucose for energy around the body; white blood cells constitute a defence mechanism against disease; and platelets ensure that bleeding stops. Blood also carries waste products from all the organs to be evacuated from the body.

Blood is living matter, which can be transfused to save lives. Serious loss of blood due to an accident or disease can cause shock. When oxygen is lacking, the brain cannot function and the heart cannot pump. Blood is also the first life link between a mother and a child. A person's health can be determined by the state of his or her blood, which reveals the innermost workings of the body. Scientists today can diagnose and investigate complex diseases by examining blood. Blood can also transmit diseases from one person to another.

A healthy person has healthy blood. Healthy blood can and does save lives.

Safe blood starts with me

Some 40-45% of blood is made up of red blood cells which carry oxygen. The remaining 55-60% is plasma with a small proportion of white blood cells for defending the body, clotting factors and platelets. All the different components of blood can be used and each component plays an important role in saving the lives of different individuals in the community.

A sophisticated defence system

ICRC Geneva

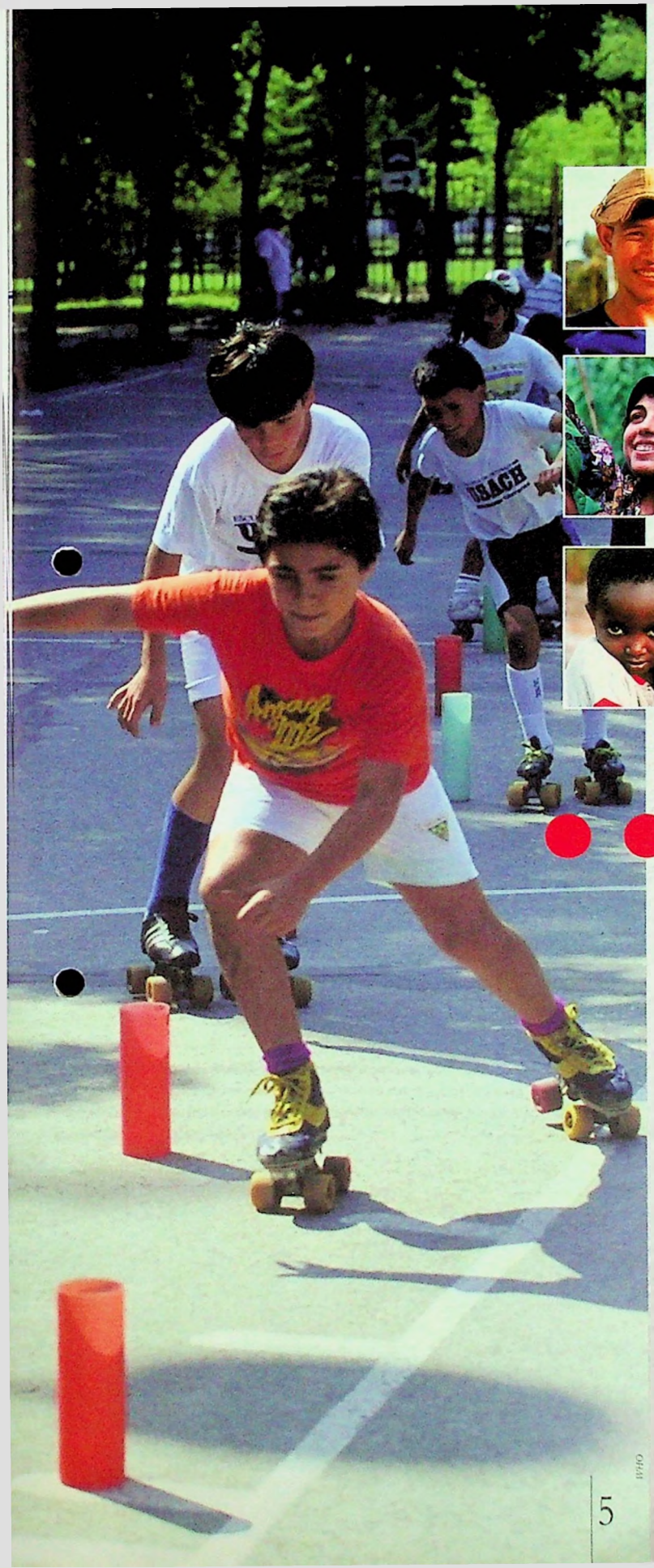
Safe blood starts with me

The average volume of blood in an adult is 4-5 litres, or about 8% of the body weight. Blood contains 4-5 million red blood cells per mm³, 4000-11 000 white blood cells per mm³, and 150 000-400 000 platelets per mm³. Red blood cells live for about 120 days and white blood cells normally last 3-9 days. New blood cells are constantly generated in the body.

The human body mounts its defence through blood. Blood flows through the various organs and, during its course, detects the presence of foreign elements and identifies any change from normal healthy conditions. Internal biological signals trigger reactions to attacks by viruses and other micro-organisms in order to protect the body. Different kinds of white blood cells, each with a specific function, attack and destroy the invaders; blood also transports the waste to other organs for disposal. Antibodies, which protect from disease and infection, are present in the plasma.

Since blood reflects the overall state of health of the body, analysis of the blood can reveal illness and chronic disease. Illnesses can affect different blood cells, harming the body's defence system and sometimes leading to death. In the case of some genetically transmitted blood diseases, the shape of blood cells and their functioning are affected.

This highly developed defence system needs right conditions in order to function at peak performance. Healthy lifestyles, adequate nutrition, and good sanitation all contribute to maintaining every individual's blood quality as well as global blood quality.



ICRC Geneva

Unicef Dhaka

Unicef Dhaka

Health, a common wealth

Our world. Our blood.
We all share the source
of life that is blood.

WHO

From womb to world

From the day that human life is conceived, blood fulfils a life-giving and nurturing role. In the womb, the mother's blood ensures that the fetus is supplied with crucial oxygen and nutrients and benefits from the mother's antibodies against diseases. Outside the womb, blood has another critical function for the newborn, that of defence against health risks as it begins to produce its own antibodies.

Around 500 000 women die in childbirth each year, mainly in the developing world. In some cases, at birth there can be heavy loss of blood and the mother may suffer distress and even die. Blood may then be needed for transfusion to save her life. Many women do not have access to safe blood, and as a consequence they run the risk of receiving contaminated blood. If only healthy individuals gave sufficient safe blood and if all the blood were systematically tested, many women who die in childbirth could be saved.

The better a mother's health, the less likely that she will need blood. Proper care from the outset of pregnancy, identification of risk factors and, if required, early treatment reduce the risks and increase the likelihood that transfusion can be avoided.

Safe blood starts with me

Every time a person's heart beats, 20% of the heart's output goes directly to the brain, carrying oxygen which is vital for survival. The average person has 25 million million red blood cells. A pregnant woman's blood volume expands by about 45% near the time of delivery. Many blood products are given every minute of the day to people exposed to risk due to disease or injury.

What is safe blood?

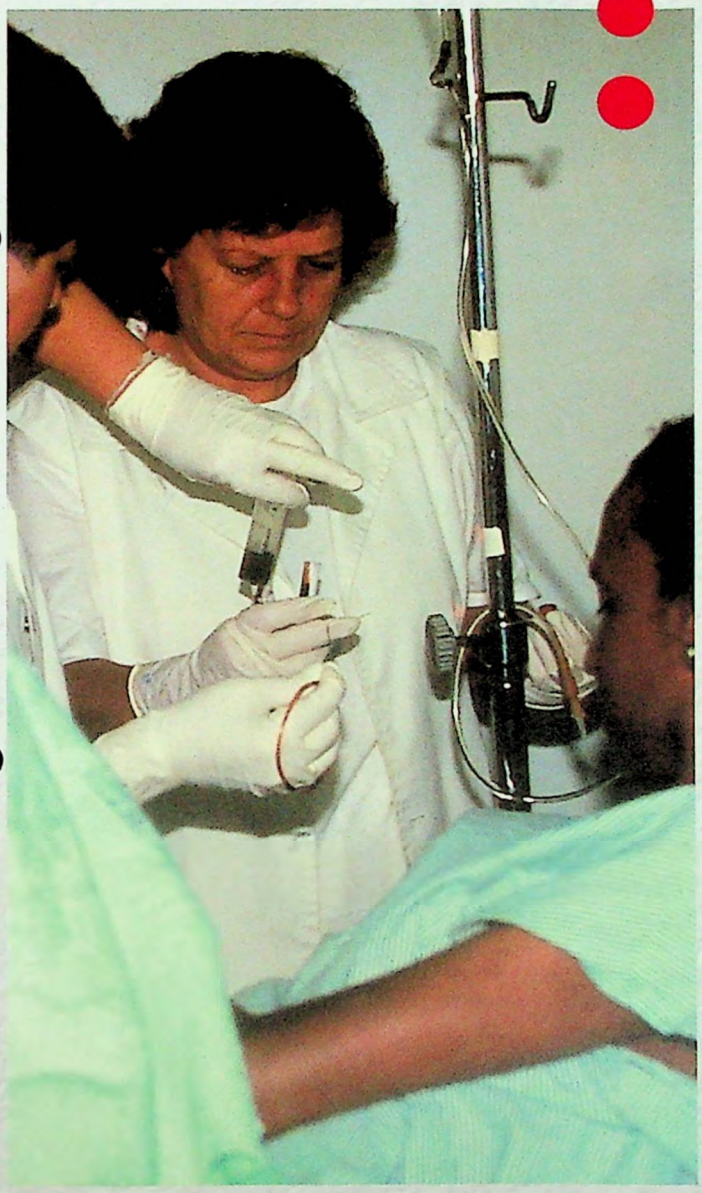
Safe blood is blood that does not contain any viruses, parasites, drugs, alcohol, chemical substances, or other extraneous factors that might cause harm, danger or disease to the recipient. People who donate blood should be in good health and should not suffer or have suffered from any serious illnesses. The recipient should not be harmed by receiving blood; the donor should not be put at risk by giving blood.

The world relies on safe blood, yet only 20-30% of the world's health systems are able to provide a safe and adequate blood supply. There are a limited number of healthy people donating blood. Every year, over 100 million blood units are collected from blood donors. Many millions more are still needed to fulfil global requirements and ensure availability of blood when and where it is needed.

Although blood can be screened for infectious agents such as viruses, it cannot be treated to kill viruses and micro-organisms because the red blood cells would be destroyed by the methods currently available. Supplies of blood tests for screening blood are sometimes interrupted in poor countries. Honesty in answering the donor questionnaire and at interviews is critical for the safety of blood transfusion. Blood donors take on a remarkable responsibility when offering themselves as life-savers.

Governments should take every opportunity to review the requirements of all health authorities and see that they are committed to supporting the blood services with sufficient funding. The health authorities should also ensure that all necessary safety procedures are available and in place, are supported financially, and are protected and enforced by national legislation.

Safety from me to you, throughout



Safe blood starts with me

Safety of blood and blood products depends on many factors, starting with the recruitment and recall (at safe intervals) of voluntary, non-remunerated blood donors who have been eliminated from any risk. Safety is ensured by providing clean conditions for blood collection, appropriate screening of donors, extensive testing, proper storage, and appropriate clinical use of transfusion.

Virus transmission and blood

Some diseases that affect the lives of millions of people are caused by viruses passing from one person to another through the blood. These risks can be decreased by ensuring safe blood supplies.

The human immunodeficiency virus (HIV), which is carried in the blood and body fluids, already affects over 33 million people, causing about 2.5 million deaths each year. In some countries, one in every four persons carries HIV, which can be passed to another person during sexual intercourse. The virus can also be transmitted from mother to child, inside the womb, or through breastfeeding. Hepatitis viruses, leading to liver disease and even cancer, can also be transmitted through the blood.

There are ways to prevent transmission of bloodborne disease. Simple tests can detect the presence of antibodies against such viruses in a person's blood. Tests for HIV and hepatitis viruses and for other infectious diseases are used in many countries, but still not widely enough. WHO and UNAIDS have worked with the diagnostics manufacturers to develop and make available cost-effective, simple and rapid tests to screen donated blood for infectious disease markers.

Testing of all donated blood should be systematic. This will result in only safe blood being available for transfusion. Systems for pre- and post-donation counselling should be established so that donors, where necessary, can be referred for further counselling and care.

In addition, safe and appropriate use of injections and skin-piercing procedures should be applied. Whenever possible, alternatives to injections, such as oral medication, should be given, and sterile procedures respected in all cases to avoid transmission of bloodborne pathogens.

Safe blood starts with me

Up to 5% of HIV infections in the developing world may still be due to transfusion of HIV-contaminated blood. HIV infection by blood transfusion is almost 100% effective in each case. This can easily be prevented by safe and sustainable blood programmes.

ICRC/Gambia

Genetically determined diseases and blood

Some genetic diseases affect the blood, such as haemophilia, thalassaemia and sickle-cell disorder. Persons with these diseases require regular supplies of safe blood to replace their deficient blood.

Haemophilia, which affects mainly men and occurs in about 1 in 5000 male births, is caused by a shortage of clotting factors: when a person is injured, there is a risk of bleeding. Accurate identification of haemophilia is made by measuring the level of specific clotting factors in the blood. Blood tests need to be carried out in a laboratory which has appropriate facilities and experience with these tests. To date, with comprehensive care and by using products containing the missing clotting factors, made from blood donations or biotechnology, even people with severe haemophilia lead nearly normal lives. In most developing countries, blood is the only source of treatment available.

In sickle-cell disorder and thalassaemia the red blood cells are unable to carry enough oxygen. Thalassaemia may lead to mild or severe anaemia and premature death. Blood transfusion is currently the main treatment for thalassaemia, which gives the person optimal chances of survival; blood is also needed for patients with sickle-cell disorder.

A strong health service infrastructure is essential to ensure continued monitoring of populations for the early detection and treatment of these diseases.

Safe blood starts with me

If every capillary, vein and artery in a person's body were lined up end to end, they would cover a distance of 150 000 kilometres. All the iron in an average person's blood could make a 5-centimetre nail; two-thirds of this iron is in the red blood cells.

Vector-borne diseases, parasites and blood

Many parasites and viruses which affect hundreds of millions of people worldwide are transmitted from person to person by bloodsucking insects (vectors), and are then transported in the body via the blood. These diseases include malaria, filariasis, dengue fever, Chagas disease, leishmaniasis and African sleeping sickness. Some of these diseases cause severe anaemia or blood loss and may require the use of blood products or transfusions in order to save lives. Malaria, which affects some 300 million people a year, may cause miscarriages, stillbirths or underweight, anaemic children.

Simple preventive measures such as sleeping under a bed net can provide protection against night-biting malaria mosquitos and from carriers of certain other insect-transmitted diseases. Appropriate insecticides, good environmental sanitation to reduce vector breeding places, and biological control methods are commonly used to combat these diseases.

Schistosomiasis and the hookworms are worm infections, affecting some 1400 million people worldwide. Both diseases cause blood loss, resulting in damage to tissues and anaemia. Cost-effective drugs exist to treat these infections effectively and safely, thereby reducing the need for blood and blood products. It has been demonstrated that regular treatment of women and children with anthelminthic drugs in endemic areas increases their haemoglobin levels.

Good health contributes to safe blood

Good health depends on lifestyle and disease prevention. Eating a balanced diet with an adequate vitamin and micronutrient supply, keeping a clean environment, and avoiding risk situations help to keep people, and their blood, healthy. A healthy society means more safe blood and a reduced need for blood transfusions.

Iron-deficiency anaemia is one of the most widespread micronutrient deficiencies in the world. It affects about 50% of pre-school-age children and pregnant women in developing countries. In children, it affects growth and impairs cognitive performance. In pregnant women, it increases the risk of diseases and maternal mortality. Additional iron in the form of iron supplements combined with a diet containing iron-rich food can improve iron status.

Cancer patients are frequently recipients of blood transfusions, especially in industrialized countries. Reducing the overall number of cancer patients through prevention measures would reduce the need for heavy treatment schedules and thus the need for transfusions. This would have many benefits including an overall gain in health and quality of life, and in economic terms as well.

Education, from primary schools onwards, plays an important part in maintaining a healthy society and promoting risk-free behaviour, and in cultivating positive attitudes towards voluntary, non-remunerated blood donation. Raising people's awareness about the importance of unpaid blood donation should increase the number of regular, safe blood donations.

ICRC Gaimard

Safe blood starts with me

Red blood cells were first described in 1658. Over 250 years later, the first four human blood groups, A, B, AB and O, were identified, followed by the Rhesus (Rh) factor which separated people into Rh positive and Rh negative. Today, experts can determine blood groups very precisely, with over a hundred subtypes.

Emergency, conflict and health

ICRC Media

Safe blood starts with me

Transfusion was used during the First World War (1914-18) when blood was transported to the battlefront in modified, clean, sterilized milk bottles. The first mobile blood bank was set up in the 1930s during the Spanish civil war.

Pan American Health Organization

Pan American Health Organization

The need for an effective health service is felt most during emergencies of any kind, whether war, natural disasters, large-scale accidents or human conflicts. Yet, it is at such times that the system often breaks down, being unable to cope with the magnitude of the demand. Internal conflicts or war may destroy hospitals and clinics, while power shortages often disrupt their work and can ruin medical stocks that require refrigeration, including blood. Caring for large numbers of wounded people puts an added burden on already strained systems.

Whenever such events occur, the need for blood donation and transfusion services increases. Many people spontaneously donate blood during a crisis, but when the crisis is over, the countries are left without a sustainable blood supply. Such situations can be avoided by setting up systematic and efficient blood services with lists of regular donors.

Safe blood starts with me

Blood can safely be donated by a healthy person three or four times a year. After each withdrawal of blood it takes 36 hours for the body to reconstitute the fluid volume and 21 days for the blood cell count to return to a normal level. Blood donors are key players in medical and surgical treatment, and save their communities millions of dollars.

You might need blood one day...

Give safe blood and save a life

ICRC Gaidoux

Anyone may need blood at any time. A serious illness or accident can happen anywhere in the world, in the course of daily routine or while travelling, with the loss of blood in life-threatening quantities. It is therefore in everyone's interest to have safe blood supplies available worldwide.

ICRC Th. G

Thanks to the people who give safe blood anonymously, lives are saved. All blood donors must know that they can save lives only if the blood given is safe (that is, free of infection). Likewise, each person should understand that when giving unsafe blood (disease-carrying) he or she will be responsible for transmitting potentially life-threatening infection to, and even killing, another person.

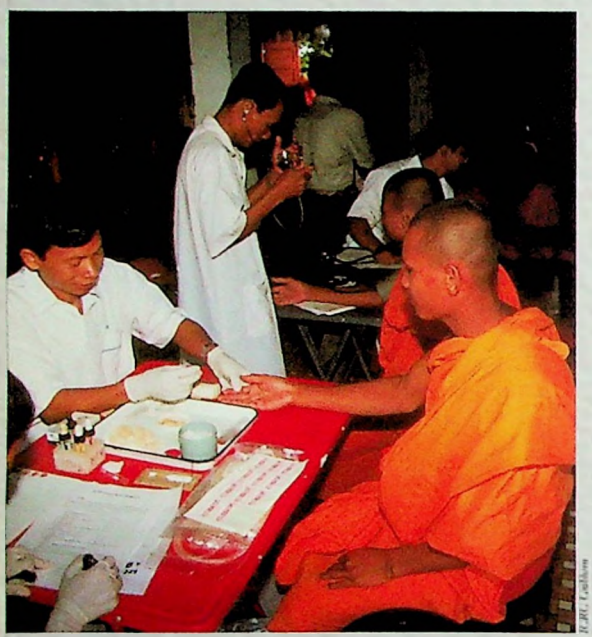
Experience has shown that the safest donor is one who gives blood at least twice a year without receiving money or goods in exchange, understands the principle of altruism, answers questions for donor selection honestly, and will defer or exclude him/herself from donation if there is any risk to the recipient.

WHO

Governments and health authorities must put into place systems for the proper selection and deferral/exclusion of potential donors so that only safe blood is collected, and for the testing of all donated blood. These systems will include effective infrastructures to collect, process and store the blood; training for health care workers to deliver blood in sterile conditions; and promotion and implementation of appropriate clinical use of blood.

An individual in need of blood should receive blood that is as safe as possible: it is the privilege of an individual to give safe blood.

A safe and well-organized blood transfusion service



An integrated national health policy should aim at self-sufficiency in blood supplies, an important component of which is blood safety. In many countries, access to health services providing safe blood, diagnostic imaging and laboratory services, and appropriate medical practices is limited. More than 60% of the world's population lacks access to these basic requirements. The need for a safe and adequate blood supply requires the commitment and support of the national health authorities, various organizations, blood donors, specialist laboratories, and blood and blood product service infrastructures.

A comprehensive strategy to ensure safe blood will include:

- commitment and support for a comprehensive blood programme by the national health authorities;
- lists of voluntary, non-remunerated blood donors from low-risk populations;
- high priority to eliminate family, replacement and paid blood donor systems;
- screening of donated blood and blood products to avoid transfusion-transmitted infections;
- safe injection technique;
- safe and appropriate clinical use of blood;
- implementation of quality control systems throughout the blood chain;
- education of physicians, health workers, and the community at large.

Safe blood starts with me

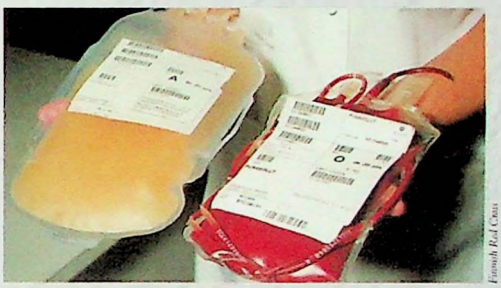
The first recorded blood transfusion into a vein or artery took place in France in 1667 - and was unsuccessful. A cupful of lamb's blood was transfused into a man via a silver tube. The man survived two transfusions and then died. It was only in the twentieth century that blood transfusions became safe medical practice.

The appropriate use of blood...

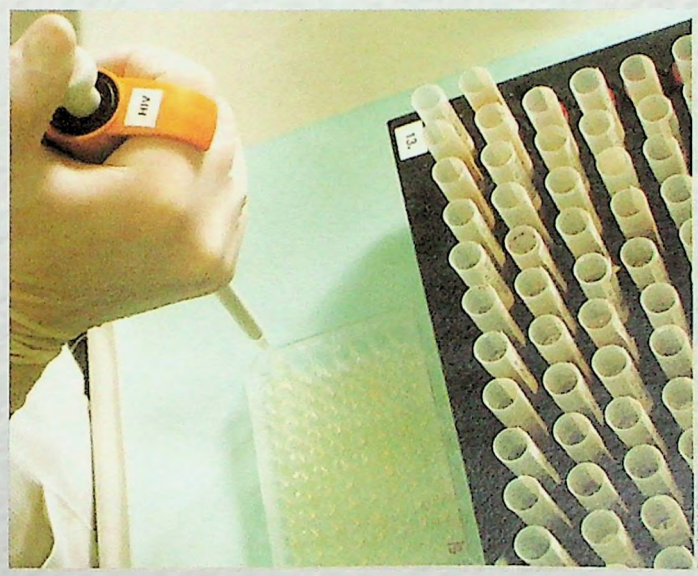
In many cases, blood transfusion may not be the most appropriate, cost-effective or safe therapeutic intervention. It is important to minimize the number of inappropriate blood transfusions through the effective clinical use of blood or blood products and the assessment of existing alternatives. This implies a respect for the use of blood, which should only be transfused if no alternative treatment is possible.

WHO recommends three key strategies:

- Developing national guidelines for giving transfusions
- Training people who prescribe blood to avoid unnecessary or inappropriate transfusions
- Ensuring accessibility and availability of volume replacement fluids, such as crystalloids and colloids, for use where appropriate.



Finnish Red Cross



Finnish Red Cross

Safe blood starts with me

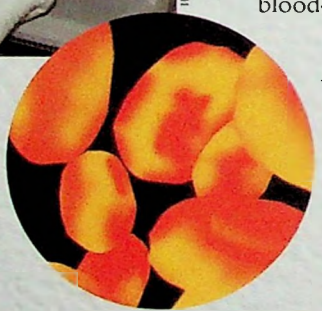
Crystalloids and colloids are used to restore blood volume when there are enough red blood cells circulating, but not enough fluid (plasma). Crystalloids are a sterile salt solution which can be used for fluid replacement without harming the cells or the tissues. Colloids are sterile, complex sugar solutions which can remain longer in the circulation.

Research and progress in blood products

WHO

To date, there is no available man-made substitute for red blood cells. Although considerable progress has been made in both preventive and curative blood-derived products, red blood cells remain a rare commodity.

Progress in technology has made it possible to separate all the components of blood and to store them at temperatures which are best suited to maintain their viability. Biotechnology research has increased our knowledge and enables some of the different components of blood to be identified and purified. Research is continuing into new blood-derived products and technologies.



Blood tests have become more sophisticated and are faster and more cost-effective, yet in many countries blood is still not screened systematically. More resources have to be identified and allocated to ensure continuous screening programmes.

A global resource to be shared

Blood, the life source that flows in every person, can be shared to help others. Blood saves lives; safe blood begins with each one of us. This unique resource upon which all lives are dependent can be shared. It is up to each and every one of us, as global citizens, to help others.

Contact your local blood transfusion service if you are healthy and can donate blood, and commit yourself to helping another person by donating blood regularly.

Safe blood starts with me

What you can do!

People around the world need blood.

How often have you seen a situation where you wondered what YOU can do to help!

You CAN think about giving blood and take positive steps to see whether you are eligible to give blood. Contact your local blood transfusion service/blood bank.

If you have already given blood, become a regular/repeat donor.

ICRC Hoet

WHO

ICRC Cashdan

ICRC Medici

Advocating safe blood services and systems

Even today, up to 13 million blood donations globally are not tested for HIV and hepatitis B and C viruses. This occurs mainly in developing countries, where 80% of the blood supply comes from paid or replacement donors and where there are a high number of infected persons in the donor population. Wherever blood transfusion services screen for HIV, counselling for voluntary testing of persons should be available.

In 1975, the World Health Assembly passed a resolution (WHA28.72) urging Member States of WHO:

a) to promote the development of national blood services based on voluntary non-remunerated donation of blood;

b) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and recipients of blood and blood products.

In recent years, the serious threat of infection by such agents as HIV and hepatitis B and C viruses to recipients of blood and blood products has highlighted the urgency of the need to develop safe and effective blood transfusion services. Underlying the advocacy efforts of both WHO and the International Federation of Red Cross and Red Crescent Societies is the push

for quality blood transfusion. There is a global need for more safe blood and sustainable, comprehensive blood programmes. WHO and the International Federation recommend that:

- all adults consider whether they are eligible to donate blood and, if they are, to become regular donors;
- transfusion therapy should be accessible, without discrimination, to all those in need;
- civic education should be taught in schools at all levels and include education on blood donation;
- health authorities should implement strategies and programmes of education and promotion for preventive health care, provide alternatives to blood for volume replacements, and provide access to essential drugs which may reduce the need for transfusion;
- all blood supplies should be systematically tested prior to use;
- blood transfusion services should be allocated sufficient funds to implement training programmes for developing quality systems and to maintain sustainable systems;
- all blood programmes of the International Federation of Red Cross and Red Crescent Societies should be familiar with the quality concepts and the Federation's quality manual, and become advocates for developing quality systems in blood centres;
- in a true spirit of capacity-building, special assistance should be given to develop strong blood programmes systematically in countries that are in most urgent need of a safe and sustainable blood supply.

World Health Organization
International Federation of Red Cross and Red Crescent Societies

For more information...

AFRICA

The World Health Organization
Regional Office for Africa (AFRO)
Parirenyatwa Hospital
P.O. Box BE 773
HARARE
Zimbabwe

Tel.: (001) 4.70.69.51 or 4.70.74.93
Fax: (001) 4.79.01.46
Email: regafro@whoafr.org
Website: www.whoafr.org/

AMERICAS

The World Health Organization
Regional Office for the Americas
Pan American Health Organization
(AMRO/PAHO)
525, 23rd Street, N.W.
WASHINGTON, DC 20037
U.S.A.

