

**Report of the meeting of**

**E**xperts in

**B**lood

**T**ransfusion

**S**ervices

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GENEVA, 22–26 NOVEMBER 1999

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**Department of Blood Safety  
and Clinical Technology**



**World Health Organization**

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## **Introduction**

A Meeting of Experts in Blood Transfusion Services was convened by the WHO/Blood Safety and Clinical Technology/Blood Transfusion Safety (WHO/BCT/BTS) Team within the cluster of Health Technology and Pharmaceuticals (HTP). It was held at WHO Headquarters, Geneva, Switzerland on 22–26 November 1999 and was attended by experts from 32 countries, including Directors of Blood Transfusion Services and representatives of WHO Collaborating Centres. A list of participants, observers and WHO Secretariat is attached as Annex 1.

The meeting followed on from an international workshop, co-funded by WHO/BTS, which was held in Edinburgh, Scotland, in 1997. This workshop had provided a unique forum for selected members of the WHO Expert Advisory Panel on Transfusion Medicine and other experts from all regions of the world to develop practical strategies for the development of safe, efficient and cost-effective blood transfusion services in developing countries. It had been attended by participants from 17 countries with blood transfusion services at different stages of development who urged that follow-up workshops should be held to review and expand the strategies developed in the workshop and to evaluate progress in their implementation.

WHO/BTS depends on the advice, cooperation and assistance of experts in blood transfusion medicine in reviewing and improving these strategies and advising on the most appropriate activities to support their implementation.

## **Objectives of the meeting**

The objectives of the meeting were as follows.

- 1 To identify needs and priorities in strengthening national blood programmes at different stages of development.
- 2 To review and advise on WHO/BTS strategies, goals and activities to improve the safety of blood and blood products.
- 3 To review WHO guidelines, recommendations and training materials on blood transfusion safety and advise on their usefulness and the need for revision, updating and the development of new materials in 2000/2001.
- 4 To review the Global Collaboration for Blood Safety, identify areas of concern and suggest mechanisms to support countries in need.
- 5 To prepare recommendations for the development of a WHO/BTS Database of Consultants to guide WHO and other funding agencies (i.e. World Bank, UN agencies and country funding agencies) in providing expertise in a systematic and coordinated way to assist in strengthening national blood programmes.

The Programme of Work is attached as Annex 2.

## **Opening session**

The meeting was opened by Dr Michael Scholtz, Executive Director, Health Technology and Pharmaceuticals (HTP). He reported that, following the restructuring of WHO in 1998, blood safety has been defined as one of WHO's strategic priorities and additional resources have been allocated accordingly. Close collaboration and links have been established with other departments within HTP and with other WHO clusters. Blood safety has been selected as the theme of World

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Health Day 2000 in order to reinforce the importance given to this area of work by WHO.

Professor Robert Beal was elected as Chairman of the meeting. Ms Jan Fordham and Ms Shân Lloyd served as rapporteurs.

### **Reorganized structure of WHO: Blood Safety and Clinical Technology**

Dr Jean Emmanuel, Director, Blood Safety and Clinical Technology, reported that, as blood safety is a priority area of work within WHO, headquarters and regional posts and activities are being strengthened. He extended a formal welcome to Dr Luc Noel, who has been appointed Team Coordinator, Blood Transfusion Safety/Quality and Safety of Plasma Derivatives, and announced the appointment of Dr Neelam Dhingra-Kumar as Medical Officer, Blood Transfusion Safety.

An outline was presented of the structure and functions of the cluster of Health Technology and Pharmaceuticals and its core themes of access, research and development, quality assurance, use and monitoring impact.

The Department of Blood Safety and Clinical Technology contains three teams:

- Blood Transfusion Safety/Quality and Safety of Plasma Derivatives (BTS/QSD)
- Diagnostic Imaging and Laboratory Technology (DIL)
- Devices and Clinical Technology (DCT).