Tel.: +1 (202) 974-3000
Fax: +1 (202) 974-3663
Telex: 248338 - 440057 - 64152 - 892744
Telegraph: OFSANPAN WASHINGTON
Email: postmaster@paho.org
Website: www.paho.org/

EASTERN MEDITERRANEAN

The World Health Organization
Regional Office for the Eastern Mediterranean (EMRO)
P.O. Box 1517
ALEXANDRIA - 21511
Egypt

Tél.: (00203) 48.300.90/6/7/8
Fax: (00203) 48.389.16 or 48.243.29
Telex: 54028 or 54684
Telegraph: UNISANTE ALEXANDRIA
Email: emro@who.sci.eg

Website: www.who.sci.eg

EUROPE

The World Health Organization
Regional Office for Europe (EURO)
8, Scherfigsvej
2100 COPENHAGEN Ø
Denmark

Tel.: (0045) 39.17.17.17
Fax: (0045) 39.17.18.18
Telex: 15348 or 15390
Telegraph: UNISANTE COPENHAGEN
Email: postmaster@who.dk
Website: www.who.dk

SOUTH-EAST ASIA

The World Health Organization
Regional Office for South-East Asia (SEARO)
World Health House
Indraprastha Estate
Mahatma Gandhi Road
NEW DELHI 110002 - India

Tel.: (0091) 11.331.7804
or 11.331.7823
Fax: (0091) 11.331.8607 or 11.332.7972
Telex: 3165095 or 3165031
Telegraph: WHO NEW DELHI
Email: postmaster@whosea.org

WESTERN PACIFIC

The World Health Organization
Regional Office for the Western Pacific (WPRO)
P.O. Box 2932
1099 MANILA - Philippines

Tel.: (00632) 528.80.01
Fax: (00632) 521.10.36 or 536.02.79
Telex: 27652-63260-40365
Telegraph: UNISANTE MANILA
Email: Postmaster@who.org.ph
Website: www.who.org.ph/

Safe blood starts with me

IFRCRC

World Health Organization
Blood Safety and Clinical Technology
World Health Organization
20 avenue Appia
CH-1211 Geneva 27
Switzerland

Tel.: + 41 22 791 21 11
Fax: + 41 22 791 07 46
Website: www.who.int/world-health-day/

International Federation of Red Cross and Red Crescent Societies
Blood Department
P.O. Box 372
CH-1211 Geneva 19
Switzerland

Tel.: + 41 22 730 42 22
Fax: + 41 22 733 03 95
Website: www.ifrc.org

World Health Organization

International Federation of Red Cross and Red Crescent Societies

Helena Zanelli Création - Text: Danièle Letoré

Blood Safety DIS·17

Safe blood starts with me

Blood saves lives

World Health Organization

WORLD HEALTH ORGANIZATION

Injection Safety

AIDE-MEMOIRE

for a national strategy for the safe and appropriate use of injections

A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in any waste that is dangerous for other people.

Worldwide, each year, the overuse of injections and unsafe injection practices combine to cause an estimated 8 to 16 million hepatitis B virus infections, 2.3 to 4.7 million hepatitis C virus infections and 80,000 to 160,000 HIV infections*. Among unsafe practices, the re-use of syringes and/or needles without sterilization is of particular concern.

Injection-associated transmission of bloodborne pathogens can be prevented through the development of a strategy to reduce injection overuse and achieve injection safety and its implementation by a national coalition, with the assistance of a coordinator.

The three elements of a strategy for the safe and appropriate use of injections are described in detail overleaf:

- Behaviour change among patients and healthcare workers to decrease injection overuse and achieve injection safety
- The availability of necessary equipment and supplies
- The management of sharps waste.

Words of advice

- **Conduct an initial assessment**
- **Secure government commitment and support for the safe and appropriate use of injections**
- **Establish a national injection safety coalition, coordinated by the Ministry of Health**
- **Develop a national policy and plan**
- **Develop a systematic strategy for behaviour change among patients and healthcare workers to decrease injection overuse and achieve injection safety**
- **Ensure the continuous availability of injection equipment and infection control supplies**
- **Set up a waste management system for the safe disposal of sharps**
- **Monitor the impact of activities on injection frequency, injection safety and injection-associated infections**

Checklist

National policy on the safe and appropriate use of injections

- ❑ Assessment of injection practices
- ❑ Coordination of injection safety
- ❑ Multidisciplinary national coalition
- ❑ National policy and plan
- ❑ Costing, budgeting, and financing
- ❑ Three-point strategy for the prevention of unsafe injection practices
- ❑ Monitoring and evaluation

Behaviour change

- ❑ National behaviour change strategy
- ❑ National standards for injection safety
- ❑ Incorporation of safe injection practices into minimum standards of care
- ❑ Promotion of safe technologies
- ❑ Promotion of rational use of injections
- ❑ Other components of behaviour change

Equipment and supplies

- ❑ Auto-disable (AD) syringes for immunization
- ❑ Appropriate types of syringes and needles for curative care
- ❑ Norms and standards for equipment
- ❑ Central bulk procurement, including safety boxes
- ❑ Central management of storage
- ❑ Efficient distribution system

Management of sharps waste

- ❑ Policy for sharps waste
- ❑ Assessment of waste management system
- ❑ Selection of appropriate waste disposal systems
- ❑ Regulatory framework
- ❑ Adequate resources
- ❑ Implementation of waste management system
- ❑ Training and supervision

* Kane A et al. Bull World Health Organ 1999, 77: 801-807.

Key elements

National policy on the safe and appropriate use of injections

It is the responsibility of governments to ensure the safe and appropriate use of injections.

The achievement of this goal requires the establishment of a national multidisciplinary coalition involving different departments of the Ministry of Health and other stakeholders, such as non-governmental organizations and associations, and private healthcare providers.

The coalition should be coordinated by a Ministry of Health team and should receive political support, adequate funding and trained staff.

Important activities include:

- Initial assessment of injection frequency, breaks in injection safety and adverse events associated with injections, including a behavioural and systems analysis
- Establishment of an injection safety unit to coordinate departments of the Ministry of Health, including health promotion, immunization, family planing, essential drugs programmes, healthcare service delivery, nosocomial infections, blood transfusion service and waste management
- Establishment of a national coalition, including WHO, universities, non-governmental organizations, behaviour change specialists and associations (e.g. consumers, public and private healthcare workers, traditional practitioners)
- Development of a national policy and plan (including costing, budgeting, and financing) by the national coalition, within the Ministry of Health's overall plan of action
- Prevention through behaviour change to reduce injection overuse and achieve injection safety; provision of sufficient quantities of injection equipment and infection control supplies; and management of sharps waste
- Monitoring of the impact through process indicators (injection frequency and injection safety) and outcome indicators (incidence of injection-associated infections, rational use of injections)

Behaviour change

The foundation for the safe and appropriate use of injections is a behaviour change strategy targeting consumers as well as public, private and lay healthcare workers.

Important activities include:

- Development of a national communication and behaviour change strategy on the basis of behaviour and systems analysis
- Definition of national standards for safe injection practices
- Incorporation of injection safety into minimum standards of care
- Promotion of safe technologies
- Promotion of the rational use of injections within essential drug programmes (e.g. restriction of unnecessary injectable drugs) and with the private sector
- Addressing issues that may lead to poor injection practices, including attitudes, emotions, incentives, beliefs, power relationship, norms and systems

Equipment and supplies

Eradication of the re-use of syringes and needles without sterilization requires the continuous, sufficient availability of injection equipment and infection control supplies in all healthcare facilities.

Important activities include:

- Adoption of auto-disable (AD) syringes for immunization
- Selection of appropriate types of syringes and needles for curative care (sterilizable, disposable or auto-disable)
- Enforcement of international norms and standards by the national regulatory authority
- Central bulk procurement of injection equipment and infection control supplies, including safety boxes
- Central management of storage
- Efficient distribution system to ensure continuous, sufficient availability in all healthcare facilities nationally

Management of sharps waste

The efficient, safe and environmentally-friendly management of sharps waste is the only means of ensuring that disposable syringes and needles are not re-used and do not lead to accidental needlestick injuries.

Important activities include:

- Formulation of a policy stating that disposal is part of the syringe lifecycle and that healthcare services have a duty to manage sharps waste
- Assessment of the waste management system, including expressed and real needs
- Selection of appropriate waste disposal systems for all levels of healthcare facilities
- Implementation of a regulatory framework
- Identification of human and financial resources required
- Implementation of a waste management system
- Training and supervision

Additional information on the safe and appropriate use of injections can be obtained on the World-Wide Web at www.injectionsafety.org and on the Safe Injection Global Network internet forum at sign@who.int

Secretariat of the Safe Injection Global Network
Department of Blood Safety and Clinical Technology
World Health Organization
20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 4836. Email: sign@who.int

GLOBAL DATABASE ON BLOOD SAFETY

Summary Report

1998–1999

World Health Organization
Blood Transfusion Safety
Department of Blood Safety and Clinical Technology
20 Avenue Appia, 1211 Geneva 27, Switzerland
Tel: +41 22 791 4385 Fax: +41 22 791 4836
http://www.who.int/HTP/BCT/BTS
E-mail: bloodsafety@who.int

Background

Millions of lives are saved each year through blood transfusions. In most developing countries, however, people still die due to an inadequate supply of blood and blood products. This has a particular impact on women (as a consequence of pregnancy-related complications), children (malnutrition, malaria and severe life-threatening anaemia), trauma victims and, especially, the poor and disadvantaged. It is estimated that up to 150 000 pregnancy-related deaths each year could be avoided with adequate transfusion therapy.

The emergence of HIV in the 1980s highlighted the importance of ensuring the safety, as well as the adequacy, of national blood supplies. In many countries, even where blood is available, many recipients remain at risk of transfusion-transmissible infections (TTIs) as a result of poor blood donor recruitment and selection practices and the use of untested units of blood.

WHO strategy for blood safety

The World Health Organization (WHO) has identified blood safety as a health issue requiring high priority and launched the Global Collaboration for Blood Safety (GCBS) as a worldwide effort to improve blood safety by building on knowledge, utilizing existing expertise, promoting dialogue and suggesting realistic, effective and practical mechanisms.

WHO has developed the following strategy for global blood safety, which is described more fully in the WHO *Aide-Mémoire: Blood Safety.*

Organization and management

The establishment of well-organized, nationally-coordinated blood transfusion services with quality systems in all areas.

Blood donors

The collection of blood only from voluntary non-remunerated donors from low-risk populations.

Blood screening

The screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis viruses and syphilis; blood grouping; compatibility testing; blood processing.

The clinical use of blood

A reduction in unnecessary transfusions through the appropriate clinical use of blood.

WHO Global Database on Blood Safety

Following the launch of the Global Collaboration for Blood Safety, it became apparent that baseline information was required about blood transfusion services in Member States to identify the exact nature of problems and develop appropriate strategies.

The WHO Global Database on Blood Safety (GDBS) was therefore established to obtain data on blood transfusion services in all Member States of the World Health Organization, with the following objectives:

- To assess the global situation on blood safety
- To obtain best available information on blood transfusion services in each Member State
- To identify problems and needs in order to provide appropriate technical support
- To identify countries for priority assistance
- To monitor progress and trends in blood safety.

A questionnaire, based on the *Aide-Mémoire*, was developed in 1997 as a tool for the standardized collection of data from Member States and was sent to national heath authorities for completion. The status of blood transfusion services in selected countries was also assessed during field visits by WHO consultants, whose observations assisted in the analysis of the data.

Data analysis

Data was obtained from 175 of the 191 Member States and was analysed on a regional and global basis. Since significant differences were revealed between some countries in the same regions, a common factor was sought to enable meaningful analysis. The Human Development Index (HDI), devised by the United Nations Development Programme *(Human Development Report,* UNDP, 1999), satisfied this requirement.

The Human Development Index classifies countries as having a low, medium or high HDI, based on the following criteria:

- Life expectancy
- Educational attainment
- Adjusted income.

In the majority of developing countries (low and medium HDI), there is little systematic collection of data at national level due to a lack of coordination of blood transfusion services. The data obtained from these countries was therefore limited to information from the main centres, usually based in cities.

Key observations

Global blood supply

Globally, more than 75 million units of blood are donated each year. Although the majority of the world's population live in low or medium HDI countries, around 60% of the global blood supply is donated in countries with a high HDI, as shown in Table 1.

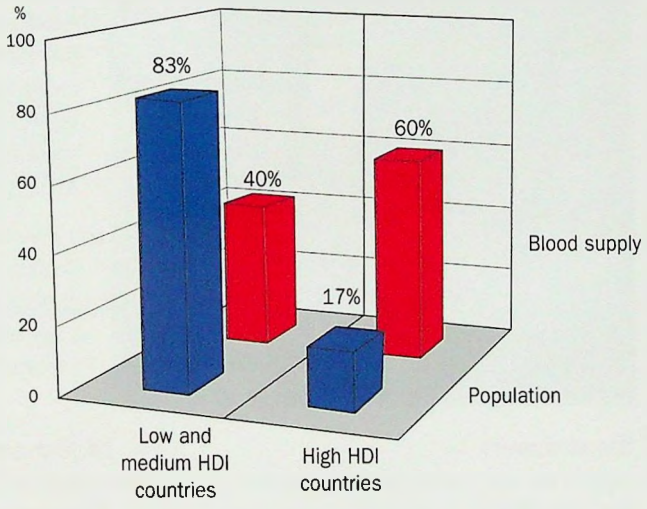
Table 1: Global annual blood donations, analysed according to HDI criteria, 1998–1999

	Low HDI countries (n=41)		Medium HDI countries (n=89)		High HDI countries (n=45)	
Blood supply, in millions of units and by percentage	1.3m	1.7%	28.9m	38.5%	44.9m	59.8%
Estimated blood donation rates per 1000 population	Average Range	2 0.3–5.3	Average Range	10 1.7–50.3	Average Range	40 10.4–74.0

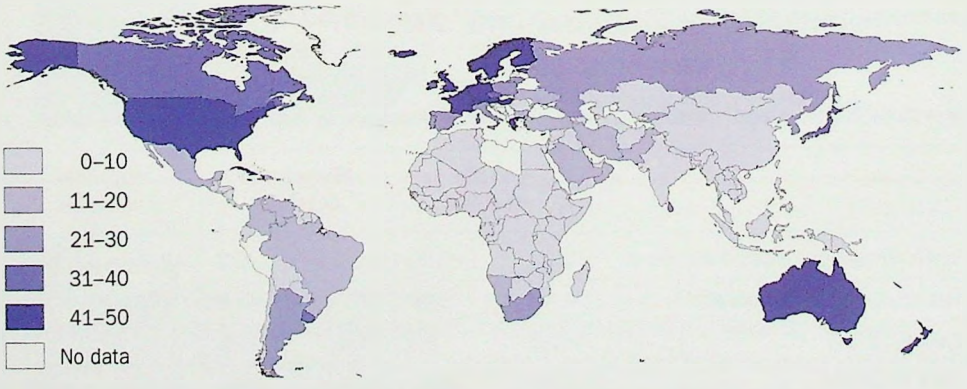
Analysis of the blood supply in relation to the population reveals that 83% of the world's population has access to only 40% of the global blood supply (Figure 1).

The blood donation rate per 1000 population is almost 20 times higher in developed countries (high HDI) than in countries with a low HDI (Map 1).

Figure 1: Global population and global blood supply, 1998–1999



Map 1: Number of whole blood donations per 1000 population, 1998–1999

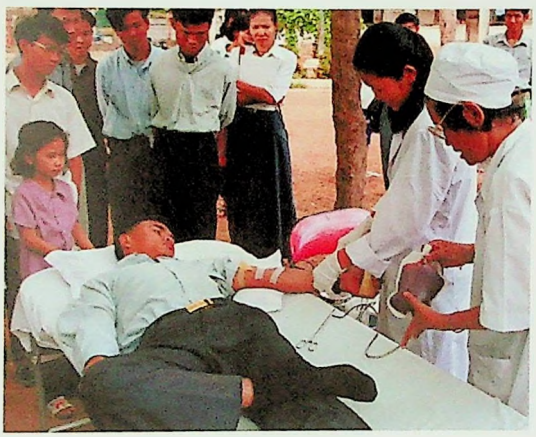


Organization and management

The safety and adequacy of the blood supply is dependent on the commitment of each national health authority to the establishment of a well-organized, nationally-coordinated blood programme. This requires official recognition of a specific organization with sole responsibility for blood transfusion services, an adequate budget and a national blood policy and plan, supported by a legislative and regulatory framework that governs all activities.

GDBS data indicates marked differences globally in the formulation and implementation of national blood policies. In the developed world (high HDI), 94% of countries with strong government commitment and support reported the implementation of a national blood policy and plan. In comparison, national policies have been implemented in only 59% of low and medium HDI countries, particularly those with hospital-based services. Only 20% of countries reported that all aspects of a well-organized BTS were in place.

A key indicator of a well-organized and coordinated national blood programme is a successful programme for the recruitment and retention of voluntary non-remunerated blood donors. Using this indicator, a marked difference is evident between countries with a nationally-coordinated blood transfusion service and those without, regardless of HDI classification.



Blood donors

In 1975, the World Health Assembly passed Resolution WHA 28.72 urging all Member States to promote the development of national blood transfusion services based on voluntary non-remunerated blood donation.

Regular, voluntary non-remunerated donors from low-risk populations are the safest blood donors. A number of studies have shown that family/replacement and paid donors have a higher incidence and prevalence of transfusion-transmissible infections than voluntary non-remunerated donors.

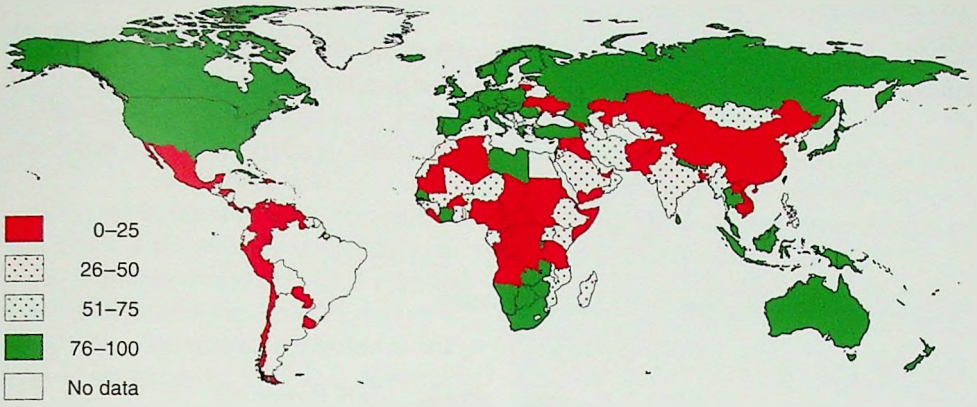
Unfortunately, the World Health Assembly Resolution has not been translated into reality in many low and medium HDI countries since it was adopted more than 25 years ago, as indicated by Table 2 and Map 2.

In low and medium HDI countries less than 40% of blood donations were from voluntary non-remunerated blood donors. In contrast, 98% of donations in high HDI countries were from voluntary non-remunerated blood donors.

Table 2: Estimated number (in millions) and percentage of donations, by type of donation, 1998–1999

	Low HDI countries		Medium HDI countries		High HDI countries	
Voluntary non-remunerated donations	0.4m	31%	11.6m	40%	43.9m	98%
Family/replacement donations	0.8m	61%	11.7m	41%	1.0m	2%
Paid donations	0.1m	8%	5.6m	19%	0.03m	n/a
Total donations	**1.3m**	**100%**	**28.9m**	**100%**	**44.93m**	**100%**

Map 2: Percentage of voluntary, non-remunerated blood donations, 1998–1999

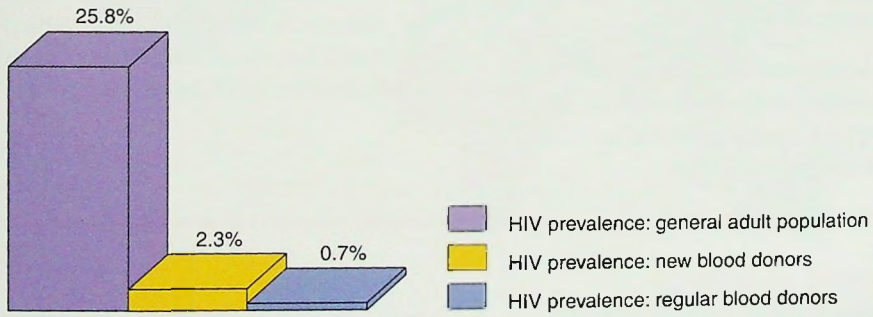


The analysis clearly illustrates that the lack of a well-organized blood donor programme based on voluntary non-remunerated blood donation leads to dependence on family/replacement blood donors. This paves the way for a 'hidden' paid and unsafe donation system since families may pay others to donate.

Globally, there were about 6 million donations from paid donors and 13.5 million from family/replacement donors. Up to 60–70% of donations in the developing world were given by family/replacement or paid donors, often in countries where the seroprevalence of HIV and other infectious agents, such as hepatitis B and hepatitis C, is relatively high.

Best practice has shown that, even in high prevalence areas for infections such as HIV, a well-organized programme of voluntary non-remunerated blood donation and effective donor selection procedures can achieve a low prevalence of infectious disease markers in the blood donor population. This is clearly demonstrated by model blood transfusion services such as those in Zimbabwe (Figure 2) and South Africa.

Figure 2: HIV prevalence in blood donors compared with the general adult population in Zimbabwe, 1998–1999



Blood screening

The WHO strategy for blood safety recommends that all donated blood should be tested for HIV, hepatitis B and syphilis. Where feasible and appropriate, all donated blood should also be screened for hepatitis C, malaria and Chagas disease. Screening for transfusion-transmissible infections, coupled with appropriate donor selection, has a major impact on reducing the risk and further spread of these infections.

available universally, despite a recognition of training needs in both the developed and developing world. Globally, 72% of countries cannot meet identified training needs and many workers remain unfamiliar with quality concepts and the application of quality management tools that can improve efficiency without extra effort or resources.

A new initiative by WHO

Recognizing the need for capacity-building, WHO initiated the Quality Management Project (QMP) for Blood Transfusion Services in 2000.

This global project aims to improve blood safety through regional training programmes in quality management, the establishment of Regional External Quality Assessment Schemes and the creation of Regional Quality Networks.

Conclusions

The data generated from the GDBS has been invaluable in assisting countries to prioritize their needs in strengthening their blood safety programmes. It has also been an important tool for major programme initiatives by the WHO Blood Transfusion Safety Team, including the GCBS and the Quality Management Project, and will assist in monitoring progress, setting priorities and allow for re-planning of activities to achieve global blood safety. The data has also been used extensively in the preparation of WHO guidelines, recommendations, learning materials and other documents.

The Global Database on Blood Safety is a dynamic, ongoing project. WHO has recently modified the GDBS questionnaire to widen its scope and it is being distributed to national health authorities for data collection for the period 2000–2001.

Acknowledgements

WHO wishes to thank the Ministry of Health and Welfare, Government of Japan, for its continued support to the GDBS project.

The invaluable effort of all WHO regional and country offices, national health authorities, directors of blood transfusion services and national blood programme managers is also fully acknowledged.

WORLD HEALTH ORGANIZATION

Diagnostic imaging

AIDE-MEMOIRE

for Diagnostic Imaging Services

Diagnostic imaging is a prerequisite for the correct and successful treatment of at least a quarter of all patients worldwide.

Diagnostic imaging services (DIS) should be:

- Developed as an integral part of national health care systems, according to the needs and social and economic structureof the country, region and area
- Regulated by governments in accordance with international standards
- Appropriate to the level of the health care system at which they are provided
- Appropriate to the therapeutic capabilities that are available.

Approximately two-thirds of patients needing diagnostic imaging can be diagnosed by the use of simple X-ray examinations and ultrasound examinations, either singly or in combination. Every hospital, from district level to university hospital level, should have the capacity to perform these techniques.

Referral hospitals and larger medical institutions should be able to provide more sophisticated techniques and procedures, in accordance with local needs.

Regardless of the type of equipment and procedures used, the following infrastructure is required.

1 Trained medical, technical and engineering staff.

2 Radiation protection.

3 Reliable supplies of clean water, electric power, X-ray films, chemicals and spare parts.

4 Adequate air quality control.

Words of advice

- **Secure government commitment and support for the national diagnostic imaging programme**
- **Establish a National Radiation Protection Control Authority to develop and enforce national regulations in accordance with international standards**
- **Plan diagnostic imaging services in accordance with national and local needs and the available therapeutic capabilities**
- **Ensure that every hospital has the capacity to perform X-ray examinations and ultrasound examinations**
- **Establish the necessary infrastructure for safe and effective diagnostic imaging services**
- **Establish a national quality system for diagnostic imaging services**
- **Train all medical, technical and engineering staff involved in diagnostic imaging**

Checklist

National level

- ❑ Government commitment and support
- ❑ National plan for diagnostic imaging services
- ❑ National Radiation Protection Control Authority
- ❑ National regulations on radiation protection
- ❑ Specialist DIS advisory groups
- ❑ Inventory and needs assessment
- ❑ Upgrading, repair and maintenance of existing facilities and establishment of new services, as appropriate
- ❑ National quality system

Local level

- ❑ Equipment and procedures relevant to each hospital's needs and the therapeutic capabilities available
- ❑ Training of all medical, technical and engineering staff involved in diagnostic imaging
- ❑ Suitable infrastructure, including radiation protection, clean water, stable power supply and air quality control
- ❑ Adequate and reliable supply of films, chemicals and spare parts
- ❑ Correct, safe functioning of equipment
- ❑ Regular maintenance of equipment by trained technical maintenance staff
- ❑ Radiation protection measurements, in accordance with national regulations
- ❑ Correct image handling, development of films and interpretation of examinations
- ❑ Quality assurance and quality control programme, including standard operating procedures

Key elements

Develop and maintain diagnostic imaging services

It is the responsibility of governments to ensure safe and adequate diagnostic imaging services (DIS) as part of national health systems. The operational responsibility may be divided between governmental and private institutions, but the overall responsibility remains with governments.

Important activities include:

- The formalization of government commitment and support
- The development of a national plan for diagnostic imaging services
- The establishment of a National Radiation Protection Control Authority to develop and enforce national regulations in accordance with international standards
- The appointment, when necessary, of specialist DIS advisory groups
- An inventory of current availability and assessment of future needs:
  - — buildings and facilities
  - — medical and technical equipment
  - — staff
  - — education and training
- The upgrading, repair and maintenance of existing facilities and the planning of new services, according to national and local needs
- The appointment and training of staff, as appropriate
- The procurement, supply, storage and distribution of films, chemicals and spare parts to ensure continuity of services
- The establishment of a national quality system, including guidelines, standard operating procedures (SOPs), accurate records, monitoring and evaluation.

Develop national guidelines and regulations

A national strategy should be developed that ensures that diagnostic imaging services at all levels adhere to national and international regulations and standards.

- National and international regulations and guidelines for radiation protection should be followed at all times
- An adequate number of trained staff should be available, in accordance with the needs of the hospital
- The technical and medical quality of examinations should conform with generally accepted international practice and recommendations
- Examinations should be performed in accordance with medical considerations.

Plan appropriate services for each level of the health care system

Diagnostic imaging services should be established as an integral part of each hospital and adapted to local needs. These will be determined by:

- The type and size of the hospital
- The number and type of patients: disease burden, inpatients and outpatients
- Therapeutic capabilities.

The structure and capacity of each diagnostic imaging facility or department should be based on existing or planned therapeutic capabilities within a hospital, region or country, in accordance with an overall, national health plan.

They should also be developed in close collaboration between national health authorities and relevant hospital clinical and technical staff.

Every hospital, from district level to tertiary level, should have the capacity to perform:

- Simple X-ray examinations
- Ultrasound examinations.

Referral hospitals and larger medical institutions should be able to provide more sophisticated techniques and procedures, including:

- Specialized X-ray based techniques, such as:
  - — Contrast media enhanced examinations (gastrointestinal tract, angiography, urography)
  - — Computed tomography (CT)
  - — Mammography
  - — Combined diagnostic and therapeutic procedures (interventional radiology)
- Doppler Technique ('Colour-Doppler')
- Magnetic Resonance Imaging (MRI)
- Nuclear medicine examinations, including Single Photon Emission (Computed) Tomography (SPECT)
- Positron Emission Tomography (PET).

Establish an infrastructure for DIS

A minimum of infrastructure should be in place for all DIS, as follows.

Department/facility

- Adequate medical and technical knowledge and skills for:
  - — correct image handling
  - — development of X-ray films
  - — interpretation and reporting of examinations
- Adequate engineering knowledge and skills for:
  - — equipment installation and maintenance
  - — radiation protection, including construction requirements and regulations
- Accessible supply of spare parts
- Reliable supply of clean water
- Reliable, stable power supply
- Adequate air quality control: pollution, temperature, humidity
- Suitable location:
  - — accessible to operating rooms and relevant departments
  - — convenient for transportation of beds and stretchers
- Adequate facilities for patients, accompanying persons and staff
- Quality control system.

Examination room and equipment

- Radiation protection in accordance with national regulations
- Correct, safe and efficient use of equipment in accordance with operation manuals and SOPs
- Regular maintenance of equipment in accordance with operation manuals and SOPs
- SOPs for:
  - — patient identification
  - — documentation
  - — archiving
- Quality control system.

Diagnostic Imaging and Laboratory Technology, World Health Organization
20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 4836

WORLD HEALTH ORGANIZATION

Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

A well-organized blood transfusion service (BTS) is a prerequisite for the safe and effective use of blood and blood products.

The HIV / AIDS pandemic has focused particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease.