Blood safety, one of the three priority areas for HTP, should be seen in a broad context. It is a common theme for all BCT activities and relates closely to:

- Minimizing unnecessary transfusions through the appropriate clinical use of blood
- Strengthening district surgical services
- Injection safety
- The WHO Haemoglobin Colour Scale and other medical devices.
- Diagnostic imaging and clinical laboratory services

The meeting represented an important opportunity to review the goals and activities of WHO/BTS in supporting Member States in achieving blood safety and to identify strategic directions and priorities for the future. The purpose of the meeting was to achieve open dialogue and constructive criticism and advice in order to define goals and strategies to strengthen WHO/BTS and identify the resources required. Participants offered an extensive range of experience and expertise and it is proposed to establish a formal Expert Advisory Group in Blood Transfusion Services that meets on at least a biennial basis.

### **World Health Day, 7 April 2000**

Blood safety was designated the theme of World Health Day 2000 (WHD 2000), which marks the launch of a five-year push for blood safety. Under the slogan of 'Safe blood starts with me', WHD 2000 is designed to raise global awareness of the importance of blood safety. A range of activities will be undertaken at international, regional and national levels, including a letter from the Director-General of WHO to all Heads of State and Ministers of Health.

The expected outcomes of World Health Day include:

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- 1 An increase in the number of countries with national policies and legislative frameworks on blood safety (80% within five years).
  - 2 An increase in donations from voluntary non-remunerated blood donors from low-risk populations through greater public awareness and understanding of the need for safe blood.
  - 3 The screening of all donated blood for transfusion-transmissible infections (TTIs).
  - 4 A reduction in unnecessary transfusions through increased awareness among clinicians of the appropriate clinical use of blood.

Joint activities undertaken by WHO and the International Federation of Red Cross and Red Crescent Societies (IFRCRCS) will continue into 2001, the UN International Year of the Volunteer, and beyond.

### **WHO/BTS team structure and functions**

Dr Luc Noel outlined the mission of WHO/BTS to promote the formation of national blood programmes which ensure the safety, quality and adequacy of blood and blood products to meet the needs of all patients; that are transfused only when necessary; and are provided as part of a sustainable blood programme within the health care system.

The Blood Safety Team collaborates with WHO Member States, other teams, clusters and programmes within WHO and with other organizations involved in blood safety to:

- Raise international awareness of the issues of blood and blood safety and to encourage global collaboration and cooperation on blood safety
- Develop strategies and guidelines on policy, planning, legal instruments, technical and national self-sufficiency issues
- Assist in identifying potential financial aid and facilitate multilateral and bilateral funding for national blood programmes
- Promote the development of clearly identifiable blood programmes, based on voluntary non-remunerated blood donation, through advocacy at the national level
- Advocate the appropriate use of blood and blood products in order to minimize unnecessary transfusion
- Encourage training for all blood programme staff, as well as the prescribers of blood and blood products
- Implement appropriate operational research to improve blood safety.

### **Strategies for blood safety**

WHO/BTS has developed the following strategies to promote the safety of blood and blood products in all regions of the world.

- 1 The establishment of nationally-coordinated blood transfusion services and quality systems in all areas of blood transfusion.
- 2 The collection of blood only from voluntary non-remunerated blood donors from low-risk populations.
- 3 The screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis viruses, syphilis and other infectious agents.
- 4 A reduction in unnecessary transfusions through the effective clinical use of blood, including

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the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

These strategies are encapsulated in the WHO/BTS *Aide-Memoire: Blood Safety* which has now been published in English, French, Spanish, Chinese, Russian, Arabic and Portuguese.

Similar Aides-Memoire are now being developed by other teams within BCT.

### **Global Collaboration for Blood Safety (GCBS)**

The establishment of a Global Collaboration for Blood Safety (GCBS) was first proposed in the Paris AIDS Summit Declaration in 1994 and was endorsed by World Health Assembly Resolution 48.27 in 1995. Its aim is to build on existing knowledge and expertise to promote dialogue, identify issues of concern and suggest practical, realistic and effective strategies and mechanisms to promote improved global blood safety.