Transfusion-transmitted infections can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- Establishment of a blood transfusion service
- Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis viruses, syphilis and other infectious agents
- Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

Words of advice

- **Secure government commitment and support for the national blood programme**
- **Establish a blood transfusion service as a separate unit with responsibility and authority, an adequate budget, a management team and trained staff**
- **Educate, motivate, recruit and retain voluntary non-remunerated blood donors from low-risk populations**
- **Screen all donated blood for HIV and other transfusion-transmissible agents and ensure good laboratory practice in blood grouping, compatibility testing, component preparation and the storage and transportation of blood products**
- **Reduce unnecessary transfusions through the effective clinical use of blood, including alternatives to transfusion**
- **Establish a quality system for the BTS**
- **Train all BTS and clinical staff to ensure the provision of safe blood and its effective clinical use**

Checklist

Blood transfusion service

- ❑ Government commitment and support
- ❑ National blood policy/plan
- ❑ Legislation/regulation
- ❑ Organization with responsibility and authority for the BTS
- ❑ BTS management committee
- ❑ BTS medical director
- ❑ BTS quality manager
- ❑ Specialist BTS advisory groups
- ❑ Trained BTS administrative and technical staff
- ❑ Adequate budget
- ❑ National quality system

Blood donors

- ❑ National blood donor programme officer
- ❑ Blood donor unit
- ❑ Blood donor recruitment officer
- ❑ Standard operating procedures
- ❑ Training of staff in blood donor unit
- ❑ Low-risk donor populations
- ❑ Educational materials
- ❑ Register of voluntary non-remunerated blood donors
- ❑ Donor selection, deferral, care and confidentiality
- ❑ Donor notification and referral
- ❑ Monitoring of TTIs

Blood screening

- ❑ Technical officer
- ❑ Screening strategies and protocols
- ❑ Training of laboratory technical staff
- ❑ Screening of all donated blood for TTIs
- ❑ Good laboratory practice, including standard operating procedures
- ❑ Continuity in screening
- ❑ Effective blood cold chain

Clinical use of blood

- ❑ National policy and guidelines on the clinical use of blood
- ❑ Training of clinicians and BTS staff
- ❑ Prevention, early diagnosis and treatment
- ❑ Alternatives to transfusion (crystalloids and colloids)
- ❑ Effective clinical use of blood
- ❑ Monitoring and evaluation

Key elements

Establish a blood transfusion service

It is the responsibility of governments to ensure a safe and adequate supply of blood. This responsibility may be delegated to a non-profit non-governmental organization, but the BTS should be developed within the framework of the country's health care infrastructure.

The BTS requires government commitment and support and recognition as a separate unit with an adequate budget, management team and trained staff.

Important activities in establishing a blood transfusion service include:

- Formalization of government commitment and support
- Development of a national blood policy and plan
- Development of necessary legislation/regulation for the BTS
- Formation of an organization with responsibility and authority for the BTS
- Formation of a BTS management committee
- Appointment of a medical director
- Appointment of a quality manager
- Appointment, when necessary, of specialist BTS advisory groups
- Appointment and training of staff experienced in each key aspect of the BTS
- Development and implementation of a budgeting and finance system to ensure a sustainable blood programme through cost recovery and/or annual budget allocation
- Establishment of national quality system, including guidelines, standard operating procedures (SOPs), accurate records, monitoring and evaluation.

Educate, motivate, recruit and retain low-risk blood donors

High priority should be given to the elimination of family/replacement and paid blood donor systems, which are associated with a significantly higher prevalence of TTIs. Voluntary non-remunerated blood donors from low-risk populations who give blood regularly are the foundation of a safe and adequate blood supply.

Important activities include:

- Appointment of an officer responsible for the national blood donor programme
- Establishment of a BTS unit responsible for donor education, motivation, recruitment and retention
- Appointment of a designated blood donor recruitment officer
- Preparation of SOPs in accordance with BTS guidelines
- Training of staff in the blood donor unit
- Identification of donor populations at low risk for TTIs
- Development of educational materials
- Establishment of a register of voluntary non-remunerated blood donors
- Assurance of safe blood collection procedures, including donor selection and deferral, donor care and confidentiality
- Donor notification and referral for counselling
- Monitoring of TTIs in the donor population.

Screen all donated blood for infectious agents

The BTS should develop and maintain a national strategy for the screening of donated blood and blood products for TTIs, using the most appropriate and effective tests, and for good laboratory practice in all areas of blood grouping, compatibility testing, component preparation, storage and transportation of blood products.

Important activities include:

- Appointment of a designated technical officer
- Development of protocols for the testing, selection and evaluation of appropriate screening assays to be used at each site
- Training of BTS laboratory technical staff
- Screening of all donated blood for TTIs, including HIV, hepatitis viruses, syphilis and other infectious agents, such as Chagas disease
- Good laboratory practice, including the preparation of SOPs in accordance with BTS guidelines
- Procurement, supply, central storage and distribution of reagents and materials to ensure continuity in screening at all sites
- Maintenance of an effective blood cold chain for the storage and transportation of blood and blood products.

Reduce unnecessary transfusions by effective clinical use of blood

Blood transfusion has the potential for acute or delayed complications and the transmission of infection. The risks associated with transfusion can be reduced by minimizing unnecessary transfusions through the effective clinical use of blood and blood products and the appropriate use of simple alternatives to transfusion which are safer and more cost-effective.

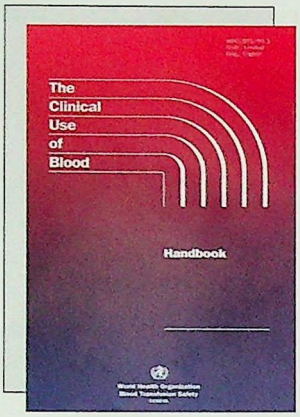
Important activities include:

- Development of a national policy and guidelines on the clinical use of blood
- Training in the clinical use of blood for all clinicians involved in the transfusion process and for BTS staff
- Commitment to the prevention, early diagnosis and treatment of conditions that could result in the need for transfusion (obstetrical complications, trauma and other causes of anaemia)
- Availability of intravenous replacement fluids (crystalloids and colloids) for the correction of hypovolaemia, and pharmaceuticals and devices to minimize the need for blood
- Effective clinical use of blood and blood products in accordance with national guidelines
- Monitoring and evaluation of the clinical use of blood.

Blood Safety Unit, World Health Organization
20 Avenue Appia, CH-1211 Geneva 27, Switzerland. Fax: +41 22 791 4836

Just Published!

The Clinical Use of Blood Handbook



World Health Organization
2001, 219 pages
ISBN 92 4 154539 9
Swiss francs 15.—
In developing countries:
Fr.s. 10.50
Order no. 1150485

The Clinical Use of Blood Handbook, provides a handy guide to the appropriate use of blood and blood products for prescribers of blood at all levels of the healthcare system. It is designed to provide a quick reference to transfusion, particularly when an urgent clinical decision is required. It summarizes key information from a more extensive module of learning material: *The Clinical Use of Blood* (see front page). Both the module and handbook have been prepared by an international team of clinical and blood transfusion specialists and reviewed by relevant WHO departments and critical readers from a range of specialties from all regions of the world.

The handbook introduces the principles of the appropriate use of blood and blood products and outlines the characteristics and indications for use of intravenous replacement fluids, whole blood, blood components and plasma derivatives. It provides a detailed guide to clinical transfusion procedures and the recognition and management of transfusion reactions. Comprehensive guidance is given on transfusion and alternatives to transfusion in the areas of general medicine, obstetrics, paediatrics & neonatology, surgery & anaesthesia, trauma & acute surgery, and burns. Key points, tables and algorithms are highlighted for easy reference and a comprehensive index is included.

ORDER FORM

MDI.BLO.201

☐ Please send me____ copies of **The Clinical Use of Blood in Medicine, Obstetrics, Paediatrics, Surgery & Anaesthesia, Trauma & Burns** at the price of Sw.fr. 40.--/ In developing countries Sw.fr. 28.-- (order no. 1150484)

☐ Please send me____ copies of **The Clinical Use of Blood Handbook** at the price of Sw.fr. 15.--/In developing countries Sw.fr. 10.50 (order no. 1150485)

Name _____

Address _____

☐ Payment enclosed

☐ Please charge to my credit card

☐ Visa ☐ American Express ☐ Diners Club

☐ Eurocard/Access/Mastercard

Card No. _____

Expiry date _____

Date of order _____

Signature _____

WHO • Marketing & Dissemination • 1211 Geneva 27 • Switzerland
Tel.: (41 22) 791 24 76 - Fax : (41 22) 791 48 57 - E.mail : bookorders@who.ch

JUST PUBLISHED!

World Health Organization

The Clinical Use of Blood
in Medicine, Obstetrics, Paediatrics, Surgery & Anaesthesia, Trauma & Burns

World Health Organization
2001, 337 pages
ISBN 92 4 154538 0
Swiss francs 40.—
In developing countries:
Fr.s. 28.—
Order no. 1150484

Blood transfusion is an essential part of modern health care. Used correctly, it can be a life-saving intervention. Inappropriate use can endanger life because of the potential risk of acute or delayed complications, including the transmission of infectious agents, such as HIV, hepatitis viruses, syphilis, malaria and Chagas disease. The decision to transfuse blood or blood products should therefore always be based on a careful assessment of clinical and laboratory indications that transfusion is necessary to save life or prevent significant morbidity.

The Clinical Use of Blood is an accessible learning tool that will assist prescribers of blood to make appropriate clinical decisions on transfusion and contribute to wider efforts to minimize the unnecessary use of blood and blood products. It has been prepared by an international team of clinical and blood transfusion specialists and has been extensively reviewed by relevant WHO departments and critical readers from a range of specialists from all regions of the world.

This module has been developed for prescribers of blood at all levels of the health system, particularly clinicians and senior paramedical staff at first referral level (district hospitals) in developing countries. It has been designed for use in undergraduate and postgraduate programmes, in-service training and continuing medical education programmes, but can also be used for independent study. Its interactive style, with learning objectives, activities and case studies, encourages users to focus on the use of transfusion in their own clinical environment and promotes the development of local guidelines on clinical blood usage. Key points, tables and algorithms are highlighted for easy reference and a comprehensive index is included.

Part 1: Principles, Products and Procedures introduces the principles of the appropriate use of blood and outlines the characteristics and indications for use of intravenous replacement fluids, whole blood, blood components and plasma derivatives. It also provides a detailed guide to clinical transfusion procedures and the recognition and management of transfusion reactions.

Part 2: Transfusion in Clinical Practice summarizes factors to consider in making clinical decisions on transfusion and provides comprehensive guidance on transfusion and alternatives to transfusion in the areas of general medicine, obstetrics, paediatrics & neonatology, surgery & anaesthesia, trauma & acute surgery, and burns.

Part 3: The Appropriate Use of Blood — Putting It into Practice explores how individual clinicians and blood transfusion specialists can make a practical contribution to achieving the appropriate use of blood, both within their own hospitals and more widely.

A companion handbook (see reverse side), contains a summary of key information from the module to provide a quick reference when an urgent decision on transfusion is required.

Publications

WHO, Marketing & Dissemination, 1211 Geneva 27, Switzerland
Tel (41 22) 791 24 76 - Fax (41 22) 791 48 57 - E.mail: publications@who.ch

WHO/BCT/BTS/01.3
Distr.: Limited
Orig.: English

Developing a National Policy and Guidelines on the Clinical Use of Blood

Recommendations

World Health Organization
Blood Transfusion Safety
GENEVA

Developing a National Policy and Guidelines on the Clinical Use of Blood

Recommendations

World Health Organization
Blood Transfusion Safety
GENEVA

Contents

Acknowledgements

WHO/BCT/BTS wishes to acknowledge with thanks the efforts of all participants in the expert group meeting at which these Recommendations were formulated — Dr Paul Fenton, Associate Professor, Department of Anaesthesia, College of Medicine, Malawi; Dr Jorge Fernandez, National Adviser, ETS/SIDA Department, Secretariat for Health, Honduras; Dr Peter Flanagan, Clinical Director, Northern Zone, National Blood Service, UK; Dr Brian McClelland, Regional Director, Edinburgh and South-East Scotland Blood Transfusion Service, UK; Dr Patricia Rivera, Consultant, BID/OPS/SSH Project, Honduras; Dr Maria de los Angeles Rodriguez, Head of the Blood Bank, Hospital Naval, Viña del Mar, Chile; and Dr Elizabeth Vinelli, Medical Director, National Blood Programme, Honduran Red Cross, Honduras.

Special thanks are due to Ms Jan Fordham, Director, Open Learning Associates, UK, for her assistance in the preparation of this document.

Introduction

Blood transfusion is an essential part of modern health care. Used correctly, it can save life and improve health. However, as with any therapeutic intervention, it may result in acute or delayed complications and carries the risk of transmission of infectious agents, such as HIV, hepatitis viruses, syphilis and Chagas disease. It is also expensive and uses a scarce human resource.

The risks associated with transfusion can only be avoided by close collaboration between the blood transfusion service and clinicians in managing the components of the transfusion process for which they are each responsible:

- An adequate supply of safe blood and blood products
- The effective clinical use of blood and blood products.

Safe blood and blood products

A prerequisite for the effective clinical use of blood is a well-organized blood transfusion service (BTS) that is able to provide blood and blood products that are safe, accessible at reasonable cost and adequate to meet national needs.

Only blood which has been obtained from appropriately selected donors and has been screened for transfusion-transmissible infectious agents, in accordance with national requirements, should be issued for transfusion, other than in the most exceptional life-threatening situations.

Low-risk blood donors

Voluntary non-remunerated blood donors from low-risk groups who give blood regularly are the foundation of a safe and adequate blood supply. A reliance on family/replacement and paid blood donors should be phased out as these donors are associated with a significantly higher prevalence of transfusion-transmissible infections.

The education, motivation, recruitment and retention of voluntary non-remunerated blood donors requires the following activities to be undertaken.

1. The establishment of a blood donor unit within the BTS, with an officer responsible for the national blood donor programme and a designated donor recruitment officer.
2. The training of staff responsible for donor education, motivation, recruitment and selection.
3. The identification of donor populations at low risk for transfusion-transmissible infections.
4. Educational and media campaigns in workplaces, communities and educational institutions.
5. The maintenance of a register of voluntary non-remunerated blood donors.
6. Safe blood collection procedures, including donor selection and deferral, donor care and confidentiality.
7. Donor notification and referral for counselling.
8. The monitoring of transfusion-transmissible infections in the blood donor population.

Screening and processing of donated blood

Quality assurance and good laboratory practice are essential in all areas of blood screening and processing. Important activities include:

1. The development and implementation of a national strategy for the screening of all donated blood for transfusion-transmissible infections, using the most appropriate and effective assays to test for HIV, hepatitis viruses, syphilis and other infectious agents, such as Chagas disease.
2. The training of BTS laboratory technical staff in all aspects of blood screening, blood grouping, compatibility testing, component preparation and the issue of blood for transfusion.
3. Good laboratory practice, including the use of standard operating procedures, in all aspects of blood screening and processing.
4. Compatibility testing of all whole blood and red cells transfused even if, in life-threatening emergencies, this is performed after they have been issued.
5. The procurement, supply, central storage and distribution of reagents and materials to ensure continuity in testing at all sites.
6. The maintenance of an effective blood cold chain for the storage and transportation of blood and blood products.

The effective clinical use of blood

The decision to transfuse blood or blood products must be based on a careful assessment of clinical and laboratory indications that a transfusion is necessary to save life or prevent significant morbidity.

Responsibility for the decision to transfuse must ultimately rest with individual prescribers of blood, although this will often be made in consultation when specialist transfusion advice is available. However, consistently effective clinical transfusion practice cannot be achieved unless the following elements are in place.

1. A national policy on the clinical use of blood, with appropriate supportive regulations.
2. National guidelines on the clinical use of blood to aid prescribers of blood in their clinical decisions about transfusion.
3. A National Committee on the Clinical Use of Blood and hospital transfusion committees at local level to implement, regularly review and update the national policy and guidelines.
4. The training of all clinical and blood transfusion service staff involved in the transfusion process, based on the national guidelines.
5. The availability of simple alternatives to transfusion (crystalloids and colloids) for the correction of hypovolaemia, and pharmaceuticals and medical devices to minimize the need for transfusion.
6. Monitoring and evaluation of the implementation of the national policy and guidelines and the use of monitoring data in a quality improvement and education programme to assist clinicians to improve their practice.

1 Steps in Developing a National Policy and Guidelines on the Clinical Use of Blood

The primary responsibility for the development of a national policy and guidelines on the clinical use of blood lies with clinicians, although the process may be initiated either by clinicians or by the BTS. Close collaboration between them is essential since the effective clinical use of blood is dependent on the availability of safe and adequate supplies of blood and blood products from the BTS.

Where there is a national blood transfusion policy and plan and a National Blood Transfusion Committee (NBTC) with required legislative support has already been established, the development of a national policy and guidelines on the clinical use of blood could be undertaken within the same framework.

In countries where an effectively functioning NBTC or similar body does not exist, a small Working Group may be initiated by the BTS or individual clinicians to prepare a draft policy and organize the drafting of the clinical guidelines.

The establishment of a National Committee on the Clinical Use of Blood will subsequently be required to ensure the effective implementation of the national policy and guidelines.

Steps

Developing and implementing a national policy and guidelines on the clinical use of blood requires systematic planning and extensive consultation. The following steps are recommended, although the sequence and timing of these steps will be determined by national circumstances.

1. Sensitization of the Ministry of Health/national health authority to the need for a national policy and guidelines on the clinical use of blood.
2. Preparation of a draft national policy on the clinical use of blood by a select Working Group comprising clinical specialists and senior personnel from the BTS.
3. Submission of the draft policy to the Ministry of Health/national health authority for approval, endorsement and support.
4. National workshop to plan and draft national guidelines on the clinical use of blood, involving:
   - Clinical specialists
   - Senior BTS personnel
   - Senior pharmacists.
5. Further development of the draft national guidelines by specialist working groups from major clinical blood use specialties and the blood transfusion service.
6. Consolidation and editing of the draft national guidelines by the select Working Group.

7 Circulation of the draft guidelines nationally for review by clinicians.

8 Incorporation of comments and amendments and preparation of the final draft of the national guidelines by the select Working Group.

9 Second national workshop to finalize the guidelines and plan a national strategy and workplan for their dissemination and implementation.

10 Submission of the revised guidelines to the Ministry of Health/national health authority for approval and endorsement and the preparation of a legislative framework, if required.

11 Establishment of a National Committee on the Clinical Use of Blood.

12 Establishment of a hospital transfusion committee in each hospital to implement and monitor the national policy and guidelines.

13 Dissemination of the national policy and guidelines to the providers and prescribers of blood.

14 Integration of education and training on the effective clinical use of blood into undergraduate, postgraduate, in-service and continuing education programmes for clinical and blood transfusion service staff.

15 Development of indicators for monitoring and the establishment of a national system to monitor and evaluate the implementation of the national policy and guidelines.

2 National Policy on the Clinical Use of Blood

A national policy on the clinical use of blood is an essential component of a strategy to ensure that blood and blood products are transfused only to treat conditions leading to significant morbidity or mortality that cannot be prevented or treated effectively by other means.

Key elements

A national policy on the clinical use of blood should define the strategy for the effective clinical use of blood, blood products and alternatives to transfusion. This should include the following key elements.

1. A commitment by health authorities, health care providers and clinicians to the prevention, early diagnosis and effective treatment of conditions that could lead to the need for transfusion by strengthening public health and primary health care programmes.
2. A blood transfusion service that is able to provide adequate and timely supplies of safe blood and blood products.
3. The promotion and availability of:
   - Intravenous replacement fluids (crystalloids and colloids) for the correction of hypovolaemia
   - Pharmaceuticals and devices to minimize the need for transfusion
   - Sterile disposable equipment for blood samples, injection and infusion.
4. The availability of national guidelines on the clinical use of blood, which include:
   - A standard blood request form
   - A model blood ordering schedule
   - Standard operating procedures for all stages of the clinical transfusion process
   - Information on the specific characteristics of blood products, plasma derivatives, intravenous replacement fluids and pharmaceuticals
   - Clinical indications for transfusion.
5. The establishment of a National Committee on the Clinical Use of Blood and hospital transfusion committees at local level.
6. Education and training in the effective clinical use of blood and blood products for all clinical and blood bank staff involved in the transfusion process.
7. Effective clinical transfusion practice in accordance with the national guidelines on the clinical use of blood.
8. Monitoring and evaluation of the clinical use of blood.

3 National Guidelines on the Clinical Use of Blood

Guidelines on the clinical use of blood should represent a national consensus by clinicians, the BTS and pharmacists on the most effective treatment for specific clinical conditions, in the context of local conditions, and should be based on the best available information. The objectives of developing and implementing clinical guidelines are as follows.

1 To define clinical and BTS requirements for the appropriate use of blood, blood products and simple alternatives to transfusion, including intravenous replacement fluids, and pharmaceuticals and medical devices to minimize the need for transfusion.

2 To make available standard operating procedures for all stages of the transfusion process.

3 To facilitate the monitoring and evaluation of transfusion practice nationally and locally in order to improve the clinical use of blood.

Principles of the clinical use of blood

The following principles should be considered in the formulation of national guidelines on the clinical use of blood.

1 Transfusion is only one element of the patient's management.

2 Prescribing decisions should be based on the national guidelines on the clinical use of blood, taking individual patient needs into account.

3 Blood loss should be minimized to reduce the patient's need for transfusion.

4 The patient with acute blood loss should receive effective resuscitation (intravenous replacement fluids, oxygen, etc.) while the need for transfusion is being assessed.

5 The patient's haemoglobin value, although important, should not be the sole deciding factor in starting transfusion. The decision to transfuse should be supported by the need to relieve clinical signs and symptoms and prevent significant morbidity and mortality.

6 The clinician should be aware of the risks of transfusion-transmissible infection in the blood and blood products that are available for the individual patient.

7 Transfusion should be prescribed only when the benefits to the patient are likely to outweigh the risks.

8 The clinician should record the reason for transfusion clearly.

9 A trained person should monitor the transfused patient and respond immediately if any adverse effects occur.

Key elements

Guidelines on the clinical use of blood should be practical, comprehensive and relevant to local circumstances for use by clinicians who need to make urgent decisions on whether or not to transfuse a patient.

1 Standard blood request form

All requests for blood and blood products should be accompanied by a blood request form that has been completed by the prescribing clinician. Ideally, a standard blood request form, developed by the blood transfusion service and reviewed and agreed by the National Committee on the Clinical Use of Blood, should be used throughout the country to promote effective clinical transfusion practice and aid in the monitoring and evaluation of clinical blood use.

Annex 1 summarizes the information that should be provided on a blood request form. It also contains a simple checklist that could be printed on the reverse of the form to assist clinicians in applying the principles of the clinical use of blood when making decisions about transfusion.

2 Blood ordering schedule

It is unnecessary for blood to be crossmatched routinely for every surgical procedure since many operations rarely require transfusion. Considerable time and expense can be saved by analysing the usage of blood and developing a blood ordering schedule as a guide to the number of units of blood and blood products that should normally be ordered for common procedures. The use of a blood ordering schedule minimizes unnecessary crossmatching and reduces the amount of blood that becomes outdated. It also makes it possible to ensure that blood is readily available for all patients who need it.

National guidelines on the clinical use of blood should therefore include a blood ordering schedule with guidance on its adaptation by clinicians, in conjunction with the hospital blood bank, in each hospital at different levels of the health system, including national, provincial/regional and district hospitals.

Each hospital's blood ordering schedule should reflect the clinical team's usual use of blood for common procedures, depending on their complexity and expected blood loss, and should take account of both local clinical conditions and the supply of blood, blood products and alternatives to transfusion that are available. It should also include guidance on the use of the group and screen policy for patients undergoing procedures for which red cell transfusion is occasionally, but rarely, required. If no clinically important antibodies are detected, fully crossmatched blood can quickly be made available using a rapid crossmatch technique. If the antibody screening test is positive, antigen negative blood should be crossmatched and reserved for the patient, even when there is little likelihood that transfusion will be needed.

Each hospital transfusion committee should agree a procedure for the prescribing clinician to override the blood ordering schedule when it is probable that a patient will need more blood than is stipulated: for example, if the procedure is likely to be more complex than usual or if the patient has a coagulation defect. In such cases, additional units of blood should be crossmatched as requested by the clinician.

Annex 2 outlines the process for developing a blood ordering schedule and contains an example of a blood ordering schedule for surgical procedures in adult patients.

3 Standard operating procedures

National guidelines on the clinical use of blood should include standard operating procedures for the following stages in the clinical transfusion process and, ideally, standard documentation such as a transfusion reaction report form.

1 Ordering blood and blood products in routine and emergency situations.

2 The issue of blood and blood products.

3 The transportation of blood and blood products and storage in the clinical setting.

4 The administration of blood and blood products.

5 Recording all transfusions in patient records.

6 Monitoring the patient before, during and after transfusion.

7 The management, investigation and recording of transfusion reactions.

Annexes 3 and 4 include guidance on monitoring the transfused patient and investigating and recording acute transfusion reactions.

4 Blood, blood products and alternatives to transfusion

The guidelines should contain information on indications, dosage, risk of transmission of infection, storage conditions, means of administration, contraindications and precautions for the blood products and alternatives to transfusion that are available.

Blood components

- Whole blood
- Red cells
- Platelet concentrates
- Plasma
- Cryoprecipitate

Plasma derivatives

- Albumin
- Coagulation factors
- Immunoglobulins

Intravenous replacement fluids

- Crystalloid solutions
- Colloid solutions

Pharmaceuticals

- Drugs
- Medical devices for blood salvage and to maximize blood volume
- Sterile disposable equipment for blood samples, injection and infusion

5 Clinical indications for transfusion

The guidelines should include clinical and laboratory indications for the use of blood and blood products in:

- Anaemia
- Chronic blood loss
- Acute blood loss
- Supportive treatment: e.g. haemophilia, thalassaemia and immunodeficiency disorders.

Listed below are some clinical disciplines for which indications for transfusion might be included.

General medicine

- Anaemia
  - Malaria
  - HIV infection
  - Haemolytic anaemias
- Oncology
- Bone marrow dysfunction
- Haemoglobinopathies
  - Sickle cell disease
  - Thalassaemias
- Disorders of haemostasis
  - Congenital
  - Acquired
- Thrombocytopenia

Paediatrics

Neonatology

- Neonatal anaemia
- Haemolytic disease of the newborn
- Exchange transfusion
- Vitamin K deficiency
- Thrombocytopenia

General paediatrics

- Severe paediatric anaemia
  - Nutritional anaemia
  - Malaria
  - Other infections
- Oncology/malignancies
- Haemoglobinopathies
  - Sickle cell disease
  - Thalassaemias
- Disorders of haemostasis
  - Congenital
  - Acquired
- Thrombocytopenia

Obstetrics

- Anaemia in pregnancy
- Major obstetric haemorrhage/complications
- Disseminated intravascular coagulation
- HIV infection

Surgery and trauma

- Elective surgery
- Acute surgery and trauma
- Disorders of haemostasis
  - — Congenital
  - — Acquired
- Thrombocytopenia
- Burns
  - — Children
  - — Adults

4 National Committee on the Clinical Use of Blood

A National Committee on the Clinical Use of Blood requires authority and support in order to ensure the effective implementation of the national policy and guidelines.

Role

The principal functions of a National Committee on the Clinical Use of Blood are to:

1. Ensure the national policy and guidelines on the clinical use of blood are disseminated to hospitals at all levels of the health system.
2. Provide guidance on the establishment of hospital transfusion committees and their roles and responsibilities in implementing and monitoring the national policy and guidelines.
3. Ensure that a standard blood request form, developed by the blood transfusion service, is available and used uniformly in all hospitals.
4. Promote the development and use of an appropriate blood ordering schedule in each hospital in which surgical procedures are performed.
5. Ensure that standard operating procedures for all stages of the clinical transfusion process are available and used uniformly in all hospitals.
6. Promote the development of an education and training programme for personnel at all levels who are involved in the prescription and administration of blood and blood products.
7. Establish a system to monitor and evaluate the pattern of blood usage, the implementation of the national policy and guidelines, and the effectiveness of the education and training programme.
8. Regularly review and, where necessary, update the national policy and guidelines and the strategy for their implementation.

Membership

The effectiveness of a National Committee on the Clinical Use of Blood will depend on the careful selection of a small number of dedicated, enthusiastic individuals with specialist expertise in clinical transfusion practice who are able to meet on a regular basis.

While the most appropriate composition of the committee will be determined by national circumstances, it should include senior representatives of both the providers and prescribers of blood and blood products, including:

1. A senior professional officer from the Ministry of Health/national health authority.
2. Representatives of clinical blood use specialties, such as:
   - Accident and emergency/casualty
   - Anaesthesia/intensive care

- Surgery
- Obstetrics and gynaecology
- Paediatrics
- General medicine
- Haematology/oncology
- Nursing.

3 Representatives of hospital transfusion committees.

4 Senior personnel from the blood transfusion service, such as:
- Medical director
- Manager/finance officer
- Quality manager
- Senior laboratory technologist.