The specific objectives of the GCBS are as follows.

- 1 To provide a forum for sharing information, ideas and experience in relation to blood safety.
- 2 To develop a common understanding of the challenges facing blood systems nationally and internationally.
- 3 To keep pace with developments in the field of blood transfusion safety.
- 4 To identify and assess possible solutions.
- 5 To establish collaborative alliances for the future.

The Secretariat for the GCBS is provided by WHO/BTS. The GCBS will comprise a broad spectrum of members, including:

- Regulatory agencies and international organizations: e.g. WHO, Council of Europe, European Commission, US Food and Drugs Administration
- International professional associations: e.g. International Society for Blood Transfusion, International Society of Haematology, World Federation of Societies of Anesthesiologists
- International non-governmental organizations: e.g. International Federation of Red Cross and Red Cross Societies
- WHO Collaborating Centres
- National service providers: e.g. national blood transfusion services
- End-users: e.g. World Federation of Haemophilia, Thalassaemia International Federation.

In its first stage, the GCBS will hold scientific meetings to provide the basis for legislative frameworks for blood safety. The first of these, an International Blood Science Conference, will be hosted by WHO/BTS in April 2000. The second stage will include meetings of policy makers and will focus on decision-making processes to strengthen global blood safety. A core group of participants in both types of meetings will prepare a framework for decision-making that can be adapted and used at national level.

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## **Ensuring the quality testing of donated blood**

### **Evaluation of test kits**

Dr Gaby Vercauteren reported on the evaluation of test kits, which was first established under the Global Programme on AIDS. The evaluation not only supports blood transfusion services but surveillance studies and voluntary testing (VCT) initiatives. The types of assays that have been evaluated include EIA, simple/rapid tests and saliva methods. Although saliva test kits are not used in blood transfusion services, they are of value for other WHO clusters, particularly those working with voluntary testing centres.

There has been regular updating of operational characteristics and Report 11 has now been issued. It is planned to begin examining the whole blood tests available, with particular reference to VCT and antenatal screening. The evaluation will be conducted by a WHO Collaborating Centre and will be followed up with field trials.

Since HIV is not the only transfusion-transmissible infection, the evaluation will also include HBsAg and HCV testing and there are plans to start an evaluation of tests for T. Cruzi. Testing for malaria is dealt with by the cluster of Tropical Diseases Research and Training.

### **External Quality Assessment Schemes (EQAS)**

Regional EQAS programmes for HIV and other TTIs will be established as they are more cost-effective and easier to manage than a global programme. WHO/AMRO has already established an EQAS and plans are in place for the establishment of regional EQAS in AFRO (Anglophone and Francophone), SEARO and WPRO. Suitable centres need to be identified in EURO and EMRO before an EQAS programme is established in these regions.

### **Other activities**

WHO/BTS plans to expand the bulk procurement programme to include blood cold chain equipment and other consumables.

Advocacy for the establishment of nationally coordinated blood programmes is ongoing and support is being provided for programmes in Egypt and Kyrgyzstan. Advocacy is also focussed on the organization of programmes for the recruitment and retention of voluntary non-remunerated blood donors.

In discussion, participants raised the following points:

- Information should be circulated on the mechanisms for non-governmental organizations to order through the bulk procurement programme
- Testing algorithms are useful and should be kept updated
- Research is needed on the sensitive issue of pooling
- There is a need to increase the specificity rather than the sensitivity of testing for T. Cruzi
- A generic document on the counselling of blood donors is required in relation to all TTIs.

### **Quality and safety of plasma derivatives and related substances**

Dr Ana Padilla outlined the principal activities of the team responsible for quality and safety of plasma derivatives and related substances.

- 1 Development of WHO guidelines on quality assurance and control:
  - WHO requirements for the collection, processing and quality control of blood products
  - Viral inactivation/removal procedures and their validation
  - Control tests to ensure quality and safety in plasma products.