5 Senior officer (pharmacy or supplies) responsible for the supply of intravenous replacement fluids, pharmaceuticals, medical devices and sterile disposal equipment.

6 Representatives of relevant organizations involved in the clinical aspects of blood transfusion, such as:
- Education and training institutions
- Non-governmental organizations:
  - National Red Cross or Red Crescent Society
  - Voluntary blood donor organizations
  - Associated voluntary organizations: e.g. Haemophilia Association, Thalassaemia Association.

Annex 5 shows a possible organizational structure for a National Committee on the Clinical Use of Blood.

5 Hospital Transfusion Committees

A hospital transfusion committee should be set up in each hospital to implement the national policy and guidelines on the clinical use of blood and monitor the use of blood and blood products at the local level. The hospital transfusion committee should have authority within the hospital structure to determine hospital policy in relation to transfusion and resolve any problems that have been identified.

Role

The principal functions of a hospital transfusion committee are to:

1. Monitor the safety, adequacy and reliability of the supply of blood, blood products and alternatives to transfusion.
2. Develop systems and procedures for the implementation of the national guidelines on the clinical use of blood within the hospital, including the development of a hospital blood ordering schedule.
3. Promote the effective implementation of the national guidelines through the education and training of all clinical and blood bank staff involved in the transfusion process.
4. Monitor the usage of blood and blood products in the hospital.
5. Monitor the implementation of the national guidelines in the hospital and take appropriate action to overcome any factors hindering their effective implementation.
6. Review incidents of severe adverse effects or errors associated with transfusion, identify any corrective action required and refer them to the National Committee on the Clinical Use of Blood.

Membership

A hospital transfusion committee should be multidisciplinary and involve all departments in the hospital that are involved in providing and prescribing blood and blood products. These may include:

1. Senior representatives of clinical specialties that prescribe blood in the hospital.
2. The responsible officer from the hospital blood bank and, where applicable, a representative of the blood transfusion service that supplies blood and blood products to the hospital.
3. The hospital staff member responsible for the supply of intravenous replacement fluids, pharmaceuticals, medical devices and sterile disposable equipment.
4. The senior nurse.

The membership of the hospital transfusion committee will be primarily clinical but, on occasions, may also need to involve other personnel, such as the hospital administrator/finance officer and the medical records officer.

6 Education and Training

The effective implementation of the national policy and guidelines requires the development of a national programme of education and training in the clinical use of blood. This should be incorporated into pre-service, postgraduate and in-service training programmes for clinicians, blood bank staff and other personnel involved in the transfusion process and into continuing medical education programmes.

Undergraduate and postgraduate programmes

- Medical schools and teaching hospitals
- Medical laboratory technology training institutions
- Schools of nursing
- Paramedical schools

In-service training

- Clinicians
- Nurses
- Blood transfusion service/hospital blood bank technical staff

Continuing medical education

- Hospital clinical meetings
- Seminars and conferences
- Medical publications

WHO training materials

Each country's national policy and clinical guidelines should be the principal resource for education and training in the clinical use of blood. The following learning resources are also available from WHO.

Aide-Mémoire: Blood Safety

The Clinical Use of Blood

- Learning materials
- Pocket handbook

Safe Blood and Blood Products

- Introductory Module: *Guidelines and Principles for Safe Blood Transfusion Practice*
- Module 1: *Safe Blood Donation*
- Module 2: *Screening for HIV and Other Infectious Agents*
- Module 3: *Blood Group Serology*

Establishing a Distance Learning Programme in Blood Safety: A manual for programme coordinators

- Manual
- Toolkit

The Blood Cold Chain (in preparation)

- Guide for Managers of Blood Cold Chain Equipment
- Guide for Users of Blood Cold Chain Equipment

7 Monitoring and Evaluation

A simple system of monitoring and evaluation is essential to assess patterns of blood usage and the impact of the national policy and guidelines on the clinical use of blood. This requires a systematic approach to data collection and analysis at all levels of the health system.

The responsibility for establishing a system of monitoring and evaluation should be shared by the blood transfusion service, the National Committee on the Clinical Use of Blood and the department responsible for the supply of intravenous replacement fluids, pharmaceuticals, medical devices and sterile disposable equipment.

Monitoring and evaluation should also be undertaken in each hospital by the hospital transfusion committee and the results reported to the National Committee on the Clinical Use of Blood.

Key elements

The following elements should be included in a system for the monitoring and evaluation of clinical blood use.

1 The safety, adequacy, and reliability of the supply of blood and blood products.

2 The adequacy and reliability of the supply of intravenous replacement fluids (crystalloids and colloids) and pharmaceuticals to avoid unnecessary transfusion, and sterile disposable equipment for blood samples, injection and infusion.

3 Differences in blood usage within hospitals and between similar hospitals at national, provincial/regional and district level.

4 The availability of the national guidelines on the clinical use of blood at all levels of the health system and the establishment of education and training programmes in their use.

5 The establishment of systems needed to ensure the effective use of the guidelines by the providers and prescribers of blood.

6 Compliance with the national guidelines in the clinical use of blood, blood products and alternatives to transfusion.

Indicators for monitoring and evaluation

The following indicators provide a simple framework for the monitoring and evaluation of the clinical use of blood by hospital transfusion committees. Annex 6 provides a more comprehensive list of indicators.

1 Are adequate, reliable supplies of safe blood and blood products available to meet demands?

Indicator Percentage of unfilled requests, by product

Annex 1

Standard blood request form

A standard blood request form should provide the following information:

- Date of request
- Date and time the blood is needed
- Where the blood should be delivered
- Patient's full name
- Patient's date of birth
- Patient's sex
- Patient's hospital reference number
- Patient's ward
- Provisional diagnosis
- Reason why transfusion is requested
- Number of units of blood or blood products required
- Whether patient's serum should be grouped, screened and held
- Standard or emergency request
- Name and signature of the person requesting the blood

Where previous records or a reliable history are available, the following information should also be provided:

- Patient's blood group, if known
- Presence of any antibodies
- History of any previous transfusions
- History of any previous transfusion reactions
- Females: number of previous pregnancies and maternal/infant incompatibility
- Other relevant medical history or condition

The simple checklist on p. 20 could be printed on the reverse of the blood request form to remind clinicians of factors that need to be considered in the management of patients who may require transfusion.

EXAMPLE

Blood ordering schedule: a guide to expected normal blood usage for surgical procedures in adult patients

Procedure	Action	Procedure	Action
General surgery		**Obstetrics & gynaecology**	
Cholecystectomy	G & S	Termination of pregnancy	G & S
Laparotomy: planned exploration	G & S	Normal delivery	G & S
		Caesarean section	G & S
Liver biopsy	G & S	Placenta praevia/retained placenta	X-M 4
Hiatus hernia	X-M 2		
Partial gastrectomy	G & S	Antepartum/postpartum haemorrhage	X-M 2
Colectomy	X-M 2		
Mastectomy: simple	G & S	Dilatation & curettage	G & S
Mastectomy: radical	X-M 2	Hysterectomy: abdominal or vaginal: simple	G & S
Thyroidectomy: partial/total	X-M 2 (+ 2)		
		Hysterectomy: abdominal or vaginal: extended	X-M 2
Cardiothoracic			
Angioplasty	G & S	Myomectomy	X-M 2
Open heart surgery	X-M 4 (+ 4)	Hydatidiform mole	X-M 2
Bronchoscopy	G & S	Oophorectomy (radical)	X-M 4
Open pleural/lung biopsy	G & S		
Lobectomy/pneumonectomy	X-M 2	**Orthopaedics**	
		Disc surgery	G & S
Vascular		Laminectomy	G & S
Aortic-iliac endarterectomy	X-M 4	Removal hip pin or femoral nail	G & S
Femoral endarterectomy	G & S		
Femoro-popliteal bypass	G & S	Total hip replacement	X-M 2 (+ 2)
Ilio-femoral bypass	X-M 2	Ostectomy/bone biopsy (except upper femur)	G & S
Resection abdominal aortic aneurysm	X-M 6 (+ 2)		
		Nailing fractured neck of femur	G & S
Neurosurgery		Laminectomy	G & S
Craniotomy, craniectomy	G & S	Internal fixation of femur	X-M 2
Meningioma	X-M 4	Internal fixation: tibia or ankle	G & S
Head injury, extradural haematoma	G & S		
		Arthroplasty: total hip	X-M 3
Vascular surgery (aneurysms, A-V malformations)	X-M 3	Spinal fusion (scoliosis)	X-M 2
		Spinal decompression	X-M 2
		Peripheral nerve surgery	G & S
Urology			
Ureterolithotomy	G & S		
Cystotomy	G & S		
Ureterolithotomy & cystotomy	G & S		
Cystectomy	X-M 4		
Open nephrolithotomy	X-M 2		
Open prostatectomy (RPP)	X-M 2		
Transurethral resection prostatectomy (TURP)	G & S		
Renal transplantation	X-M 2		

X-M = Crossmatch G & S = ABO/Rh group and antibody screen

(+) indicates additional units may be required, depending on surgical complications

Annex 3

Monitoring the transfused patient

1 **For each unit of blood transfused**, monitor the patient at the following stages:
   - Before starting the transfusion
   - As soon as the transfusion is started
   - 15 minutes after starting transfusion
   - At least every hour during transfusion
   - On completion of the transfusion
   - 4 hours after completing the transfusion.

2 At each of these stages, record the following information on the patient's chart:
   - Patient's general appearance
   - Temperature
   - Pulse
   - Blood pressure
   - Respiration
   - Fluid balance:
     - — Oral and IV fluid intake
     - — Urinary output.

3 Record:
   - Time the transfusion is started
   - Time the transfusion is completed
   - Volume and type of all products transfused
   - Unique donation numbers of all products transfused
   - Any adverse effects.

4 Monitor the patient particularly carefully during the first 15 minutes of the transfusion to detect early signs and symptoms of adverse effects.

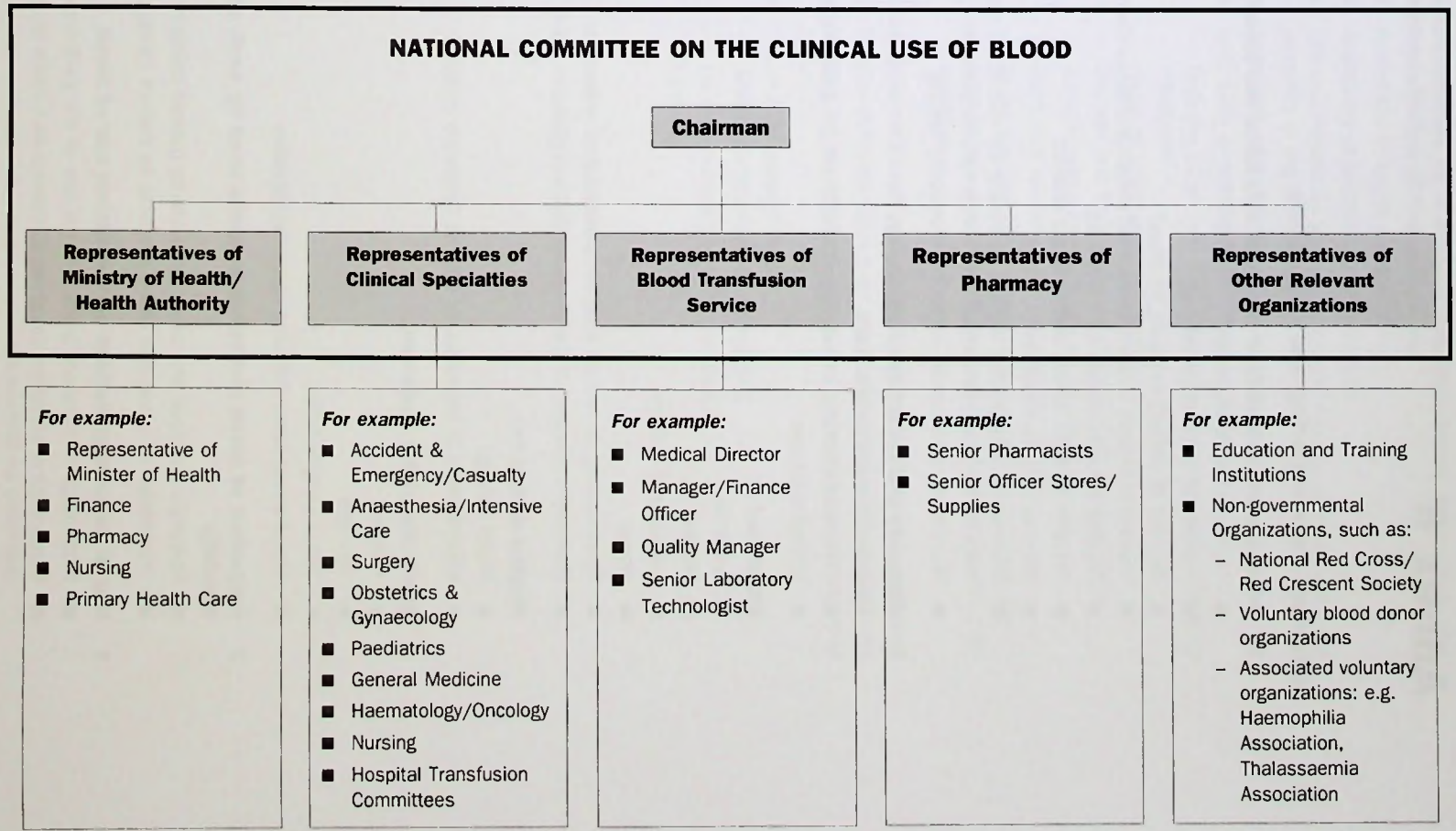
Annex 4

Investigating and recording acute transfusion reactions

1. Stop the transfusion and keep the IV line open with normal saline while making an initial assessment of the acute transfusion reaction and seeking advice.
2. Immediately report all acute transfusion reactions, with the exception of mild urticarial reactions, to a medical officer and to the blood bank that supplied the blood.
3. Record the following information on the patient's notes:
   - Type of transfusion reaction
   - Length of time after the start of transfusion that the reaction occurred
   - Volume and type of blood products transfused
   - Unique donation numbers of all products transfused.
4. Immediately the reaction occurs, take the following samples and send with a request form to the blood bank for laboratory investigations:
   - Immediate post-transfusion blood samples (1 clotted and 1 anticoagulated: EDTA/Sequestrene) from the vein opposite the infusion site
   - Blood culture in a special blood culture bottle, if septic shock due to a contaminated blood unit is suspected
   - The blood unit and giving set containing red cell and plasma residues from the transfused donor blood
   - The first specimen of the patient's urine following the reaction.
5. Complete a transfusion reaction report form.
6. After the initial investigation of the transfusion reaction, send the following to the blood bank for laboratory investigations:
   - Blood samples (1 clotted and 1 anticoagulated: EDTA/Sequestrene) taken from the vein opposite the infusion site 12 hours and 24 hours after the start of the reaction
   - All patient's urine for at least 24 hours after the start of the reaction.

Annex 5

Possible organizational structure for a National Committee on the Clinical Use of Blood



Annex 6

Indicators for monitoring and evaluation

1 **Adequacy and reliability of supply of safe blood and blood products**

- Number of units requested
- Number of units crossmatched
- Number of unfilled requests for blood
- Number of elective surgeries cancelled because of blood shortages
- Number of units issued for transfusion
- Number of units issued and returned unused
- Number of units discarded
- Number of units issued without screening for infectious disease markers (HIV, hepatitis, syphilis and other nationally-required tests)
- Number of units issued without compatibility testing

2 **Adequacy and reliability of supply of:**

Intravenous replacement fluids

- Crystalloid solutions, including normal saline (0.9% sodium chloride)
- Colloid solutions

Drugs used in:

- Anaemia
- Malaria
- Labour and delivery
- Shock
- Child-spacing (to reduce pregnancy-associated anaemias)
- Haemolytic disease of the newborn (immunoglobulin anti-D)

Medical devices for:

- Blood salvage
- Maximization of intravascular volume (pressure cuffs)

Sterile disposable equipment:

- Needles
- Syringes
- Blood sample tubes
- Blood giving sets, including cannulae/needles

3 **Proportion of blood and blood products used by each clinical specialty**

- Requests for blood and blood products by patient category
- Transfusion of blood and blood products by patient category

4 **Use of national guidelines on the clinical use of blood**

- Percentage of clinicians trained in the use of the guidelines
- Percentage of clinicians using the guidelines as a basis for clinical decisions on transfusion

5 Establishment of a system and procedures to support the implementation of the guidelines

- Availability of blood request form
- Availability of blood ordering schedule
- Efficient system for transportation and storage of blood and blood products in the clinical setting
- Availability of transfusion reaction report form
- Availability of standard operating procedures for:
  - — Ordering blood and blood products in routine and emergency situations
  - — Issue of blood and blood products
  - — Storage and transportation of blood and blood products
  - — Administration of blood and blood products
  - — Recording all transfusions in patient records
  - — Monitoring the patient before, during and after transfusion
  - — Management, investigation and recording of transfusion reactions

6 Compliance with national guidelines on the clinical use of blood

- Number of transfusions given in accordance with national guidelines
- Number of transfusions not given in accordance with national guidelines
- Outcome of transfusions:
  - — Acute complications of transfusion
  - — Delayed complications of transfusion
  - — Mortality

World Health Organization, Geneva

WHO HIV Test Kit —

Bulk Procurement Scheme

"ensuring access to high quality, low cost HIV test kits"

The Issue

HIV test kits are essential for:

- ✓ Diagnosis of HIV infection
- ✓ Screening of donated blood
- ✓ Surveillance
- ✓ Voluntary counselling and testing
- ✓ Prevention of mother-to-child transmission

However...

- HIV test kits account for a substantial proportion of the budgets of most National AIDS Control Programmes.
- National and local blood transfusion services in many countries do not have the financial resources to purchase the required number of test kits.
- Many countries have interrupted supplies of test kits.
- Many countries require additional information to ensure that the kits they do purchase are of high quality and are suitable for their particular situation.

The Response

WHO established the HIV Test Kit Bulk Procurement Scheme in 1989. The goals of the scheme are to:

- Facilitate access to:
  - ✓ *high quality* test kits
  - ✓ at a *low cost*
  - ✓ through an *easy purchase procedure*
- Provide additional information and assistance to those selecting/purchasing test kits to ensure that the chosen kits will be appropriate for the conditions in which they will be used and will meet the overall testing objectives.

The Bulk Procurement Scheme is directed towards and assists:

- National AIDS Control Programmes
- Blood transfusion services
- UN agencies
- Nongovernmental organizations
- Donor supported HIV/AIDS projects
- Other recognized groups

High Quality

All HIV test kits available through the Bulk Procurement Scheme have been evaluated by WHO. These evaluations assess the operational characteristics of the tests i.e. sensitivity, specificity, ease of performance and storage conditions. To be eligible for inclusion in the Bulk Procurement Scheme, the evaluated test kits must meet current standards. All test kits included in the Bulk Procurement Scheme are reviewed annually.

The Bulk Procurement Scheme encompasses the main types of tests used to detect HIV antibodies today – Enzyme Linked ImmunoSorbent Assays (ELISAs), Simple/Rapid assays and Confirmatory assays. There are 22 tests on the current Bulk Procurement Scheme List of Available Assays, including a greater number of Simple/Rapid Assays than ever before.

When selecting a test kit, the following issues should be considered:

- The number of samples to be tested
- The laboratory facilities available
- The level of laboratory staff training
- The objective of the testing
- The testing strategy being followed

No single test is suitable for all testing objectives in all settings. It is important to choose the test kit which will produce the best working performance in actual, routine use.

In addition to the Bulk Procurement Scheme, recommendations and guidelines have been developed by WHO to assist with the selection of appropriate kits.

Low Cost

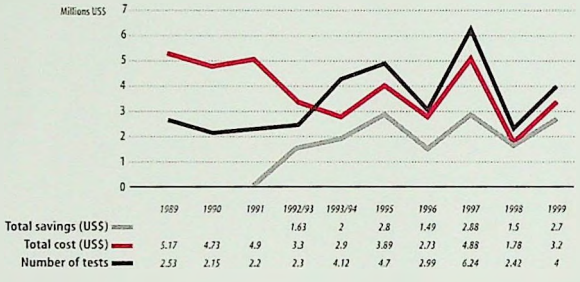
WHO negotiates prices for all assays in the Bulk Procurement Scheme directly with the manufacturers. This process enables WHO to offer a per test cost approximately half that of the open market price.

Main types of tests	Range – Open Market Price (US$)*	Average – Bulk Procurement Price (US$)*
ELISA	1.00 to 2.00	0.50
Simple/Rapid	2.00 to 8.00	1.00
Confirmatory	20.00 to 30.00	11.00

Prices as of 2000

The resulting savings are substantial, enabling countries with limited resources to buy more HIV test kits with their funds, or to channel more resources into other areas of need, such as HIV care. The savings for 1999-2000 amounted to US$ 5 million.

HIV Bulk Purchase 1989–2000



Easy Purchase Procedure

The HIV Test Kit Bulk Procurement Scheme accepts purchase requests from programmes/institutions/ organizations in 3 categories:

- Category A – WHO programmes & UN agencies
- Category B – WHO Member States & NGOs in official relations with WHO
- Category C – Other clients ie. Donor supported AIDS projects, regulatory bodies

The HIV Test Kit Bulk Procurement Scheme provides an easy-to-follow purchase procedure. Simply complete the steps indicated by this symbol ⓘ and let WHO do the rest!

ⓘ Step 1: Prepare a request which includes the following information:
- Name of requesting programme
- Contact person (ie. name, telephone)
- Test kit name & manufacturer*
- Order code*
- Number of test kits required (indicate number of tests per kit where necessary)

*as on the Bulk Procurement List

ⓘ Step 2: Submit this request to one of the appropriate offices for your category:
- WHO Headquarters, Geneva (Category A)
- WHO Regional Office (Category A, B)
- WHO Country Representative (Category B)
- UNAIDS Representative (Category B, C)
- Ministry of Health (Category C)

Step 3: Payment will be debited from your account (Category A) or a proforma invoice will be issued to you (Category B and C). Goods must be paid for in full before purchase is initiated.

Step 4: Procurement Services purchases the requested kits.

Step 5: WHO ships the goods to the airport of destination.

Step 6: The consignee is responsible for customs clearance and delivery of the goods.

Further Information

Further information on the WHO HIV Test Kit Bulk Procurement Scheme is available from the following sources:

WHO Headquarters —
for procurement assistance:
Procurement Services
Tel: +41 22 791 2801 Fax: +41 22 791 4196
Email: procurement@who.int

for technical assistance:
Blood Safety and Clinical Technology
World Health Organization
Avenue Appia 20, 1211 Geneva 27
Switzerland

Internet —
Visit the BCT section of the WHO website at www.who.int/bct and follow the links to Key Initiatives, HIV Diagnostics, HIV Test Kit Bulk Procurement Scheme. In addition to general information, PDF versions of the WHO HIV Test Kit Bulk Procurement Scheme Information Booklet, several fact sheets, and this brochure are (or will soon be) available for downloading. In addition, information on Test Kit Evaluation is available on this website.

Regional Offices/Country Representatives —
Contact your WHO Regional Office, WHO Country Representative, or nearest UNAIDS representative.

If you are a manufacturer and wish to submit your kit for evaluation by WHO to become eligible for inclusion in the Bulk Procurement Scheme, please visit our website or contact Blood Safety and Clinical Technology:
Fax: +41 22 791 4836
Email: bloodsafety@who.int

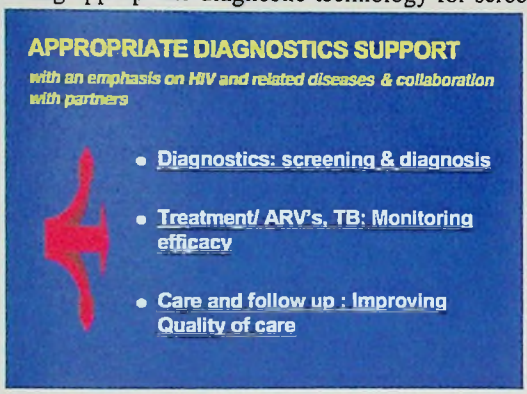
August 2001

WHO Department of Blood Safety and Clinical Technology

Diagnostic Support
for diagnosis, treatment and care
Responding to the HIV Initiative

Providing diagnostic support is an essential part of ensuring quality health care in the fight against the HIV/AIDS epidemic. There has been a strong call for access to drugs to help in this fight; however, it must be remembered that this battle is a process which not only requires access to treatment, but also access to accurate diagnostics, quality of care and follow up. The diagnostic support activities of the Blood Safety and Clinical Technology (BCT) department of WHO play a vital role in all three phases of this process.

Using appropriate diagnostic technology for screening and diagnosis is the starting point in the process. In addition to the actual diagnosis of patients' HIV status, diagnostic technology must be used for screening of donated blood to prevent transmission through transfusion. Diagnostic tests are also instrumental for surveillance, providing epidemiological data to monitor the spread of the HIV/AIDS epidemic. Use of reliable tests and appropriate testing strategies are important in the prevention of mother-to-child transmission, and for voluntary counselling and testing services. In these settings, simple/rapid diagnostic tests can provide accurate, same-day diagnosis resulting in timely treatment where needed.



Once individuals are identified as being infected with HIV, and/or related opportunistic infections, diagnostics are used to determine the appropriate treatment intervention. For example, diagnostic tests may indicate resistance to certain drugs and thus provide guidance on appropriate drug regimes. Subsequent diagnostic technologies are required to monitor the safety and effectiveness of treatment on a continuing basis. Additional diagnostic imaging and basic clinical laboratory tests will provide information to ensure the ongoing quality care and support provided to those infected with HIV and suffering from associated infections and illnesses such as TB.

Several key activities within BCT contribute to the provision of high quality, cost-effective health care as related to the HIV epidemic. BCT aims to ensure that the diagnostic technologies used in diagnosis and screening meet the highest standards, and that they are available and used appropriately. The operational characteristics of HIV test kits are evaluated, and reports providing technical information on their quality are issued regularly. Alternative HIV testing strategies for the various testing objectives have been developed, and are updated as required. The WHO HIV Test Kit Bulk Procurement Scheme facilitates access to high quality, low cost diagnostic tests to Member States and UN agencies.

BCT is assessing the available technologies for monitoring the efficacy of HIV treatment (CD4, p24, and viral load testing) that are suitable for countries with limited facilities and resources. Tool kits for clinical laboratory monitoring at the district hospital (1st referral) and centralized referral hospital (2nd referral) levels are currently being developed. To ensure reliable results, existing schemes for monitoring laboratory performance will also be expanded to cover all HIV related diagnostic areas.

BCT is also providing guidance and training to support and improve health care services in areas of blood safety, clinical laboratory and diagnostic imaging, all of which contribute to improved quality of care. Capacity building to improve skills and knowledge at all levels for appropriate diagnostic support is an overarching aspect of BCT's activities.

Many of these activities are carried out in collaboration with other WHO departments and with UN agencies such as UNAIDS and UNICEF, WHO Collaborating Centres and key international partners. These partnerships are, and will continue to be, an integral part of BCT's response to the HIV Initiative.

HIV and YOUTH

Pledge 25 Club

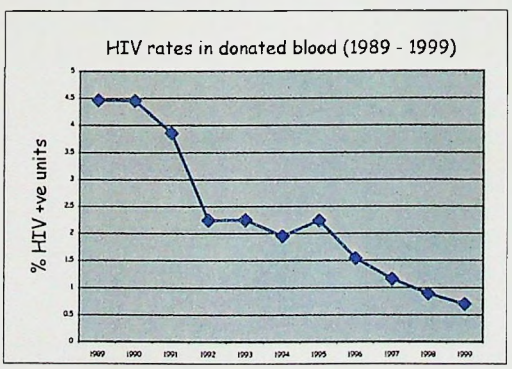
Zimbabwe's youth realized that their future was in their own hands. This is why, some years ago, a project was launched by youth themselves which has significantly contributed to the success of the nation's safe blood supply. The project, already being emulated in neighbouring countries, is called the "Pledge 25 Club".

HIV caused Blood Transfusion Services across the world to rethink seriously their blood donor recruitment strategies and, in 1989, Zimbabwe started targeting an as yet untapped pool of low-risk donors: school-children aged 16-19. However, history proved that – successful as the programme was – most school blood donors ceased to donate regularly upon leaving school. The Pledge 25 Club was therefore created by and for school leavers, who pledge to make at least 25 donations of blood. Members also actively share information and knowledge with other current and prospective donors and, in this way, help to promote healthy lifestyles, and reduce the level of HIV prevalence in peer groups and the amount of infected blood collected. Club members were honoured on World Health Day in April 2000, and the first group of Club members had their graduation ceremony – to mark their 25th donation – at the Annual General Meeting of the National Blood Transfusion Service (NBTS) on 6 September 2000. Many of the pioneers are considering the formation of a "Pledge 50" division.


Minister T.J. Stamps at the blood donor shield presentation ceremony

The Club elects national and provincial administrative committees to ensure the running of their affairs. Selected Peer Donor Promoters now assist the NBTS with the recruitment of voluntary, non-remunerated, regular donors from low-risk groups and in turn, the NBTS supervises and counsels the Club.

It is critical to reiterate the self-motivated commitment of the pupils themselves that has led to a window of hope for the national blood bank. It is thanks to the students, who instituted a National Youth Blood Donors Day, that the availability of safe blood at peak times of the year such as Christmas, has gone from 50% to 80% and is still rising. Other statistics speak for themselves: HIV sero positivity among blood donors has fallen from an average of 4.45% in 1989 to 0.7% in 1999 (compared to sero prevalence in the sexually active population in general: 25.8%); 99.3% of all blood collected in 1999 was HIV-negative; and nearly 70% of the 82,365 units collected in this same year were donated by pupils.



"...and we have about 1,000 [Pledge 25 Club members] who have already reached their certificate, so that's how successful the programme has been".

(Dr T.J. Stamps, Minister of Health and Child Welfare, Zimbabwe during an interview for World Health Day 2000 on Safe Blood Starts With Me)

Haemoglobin Colour Scale

...a practical answer to a vital need

The Haemoglobin Colour Scale
is a simple, reliable and inexpensive tool developed by the World Health Organization to screen for anaemia in the absence of laboratory-based haemoglobinometry.

Anaemia

is the most serious complication of iron deficiency and a significant cause of death. More than half of the pregnant women in developing countries suffer from anaemia. The accurate estimation of haemoglobin levels is an essential prerequisite in a variety of other health issues, such as trauma care, selection of blood donors, epidemiological studies, and general primary health care.

Detection and management of anaemia

The measurement of haemoglobin has long been recognized as fundamental in routine health checks, for the diagnosis and treatment of disease and, given the global incidence of anaemia, in public health care.

The measurement of haemoglobin in blood as an indicator of anaemia has traditionally relied on the services of a well-equipped clinical laboratory. Simple techniques do of course exist, but even these are relatively expensive and require commercial reagents, a good degree of technical skill and are not readily available in peripheral health clinics or at point of care for clinicians and midwives.

In primary health care centres, when laboratory facilities are not available, anaemia is usually diagnosed from clinical signs (pallor of the conjunctiva, tongue, palms and nail beds, using anaemia recognition cards if available), although accurate interpretation of these signs depends a great deal on effective training. However, in rural areas where anaemia is common and where appropriate prevention and treatment strategies may be most beneficial, an alternative method is needed to screen for anaemia easily and economically. The less sophisticated the device, the more easily we can respond – in a sustained way – to the needs of primary health care centres in developing countries.

Revisiting a powerful concept

The idea is not new. Tallqvist, among others, tried in vain as long ago as 1900 to substantiate the theory that the colour of a drop of blood could reliably indicate anaemia. The blood would be matched against predetermined hues of red, telling the health care worker whether the patient is anaemic and, if so, the severity of the condition. The colour printing technology and test-strip paper available at that time were such that the results were inaccurate and the concept shelved.

It has taken modern technology to perfect the material on which blood can be absorbed, and computerized spectrometric analysis to identify colours that can accurately match shades of haemoglobin at different concentrations.

Following many years of development by WHO, the Haemoglobin Colour Scale will be available from May 2001 as a simple and effective medical device for the accurate estimation of haemoglobin levels in blood.

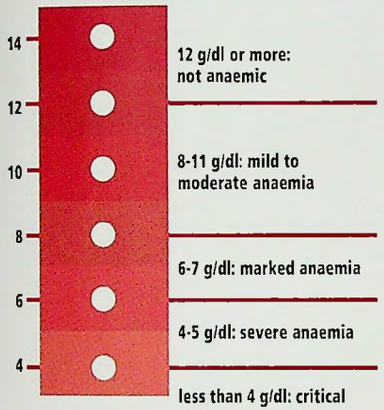
How does it work ?

The Haemoglobin Colour Scale comprises a small card with six shades of red that represent haemoglobin levels at 4, 6, 8, 10, 12 & 14 g/dl respectively. The device is simple to use:

- place a drop of blood on the test strip provided
- wait about 30 seconds
- match immediately the colour of the blood spot against one of the hues on the scale.

The less sophisticated the device, the more easily we can respond...

This will indicate whether the patient is anaemic and, if so, the severity of anaemia in clinical terms (see diagram below). It will not identify minor changes in haemoglobin during treatment, but rather assist in the management of any patient with suspected anaemia, e.g. to decide whether a patient may require a blood transfusion,[9] a blood count, be referred for laboratory tests or to a hospital or clinic for treatment[7].



N.B. Colour and size of the Scale are approximate and for illustration only. Whilst g/l is acknowledged as the standard measurement, g/dl is still in common use for clinical and public health purposes.

Validation in the field

Since the early series of studies carried out by WHO in 1995 and the first published data describing the device in the same year[1], extensive testing and field trials have been carried out on the performance of the Scale. An international validation study and recent published papers have confirmed its reliability when used in general health centres and antenatal clinics, and in blood transfusion centres for donor selection (see comprehensive bibliography).

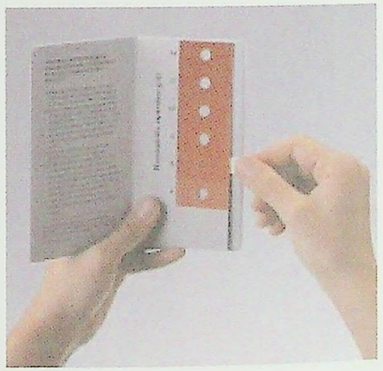
Sensitivity and specificity of the Scale to screen for anaemia

For severe anaemia, the Scale shows a sensitivity of 95% and a specificity of 99.6%. To distinguish normal Hb levels from mild anaemia, the sensitivity and specificity are 98% and 86% respectively, results that are well above the reliability of any clinical measurement.[4,8]

Using a photometer (HemoCue©) as a reference, the Scale was compared with the copper sulphate specific gravity method that is traditionally used to screen blood donors for anaemia. The scale was accurate to 98% in distinguishing among 2,800 volunteer blood donors those with normal Hb from those rejected because of anaemia. The Scale was more reliable than copper sulphate, the tests giving 2.4% and 5.4% false readings respectively[4]. Moreover the copper sulphate presents a potential environmental hazard in the disposal of used solutions.

Training

In a validation study, most results were accurate to within 1-1.5 g/dl. Further analysis showed that the discrepancies in the results of the original study were largely due to a lack of training and thus incorrect technique, e.g. not waiting for 30 seconds, reading in a shadow or not having an adequate sized drop of blood.[7,8]



As a result, it was shown that a half-hour training session was sufficient for health workers to estimate haemoglobin to within 1g/dl, and assess levels of anaemia much more effectively than by traditional clinical diagnosis.

Important: clear instructions for use accompany the scale, which must be followed.

Haemoglobin Colour Scale starter kit:

- booklet of 6 shades of red;
- instructions for use;
- dispenser of 200 specially absorbent test-strips in handy box;
- 4 spare dispensers (800 tests).

Refill kits contain dispenser boxes of test-strips only.

N.B. Use only the approved test strips provided.

The Starter Kit will be available in English and French, followed by Spanish, Russian, Arabic, Chinese, Portuguese, and other languages as appropriate.

How much is it?

The Starter Kit with approved test strips for 1,000 tests will cost about US$ 20. This works out at less than 2c per test – cheaper than copper sulphate and considerably less than a laboratory test – with the cost per test falling at each purchase of refills.

The Scale was much more reliable than copper sulphate

Summary

After several years of development and field trials, the Haemoglobin Colour Scale will move to production and distribution in May 2001, primarily to assist developing countries in the detection and management of anaemia. The device is not intended to compete with existing laboratory haemoglobinometry, but rather increase access to health technology for peripheral health services in resource-poor settings.

The clinical utility of the Scale has been demonstrated in the screening of blood donors for anaemia, malaria management, antenatal and child health programmes, iron therapy control, in hookworm infection and in decisions to refer severe anaemia patients for hospital treatment. It will also be an extremely useful tool for point of care anaemia checks anywhere, mainly for women and children suspected of being anaemic.

Use of this medical device requires no specialized training. It doesn't depend on electricity or batteries and needs no maintenance. It is portable and the results are immediate.

The Haemoglobin Colour Scale is a practical answer to a vital need, a need contained in the first strategic direction of WHO: to reduce mortality and morbidity, particularly of the world's poor and marginalized populations.

The Haemoglobin Colour Scale requires no specialized training, electricity or battery ... It's portable, and the results are immediate

Bibliography

1. **Stott GJ, Lewis SM.** A simple and reliable method for estimating haemoglobin. *Bulletin of the World Health Organization*, 1995, **73**: 369-373
2. **Münster M et al.** Field evaluation of a novel haemoglobin measuring device designed for use in rural setting. *South African Medical Journal*, 1997, **87**: 1522-1526
3. **Beales PF.** Anaemia in malaria control: a practical ap-proach. *Annals of Tropical Medicine & Parasitology*, 1997, **91**: 713-718
4. **Lewis SM, Stott GJ, Wynn KJ.** An inexpensive and reliable new haemoglobin colour scale for assessing anaemia. *Journal of Clinical Pathology*, 1998, **51**: 21-24
5. **Van den Broek NR et al.** Diagnosing anaemia in pregnancy in rural clinics: assessing the potential of the Haemoglobin Colour Scale. Bulletin of the World Health Organization, 1999, **77**: 15-21
6. **Montresor A et al.** Field trial of a haemoglobin colour scale: an effective tool to detect anaemia in preschool children. *Tropical Medicine and International Health*, 2000, **5**: 129-133
7. **Gosling R et al.** Training health workers to assess anaemia with the WHO haemoglobin col-our scale. *Tropical Medicine and International Health*, 2000, **5**: 214-221
8. **Ingram CF, Lewis SM.** Clinical use of WHO haemoglobin colour scale: validation and critique. *Journal of Clinical Pathology*, 2000, **53**: 933-937
9. **Lewis SM, Emmanuel J.** Validity of the haemoglobin colour scale in blood donor screening. *Vox Sanguinis*, 2001, **80**: 28-53

The Scale does not replace a laboratory test. It is a clinical device for use near the patient at point of care, where no immediate laboratory facility exists

Haemoglobin Colour Scale

Find out more...

For further information on how to procure the Haemoglobin Colour Scale, please contact the WHO Secretariat at the following address:

Department of Blood Safety and Clinical Technology
World Health Organization
20 avenue Appia
1211 Geneva 27
Switzerland
Fax: +41 22 791 4836
Email: hbcolourscale@who.int
Web page: www.who.int/technology/

World Health Organization
Geneva, Switzerland

Blood Safety and Clinical Technology

Strategy 2000-2003

This document was produced by the Department of Blood Safety and Clinical Technology

Ordering code: WHO/BCT/01.01
Printed: May 2001
Copies may be requested from:
World Health Organization
Department of Blood Safety and Clinical Technology
CH-1211 Geneva 27, Switzerland
Fax: 004122-7914836
E-mail: velazquezi@who.int

Design & Layout: L'IV Com Sàrl, Morges, Switzerland

WHO/BCT/01.01
Original: English
Distribution: General

Blood Safety and Clinical Technology

2000-2003 Strategy

Department of Blood Safety and Clinical Technology

World Health Organization, Geneva

Contents

Abbreviations

ABO	blood group serology
AD (syringes)	autodisable (syringes)
AFRO	African Regional Office of WHO
AMRO	American Regional Office of WHO
BCC	blood cold chain
BRM	biological reference material
BTS	blood transfusion service
BTTI	blood time temperature indicators
CBER, USA	Central Bureau for Evaluation and Research, WHO Collaborating Centres for Biological Standards, USA
CLB, NL	Central Laboratory of Biological Standards, WHO Collaborating Centres for Biological Standards, the Netherlands
DSS	district surgical services
ECBS	Expert Committee on Biological Standardization
EHTP	essential health care technology package
EQAS	external quality assessment schemes
FDA	Food and Drugs Administration US
GHTF	Global Harmonization Task Force
HbCS	haemoglobin colour scale
HCWM	health care waste management
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HTMM	health care technology management and maintenance
IAEA	International Atomic Energy Agency
IBGRL, UK	International Blood Group Reference Centre, WHO Collaborating Centre for Blood Grouping Reagents
IEQAS	international external quality assessment scheme
IREQAS	interregional external quality assessment schemes
ISBT	International Society for Blood Transfusion
ISO	International Organization for Standardization
ISTH	International Society on Thrombosis and Hemostasis
NAT	nucleic acid amplification technology nucleic acid-based tests
NEQAS	national external quality assessment schemes
NIBSC, UK	National Institute of Biological Standards and Control, WHO Collaborating Centres for Biological Standards
O.i.	opportunistic infections
PAHO	Pan American Health Organization
PIC/S	pharmaceutical inspection co-operation scheme
REQAS	regional external quality assessment schemes
SADC	Southern African Development Community
SEARO	South-East Asia Regional Office of WHO
SOGAT	WHO Working Group for the Standardization of Gene Amplification Technology
TB	tuberculosis
SUP	supplies service
TSE	transmissible spongiform encephalopathy
TTI	transfusion transmissible infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO ECBS	WHO Expert Committee for Biological Standards
WPRO	Western Pacific Regional Office of WHO
WSH	water, sanitation, and health

Preface

Millions of lives are saved each year through blood transfusions. However, in many developing countries people still die owing to a lack of blood and blood products while many millions more are at risk of being infected by untested blood transfusions. In many countries, the lack of adequate blood donor recruitment services, combined with the high prevalence of infectious agents, leads to high prevalence rates of infections in donated blood. Overuse and inappropriate use of blood are also factors to be addressed. There is a need to work globally to ensure that blood and blood products are safe, accessible, available at reasonable cost, used appropriately and are provided within a sustainable health care system. This impacts mostly on women, children and trauma victims, especially the poor. Equitable and safe blood transfusion and injections are not readily available. This is why they are the core of a vital, renewed programme within WHO, which we want to strengthen to respond to the needs of all populations, and particularly the poor and marginalized populations in the developing countries.

In most developing countries a lack of quality management for the safety of blood and blood products, injections, diagnostic imaging, clinical and laboratory technology services adversely affects the quality of care to the patients.

Furthermore, Blood Safety and Clinical Technology in most developing countries suffer from a lack of finance, skilled manpower, inappropriate equipment and poor quality management: medical equipment and devices are either not available, not used or malfunctioning; consumables and reagents are lacking; and there is a dearth of infection control and waste management systems.

Thus, within the overall goal of ensuring equitable access to safe blood, quality care and affordable technology, particularly in developing countries, WHO's objectives are to:

- Increase access to safe blood, blood products and safe health care technologies
- Promote quality health care services that are supported by safe and cost-effective technologies.

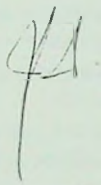
In the following pages, the global Blood Safety and Clinical Technology Strategy is laid out. Included are brief descriptions of the key activities proposed in the areas of quality and safety of blood and blood products, injection safety, diagnostic imaging, clinical and laboratory technology services and medical devices. These activities will result in:

- ✓ National, regional and global policies, plans and strategies which will improve access, quality and safety of blood and blood products, injections, diagnostic imaging and clinical laboratory services
- ✓ Systems developed leading to better coordinated, organised, managed and funded blood transfusion programmes
- ✓ Access to safe blood in all main hospitals in more than 60% of developing countries
- ✓ Reduction of diseases attributable to unsafe blood, unsafe injections, or lack of access or unsafe use of diagnostic and health care technologies

- ✓ Validated norms, standards and biological reference preparations
- ✓ Upgraded technical expertise of national regulatory authorities for the evaluation and control of blood products and related biologicals
- ✓ Knowledge and skills in the areas of blood transfusion medicine and clinical technology including laboratory services and diagnostic imaging
- ✓ Information systems to monitor impact
- ✓ Global collaboration to build consensus on effective strategies to improve blood safety and injection safety.

Under the key cross-cutting themes of policy, quality and safety, access and use, we believe these activities are integrally coherent within the strategy, and that they best respond to the expressed needs in the countries. The BCT Strategy is a component of the new Health Technology and Pharmaceuticals Strategy, which is in turn coherent and consistent with WHO's overall corporate strategy, as will be described below.

In many cases these activities are the very first steps on the long road to ensure blood safety. Thus, they are designed as being progressive. There is a need to lay down a foundation for the major efforts that are yet to come before everyone in the world has access to safe blood, blood products and safe health care technologies, and to quality health care services that are supported by safe and cost-effective technologies.



Dr. Jean C. Emmanuel
Director, Blood Safety and Clinical Technology
Health Technology and Pharmaceuticals
Geneva, May 2001

Introduction — Blood Safety and Clinical Technology

The department of Blood Safety and Clinical Technology was established in 1998 as part of WHO's new cluster on Health Technology and Pharmaceuticals (HTP). Its mission is to promote the safety, quality and adequacy of blood and blood products, injections, diagnostic and clinical technologies, and medical devices that are essential for the provision of health care.

BCT and WHO's corporate strategy

Blood safety has been accorded a high priority by the Director General, and is an issue of concern to many WHO Member States in the developed world and all of the developing countries. Acknowledging the importance of blood safety, the World Health Day theme for the year 2000 was "Safe Blood Starts with Me – Blood Saves Lives".

WHO's four corporate strategic directions are:

- To reduce excess mortality, morbidity and disability, especially in poor and marginalized populations
- To promote healthy lifestyles and reducing factors of risk to human health that arise from environmental, economic, social and behavioural causes
- To develop health systems that equitably improve health outcomes, respond to peoples' legitimate demands, and are financially fair
- To develop an enabling policy and institutional environment in the health sector, and promoting an effective health dimension to social, economic, environmental and development policy.

The following figure illustrates how the priority activities in the BCT Strategy contribute to WHO's four strategic directions.

BCT contribution in WHO's four strategic directions

This same summary diagram can be drawn for each of the departments in the Health Technology and Pharmaceutical Cluster, and is a convincing statement of the coherence of BCT Strategy with that of HTP and WHO as a whole.

In achieving its strategic objectives, BCT is acutely conscious of the need to forge strong partnerships to ensure that blood safety and clinical technology is included in wider health and development agendas. This includes such major international initiatives that are being steered by the department as the Global Collaboration for Blood Safety, the Safe Injection Global Network, Regional Programmes for Quality Management for Blood Transfusion Services , all of which are described later in this document.

Organization of the BCT Department

The Department has four teams that address the following health issue areas:

- Blood transfusion safety
- Quality and safety of plasma derivatives and other related substances
- Safety of injections
- Diagnostic imaging technology
- Laboratory technology
- Clinical technology
- Medical devices.

There are several overarching themes that may be identified throughout the work of the department as a whole. These include policy issues, such as the promotion of sustainable national programme, setting global norms and standards for quality and safety of blood products and related biologicals, areas of research and development and promotion of the equity of access and use of blood, blood products, injections, diagnostic and clinical technology and medical devices. Activities such as capacity building and the facilitation of technology transfer are included among the key strategies.

Of the three departments in the HTP cluster, the department of Blood Safety and Clinical Technology is the smallest. It has limited manpower and budgetary resources, despite the very important role that it has been assigned. In order to meet the concerns of Member States and carry out its responsibilities, the department is seeking to strengthen manpower where required, outsource activities where it is cost efficient, and seek extra-budgetary funds to carry out agreed strategic activities.

Main areas of work

Blood Transfusion Safety

The mission of the Blood Transfusion Safety (BTS) team is to "promote the formation of national blood programmes which ensure the safety, quality and adequacy of "blood and blood components" to meet the needs of all patients, transfused only when necessary and are provided as part of a sustainable blood programme within the health care system".

Blood safety activities should be seen in the context of promoting sustainable national blood programmes which ensure the safety, quality and adequacy of "blood and blood components", free from all transfusion transmissible infections which include among others: HIV, hepatitis B and C, and Chagas disease.

Among the strategic activities of BTS are to:

1. Strengthen "blood transfusion services" with necessary guidelines and national regulatory authorities with necessary guidelines, recommendations, training materials and technical support in the areas of: national policies and plans for establishment of organized nationally coordinated BT services, and legislation/regulations.
2. Promote blood donor programmes based on voluntary non-remunerated blood donors from low-risk populations.
3. Promote the implementation of quality management in blood transfusion services.
4. Ensure the testing of all donated blood for relevant transfusion transmissible infections, blood

products using good manufactured practices

5. Promote appropriate clinical use of blood to prevent unnecessary transfusions

6. Improve the quality and safety of blood transfusion services, especially in developing countries

7. Further develop the Global Collaboration for Blood Safety (GCBS).

The BTS team works in close collaboration with other clusters such as FHS/AIDS /child and adolescent health (CAH), HIV/AIDS (HSI), Making pregnancy safer, (HSI) and Nutrition (CDS).

Quality and Safety of Plasma Derivatives and Other Related Substances

Its mission is to "develop, establish and promote WHO International Standards, Guidelines and Technical Recommendations to support implementation of quality and safety systems for the production and control of blood products and related biologicals. Main duties of the team form an integral part of the WHO's normative functions in the area of quality, safety and biological standardization of blood products and related biologicals, including biotechnology products, used in the prophylaxis, therapy or diagnosis of human diseases.

The strategic activities of QSD are to:

- Assess, apply and promote relevant new technologies and methods for the standardization and control of blood products and related biologicals
- Development of WHO Guidelines and Recommendations for the production and control of Blood Products and Related Biologicals
- Provide technical advice/assistance on quality assurance and safety of blood products and related biologicals to National Regulatory Authorities and their Control Laboratories
- Expert Committee on Biological Standardization (ECBS), the WHO Committee responsible for setting global physical and written standards for biological substances used in human medicine: Subcommittee for Blood Products and related Biologicals.

Safe Injection Global Network (SIGN) Project

The Safe Injection Global Network (SIGN) Project is an international coalition of stakeholders that share a common interest in the safe and appropriate use of injections. The SIGN coalition is coordinated by a WHO secretariat housed in the department of Blood Safety and Clinical Technology. In addition to housing the SIGN secretariat, BCT conducts its own activities for the safe and appropriate use of injections.

The strategic objectives of BCT for the safe and appropriate use of injections worldwide include:

- ***Policy:*** To strengthen the capacity of countries to formulate, implement, monitor, and update national policies for safe and appropriate use of injections
- ***Quality and Safety:*** To ensure quality and safety of injection devices
- ***Access:*** To ensure equitable availability and affordability of injection devices
- ***Use:*** To promote appropriate, rational, and cost-effective use of injections and other percutaneous or permucosal procedures performed in medical and other settings.

Diagnostic Imaging and Laboratory Technology

The Diagnostic Imaging and Laboratory Technology (DIL) team plays an important role in strengthening the quality of performance of health laboratory services and imaging technology in countries, with emphasis on the intermediate level. It is comprised of a Diagnostic Imaging group and a Laboratory Technology group.

The mission of the Diagnostic Imaging group is to "promote quality, quantity, and equity of diagnostic imaging services according to local needs", and its main strategic activities include:

- Preparing guidelines for effective choices in diagnostic imaging
- Creating educational programmes and learning material for appropriate and adequate use and maintenance of diagnostic imaging equipment and procedures
- Providing global guidance for radiation protection in medicine and global quality control of radiotherapy installations.

The mission of the Laboratory Technology group is to "promote and advocate standards for establishing appropriate medical diagnostic laboratory services to ensure quality of health care and prevention of diseases", and its strategic activities include:

- Global standardisation of laboratory procedures and reagents for the diagnosis, prevention and monitoring of disease
- Development and implementation of internal quality control and external quality assessment procedures
- Supporting countries by developing strategies for the improvement of diagnostic laboratory services, with emphasis on the primary health care level
- Facilitating transfer of appropriate diagnostic laboratory technology to countries in need through capacity building and development, assessment and distribution of information on technology.

Devices and Clinical Technology

The Devices and Clinical Technology (DCT) team facilitates the transfer of techniques and devices for the clinical treatment of patients. The team is comprised of a group dealing with Devices and one dealing with Clinical Technology (District Surgical Services).

The ***Clinical Technologies group*** has the mission to "promote the quality of clinical care through identification, promotion and standardisation of procedures, equipment and materials particularly at first referral level (district hospital)". Its main strategic activities include:

- The development of guidelines on effective clinical procedures particularly at the district level (surgery, obstetrics, anaesthetics, orthopaedics, etc.)
- To advocate and promote the development and use of selected appropriate innovative equipment and materials (oxygen concentrator, haemoglobin colour scale, etc.)
- To promote and facilitate the training of health care providers to improve clinical care and support capacity building.

The ***Devices group*** has the mission to "advocate and provide technical support for appropriate health technology to enable the expansion or development of sustainable and cost-effective health services", and its strategic activities include:

- Supporting research and development of appropriate technology for health services for countries in need
- Strengthening capacity building, improving the process of equipment donations and technology transfer in developing countries in regard to the safety and efficacy of devices (i.e., selection, use and disposal of skin-piercing medical devices to ensure safety)
- Supporting countries in the application of health technology for safe and efficient waste management
- Strengthening countries capacity to improve health care technologies management and maintenance within a broad context of health systems and services development.

In order to perform some of these DCT activities, we are collaborating intensively with departments in other clusters. Worthy of note are the inter-cluster collaborations: BCT and the Evidence and Information for Policy cluster's Organization of Health Services Delivery (OSD) department for activities on health technology management and maintenance. Development of technical guidelines and distance learning material will be part of the management and maintenance project for developing countries; and also child and adolescent health (CAH), HIV/AIDS (HSI), Emergency preparedness and response (EHA), Making pregnancy safer (HSI), (FHI) Diagnosis of Tuberculosis.

This activity will consider such issues as: needs assessment (with the assistance of a software based planning and management tool called the Essential Health care Technology Package), spare parts, training, preventive maintenance, repair of existing equipment and guidelines on medical equipment donations. Based on WHO's past experience on health technology management, national projects will be implemented or improved in selected countries.

The second inter-cluster collaboration is between BCT and the Sustainable Development and Healthy Environments cluster's Protection of the Human Environment (PHE) department, for activities on health care waste management. The strategy relies on the following elements: Development of a database, preparation of guidance material, availability of waste management options and development of country plan.

Main activities

Each of the main activities of BCT are described in the context of the BCT Strategy in the next section, by primary objective, overall target and giving the critical indicators of performance. A further chapter lists the principal special initiatives currently being undertaken or proposed.

The BCT Strategy hinges on four key primary objectives: policy, quality and safety, access, and use. These terms have a particular significance to the Strategy, and often a particular meaning, and thus it is worth providing a description and rationale for the choice of these primary objectives.

Policy

An absence of policies based upon the quality cycle – in which action plans are formulated, implemented, evaluated, and updated – limits the ability to progress in blood and injection safety as well as in diagnostic and clinical technology. Thus our first objective is to strengthen the capacity of countries to formulate, implement, monitor, and update national policies and plans for blood, blood products, injections, diagnostic, clinical technologies, and medical devices. This includes policies, global collaborations, and global systems to monitor impact.

Quality and Safety

Blood products and technology can only reach the quality and safety required for their intended use if the necessary guidelines and systems are in place to optimise processes. In addition, appropriate controls must be applied on the production and on the product, as applicable. Thus, our objective is to assist countries in ensuring the quality and safety of blood and blood products and related substances, injections, diagnostic and clinical technologies, and medical devices. This includes the development of norms, standards, establishment of guidelines, and international reference preparations; research, development, and evaluation; and national quality systems through comprehensive training and creation of networks and strengthening the technical expertise of national regulatory authorities.

Access

The global database on blood safety indicates that 80% of the world's

population does not have access to reliable and safe blood. Thus, a primary objective of the BCT Strategy is to support countries in ensuring equitable availability and affordability of blood, blood products, injections, diagnostic, clinical technologies, and medical devices. This includes ensuring continuous and sufficient quantities of appropriate equipment, reagents and supplies, and strengthening their capacity to produce basic supplies locally.

Use

Access to appropriate health technology, including safe blood and safe injections, can only be ensured to the extent that they are used appropriately and in a reliable manner. Thus a primary objective is to promote the appropriate and cost-effective use of blood, blood products, injections, diagnostic, clinical technologies, and medical devices. Use also involves maintenance of equipment, appropriate use of test kits and reagents in order to produce reliable results. An additional aspect is training and building the necessary skills to correctly use the available health technology. ❐

The Blood Safety and Clinical Technology Strategy

The four primary objectives of the Blood Safety and Clinical Technology relate to **policy, quality and safety, access** and **use**. In this chapter, the relevant targets within each objective are discussed. These are then illustrated by the main activities proposed for 2000-2003, their expected outcomes, and the ways in which we aim to measure performance.

Policy

Target 1: Formulation, implementation, monitoring, and updating of national policies and plans

Advocacy for nationally coordinated blood transfusionprogrammes

Blood transfusion services in countries are often given low priority and many are still very poorly organized. Government commitment and support for a well organized nationally coordinated service is the first step to ensure sustainability, and is a prerequisite to ensuring safe blood and blood components. This commitment should include financial support.