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- 2 Development of WHO biological reference preparations:
- HBsAg and anti-HCV/HIV antibodies (serological tests)
  - Nucleic Acid Amplification Tests
  - Transmissible Spongiform Encephalopathies
  - Blood Typing Sera
  - Haemostasis and Thrombosis.

An international Working Group has been established on reference preparations for HBsAg and anti-HCV/anti-HIV antibodies, with the aim of assisting member States.

- 3 Provision of technical advice to National Control Authorities/Laboratories on the quality assurance of plasma-derived medicinal products and plasma fractionation. The objective is to prevent the transmission of bloodborne viral diseases via plasma products by upgrading the expertise of National Control Authorities/National Control Laboratories in manufacture, quality and safety procedures. Activities include multicountry regional workshops and educational activities.

Particular challenges in this area include:

- A lack of effective national control authorities
- The need to improve the quality and safety of plasma globally
- The need to introduce viral inactivation procedures and validation
- The need for biological standardization and control measures to keep pace with new technologies.

### **Distance learning materials: Safe Blood and Blood Products**

Ms Jan Fordham, Open Learning Associates, UK, reported that the WHO distance learning materials have now been published in English, French, Spanish and Chinese. Russian and Portuguese editions will be published in early 2000 and an Arabic edition is in preparation. The materials have also been translated into a number of national languages.

Between 1994 and 1998, a series of eight regional and sub-regional workshops were held for senior blood transfusion service personnel from 95 countries on establishing national distance learning programmes in blood safety. Three national workshops have been held in China to train two personnel from each province and municipality.

*Establishing a Distance Learning Programme in Blood Safety: A guide for programme coordinators* was published in 1998 to assist national blood programmes in establishing efficient and cost-effective distance learning programmes in blood safety. A Spanish edition has been prepared and other language editions are in development.

An evaluation of the distance learning materials and the impact of the regional workshops commenced in 1999 with the distribution of evaluation questionnaires to countries that participated in the regional workshops. Responses are still awaited from some countries, but programmes have now been established in at least 33 countries and are planned in a further 24 countries. Their responses indicate that critical success factors in the establishment of successful programmes include:

- The appointment of a national programme coordinator and, where appropriate, provincial coordinators
- Official approval and support from the Ministry of Health and other relevant government

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departments

- The establishment of a programme Advisory Group or Steering Committee
- Validation and accreditation by an academic institution or other recognized body.

Field evaluation visits will be made to selected countries in each region in order to share the lessons from successful programmes with other countries at an earlier stage of programme development.

### **Distance learning in Argentina**

Dr Ana del Pozo, National Coordinator of the Distance Learning Programme in Argentina, reported that the programme was launched in 1998 following the translation of the WHO/BTS distance learning materials into Spanish. Funding was sought for the programme as a means of reducing transfusion-transmitted infection through improved systems for blood donor recruitment and selection, the screening of all donated blood for TTIs and the establishment of quality systems.

A national workshop was held in April 1998 at which representatives from 23 provinces agreed that distance learning was an appropriate approach to extending education and training for laboratory technical staff in blood transfusion centres and hospital blood banks. Two national coordinators and two deputy coordinators were subsequently appointed and a National Executive Committee was formed, including representatives of the Ministry of Health, the Argentinian Red Cross Society and UNAIDS. Coordinators and Advisory Groups have also been appointed at provincial level.

The programme was started on a pilot basis in six provinces in 1998 and was extended to two further provinces in 1999. By September 1999, a total of 2711 students, 478 tutors and 190 instructors were involved in the programme, which had already been completed in five provinces. While the programme focuses particularly on laboratory technical staff with limited training, a number of medical doctors have also been enrolled. The evaluation of learning is primarily conducted through students' work on the activities in the modules and certificates were awarded to the first cohort of students in December 1999.

In Argentina, which is a federal country and has no national blood programme, the establishment of the distance learning programme has already stimulated one province to initiate a provincial blood programme. Furthermore, a national workshop will be held in 2000 to plan the introduction of a national blood programme.