Thus, WHO aims to carry out a programme of high-level advocacy with national governments, ministries of health, ministries of finance and ministries of education in respect of blood transfusion services. Each country should make the political and financial commitment to establish and maintain a nationally coordinated blood transfusion service. WHO will achieve this by producing and distributing guidance materials on developing national policies and plans, and by holding workshops and undertaking personal meetings with relevant government ministries and health service officials. This activity also relates in providing advocacy to the Ministry of Health to ensure:

- Availability of adequate trained staff at all level in BTS
- Economy of scale by centralising activities
- Development of costing procedures
- Regulation by competent national regulatory authorities
- Development of ability to handle disaster situations.

WHO can act as a adviser and provide technical assistance for bilateral or multilateral financial support; contact ministries to discuss restructuring their blood programmes; organize a regional workshop on national blood programmes, including policies and plans; and expect to find the restructuring of blood transfusion services in progress in 2-3 countries.

The result of this programme will be a communication/advocacy/funding strategy on blood safety (to build on the World Health Day on Blood Safety launched in 2000).

The success of this activity will be measured by the number of countries that have shifted towards a nationally coordinated blood transfusion service, and the number of countries with an appropriate financing system to ensure the sustainability of the blood programme and an improvement in the Safety Quality and adequacy of Blood Supply.

Strengthening diagnostic laboratories through appropriate national policies

The majority of developing countries lack experience both in the creation of national policies for health laboratory services, and in the management of the national health laboratory services network. As a result of the lack of national policies, countries have not ensured that laboratories meet the minimal requirements needed in order to provide authorities with information for disease surveillance and to support clinical services in patient care effectively.

The objectives of WHO's activities are thus to formulate, implement and update national policies and plans for clinical diagnostic laboratory services and technologies to meet requirements for disease surveillance and patient care. We ? aim to create a generic policy and plan (i.e., standardised items that should be included in national policies) to enable well functioning laboratories within the health structure.

Steps in the process include the staging of two inter-country workshops to prepare plans of action; organizing an informal consultation on the role of public health laboratories; and assessing the national laboratory network in four countries, and providing them with advice on appropriate strategies for the establishment of laboratory quality systems.

Clearly, the success of this activity will be measured by the number of countries with a national policy, plans, for laboratory services; developed and/or implemented.

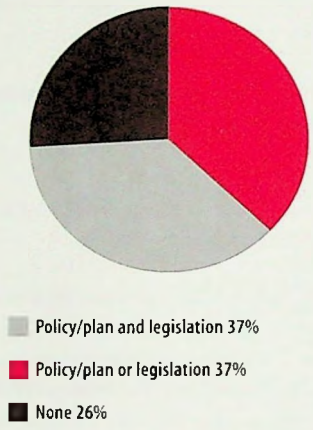
Nationally coordinated use of appropriate and safe diagnostic imaging services

In at least one third of all patients, diagnostic imaging is an absolute requirement for proper diagnosis and treatment, and the need increases as the life expectancy of the population is improving. In several developing countries, such services are either insufficient, or not at all available, and national coordination is often lacking. The main reason for this is the lack of properly trained staff. The salaries offered to properly trained personnel in governmental institutions are generally too low compared with those offered by private institutions. We advocate that staff at all levels receive proper training, and that steps should be taken to avoid properly trained staff members being tempted to leave governmental institutions.

Working with ministries of health to discuss the structure and future development of diagnostic imaging services, and organize regional workshops on appropriate use of such services.

Among the indicators of performance will be the number of countries with properly functioning diagnostic imaging services, and the number of countries with sufficiently trained staff.

Figure 1: Regulation of the BTS



Safe and appropriate use of injection policies

The aim of this activity is to strengthen the capacity of countries to formulate, implement, monitor and update national policies for safe and appropriate use of injections.

Key areas of work include (1) advocacy for national policies and plans for injection safety, (2) global monitoring system for injection safety (including estimation of the global burden of disease attributable to unsafe injection practices and standardized tools to assess and evaluate injection practices), and (3) maintenance of the Secretariat of the Safe Injection Global Network (see also the section on Key Initiatives below).

Indicators of the performance of this activity include (1) the number of countries with policies and plans for safe and appropriate use of injections, (2) the availability of a Global Database on Injection Practices and (3) the number of associates in the Safe Injection Global Network.

Advocacy for national policies and plans for district surgical services

Many patients presenting at district hospitals require surgical treatment for trauma, obstetric, orthopaedic and abdominal emergencies, but often surgery cannot be safely postponed to allow the transfer of the patient to a secondary or tertiary-level hospital. In many developing countries, acute surgical and anaesthetic care in district hospitals is provided by inadequately-trained, non-specialist medical, nursing and paramedical personnel, with limited facilities, equipment and supplies. The poor organization and inadequate resourcing of district surgical services contributes to unacceptable rates of mortality resulting from trauma, obstetric complications, non-traumatic surgical disorders and disability resulting from injury.

The objective of this activity is to improve standards of surgical and anaesthetic care at first-referral level, particularly in general surgery, anaesthesia, obstetrics and gynaecology, traumatology, orthopaedics and rehabilitation. WHO will provide advocacy to Ministries of Health to promote government commitment and support for the development of effective district surgical services, with adequate human and financial resources. It will also promote the development of policies and plans at both national and district level to strengthen district surgical services, including:

- Organization and management of district surgical services
- Education programmes for all personnel involved in surgical and anaesthetic care, in conjunction with academic institutions and professional bodies
- Upgrading, repair and maintenance of district hospitals to required standards
- Appropriate physical facilities and clinical support services for surgical, obstetric and acute care
- Appropriate equipment and instruments
- National systems for the supply of essential drugs, surgical supplies and other consumables required for common surgical and obstetric emergencies
- National quality systems for surgical services, including standards, clinical guidelines, standard operating procedures, records and audit.

The activity will include the preparation of guidelines and recommendations on the organization and resourcing of essential surgical services at first-referral level. This will be followed by regional workshops to promote the development of national policies and plans for district surgical services and continuing education for all personnel involved in acute surgical care.

Indicators for monitoring this activity will include the number of countries that develop and implement national policies and plans to strengthen district surgical services; the number of countries that establish continuing education programmes in acute surgical care; the number of countries that establish systems to ensure adequate and reliable supplies of drugs, surgical supplies and other consumables; the number of countries that establish national quality systems in surgical services.

Policy

Target 2: Global collaborations

WHO will participate actively in world-wide networking through the Global Collaboration for Blood Safety (GCBS) and the Safe Injection Global Network (SIGN), both of which are described among the key initiatives of the Strategy in Chapter 3. Success in these endeavours is measured by the number of countries joining the collaborations as associates.

Target 3: Global systems to monitor impact

Global Database on Blood Safety

Information on blood and blood products safety and on blood transfusion services in countries and regions needs to be collected and analysed in order to assess needs, formulate strategies, plan, implement and evaluate activities, and conduct research and assist the various bilateral and multilateral agencies to coordinate and effectively implement support projects. The objective of this activity is to collect and analyse data from all countries on blood and blood product safety as the basis for effective action to improve safe blood transfusion capabilities globally

Questionnaires on blood and blood products safety and on blood transfusion services have been developed and are being sent out bi-annually. Based on the replies received, the questions have been refined in order to enhance the scope of data collection. Questionnaires are being translated into the main WHO languages and additional background information will be provided to facilitate the completion of the questionnaire. Data are analysed per region and globally; a summary of the findings are made available through the WHO web-site, and printed reports are issued bi-annually.

Among the expected outcomes of this activity are a global database for blood safety and a global database for injection practices (with annual updates). Indicators to measure performance include the number of countries for which complete information required for progress indicators is available.

Quality and Safety

Target 4: Development and establishment of norms and standards: guidelines and reference materials

The principal activities undertaken in support of this target are given below. In general, a range of results is expected, including WHO recommendations and guidelines for the quality and safety of blood, blood products, and related substances, WHO biological reference preparations for blood products, related substances, WHO reference documents on diagnostic imaging and laboratory diagnostics, international standards on medical devices, the harmonisation of medical devices regulations, and strengthen national regulatory authorities for devices and biologicals.

These are measured by reviewing the number of countries implementing WHO recommendations and guidelines on quality and safety of blood, blood products, and related substances, the number of institutions with improved efficiency and quality of diagnostic imaging and laboratory services, the number of standards and WHO international biological reference preparations developed and used, and the number of countries implementing regulations on medical devices and biologicals based upon international standards.

International Biological Reference Materials for Blood Products and Related Biologicals

This activity aims to develop, establish, and promote international biological reference materials (physical standards) which form the basis for global comparability of biological activities in blood products and related biologicals used in prophylaxis, therapy and diagnosis of human diseases. The production of these materials involves considerable international collaboration and coordination of laboratory work, in both developed and developing countries as appropriate,

through WHO international collaborative studies, the results of which are considered by the Expert Committee on Biological Standardization, and if acceptable established. The following activities are included under this item:

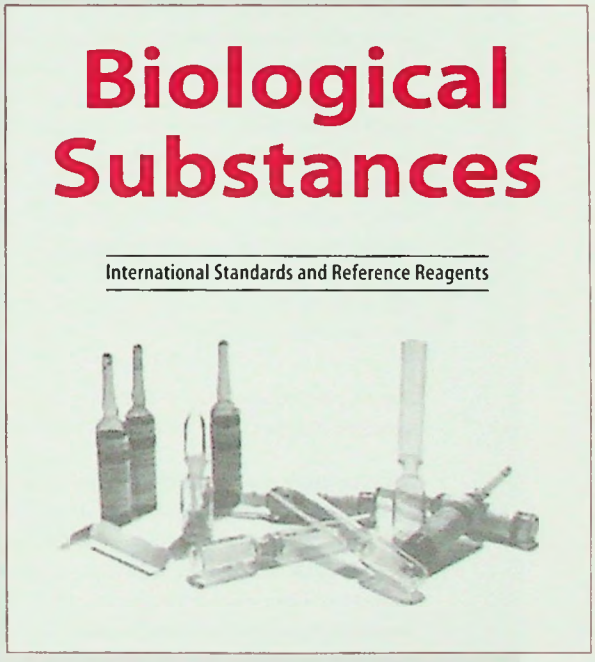
- Biological Standardization in thrombosis and haemostasis
- International Biological Standards for in vitro diagnostic procedures
- Review and update of the WHO International Standards for Blood Grouping Reagents
- WHO Reference Preparations for Diagnostic Kits used for the detection of HBsAg, anti-HCV and anti-HIV antibodies
- Standardization of Nucleic Acid Amplification Techniques (NAT) for virological safety testing
- WHO Biologicals web site: a catalogue of WHO international biological reference preparations established by the WHO Expert Committee on Biological Standards is published via Internet at the following address: http://www.who.int/technology/biological.html. This Catalogue is updated annually to include the new adoptions and discontinuations of materials by the Expert Committee. At the request of the Expert Committee, web hyperlinks will be developed with available web sites of the WHO International Laboratories for Biological Standards, national regulatory authorities and relevant international pharmacopoeias. A database for national biologicals regulatory control laboratories is also under development so that we can assure the widest promotion of WHO guidelines and technical recommendations and international reference materials world-wide.

WHO guidelines and recommendations for the production and control of blood products and related biologicals

WHO recommendations and guidelines on the production and quality control of biological products, including blood products, constitute an authoritative guidance for national regulatory authorities and for manufacturers. The nature of blood products and related substances raises complex issues surrounding standardization, quality control and safety, which require coordinated research and consideration on an international level. In practice, WHO standards, guidelines and recommendations serve as advice to Member States for incorporation in to guidance documents and form the basis of national standards and technical regulations. The norms and standards established by WHO form the basis for harmonization of biological products world-wide.

Among the indicators measuring the performance of this activity are: the increase in the level of harmonization on regulation between countries; the number of countries implementing regulatory programmes for the evaluation and control of blood products and related biologicals according to WHO Guidelines and recommendations. The following activities are included under this item:

- Guidelines on viral inactivation/removal procedures for plasma and plasma derivatives
- Guidelines for the control and standardization of Factor VIII and Factor IX biological measurements
- Guidelines on technical issues regarding plasma contract fractionation
- Guidelines for the collection of plasma for manufacture of plasma derived products.



Expert Committee on Biological Standardization

The programme for developing WHO international biological reference materials, guidelines and recommendations for blood products and related biologicals is approved by the WHO Expert Committee on Biological Standardization. The WHO Expert Committee on Biological Standardization is supported and assisted by the interdepartmental biologicals cross-cutting quality assurance group, located in the departments of Vaccines and Biologicals and Blood Safety and Clinical Technology. A subcommittee structure specific to the areas covered by the Committee, including blood products and related biologicals, aims to ensure best interactions with national regulatory authorities and systematic consensus building regarding international standards, guidelines and recommendations.

This activity aims at 1) ensuring the adoption of guidelines on the quality assurance of blood products and related substances, 2) the establishment of WHO international biological reference preparations, 3) providing guidance for the preparation, characterization and establishment of international and other standards and reference reagents for biological substances, 4) supporting regulatory research to ensure quality and safety of plasma and plasma derived products, and 5) technical coordination with medicines control authorities, pharmacopoeias, WHO laboratories for biological standards and Collaborating Centres, NGOs, international scientific societies, manufacturers associations and other interested parties.

Harmonization on the regulation of medical devices

The regulation of medical devices is an increasingly important component of health care that is growing in complexity. At a time when developed countries have installed quality systems and quality control, only a few developing countries have functional systems to regulate imported or locally manufactured medical devices (which would assure their safety and effectiveness), or the technical capacity to implement these.

The objective of this activity is to cooperate with WHO regions for the development of regional projects in the area of medical device regulation. This would include joint activities with the Global Harmonization Task Force (GHTF), a multinational consortium formed in 1992, and its study groups to unify international regulatory requirements. WHO would encourage more countries to join the Task Force, in order to benefit from the experiences of its participant nations and avoid the further proliferation of disparate regulatory regimes for medical devices.

The specific activities include: the translation and circulation of the existing documents (the revised FDA Model program for medical devices: an international guide, and the Guideline for the development of medical device regulation prepared for PAHO) for comments; the revision of the existing documents and the development of a new draft on medical device regulation to come with our WHO guideline by 2002; the participation at the GHTF conferences and contribution to the work of study group 2 on vigilance and post market surveillance (devices problem, recalls, and alerts to the global community). Regional workshops on the regulation of medical devices will be staged. We will promote and identify information sources for medical devices regulation, establish a uniform format to certify that product exported by countries comply with their domestic regulatory requirements.

Among the indicators measuring the performance of this activity are: the increase in the level of harmonization on regulation of medical devices between countries; the number of countries implementing regulatory programs for medical devices according to WHO guidelines and recommendations; the number of countries with national external medical devices quality assessment schemes increased.

Quality and safety of injection devices

Quality and safety of medical devices starts with good quality systems and controls during the development and manufacturing phase of the device.

This aim of this activity is to ensure the quality and safety of injection devices by working in close relation with the industry on the organization of clinical trials for evidence based decision on recommendation for new technology and improvement of the existing one.

Key areas of work include (1) providing safer injection device by carrying our field evaluations of newer, safer injection devices and (2) establishing an international vigilance system for injection devices.

Indicators of the performance of this activity include (1) the number of appropriate new devices and equipment that have been evaluated and (2) the existence of an operational system to control the quality of injection devices.

Establishing norms and standards for medical devices

Norms and standards are essential tools to ensure the quality and safety of medical devices. An important part of this activity will be to provide coordination for the better control of the application of international norms and standards.

Ensuring the greater participation of all the stakeholders will be our major objective. The International Organization for Standardization (ISO), and federation of national standards bodies, will be assisted by WHO to build more bridges for a better medical devices standardization throughout the world.

To achieve this WHO will Establish or reinforce liaison status with ISO and provide comments on the work of some ISO technical committees (TC 84, TC 210,....), for the better control of the application of international norms and standards and finally to ensure a greater participation of all the stakeholders. The development of norms and standards will be a join activity between medical device manufacturers, regulators, users of the medical device, the Global Harmonization Task Force (GHTF) and ISO. Our activity will focus on some target groups as the autodisable (AD) syringe manufacturers to begin the process of drawing up norms and standards on AD syringes for therapeutic applications, as a contribution to the injection safety project. An aide-memoire on medical device quality and safety will be prepared.

The success of this activity will be measured by the number of national regulations referring to norms and standards; the availability of international standard for AD syringes; the number of syringe manufacturers producing safe syringes according to international standards.

Quality and Safety

Target 5: Research, development, and evaluation of new technologies and methods

Among the principal results of the activities aimed at achieving this target are: 1) international reference preparation for new technologies for the diagnosis of infectious agents representing an emerging threats to blood safety (e.g., transmissible spongiform encephalitis), 2) the evaluation of reagents, procedures, and equipment for laboratory services, including new tests for transfusion-transmitted infections, 3) the evaluation and post market surveillance for new medical devices, including syringes supporting safer use of injections, 4) the evaluation of new waste disposal options, and 5) collaboration with partners for the development of equipment, including equipment related to safe processing of blood.

Specific activities are given below.

Evaluation of HIV test kits

Blood transfusion saves millions of lives but is unfortunately also an efficient route of transmission of HIV and other transfusion transmissible infections (TTIs). Today, a new generation of test kits for HIV are available (which are, for example, able to detect simultaneously HIV antigen and HIV antibody), enabling the early detection of infection. This is a crucial line of defence in blood safety. Increasing numbers of HIV test kits are produced in developing countries, requiring an independent organization such as WHO to assess

their quality. Data on locally produced test kits are lacking. The capacity of test kits to detect different variants and strains is not uniform. Therefore our evaluations are performed on panels of more than 1000 well characterized specimens from diverse geographical origins.

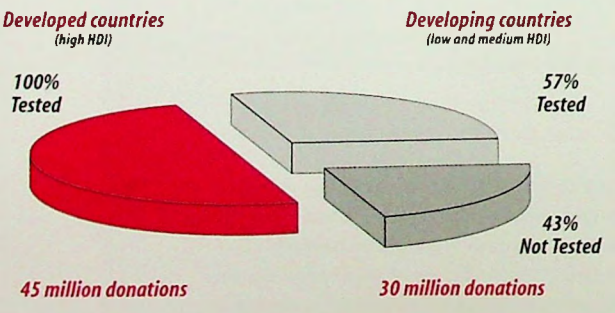
This activity, which is carried out with our WHO Collaborating Centre in Antwerp, is thus aimed at providing Member States, UN agencies and other partners with technical information and advice on the quality of HIV test kits, in order to enable them to select screening tests most appropriate for HIV testing strategies in different settings.

Specific activities include: the preparation, publication and wide distribution of an evaluation report on the operational characteristics of HIV test kits; the initiation of evaluations of HIV Ag/Ab tests, ongoing evaluation of new HIV ELISA tests, including local produced kits, and the publication of a report on these activities, covering operational characteristics.

Evaluation of saliva and whole blood tests for HIV

Saliva and whole blood tests are among the new, simple HIV tests used in prevention and care interventions for HIV/AIDS. This activity seeks to improve these testing technologies by evaluating their operational characteristics and comparing their intrinsic accuracy with current standards. We will facilitate and increase access to information on the quality of simple HIV tests based on new technology (serum, whole blood and saliva), and define their appropriateness for particular settings – for example blood transfusion centres, antenatal clinics, voluntary testing and counselling settings. The evaluations will be carried out in field sites in different WHO regions. Among the indicators used to measure the performance of this activity are: the increased accessibility of WHO/UNAIDS information and technical guidelines for HIV testing; independent data to enable rational selection of the most appropriate whole blood and/or saliva HIV tests in different settings; improved HIV testing in antenatal clinics, voluntary testing and counselling centres; the number of saliva assays evaluated; the number of whole blood tests evaluated; reports published; updated recommendations issued.

Figure 3: Blood safety



Evaluation of test kits for the detection of hepatitis B and hepatitis C

It has been determined that, world-wide, 17 % of all blood donations are not reliably tested for transfusion transmissible infections (TTIs). This number increases to 43% if we consider only the non-industrialised countries. Very few non-industrialised countries test all blood donations for either hepatitis B or C infection on a continuous basis. Existing test kits are often inappropriate for situations in developing countries and test kits are often not affordable due to exorbitant prices (particularly for hepatitis C). Recently new, appropriate technology has become available for the detection of hepatitis B and hepatitis C infection, some of which are produced in developing countries. However, comparative data on these new test kits are lacking.

The capacity of test kits to detect different variants and strains is not uniform. Therefore our evaluations are performed on panels of well-characterised specimens (over 1,800 specimens) from diverse geographical origins, including seroconversion and low titre performance panels.

Quality assessment of test kits are performed at the WHO Collaborating Centre in London and at various field sites in the different WHO regions.

Our aims are therefore to provide Member States and agencies with technical information and advice on the quality of test kits, so as to enable them to select screening tests most appropriate for their particular needs, and to develop appropriate testing strategies for hepatitis B and hepatitis C infection.

The indicators for this activity include the number of high quality hepatitis C rapid tests identified, the number of high quality hepatitis C EIA tests identified, the number of high quality hepatitis BsAg S/R tests identified, and the number of high quality hepatitis BsAg EIA tests identified.

Appropriate testing technologies and strategies for Chagas Disease

In geographical areas where Chagas Disease is endemic, all blood donations should be screened for infection with Trypanosoma Cruzi (T. cruzi). Although T. cruzi infection is most important in Latin America, other countries (USA, Europe) are considering testing all blood donations for T. cruzi due to migrant populations and increased tourism. Available test kits, of which most are produced in Latin America, will be evaluated and guidelines and appropriate and reliable testing strategies will be developed. Discussions with industry will be held to improve current technology. Partnerships include the WHO Collaborating Centre in Sao Paulo, as well as the University of Iowa and international experts.

Indicators include number of test kits evaluated and evaluation reports distributed.

Biological reference preparations for the development of diagnostic tests for transmissible spongiform encephalopathies

This activity envisages creating a WHO repository to facilitate the development of improved diagnostic tests for transmissible spongiform encephalopathies (TSEs) based on available research methods. Internationally agreed-upon biological reference materials (BRMs) will be used for the assessment and validation of assay systems to be applied in diagnostic procedures of TSEs and for a global harmonization in evaluating process validation data (clearance of TSE agents from biological products).

The specific activities include the identification of priorities for development of BRMs relevant to public health, the development of a WHO repository for positive and control materials derived from humans and animals with TSEs (selection and characterization of appropriate candidate materials, development of protocols for WHO Collaborative studies), the development of internationally agreed-upon parameters for classification of human TSEs (harmonization of procedures and reagents used for the classification and nomenclature of PrPSc typing in human TSE cases), the consideration of issues concerning the appropriate uses of the BRMs, and follow-up of scientific developments with potential public health impact in the field.

Quality and Safety

Target 6: Development and implementation of national quality system

Quality assurance of plasma-derived medicinal products and plasma fractionation activities

WHO has long recognized the importance of capacity-building and improving the performance of national regulatory authorities and manufacturers in meeting appropriate international standards. Considerable effort is planned for strengthening developing country regulatory activities in the area of plasma-derived medicines, the goal being to upgrade their technical expertise for the evaluation, control and national standards setting so that all plasma derivatives used would be of assured good quality and safety.

This activity aims at preventing the transmission of blood-borne viral diseases via plasma

products, upgrading the expertise of national control authorities and laboratories in quality assurance of plasma derived products, promoting closer regional collaborative links among national control authorities, and facilitating the transfer of information and technology.

The activity will be carried out in collaboration with the WHO Regional Advisers at the Regional Offices and upon the request of the countries. Partners in the project will form part of a Task Force, including WHO Collaborating Centres, experts in the quality assurance of plasma products and plasma fractionation (from national control authorities and industry or other institutions); international scientific societies; Pharmaceutical Inspection Co-operation Scheme (PIC/S), and the Expert Committee on Biological Standardization.

Specific tasks include setting up the Task Force on Quality Assurance of Plasma Derived Medicinal Products, multi-country and regional seminars and workshops (on quality and safety of plasma for fractionation, strategies to meet the requirements for producing safe plasma products, viral inactivation or removal procedures and their validation, control tools to assure quality and safety in plasma products), the development of guidelines on viral inactivation or removal procedures and validation that are established by the Expert Committee on Biological Standardization.

Increased safety and quality of radiotherapy

Radiotherapy is increasingly being used worldwide for curative as well as palliative treatment of malignant diseases. Especially in poor, developing countries without proper access to modern oncological treatment, radiotherapy often is the only treatment available for such patients. However, the lack of sufficient trained personnel and the absence of proper maintenance and calibration of equipment may reduce the effect of radiotherapy, or cause severe and life-threatening side-effects to the patients..

Therefore, our main objective is to have as many radiotherapy installations as possible included in the WHO/IAEA quality assurance programme. Specifically, we will start by having at least one radiotherapy institution in each of the African countries included, eventually extending this to include all countries in the former Soviet Union. We will develop a complete knowledge base on radiotherapy installations in the African Region (to be collected together with the African Regional Office) and in the former Soviet Union (to be collected together with the European Regional Office).

Among the indicators will be the number of radiotherapy institutions included in the WHO/IAEA quality assurance programme, and the number of radiotherapy institutions with improved quality and safety.

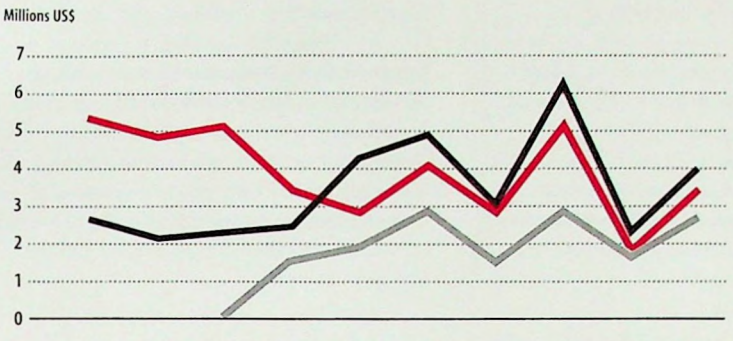
Access

Target 7: Continuous and sufficient quantities of appropriate equipment and supplies

WHO bulk procurement of test kits for HIV, hepatitis B and hepatitis C

The risk of transfusion transmissible infections (TTIs) can be substantially reduced by screening for all main TTI's, HIV, hepatitis B and hepatitis C. Although a large number of screening tests with varying characteristics have been developed, the cost of these test kits is often prohibitive for many developing countries. Countries and UN organizations can make considerable savings through the bulk procurement of test kits. In 1999, for example, the total savings on all HIV test kits purchased amounted to US$ 2.7 million. This

Figure 4: HIV diagnostics – HIV bulk purchase 1989-1999



1989	1990	1991	1992/93	1993/94	1995	1996	1997	1998	1999	
			1.63	2	2.8	1.49	2.88	1.5	2.7	Total savings (US$)
5.17	4.73	4.9	3.3	2.9	3.89	2.73	4.88	1.78	3.2	Total cost (US$)
2.53	2.15	2.2	2.3	4.12	4.7	2.99	6.24	2.42	4	Number of tests

means that funds are freed to buy an increased number of test kits, or can be used to cover other indispensable purchases.

The main activity proposed is (in collaboration with WHO's procurement services, other interested parties in WHO, and UNAIDS) to promote and negotiate the availability of high quality HIV, hepatitis B and hepatitis C test kits at a reasonable cost.

Based on an updated selection of high-quality HIV test kits (ELISAs, simple/rapid and confirmation tests), a new tender will be organized for bulk procurement of HIV test kits, and develop and publish an information booklet on the bulk procurement programme for UN agencies, governments, national AIDS programmes, and NGOs. We will also select and organize a tender for bulk procurement of hepatitis B and hepatitis C test kits.

Among the indicators that can be used to monitor this activity are the number of test kits purchased in each category , and the cost savings as compared to the market (catalogue) prices, analysed by regions.

Access to technology for laboratory diagnostics

With a view to supporting countries in ensuring equitable availability and affordability of diagnostic laboratory technology, this activity aims at strengthening the capacity to produce laboratory diagnostic materials locally. Workshops on local production of diagnostic laboratory materials organised in at least two Regions. The activity will be assessed in terms of the number of countries with local capability to produce laboratory reagents.

Minimum requirements for district surgical services

District hospitals in developing countries perform a wide range of surgical procedures, often with inadequately trained, non-specialist staff, poor facilities and limited, low-technology apparatus and equipment.

WHO will promote the provision of safe surgical and anaesthetic care through:

- Development of recommendations on minimum requirements for district surgical services
- Assistance to national health authorities in the development of national lists of essential equipment and supplies required at first-referral level
- Advocacy to promote the development and use of appropriate innovative equipment and materials
- Feasibility study on the bulk purchasing of essential surgical and anaesthetic equipment and instruments (oxygen concentrator).

Ensuring equitable availability and affordability of injection devices

This aim of this activity is to ensure equitable availability and affordability of injection devices.

Key areas of work include (1) decision-making guide for the choice of injection devices, (2) guidelines on financing of injection devices for countries and donors, (3) bundling financing plan for injection devices, and (4) technology transfer for the production of safer injection devices.

Indicators of the performance of this activity include (1) the number of countries using the guidelines to make choices of injection devices, (2) the number of countries increasing the availability of injection devices, (3) the number of donors adopting the "bundling" policy statement and (4) the set-up of local production of safer injection devices.

Use

Target 8: Appropriate collection, processing, and clinical use of blood and blood products

Promotion of blood donor programmes based on voluntary non-remunerated blood donors

Although regular, voluntary, non-remunerated blood donors from low-risk populations are considered as the safest donors, blood donation systems in many developing countries are still dependent predominantly on replacement/family/paid donors. There is lack of properly organized blood donor programmes in most of the developing countries. Similarly, there is no database of regular blood donors and only a very small fraction of voluntary donors are regular blood donors. Most of the blood transfusion centres do not have trained donor recruiters.

There is a great need for advocacy and providing technical support for developing national blood donor programmes. The activities aim at developing and/or strengthening the national blood donor programmes in WHO Member States based on voluntary, non-remunerated blood donors from low-risk populations, depending on the local situation, requirements and available work force. This includes organization of training workshops at country level for training of blood donor organisers, donor recruiters and blood transfusion personnel involved in donor recruitment and retention activities.

Indicators to monitor and evaluate the outcome of this activity include increase in total number of voluntary, non-remunerated donors, number of staff trained in donor recruitment, reduction in number of paid donors and reduction in prevalence of transfusion transmissible infections among blood donors.

Safe blood collection systems and component production

Procedures for safe and effective blood collection are required to reduce the risk of bacterial contamination of donated blood and to ensure the quality and efficacy of blood components prepared from the donated blood unit.

The activity aims at developing learning materials on safe and effective blood collection and production of quality blood components. The learning materials will be developed in two phases. They will be developed as a supplement to the existing distance learning materials on "Safe Blood and Blood Products" and will promote the use of standardized procedures for safe blood collection and, ultimately, the production of high-quality blood and blood components.

Indicators to evaluate the utilization of learning material include a decrease in the number of

discarded blood units due to inappropriate blood collection, a reduction in the rate of bacterial contamination of blood components, improved traceability of plasma and serum used for processing, improvements in the quality and efficacy of blood components and in the quality of plasma for processing and fractionation. This will lead to greater safety and efficacy of blood products and also minimizing the risk to both donors and recipients.

Distance learning programme for safe blood and blood products (DLP)

Blood transfusion staff, especially those in small hospital blood banks in developing countries, often lack opportunities for further training and to participate in refresher courses. Distance learning offers a flexible, cost-effective way of providing training in blood safety for larger numbers of staff, at lower cost and with less disruption to services than is possible with conventional courses. In promoting the use of distance learning in transfusion medicine, WHO/BTS has published five modules of learning materials, Safe Blood and Blood Products, for staff with responsibility for donor recruitment and for the collection, processing and issue of blood for transfusion. It has also trained senior blood transfusion service personnel from over 100 countries in establishing distance learning programmes (DLP) in blood safety supported by the learning materials entitled Establishing a Distance Learning Programme in Blood Safety: A Guide for Programme Coordinators. This activity aims at increasing the quality and coverage of training for blood transfusion service staff within the workplace as part of the process of improving the quality and safety of national blood supplies.

English, French, Spanish, Chinese, Russian and Portuguese editions of the modules are now available. An Arabic edition is being produced and several countries are translating the modules into their national languages.

Priorities for the future development of the distance learning programme include the evaluation of successful national distance learning programmes and technical support to countries that plan to start programmes, notably China and India.

Clinical use of blood

A large proportion of transfusions are given inappropriately. The appropriate clinical use of blood is critical, particularly in areas with a high prevalence of transfusion transmissible infections and in areas where there is a shortage of blood units and resources for health are limited. The objective of this activity is to develop and promote good transfusion practice to ensure that the right patient receives the right blood for safe administration at the bed side, as well as the right reason, in accordance with national guidelines on the clinical use of blood. This will be achieved through the dissemination of WHO learning materials as well as training of prescribers of blood and blood products (nurses, surgeons and anaesthetists and others).

Regional workshops using the clinical use of blood learning materials (English version) have been organized. Learning materials are being translated into French and Spanish, Chinese, Russian, Arabic and other languages.

Haemoglobin Colour Scale

The Haemoglobin Colour Scale was developed by WHO as a simple, accurate, and cost effective clinical device for the detection and management of anaemia for use in areas where laboratory facilities are not readily available, and for haemoglobin surveys to identify populations at risk.

It was developed in response to such situations and will be important in a variety of areas including blood donations, primary health care, antenatal, paediatric and trauma care. The Scale would be invaluable in peripheral health services, especially in developing countries, and in the screening of blood donors. It is ideal for determining blood donor suitability, particularly as a replacement for the copper sulphate specific gravity (SG) method).

WHO has evaluated the device extensively in laboratory and field conditions. Over the past four years, the field evaluations were carried out in all six WHO regions, in developed and developing countries, in blood transfusion services, antenatal clinics, primary health care settings, and nutritional survey/research studies. The results of

these trials have led to minor modifications in the instructions to ensure correct use.

After the production of several batches of the Scale we now have achieved the required quality in the printing of the colours in the Scale. Limited quantity of the WHO Haemoglobin Colour Scale has been allocated to selected sites in all regions.

The objective is to transfer the production, marketing, logistic for distribution and sales to a commercial partner ready to finance the initial cost to bring the product to the market. A licence Agreement has been signed with a German company, COPACK.

The work will include: the control of the manufacturer activity in accordance with the licence agreement signed for the production and distribution of the scale, the coordination of the validation of the scale by a WHO collaborating centre; the identification of new donors to facilitate the access to the device; the development of flier and other information tools; development of the HbCS starter kit; the largest dissemination of the scale to the public sector will still require work with the manufacturer and development of tools for promotion and training.

A second generation of the Haemoglobin Colour Scale will be developed and other non-invasive haemoglobin monitoring technologies will also be investigated to help detecting anaemia, particularly of pregnant women.

The starter kit will be first available in English and French; other language editions of the Scale will be prepared to respond to the worldwide needs.

Monitoring and evaluation will be provided by the number of countries currently using the scale as a screening tool for blood donors and other application; the increase in anaemia detection programmes using the scale; The quantity of the haemoglobin colour scale produced and distributed by the manufacturer.

Use

Target 9: Appropriate use of diagnostic imaging and laboratory technologies

Among the expected outcomes related to this target are 1) Regional external quality assessment schemes (EQAS) for transfusion-transmissible infections, immuno-haematology, and selected laboratory disciplines, 2) educational material and training programmes on use and maintenance of diagnostic imaging facilities and equipment, 3) guidelines for the use and cost-effective strategies for laboratory methods and diagnosis of transfusion-transmitted infections, and 4) guidelines for good diagnostic practices.

The associated critical indicators include 1) The number of countries participating in External Quality Assessment Schemes (EQAS) for transfusion-transmissible infections, immuno-haematology, and other laboratory disciplines, 2) the number of countries with improved, safe, and appropriate imaging services, 3) the number of countries with established standard operating procedures in laboratory services, and 4) the number of countries implementing good diagnostic practices.

Regional external quality assessment schemes for transfusion transmissible infections (HIV hepatitis B and hepatitis C)

There are many steps and procedures required between blood being drawn from the donor and the patient receiving the transfusion. An adequate quality system should be in place to monitor each step. In many countries there is a need and demand for technical guidance and didactic material on how to implement a quality system. The principal objective of this activity is thus to promote the concept of quality systems and to assist blood transfusion services and national authorities in implementing quality systems, including quality assurance, quality control, standard operating procedures and external quality assessment for testing and safe blood supply.

Regional external quality assessment schemes (REQAS) for transfusion transmissible infections will be established covering four WHO regions: two in Africa (one for anglophone countries and one for francophone countries) and for South-East Asia and the Western Pacific.

Partners include the CPHLS, London; NRLs, Melbourne; Hopital Le Dantec, Dakar, and NBTS, Harare.

A Newsletter discussing issues related to quality assurance and quality management will be distributed to participants of the scheme.

As indicators to measure the performance of these activities we may use the number of countries participating in regional EQAS for the main TTIs, the number of countries of newly implemented or improved quality systems, the number of countries with a NEQAS.

Development of Regional External Quality Assessment Schemes (REQAS) in Blood Group Serology

Adequate testing of all donated blood units in blood group serology is an important strategy for ensuring safe blood transfusion. Quality management in blood transfusion laboratory has attained a greater significance in view of the risks associated with blood transfusion due to poor quality. Establishment of External Quality Assessment Scheme (EQAS) is required to ensure quality testing in blood group serology for all donated blood units.

The activity aims at assisting WHO Member States in promoting the concept of quality systems and in implementing national quality systems. Activities include organizing regional EQAS in Blood Group Serology, conducting regional training workshops, identifying areas for further training and providing support in the areas of need. Regional external quality assessment schemes in Blood Group Serology will be established covering four WHO regions: two in Africa (one for anglophone countries and one for francophone countries) and for South-East Asia and the Western Pacific.

Indicators to measure the performance of these activities include development of WHO guidelines for organizing a National EQAS, number of countries participating in regional EQAS in Blood Group Serology, number of training workshops and educational activities carried out during the specified period and number of personnel trained in concept of Quality Assurance and External Quality Assessment.

Establishing regional training centres for quality management

These will be discussed below (under Key Issues) in detail.

Use

Target 10: Safe and appropriate use of injections

Appropriate, rational and cost effective use of injections

This aim of this activity is to ensure appropriate, rational and cost effective use of injections and injection devices.

Key areas of work include (1) pilot projects in each WHO region, (2) injection safety standards, (3) guidelines for universal precautions, (4) toolbox for behaviour change and implementation.

Indicators of the performance of this activity include (1) availability of evaluation for pilot projects, (2) availability of injection safety standards, (3) availability of universal precautions guidelines, and (4) the availability of a behaviour change and implementation toolbox.

Target 11: Appropriate use of devices and clinical technologies

Improving blood safety by ensuring reliable and appropriate HIV testing

In many non-industrialized countries, HIV transmission through blood is still occurring. Assistance will be given to countries to develop and implement national HIV testing policies, provide updated operational guidelines on appropriate and reliable testing for HIV and training of staff. Educational material will be made available for training staff on these concepts.

The specific objectives are to assist and encourage countries to develop and implement national testing strategies to ensure safe blood, and to provide technical advice and training on operational aspects of reliable testing of HIV and other TTIs. The content of the advice will cover principles of screening assays, selection of assays and automated systems and good laboratory practice.

We will produce an educational set (document and slides) on principles of screening assays, selection of appropriate assays, and on quality systems in BTS. After a workshop and field testing, we will produce these educational materials in English, French, Spanish and Russian. Follow-up actions will include assessment visits, and further intercountry workshops.

Blood cold chain

An effective blood cold chain (BCC) from donation to transfusion is an essential part of a national blood transfusion service if it is to ensure safe blood for the patient.

Thus DCT aims to carry a programme: to determine the specifications of selected blood cold chain equipment; to perform laboratory and field evaluation of devices and indicators for the safe storage of blood or blood product in all environments; to inform and educate users of cold chain equipment on specifications of appropriate equipment and devices for use in the maintenance of the blood cold chain by producing a publication with specifications for BCC equipment and devices and by developing learning materials for the maintenance of the blood cold chain .

The result of this programme will be: the establishment of WHO specifications for selected BCC equipment; the development of protocols for laboratory and field evaluations; the production of reports on the laboratory evaluations done on CFC-free refrigeration equipment for BCC, and on blood time temperature indicators, by specialized testing centres. Accordingly, we will produce a publication with specifications for BCC equipment and devices evaluated in the laboratory and in the field, and will develop learning materials for the maintenance of the blood cold chain. Additional essential equipment for the blood cold chain has been identified (e.g., plasma shock freezers, platelet agitators), laboratory and field evaluations will be conducted and appropriate specifications will be determined in order to expand the range of equipment and devices necessary to further improve the blood cold chain: The work will also include: the collection of BCC equipment and material for the preparation of a product information sheet book; the field evaluation and final editing of learning material; the development of a specific project with a Swiss school of engineers on the management of the logistics of the blood cold chain.

Longer-term activities include the production of a practical manual on the management of blood inventory, the establishment of minimal standards for blood cold rooms, concept development of a mobile unit for blood collecting, improved "hold over time" for refrigerators and a review of alternate energy sources for refrigerator and freezers.

Indicators to measure performance include the number of countries or health care centres ensuring safe blood transmission to patient by implementing a BCC service; the numbers of BCC equipment tested; the numbers of blood transportations done with blood time temperature indicators.

Essential surgical procedures at district hospitals

District surgical services should be able to manage the majority of patients with trauma and

obstetric, orthopaedic and abdominal emergencies. Many first-referral level facilities in developing countries do not have specialist surgical teams and are staffed by medical, nursing and paramedical personnel who perform a wide range of surgical procedures, often with inadequate training. This contributes to unnecessarily high rates of maternal mortality and death and disability resulting from trauma.

This project aims at ensuring that medical officers and other personnel responsible for surgical and anaesthetic care at first-referral level receive appropriate training in the skills required for the management of trauma and common surgical and obstetric emergencies.

The activity will include:

- Identification of future requirements in training in surgery and anaesthesia at first-referral level in developing countries
- Development of a global strategy for essential surgical care
- Development of a comprehensive set of learning materials for use in in-service training, short courses, basic and continuing education programmes for medical, nursing and paramedical personnel
- Advocacy to promote the development of national standards and clinical guidelines on acute surgical care
- Capacity-building through the establishment of a team of Regional Facilitators to promote and support the development of national training activities in acute surgical care
- Organization of regional and inter-regional workshops to promote both the recognition of the special training needs of surgical and anaesthetic personnel at first-referral level and the provision of appropriate training in both basic and continuing education programmes
- Establishment of an Expert Panel on Essential Surgical Services
- Strengthening of collaborative partnerships between WHO, non-governmental organizations and WHO Collaborating Centres in the development of integrated approaches to training.

Indicators for this activity include the number of countries that develop national standards and clinical guidelines; the number of countries that establish specialized training programmes in acute surgical care; and the number of countries that use the WHO learning materials as part of their overall training strategy.

Information technology in transfusion safety

The objectives of this activity are to provide national blood transfusion services with tools to help in the implementation of computerized information management systems. Such tools will help to reduce transcription errors, improve records and traceability and increase effectiveness of donor recruitment and management. We will also develop guidelines on evaluating the relevance of computerized information management and implementation in blood transfusion, as well as specifications for blood transfusion software and a guide for validation.

Training programmes and training material in diagnostic imaging

A major reason for the non-functioning or malfunctioning of diagnostic imaging services in many countries is the lack of proper education and training, both medically and technically, of those involved. The objective of this activity is thus is to improve local knowledge and skills by developing and implementing adequate training programmes and training materials. This would be done in close collaboration with international and national experts, and with the concomitant establishment of regional and national centres of excellence for diagnostic imaging services.

Specific targets include: the establishment of centres of excellence for education and training in diagnostic imaging (two in the WHO African Region, two in Central and South America, one in South-East Asia, and one in the Western Pacific Region); the further development, distribution and implementation of both medical, technical and managerial training material and programmes targeting the need of small hospitals and clinics with limited resources as well as updated material for the proper use of the World Health Imaging System for Radiography.

Among the indicators for this activity are the number of hospitals/institutions with properly functioning diagnostic imaging, and the number

of hospitals/institutions with sufficiently trained staff.

Access to medical devices, R&D and technology transfer to developing countries

Since about 90% of the world's medical devices are produced in Europe, Japan and the United States of America, we could improve the access to medical devices by facilitating the transfer of technology so that local production is stimulated in the rest of the world.

The objective is to work with manufacturers, governments, and users to allow developing countries to have more equity and better access to safe and effective medical devices and clinical technologies. This activity includes a range of technical and educational projects, some of which are more "product-oriented" (relating to the evaluation, and research and development, of new medical devices in partnership with industry), while the other projects are more "service-oriented" (involving the provision of tools for a better access to technology, learning material, and guidelines for an appropriate and safe use of technology).

Specific activities include: the harmonization of the relevant nomenclature and device classification systems by using for the Global Medical Device Nomenclature System (GMDN); regional information-gathering and needs assessment meetings; guidelines for the procurement of medical devices; the elaboration of a communication/advocacy/funding strategy for medical devices; the development and evaluation of new technologies (e.g., a low-cost blood transportation box); the measure of the impact of the reuse of medical devices (including safer use of injections, safe refurbishment of medical devices); the strengthening of local capacity to produce equipment and supplies (WHO bulk procurement system for medical devices including AD syringes; the technology transfer for local production of medical devices, including AD syringes, meeting with manufacturers on technology transfer to developing countries); the promotion of appropriate technologies for district surgical services (oxygen concentrators, orthopaedic appliances, skills training) and the production of distance learning materials for essential surgical care for district surgical services at first referral hospital (manuals for district level surgical procedures on anaesthetics, surgery, trauma, orthopaedics, and obstetrics).

Among the indicators available to measure this activity are the number of countries implementing WHO guidelines and recommendations for selection, use, and maintenance of technologies; the number of new devices developed; and the number of new devices and new techniques evaluated (including a "universal blood transportation box" to be developed in partnership with a Swiss school of engineers).

Management and maintenance of health care technology

This activity will be carried out in collaboration with the Department for the Organization of Health Services Delivery to help health authorities in the process of needs assessment, planning, selection and acquisition of health care technologies. It includes the development of technology management toolkits, one of which is a software-based planning and management tool called the Essential Health care Technology Package (EHTP).

A pilot project on Health care technology management and maintenance started in Mozambique including a country situation analysis and first sensitization of the MOH to the EHTP.

This activity aims at:

- Supporting the field testing of this software-based planning and management tool in some selected countries: Mozambique, Tunisia, China and others
- Contributing to the finalization and implementation of the EHTP.

The other part of the project will be built on the WHO Guidelines for Health care Equipment Donations. The specific activities include the support and promotion of the improved process of technology transfer, particularly with regard to equipment donation, through application of the WHO Guidelines on Equipment Donation. The maintenance information system developed in Mozambique will also be tested for exportation to other countries.

Among the other activities are: the development of learning materials on management of health care equipment (guidelines on safety, care, maintenance and use of medical equipment at district hospital level); the support on specific preventive maintenance including blood bank, laboratory and X-ray equipment.

The impact of the project will be measured by: the number of appropriate equipment donations; the reduction of the number of unused equipment, the number of countries using a management and maintenance information system; the number of countries using the EHTP.

Health care waste management

In many countries, the improper management of wastes generated in health care facilities has a direct impact on the health of the community, of the personnel working in health-care facilities, and on the environment. In addition, pollution caused by the inadequate treatment of waste can also have indirect effects on community health. The disposal of certain types of clinical devices should follow specific safety rules. For example, a syringe is a common item that requires safe disposal.

Health care waste management (HCWM) includes the management of discarded blood, blood transfusion bags, laboratory sample, sampling equipment, waste generated by diagnostic imaging, and devices (e.g., syringes and needles). There has been an increasing demand for WHO to take an active role in implementing safe HCWM on a larger scale.

Waste management options need to be efficient, safe and environment-friendly in order to protect people from voluntary and accidental exposure to waste when collecting, handling, storing, transporting, treating or disposing of waste.

The main objective of this activity is to determine how health care waste management is being carried out and how to improve it. The activity will include: the identification of centralized waste management and disposal resources available; the proposal of a choice of management and disposal options (which will depend on their affordability, sustainability, environmental friendliness, efficacy, on the worker's safety and in order to assure the prevention of re-use); and the identification of appropriate options for all levels of health care facilities.

This activity, which is the result of collaboration with the WHO cluster on Sustainable Development and Healthy Environments, aims to focus on waste blood and any waste materials containing, or which have contained, blood regarded as hazardous waste for a specific contribution to global blood safety

Steps in the process require a comprehensive approach and considerable resources. A global action plan for the implementation of the strategy to reduce disease burden caused by inadequate HCWM will have the following targets:

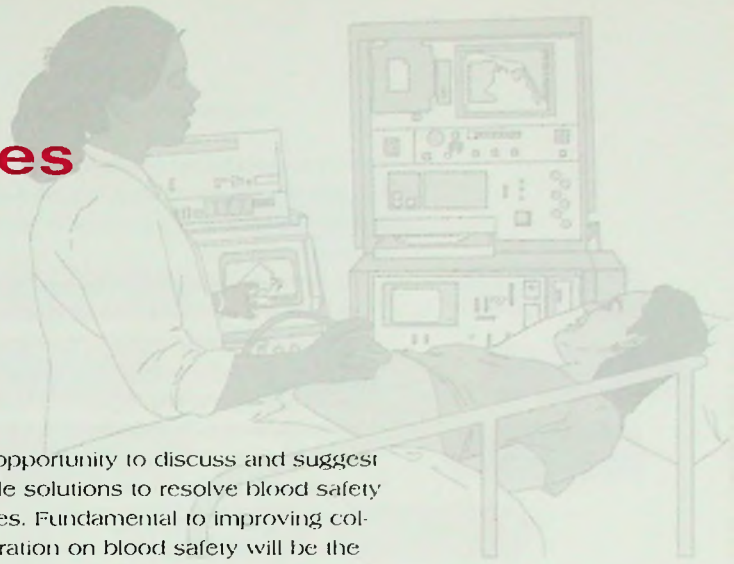
- Evidence and information for policy (a data base on health care waste management will be organized to evaluate practices and options available and for the monitoring of country progress)
- Reference and guidance material (including guide, a primary health care decision making guide, an aide-memoire on HCWM)
- Safety and availability of waste management options (an Internet-based database, with field tests for health care waste management options)
- Country plans (implementation of waste management system, national workshops).

Our contribution to this activity will include: the development of literature search and a review of health impacts from microbiological hazards in health care wastes; the preparation of a guidance document for the appropriate management of blood waste and waste contaminated with blood and a primary health care decision-making guide.

The medical device industry is expected to be among the partners in this activity, and encouraged to develop more environmentally friendly health care products.

Indicators for the success of this activity will include the number of countries with safe waste management systems implemented; the number of primary health care centres currently using the decision-making guide; the number of options available for safe health care waste management; the number of successful cases of technology transfer in waste disposal.

Key Initiatives



Global Collaboration for Blood Safety

Each national government has the responsibility to ensure a safe and adequate supply of blood and blood products for its citizens. However, there are many parts of the world where the safety and adequacy of the blood supply is lacking. Global blood safety requires urgent attention, and it is only through improved collaboration between organizations and institutions involved in the area of blood safety that the safety of the global blood supply can be improved.

The recommendations made at the AIDS Summit of December 1994 in this respect were reinforced by a resolution of the World Health Assembly in 1995 (WHA 48.27). Taking up the initiative, WHO proposed that a broadly constituted forum in which to communicate and to propose joint and complementary action would lead to the required improved collaboration. This forum could include national and international organizations involved in blood and blood product safety; manufacturers of plasma, plasma derivatives and blood devices; users and prescribers of blood; blood donor organizations, source plasma donors and recipients of blood and blood products.

The collaborative mechanism will build on existing knowledge and conventional wisdom in the area of blood safety; utilize existing expertise; promote dialogue on blood safety issues; and suggest realistic, effective and practical mechanisms to improve blood and blood product safety. The collaboration should be one of representation offering the opportunity to discuss and suggest viable solutions to resolve blood safety issues. Fundamental to improving collaboration on blood safety will be the issue of improving collaboration between the developed and developing regions of this world. Developing countries will have representation in the mechanism to help identify and offer realistic approaches to priorities in blood safety.

In October 1995, WHO held the First Preparatory Meeting for the Formation of a Task Force for Global Collaboration for Blood Safety in Geneva, to prepare a proposal. The meeting involved most of the major organizations and institutions involved in the area of blood safety and it reviewed the WHO proposal and formulated recommendations for a mechanism to improve global blood safety. The first full meeting of the Global Collaboration of Blood Safety (GCBS) was held in November 2000 and the follow up Working Group meeting and Annual meeting will be held in 2001. During discussions, the meeting agreed on a title for the collaborative mechanism and on the following recommendations:

Recommendations for the formation of the Global Collaboration for Blood Safety (GCBS)

Goal: Promote and strengthen international collaboration on safety of blood products and transfusion practices.

On 1 December 1994, the Paris AIDS Summit declared the GCBS should be established, and consequently the forty-eighth World Health Assembly, held in

May 1995, produced resolution WHA 48.27 covering the formal establishment of GCBS. The following mission was adopted:

> ***To improve collaboration among organizations and institutions involved in the area of transfusion safety with a view to encouraging and facilitating information exchange, promoting standards for good manufacturing practices for blood and related products for transfusion, and fostering the establishment and implementation of cooperative partnerships to ensure donor and recipient safety in all countries.***

GCBS (structure and functions)

It is recommended that to ensure an effective and efficient GCBS, it should be made up of a small number of specialists and representatives of internationally recognized organizations and institutions involved in the area of transfusion safety, as well as national representatives of different global regions.

The GCBS should ideally comprise the following organizations:

Participants

1. American Association of Blood Banks (AABB);
2. European Plasma Fractionation Association (EPFA);
3. Fédération internationale des Organisations de Donneurs de Sang (FIODS);
4. International Federation of Red Cross and Red Crescent Societies (IFRCRCS);
5. International Plasma Products Industry Association (IPPIA);
6. International Society of Blood Transfusion (ISBT);
7. World Federation of Hemophilia (WFH);
8. World Health Organization (WHO) (Blood Safety unit, Biologicals unit, Health Laboratory Technology unit);
9. Participants from developing countries to ensure appropriate regional representation;
10. Representation of relevant health industry manufacturers/medical devices; and
11. Representation of prescribers of blood and blood products.

Observer Participants

1. Commission of the European Communities (CEC);
2. Council of Europe (CE);
3. Food and Drug Administration (FDA), United States of America; and
4. National Institute of Health (NIH), Japan.

Key points related to the constitution and operation of GCBS are as follow:

- Subject to sufficient funds being made available for that purpose, the GCBS Secretariat will be provided by the Blood Safety unit of the World Health Organization
- The GCBS will elect a chairman for a one-year to two-year term. The functions and activities of the chairmanship will be decided at the first meeting of the GCBS
- The GCBS will hold at least one to two meetings per year, with dates agreed by a majority decision of the members
- The GCBS will produce and disseminate documents which, among other things, analyze problems and advocate research to find solutions relating to transfusion safety. The GCBS will form and utilize the expertise of ad hoc Working Groups to debate specific issues relating to blood and blood product safety and to provide recommendations and guidance to the GCBS. In some instances, the Working Groups may need to be formally constituted and required to meet to reach consensus on particular issues. In other cases, a Working Group may be constituted less formally and carry out its task by correspondence
- The GCBS will make the decision on the functions and activities of each Working Group and make appropriate provision for the costs involved in each task

assigned, (i.e., a particular organization such as WHO, IFRCRCS, ISBT, etc., may be able to carry out the necessary task through its plan of work and budget for blood safety activities. In other cases a project proposal may need to be developed to seek funding for a specific Working Group activity).

GCBS funds

Funds will need to be raised to support the GCBS activities, i.e., from governments, non-governmental organizations and, if necessary and appropriate, from the private sector. With regard to potential financial support from the private sector, care should be taken, however, to avoid the risk of actual or perceived conflicts of interest. Commercial donors should not seek promotion of the fact of their donations. In this regard, the participants in the GCBS will need to ensure that all fund-raising efforts are in accordance with their respective policies and principles. Under the direction of the GCBS, the WHO Blood Safety unit will administer financial contributions intended to support the activities of the GCBS through a trust fund entitled Global Collaboration for Blood Safety. This trust fund will be administered in accordance with WHO's financial regulations, rules and practices and be subject to WHO's normal programme support costs. Periodic financial reports will be provided by the Secretariat to the membership of the GCBS, justifying how funds designated to support the activities of GCBS have been used.

The formation of, and participation in, the GCBS may, however, dependent on how much funding is available in the above-mentioned trust fund, require financial commitments from some or all of the participants.

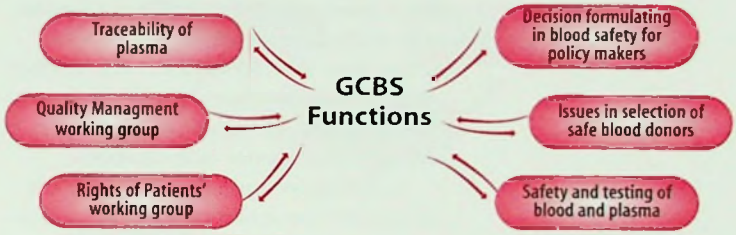
GCBS objectives

The GCBS objectives are as follow:

- to promote international consensus on essential principles of global blood safety;
- to promote the improvement of global blood safety and encourage governments to recognize and establish national blood programmes;
- to assist countries, upon request, to identify national blood safety priorities and prevent transfusion transmitted disease;
- to assist countries, upon request, in the implementation of appropriate and recognized transfusion practices to ensure donor and recipient safety and freedom from discrimination;
- to promote effective recruitment of safe donors through the use of appropriate selection criteria;
- to promote the appropriate preparation and utilization of blood and blood products;

Figure 5: GCBS – WHO Secretariat

Figure 6: GCBS – Partners and WHO Secretariat



- to encourage safe international practices for the collection, storage and transport of plasma and the preparation and distribution of its derivatives;
- to promote the bi-directional traceability of blood products between donor and recipient whether in-country or across national borders; and
- to facilitate the exchange and use of information by encouraging data collection, management and dissemination.