### **Distance learning in China**

Dr Feng Gao, Vice Director, Shanghai Blood Centre, People's Republic of China, reported that following three national workshops held in 1997 and 1999, distance learning programmes have been established in four provinces and municipalities. It is planned that the programme will be extended to all provinces within a period of two or three years, although at present there are insufficient numbers of qualified personnel to act as trainers.

A network of coordinators is being established at national, provincial and regional level and an assessment system has been designed by the National Medical Testing Centre. Supplementary materials are being prepared on component therapy, plasmapheresis and the clinical use of blood.

The Ministry of Public Health and Welfare has declared its intention to use the programme as a

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basis for the professional licensing of over 100,000 personnel in 420 blood centres, 200 plasma centres and hospital blood banks. It is proposed that the budget for the printing of the materials and for provincial coordination should be provided at provincial level.

### **The clinical use of blood**

Dr Brian McClelland, Director, South-East Scotland Regional Blood Transfusion Service, outlined the document *Recommendations on Developing a National Policy and Guidelines on the Clinical Use of Blood*, published by WHO/BTS in 1998 in support of its strategy to minimize unnecessary transfusions.

In 2000, WHO/BTS will also publish *The Clinical Use of Blood*, a module of interactive learning material and a pocket handbook for use by prescribers of blood. The materials are designed for use at all levels of the health system, including:

- Medical students doing clinical studies
- Clinicians, including anaesthetists, surgeons, obstetricians, paediatricians, medical officers, house officers and interns
- Nurses and midwives working in areas such as anaesthesia, trauma, intensive care, maternal and child health, and other medical specialties
- Medical assistants at district hospital level with post-qualification training in areas such as anaesthesia, trauma, intensive care, maternal and child health, and other medical specialties.

The materials will also be a valuable resource for educational institutions providing education and training for medical, nursing and paramedical staff.

The recommendations and learning materials will be disseminated through WHO Regional Offices and a series of regional workshops to promote the development of national policies, guidelines and education programmes on the clinical use of blood. Assistance will be requested from national blood transfusion services in the selection of senior anaesthetists and other clinicians to participate in these workshops.

BCT/BTS is promoting an integrated approach to the clinical use of blood by forging collaborative links with other WHO clusters and non-governmental organizations in official relations with WHO. The WHO Departments of Reproductive Health and Research, Child and Adolescent Health and Development, and Rehabilitation are incorporating material from *The Clinical Use of Blood* into their own publications and documents.

### **External relations/projected strategies for BCT/BTS and potential improvement**

Dr Luc Noel reported on the strategic plan being developed by BCT in support of its mission to promote the safety, quality and adequacy of blood, blood products, injections, diagnostic and clinical technologies, and medical devices that are essential for the provision of effective health care. It focuses on four broad objectives.

#### **A: Policy**

To strengthen the capacity of Member States to formulate, implement, monitor and update national policies in relation to blood, blood products, injections, diagnostic and clinical technologies, and medical devices, including:

- National policies and plans
- Global collaboration
- Global systems to monitor impact.

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### **B: Quality and safety**

To ensure the quality and safety of blood, blood products, injections, diagnostic and clinical technologies, and medical devices, including:

- Development of norms, standards, guidelines and reference materials
- Research, development and evaluation of new technologies and methods
- Development and implementation of national quality systems.

### **C: Access**

To ensure equitable availability and cost-effective use of blood, blood products, injections, diagnostic and clinical technologies, and medical devices, including:

- Increasing the capacity of countries to ensure continuous and sufficient quantities of appropriate equipment and supplies
- Strengthening the capacity of countries to produce equipment and supplies locally.

### **D: Use**

To promote the appropriate and cost-effective use of blood, blood products, injections, diagnostic and clinical technologies, and medical devices, including

- The appropriate collection, processing and clinical use of blood and blood products
- The appropriate use of diagnostic imaging and laboratory technologies
- The safe and appropriate use of injections
- The appropriate use of devices and clinical technologies.

Blood safety is an integral component of all activities undertaken by the Department of Blood Safety and Clinical Technology. WHO/BTS has reached a transitional stage with the expansion of its staff and activities following the designation of blood safety as one of WHO's strategic priorities. The meeting therefore offered an important opportunity to guide its strategies and actions in the new Millennium.

## **Global Database on Blood Safety**

Mrs Shân Lloyd, Quality Manager, Zimbabwe National Blood Transfusion Service, reported on the development of the Global Database on Blood Safety (GDBS). Its objectives are to:

- Provide baseline data on the status of blood transfusion in Member States and support and assist the Global Collaboration for Blood Safety
- Identify priority areas for advocacy and technical support to strengthen blood safety at global, regional and national levels
- Identify priority countries for support
- Monitor and evaluate the effectiveness of strategies and interventions
- Identify priority training needs.

Ms Bronwen van der Wal reported that since 1997, data have been collected primarily through a short checklist that is distributed to national blood transfusion services, WHO Collaborating Centres and other agencies responsible for blood transfusion. Particular assistance has been provided by WHO Regional Advisers. A more detailed questionnaire has been developed for use by consultants during visits to individual countries.

A draft report on GDBS data from the WHO African Region was presented by Dr Gaby Vercauteren.

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## **WHO Haemoglobin Colour Scale and medical devices**

Dr Gerald Verollet reported on the medical devices programme within the Department of Blood Safety and Clinical Technology which aims to ensure greater equity in health care for poor and marginalized populations. It has three main goals.

- 1 To increase access to clinically beneficial medical technologies to enhance the quality of health care in developing countries.
- 2 To ensure the appropriate expenditure of limited national health care resources.
- 3 To ensure that medical devices imported into or manufactured in developing countries are safe and of high quality.

Its main areas of activity are:

- Harmonization on the regulation of medical devices through links with the Global Harmonization Task Force for Medical Devices
- The evaluation and development of appropriate technology
- The management of blood waste and waste contaminated with blood
- Blood safety medical devices, including the WHO Haemoglobin Colour Scale, the blood cold chain and an autologous transfusion device.

Future developments include collaboration and partnerships with manufacturers to devise a new non-invasive device for blood analysis and a low-cost, disposable, automated autologous transfusion device.

The WHO Haemoglobin Colour Scale is a simple, inexpensive clinical device for estimating haemoglobin levels. It is particularly designed for use where laboratory-based haemoglobinometry is not readily available and can also be used for screening blood donors. The Colour Scale kit consists of a booklet containing a standardized set of colours based on WHO International Reference Standards representing haemoglobin values from 4 g/dl to 14 g/dl, a dispenser containing special absorbent test-strips and an instruction leaflet. By matching the colour of a drop of blood on a test-strip with one of the shades of red, it is possible to determine the presence and severity of anaemia.

The Colour Scale has been subjected to field trials in a number of countries, the last of which will be completed in Tanzania in March 2000 where its performance is being evaluated in antenatal screening and in relation to low haemoglobin values. Field testing has shown its reliability and validity when used in accordance with the instructions and when the special test-strips are used.

While simple to use, the Colour Scale requires very sophisticated production techniques that ensure consistent quality. Protocols are being developed to enable its manufacture on a larger scale and funding is being sought for the production and distribution of 1 million kits.

## **The Blood Cold Chain**

Mr David Mvere, Technical Director, Zimbabwe National Blood Transfusion Service, reported on the WHO/BTS Blood Cold Chain Project which was established with the following objectives.

- 1 To identify equipment and devices essential for an effective blood cold chain.
- 2 To determine and publicize specifications for blood cold chain equipment.

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- 3 To develop learning materials for the managers and users of blood cold chain equipment.
  - 4 To promote the transfer of technology.

The project is designed to increase access to affordable blood cold chain equipment and improve the quality management of the blood cold chain with the aim of reducing morbidity and mortality through the improved storage and availability of blood and blood products.