The development of GCBS

The Department of Blood Safety and Clinical Technology continues to host the secretariat of the GCBS, bringing together national and international organizations involved in blood and blood product safety, and associations of manufacturers of plasma, plasma derivatives and blood devices and diagnostics, of prescribers, users, and recipients of blood and blood products as well as blood donor organizations.

In the short term, a review of existing safety interventions along the transfusion chain will be carried out with a view to devising and agreeing on an objective assessment framework. This will constitute a tool for developed and developing countries to prioritize intervention strategies, and it will help decision-makers.

Safe Injection Global Network

While it is the responsibility of each national government to ensure safe and appropriate injections, prevention of adverse events associated with injections will require improved collaboration between organizations and institutions sharing a common interest in this goal. The Safe Injection Global Network (SIGN) is a new mechanism for coordinating activities aimed at the safe and appropriate use of injections worldwide.

Unsafe injections waste precious health care resources

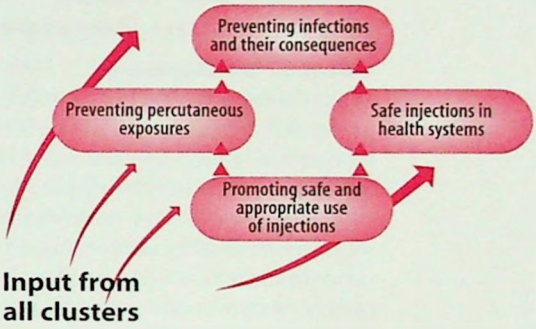
A literature review published in 1999 indicated that, of all medical procedures, injections are probably the most common. About 12 000 million injections are administered each year throughout the world. Less than 10% are for immunizations. Many of the therapeutic injections, the widest application, could be avoided. In many countries, both patients and health care workers prefer medicines to be administered by injection. Reportedly, patients ask for injections because they believe that medication is more efficacious by that route and that the pain of the injection is a marker of that efficacy. Reasons for health care workers to inject excessively include the desire to respond to a perceived patient preference, the wish to monitor compliance directly and, in some instances, the possibility of charging a higher fee for service. Overall, unnecessary injections lead to high out-of-pocket health care expenses for patients and their families.

Poor injection practices cause a high burden of disease

Many injections administered in the world are unsafe. Of particular concern is the reuse of injection equipment without sterilization - a frequent practice in developing countries and those in transition, where it is common simply to rinse syringes and needles in containers of tepid water between injections. In these countries, injections account for a high proportion of new infections due to hepatitis B and hepatitis C viruses. Each year, globally, reuse of dirty injection equipment causes an estimated eight to 16 million infections with hepatitis B virus, 2.3 to 4.7 million infections with hepatitis C virus, and 80 000 to 160 000 infections with HIV. Together, these chronic infections are responsible for an estimated 1.3 million early deaths and 26 million of years of life lost, and lead to US$ 535 million in direct medical costs.

Figure 7: SIGN Associates and SIGN Secretariat

Figure 8: Cross Cluster Collaboration within WHO



Poor injection practices can be eliminated

To reduce overuse of injections and to assure safe injection practices, multidisciplinary strategies comprising three elements should be implemented. First, there needs to be a change in behaviour: patients and health care workers should be encouraged to adopt safe practices and to avoid unnecessary injections. Second, sufficient quantities of clean injection equipment should be available in each health care facility. Third, mechanisms should be in place so that "sharps" (i.e. needles and syringes) are so disposed of as to ensure that dirty injection equipment is not reused and the risk of accidental needle-stick injuries is minimized. Interventions based on each of these three elements have proven to be successful and demonstrated that poor injection practices can be eliminated. For example, in Indonesia, behavioural change interventions have resulted in a substantial and sustained decrease in the overuse of injections. In Burkina Faso, increasing the availability of clean, disposable injection equipment through community pharmacies has almost eliminated unsafe injection practices. In a pilot project in Côte d'Ivoire, the introduction of small-scale, locally-built incinerators and at the same time training of health care workers have successfully eliminated dangerous needles and other sharps waste from the environment.

Safe and appropriate use of injections does not require a new programme

In every country, efforts to ensure safe and appropriate use of injections require collaboration between all partners. Because multidisciplinary interventions are needed, the basis of preventive activities should be careful coordination of already existing initiatives rather than the creation of new programmes. National health authorities responsible for health promotion, HIV prevention, integrated management of childhood illnesses and blood transfusion services should promote safer behaviour among patients and health care workers. Similarly, national authorities responsible for access to essential drugs, immunization services and family planning should increase the availability of clean injection equipment. It is recommended that responsibility for safe management of health care waste should be assigned to health care services.

WHO activities for the safe and appropriate use of injections

Because unsafe injections waste precious health care resources, transmit bloodborne pathogens on a large scale and can be eliminated, WHO has increased its activities to improve injection safety. First, WHO hosts the secre-

tariat of the Safe Injection Global Network, a coalition, created in 1999, of stakeholders who strive for safe and appropriate use of injections worldwide. Working within a common strategic framework, the secretariat coordinates the activities of the network. Second, WHO has coordinated its relevant activities, which include safety of immunization injections, rational use of medicines, blood transfusion safety, laboratory safety, medical devices, management of health care waste, prevention of viral hepatitis, and prevention of injection drug use.

Quality Management Project for Blood Transfusion Services

General Background

Quality management in all areas of blood transfusion is crucial for the provision of safe blood for all those requiring transfusion. In most developing countries, there is a lack of quality management for the safety of blood and blood products which adversely affects the quality of care to the patients. WHO has identified that urgent attention and action needed to be devoted to quality in the blood transfusion services.

In order to implement a quality system, the capacity of the Blood Transfusion Services (BTSs) needs to be improved through comprehensive training. There is an acute shortage of trained manpower in blood transfusion in developing countries. Quality management has therefore been identified as a key strategy for global blood safety and has been targeted by WHO as a priority for training.

WHO has developed the ***Quality Management Project (QMP)*** as a new initiative to be carried out in all regions starting from 2001 as a part of a strategy for building capacity at global level. The project addresses the need to adopt the principles of quality management in all areas of the blood transfusion services in order to ensure good organization and management, donation from safe blood donors, testing of all donated blood for HIV and other transfusion transmissible infections (TTI), quality component production and appropriate clinical use of blood. This project aims to ensure the safety of blood transfusions to significantly reduce mortality, morbidity, and the global disease burden due to the transfusion of infected blood and blood products.

QMP has been developed as a long-term collaborative and sustainable project with effective co-operation and collaboration with other international organizations already involved in quality management such as the American Association of Blood Banks, International Federation of Red Cross and Red Crescent Societies, and the International Society of Blood Transfusion.

Activities have been planned for all the WHO regions, focusing on promoting the principles of quality systems and assisting blood transfusion services and national authorities in implementing quality systems.

Figure 9: Quality Management Project

Goal

To build capacity in the area of quality management for blood transfusion services covering all aspects of blood transfusion, through an integrated approach of training and assessment, in all member states of WHO with regional cooperation.

Objectives

- To assist WHO Member States in improving the quality, safety and adequacy of blood
- To upgrade national capacity, knowledge and skills of WHO member states in all aspects of quality management in blood transfusion through regional training courses
- To establish regional quality training centre(s) for ongoing training for BTSs in each WHO region
- To develop regional external quality assessment schemes (REQAS) in coordination with international external quality assessment scheme for TTI and blood group serology
- To upgrade the facilities and build a Quality Area Desk in BTS at national level
- To establish a sustainable national quality system in BTS in each Member State.

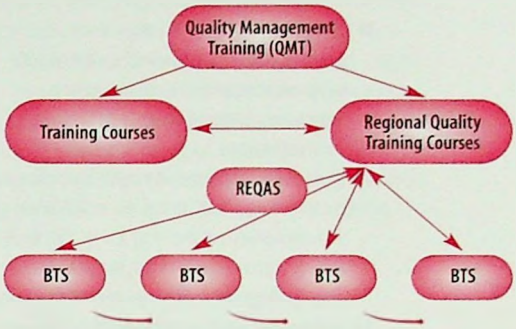
Activities

- Identify quality training centre(s) in each of the WHO region which will be responsible for organizing regular Quality Management Training (QMT) courses in all aspects of blood transfusion
- Organize QMT courses for blood transfusion services
- Establish REQAS with the countries participating in the training course for TTI and blood group serology, integrated within the training courses in quality management for BTS
- Develop an effective quality network for BTS between the regional quality training centre and the participating centres.

Quality Management Training for Blood Transfusion Services

Considering the need to train staff in blood transfusion services, Quality Management Training (QMT) constitutes an important component of the project. QMT essentially includes organization of

Figure 10: Components of QMP



Replication of Regional Activities at National Level

4-week training courses and post-training support and follow up to the participants of the courses to assist them in implementing their plans of action for establishing quality systems in their blood transfusion services. The participants will also be a resource for establishing the national quality systems in BTSs.

Objectives

- To assess current status of quality system in blood transfusion services in the participating countries
- To develop the participants' knowledge and skills in quality assurance
- To improve knowledge and skills in good laboratory practices
- To develop a plan of action for implementation of quality system for the participants' BTS/Blood Bank
- To suggest future requirements for continuous training and staff development in quality management.

Participants' profiles

The profiles of the participants attending the courses organized by the training will be adapted to the different types of courses organized. Two categories of

participants from the countries in the region should be nominated for each of these courses. The basic requirements are:

- a qualification in Medical Laboratory Sciences preferably with specialized training in Immuno-haematology/Blood Transfusion
- the participants should be currently working full-time in a Blood Transfusion Service or a Blood Bank with sufficient supervisory experience in blood transfusion safety/blood transfusion service/blood bank
- it would be an added advantage if the participant has experience in management skills and quality assurance and a basic knowledge of the aspects of blood transfusion science other than laboratory/technical matters i.e. blood donation practices, component production, and the technical aspects of use of blood in clinical situations.

The number of participants in each course will depend on the number of countries in the region as well as the size of the countries. At least, two participants will be selected initially from each country. However in large countries, there would be a need for a country-specific QMT.

Participants should be able to take on the role of quality manager/officer after attending the course. The participants will be expected to initiate and strengthen the implementation as well as monitoring of the quality systems in their own BTS as well as contribute in developing national quality systems.

Methodology of work

Each year, two or three 4-week courses will be organized. Participants from the countries in the region could be nominated each year for the training course. The training course will be organized in a modular form, covering general quality context and quality principles applied to specific areas in BTS.

A curriculum has been developed for the QMT courses after several consultative discussions and appropriate training materials is being developed according to the final curriculum, considering the different level of knowledge and skills of the participants. Background material for the case studies and group activities is also being prepared.

The training courses consist of formal lectures, case study exercises and group activities. In addition to the staff of the training centre and WHO's technical assistance, external facilitators will be used to cover specific topics within their area of expertise. Prior to the training course participants will receive a questionnaire to assess their BTSs. The knowledge of participants will be assessed at the beginning, during and at the end of the course. Sufficient time will be devoted to enable participants in developing a one-year follow up action plan to improve their BTSs. The concept of regional external quality assessment schemes (REQAS) will be introduced to the participants and centres participating in REQAS will be identified.

Depending on the evaluation of the 4-week course and the participants' needs, one or two 2-week refresher course(s) will be organised dealing with specific aspects of quality in blood transfusion such as intensive courses in TTI, blood group serology, quality in blood component production, etc. Considering the regional variations, the training courses could be adapted to the regional needs for training. Mechanisms will be developed to assess the implementation of action plan by the participants as well as to assist them in overcoming the problems faced in implementation of the action plan.

Expected outcome

- Participants will acquire the knowledge and skills to establish quality system for blood transfusion services/blood banks
- Knowledge and skills in good laboratory practices will be improved

- The current status of the quality system in blood transfusion services will be assessed in the participating countries
- A plan of action for implementation of quality system for the participants' BTS/Blood Bank will be developed
- Future requirements for continuous training and staff development in quality management will be proposed.

Establishing a Regional Quality Training Centre in each WHO Region

In most of the WHO regions, one of the WHO collaborating centres in blood transfusion or one of the national institutions working in the area of blood safety has been identified by WHO to undertake training in quality management for blood transfusion services. The identified centres should have facilities for training such as lecture rooms, office space for facilitators, communication means, including Internet access, distance teaching, multimedia, a laboratory for trainees and dedicated staff to take over the responsibility of organizing the training courses. Ideally, the centre should also have facilities for accommodation for the trainees. For those regions where such a training centre does not exist, a centre may need to be upgraded to carry out this task. Depending on the requirements of the centre, the facilities may need to be upgraded for ongoing training activities with the assistance of WHO. The centre would be strengthened through upgrading its training facilities, provision of laboratory equipment and appointing full-time training facilitators. An area in the centre should be dedicated for the preparation of REQAS materials and training of BTS staff from the countries identified for the project.

In addition to providing training for the participants from the blood transfusion services in the region, the regional quality training centre or another identified centre with previous experience of organizing quality assessment schemes will take the opportunity to establish the regional EQAS and assist in establishing national external quality assessment scheme.

The training centre will not only also act as a regional resource training centre but also hold annual meetings of quality managers and be seen as an instrument to promote networking in the region in the area of blood transfusion safety.

Establishment of Regional External Quality Assessment Schemes

Regional External Quality Assessment Schemes (REQAS) will be established which would be introduced within the quality management training and have been integrated within the quality management project. The aim of this integrated approach of providing training courses and introducing REQAS at the same time, is to enable participating BTS in upgrading their knowledge and expertise and at the same time providing them with the information about the need and role of EQAS in improving the performance of their laboratories.

Objectives

- To develop regional external quality assessment schemes which would be integrated with international external quality assessment scheme for transfusion transmissible infections and in blood group serology
- To improve national quality systems by assisting WHO Member States to establish national EQAS
- To assess the quality of laboratory performance on a national/regional level.

The participants in the QMT course will be identified as the focal points for participating in the WHO regional external quality assessment schemes for transfusion transmissible infections (HIV, hepatitis B, hepatitis C) and blood group serology (ABO & Rh D grouping and

cross- matching). The IEQA panels will be sent by WHO/HQ to REQAS organisers who in turn will send their panels initially to participating laboratories, two or three times a year. Subsequently the capacity of the organizing centres will also be strengthened to enable them to prepare their own proficiency panels and bring them into conformity with the international standards.

Methodology of work

At the refresher training course the results of the REQAS will be discussed, and special emphasis will be given to the identified problem areas. In addition, the plan of action will be reviewed with each of the participating BTS and an evaluation of the progress (failures and achievements) will be made. Possible solutions for the problems and difficulties encountered will be sought. The Plan of Action will be revised based on the evaluation results of REQAS, and the establishment of the national quality system will be promoted.

Establishment of Regional Quality Network in Blood Transfusion Services

Today, most blood transfusion services in the developing countries work in isolation. There is a need for mutual communication and access to information through newsletters and networks for BTS. Training in quality management and provision of necessary information technology packages will make it possible to achieve the goal for blood safety and will substantially contribute to improving blood safety globally. This is one of the seven priorities of WHO.

Objectives

- To develop a formal structure for interaction between Regional Quality Training Centres and blood transfusion services in countries in the region, in partnership with collaborating centres experts and non-governmental organisations, for the effective implementation of quality management systems at the national level
- To develop and upgrade the facilities of information technology for interaction between BTS at regional, sub-regional and country level, including policy makers, WHO collaborating centres and non-governmental organizations
- To create effective electronic national networks to enable the sharing of critical resources in blood transfusion services such as the blood donor database, information on blood collection, testing of blood units, inventory of blood and its components, availability of technical expertise, and information on issuing and utilization of blood
- To provide on-line assistance to BTS and facilitate training in blood safety.

Activities

- Equip major blood transfusion services with hardware (desktop computer, printer, continuous power unit), software and Internet access
- Train the participants in computer skills: development of skill for information access and management, application of information technology to blood transfusion services, and its utilization for developing an effective electronic network system
- Provide access to have information on the Internet, download relevant technical knowledge, use e-mail for exchange of information and for problem solving, and use voice/telephone facilities to encourage teleconferencing.

Given access to information on the Internet, participating centres will be able to communicate with the regional quality training centre, download relevant technical material, receive newsletters and training materials, get information on EQAS and receive the results of EQAS.

The establishment of a regional quality network in blood transfusion services will lead to improvement in the safety, accessibility and quality of blood supply.

Expected outcomes

- The Quality Management Project for Blood Transfusion Services is developed as a six-year project (2000-2005) and expected outcomes are reviewed every year
- At least two persons from each country in every region will have been trained every year as quality managers/officers
- The regional quality training centre(s) will be established for ongoing quality management training for BTSs. Based on the needs, the identified regional quality training centre will be strengthened in terms of infrastructure, equipment and staff in order to improve the capacity for training
- Member States in each WHO region will participate in Regional External Quality Assessment Schemes
- Member States will have established a sustainable national quality system including a national EQAS
- The facilities in a Quality Area Desk in BTS will be upgraded
- All donated blood will be adequately tested for HIV and other TTIs, blood group serology, processed using good laboratory and manufacturing practices in at least 80% countries of the region by 2005, on a consistent basis
- The quality, safety and adequacy of blood will be improved in all Member States.

Monitoring and evaluation

Among the indicators used to assess the performance of this project will be the following:

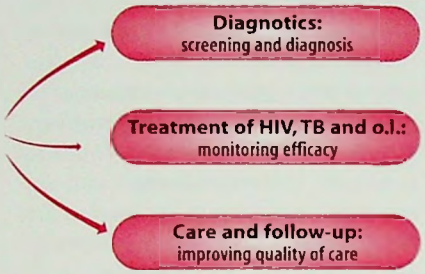
- Number of participants trained per country
- Proportion of countries trained in the region
- Number of training courses held as per plan
- Quality of the training course developed
- Participants' satisfaction with the course
- Use of the centre as a resource
- Improvement in quality of work at the BTSs of the participants' after 6 month/1 year of training
- Number of centres participating in the REQAS and of centres showing satisfactory performance
- Number of centres taking corrective measures
- Number of centres provided with the facilities for electronic networking
- Number of centres using electronic network facilities.

Providing Appropriate Diagnostic Support in HIV/AIDS Control

Providing diagnostic support is an essential part of ensuring quality health care in the fight against the HIV/AIDS pandemic. There has been a strong call for access to drugs to help in the fight against HIV, however, it must be remembered that this battle is a process which does not only require access to treatment, but also access to accurate diagnostics, quality of care and follow up. The diagnostic support activities of the BCT play a vital role in all three phases of this process.

Using appropriate diagnostic technology for ***screening and diagnosis*** is the starting point in the process. In addition to the actual diagnosis of patients' HIV status, diagnostic technology must be used for screening of donated blood to prevent transmission through transfusion. Diagnostic tests are also instrumental for surveillance, providing epidemiological data to monitor the spread of the HIV/AIDS epidemic. Use of reliable tests and appropriate testing strategies are important in the prevention of mother-to-child transmission, and for voluntary counselling and testing

Figure 11: Appropriate diagnostic support with an emphasis on HIV and related diseases, and collaboration with partners



services. In these settings, simple/rapid diagnostic tests can provide accurate, same-day diagnosis resulting in timely treatment where needed.

Once individuals are identified as being infected with HIV, and/or related opportunistic infections, diagnostics are used to determine the appropriate ***treatment*** intervention. For example, diagnostic tests may indicate resistance to certain drugs and thus provide guidance on appropriate drug regimes. Subsequent diagnostic technologies are required to monitor the safety and effectiveness of treatment on a continuing basis. Additional diagnostic imagine and basic clinical laboratory tests will provide information to ensure the ongoing ***quality care and support*** provided to those infected with HIV and suffering from associated infections and illnesses such as TB.

Several key activities within BCT contribute to the provision of high quality cost effective health care as related to the HIV epidemic.

BCT aims to ensure that the diagnostic technologies used in diagnosis and screening meet the highest standards, and that they are available and used appropriately. The operational characteristics of HIV test kits are evaluated, and reports providing technical information on their quality are issued regularly. Alternative HIV testing strategies for the various testing objectives have been developed, and are updated as required. The WHO HIV Test Kit Bulk Procurement Scheme facilitates access to high-quality, low-cost diagnostic tests to Member States and UN agencies.

BCT is assessing the available technologies for monitoring the efficacy of HIV treatment (CD4, p24, and viral load testing) that are suitable for countries with limited facilities and resources. Tool kits for clinical laboratory monitoring at the district hospital (1st referral) and centralized referral hospital (2nd referral) levels are currently being developed. To ensure reliable results, existing schemes for monitoring laboratory performance will also be expanded to cover all HIV related diagnostic areas.

BCT is also providing guidance and training to support and improve health care services, in areas of blood safety, clinical laboratory and diagnostic imaging, all of which contribute to improved quality of care. Capacity building to improve skills and knowledge at all levels for appropriate diagnostic support is an overarching aspect of BCT's activities.

Many of these BCT activities are carried out in collaboration with other WHO departments to improve synergies and with UN agencies such as UNAIDS and UNICEF, WHO Collaborating Centres and key international partners. These partnerships are, and will continue to be, an integral part of BCT's response to the HIV/AIDS pandemic. ❐

Information, Education, Communication and Resource Mobilization **Strategy**

Information, Education and Communication

The Department of Blood Safety and Clinical Technology has a challenging programme of work over the four-year period covered by this Strategic Plan to achieve the objectives and targets set. The success of our endeavours will depend, to some extent on available resources – both human and financial – and on a coherent communications strategy.

A small communications team has been formed within the department to enhance awareness and visibility of the work of BCT, to promote the mission and key messages of the teams, and to strengthen links between existing and potential donors and partners at all levels.

They will focus on ensuring that the information disseminated is consistent, credible and communicated effectively to all relevant audiences in an appropriate format, and using the various channels available, such as:

- the written medium (technical documents and guidelines, meeting reports, information sheets and other advocacy papers, learning materials, etc.)
- audiovisual support (standardized presentations, graphic images, audio and video cassettes)
- electronic mail and Internet facilities
- personal contact.

The Department will place increasing emphasis on passing information through its Internet pages and by using individual and thematic electronic mail addresses. This endeavour in no way replaces the need for the printed page, especially in resource-poor settings where equipment is often unavailable or inappropriate. It will however, be an extremely useful tool to access credible information, and even fulfil an interactive role in information sharing – for example through restricted, extranet pages – or in distance learning techniques.

The communications strategy will also target appropriate major international events and other types of meeting as valuable opportunities to share information and enlist support for the priority activities of the Department. Networking will also be undertaken broadly to ensure that government and nongovernmental organizations alike have the tools they need to reach their national objectives in areas related to blood safety and clinical technology.

Resource Mobilization

The resource mobilization objective of the Blood Safety and Clinical Technology department is ultimately to secure that the department receives adequate funding from appropriate donor sources to allow it to carry out its planned activities.

BCT's activities have largely been funded by WHO's regular budget and the department has historically had only a few government donors such as Belgium, Italy, Japan, Luxembourg, Netherlands and United Kingdom, providing extrabudgetary support.

Given the scaling up of department activities, the urgency in addressing global challenges such as HIV/AIDS or poor quality management and the

increased internal and external demands made on the department, a comprehensive resource mobilization strategy is needed to meet the current and expected funding gap.

The BCT resource mobilization strategy will form part of the HTP cluster strategy and build on the experience and lessons learned from sister departments. Special attention will be given to:

- maintaining and increasing extra-budgetary contributions from existing donor governments;
- identifying potential new donors in the public and private sectors;
- finding innovative ways of positioning department projects in funding requests within and outside WHO; and
- raising awareness about the department's activities within and outside WHO. ❐

Annex: Summary Budgetary Figures

The budget and unmet needs quoted in this section are as at January 2000. BCT's 2000-2001 budget will be adjusted during its implementation to reflect the actual income.

Changes to the original core budget will be reflected in a working budget, and reported at the 2001 session of the Meeting of Interested Parties.

Figure 12: Additional income required for three priority areas

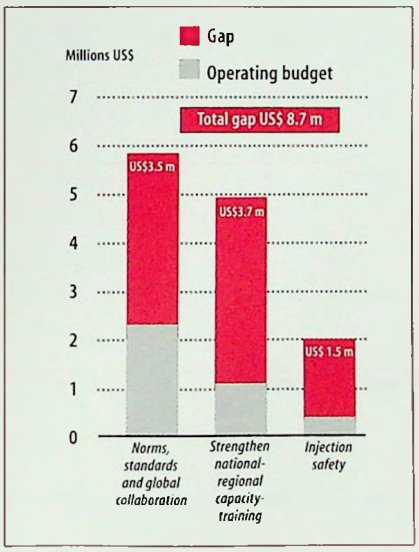


Figure 13: Income expected and unfunded priorities

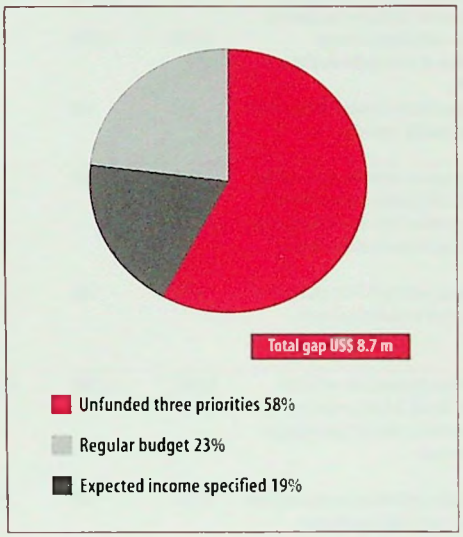


Table 1: Planned cost, core budget and unfunded priorities by objectives and target, and by source of funds, 2000-2001, excluding department director's office, as at January 2000, (all amounts in US$ thousand, inclusive of programme support cost on voluntary contribution)

Area of work • Objective • Target	*Planned cost (a)*	*Total core budget (b)*	*Unfunded priorities (c = b - a)*	*WHO regular budget allocation (d)*	*Voluntary contributions (e = f + g)*	*Unspecified (f)*	*Specified (g)*
Policy: To strengthen the capacity of countries to formulate, implement, monitor, and update national policies and plans for blood, blood products, injections, diagnostic, clinical technologies and medical devices	**6,399**	**2,274**	**-4,125**	**1,479**	**795**	***0***	***795***
T1 Formulation, implementation, monitoring and updating of national policies and plans	4,044	1,043	-3,001	771	272	*0*	*272*
T2 Global collaborations	2,192	1,186	-1,006	663	23	*0*	*523*
T3 Global systems to monitor impact	163	45	-118	45	0	*0*	*0*
Quality and safety: To assist countries in ensuring the quality and safety of blood, blood products, injections, diagnostic, clinical technologies and medical devices	**4,473**	**2,509**	**-1,964**	**1,255**	**1,254**	***0***	***1,254***
T4 Development of norms, standards, guidelines and reference materials	2,028	1,188	-840	793	395	*0*	*395*
T5 Research, development and evaluation of new technologies and methods	2,212	1,078	-1,134	219	859	*0*	*859*
T6 Development and implementation of national quality systems	233	243	10	243	0	*0*	*0*
Access: To support countries in ensuring equitable availability and affordability of blood, blood products, injections, diagnostic, clinical technologies and medical devices	**512**	**230**	**-282**	**230**	0	***0***	***0***
T7 Continuous and sufficient quantities of appropriate equipment and supplies	512	230	-282	230	0	*0*	*0*
Use: To promote appropriate and cost-effective use of blood, blood products, injections, diagnostic, clinical technologies and medical devices	**6,362**	**1,788**	**-4,574**	**787**	**1,001**	***0***	***1,001***
T8 Appropriate collection, processing and clinical use of blood and blood products	3,923	943	-2,980	454	489	*0*	*489*
T9 Appropriate use of diagnostic imaging and laboratory technologies	1,075	336	-739	295	41	*0*	*41*
T10 Safe and appropriate use of injections	616	171	-445	0	171	*0*	*171*
T11 Appropriate use of devices and clinical technologies	748	338	-410	38	300	*0*	*300*
Sub-total	**17,746**	**6,801**	**-10,945**	**3,751**	**3,050**	***0***	***3,050***
Departmental management, advocacy & coordination	3,078	2,209	-869	685	1,524	*0*	*1,524*
Programme support costs on unmet needs			-1,536				
Grand total	**20,824**	**9,010**	**-13,350**	**4,436**	**4,574**	***0***	***4,574***