The project has identified the following requirements for an effective blood cold chain:

- Blood bank refrigerators: compression, ice-lined and solar-DC types
- Plasma freezers: compression, ice-lined, rapid plasma freezers, plasma thawers
- Walk-in cold rooms and freezers
- Cold transport boxes
- Temperature monitoring devices: recording systems, thermometers and alarms
- Blood time/temperature indicators
- Platelet agitators, with or without incubator
- Accessories: voltage stabilisers, stand-by generators.

The project has collaborated with manufacturers to develop equipment specifications and has commenced laboratory and field evaluation of blood cold chain equipment following agreed protocols. The learning materials are in the process of development and will be pilot-tested in 2000. The specifications and learning materials will be published in early 2001.

## **Safe Injection Global Network**

Dr Yvan Hutin reported on the Safe Injection Global Network (SIGN) which aims to achieve safe and appropriate use of injections world-wide in order to reduce the transmission of bloodborne pathogens. It consists of a secretariat, based in WHO/BCT and a voluntary association of stakeholders, including international organizations and programmes, non-governmental organizations, governments, universities, health care worker and student organizations, consultants and industry.

It has defined the following approaches to injection safety:

- Behaviour change aimed at:
  - Reducing the overuse of injections
  - Achieving injection safety
- Provision of sufficient quantities of appropriate injection equipment and infection control supplies
- Establishment of a waste disposal infrastructure.

A strategic framework has been developed with the following targets:

Target A: Pilot interventions aimed at safe and appropriate use of injections

Target B: Large-scale introduction of new technologies

Target C: Implementation of national policies and plans

Target D: Injection safety in donor or lender-funded services.

## **Reports from Working Groups**

### **Critical factors for an effective blood transfusion service: issues arising from country reports**

Country reports were presented by participants on the strengths and weaknesses of their national

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blood programmes and on the opportunities and threats that they faced. Their reports highlighted the following requirements for blood safety, which were consistent with the WHO/BTS strategy for blood safety, outlined in its *Aide-Memoire: Blood Safety*.

### **Development of blood transfusion services**

Government recognition of the importance of safe and adequate blood supplies within the health care system is a prerequisite for the development of efficient and cost-effective blood transfusion services. It also requires official commitment and support for the national blood programme through the development of a national blood policy and plan and a legislative framework, covering both the public and private sectors.

The national coordination of blood transfusion services is essential to ensure uniform standards and approaches and the cost-effective use of resources. The blood programme should be established with an identifiable infrastructure, including the accreditation of blood transfusion centres and blood banks. It should not be dependent on external donor aid, but should be financially sustainable through the provision of an identifiable budget or a cost recovery system. In some countries, the introduction of cost recovery has led to significant decreases in the clinical use of blood as hospitals and individual clinicians become more aware of the true costs of blood and blood products.

A nationally-coordinated blood transfusion service requires a national executive with *active* participants and specialist advisory groups. Collaborative partnerships should be established with organizations such as national Red Cross and Red Crescent Societies, voluntary blood donor organizations, professional bodies and patient associations (e.g. Haemophilia, Thalassaemia, Immunodeficiency).

The blood transfusion service is part of the wider public health system and should demonstrate its credibility in terms of its systems and expertise. It requires clear goals and objectives and should undertake a regular, critical review of its functions. Quality systems, training and research and development are essential in maintaining the confidence of clinicians.

The blood transfusion service should create a positive image of blood donation, blood transfusion and the service itself amongst its various stakeholders:

- National health authorities
- The general public
- Blood donors
- Prescribers of blood
- Patient groups.

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## **Blood donors**

Evidence from all regions confirms that there is a lower risk of transfusion-transmitted infection among voluntary non-remunerated blood donors than paid donors and family/replacement donors. Data presented by some participants also indicated significant differences in the seroprevalence of infection among first time, occasional and regular voluntary non-remunerated donors. A national strategy for the recruitment and retention of regular voluntary non-remunerated donors is therefore essential, including a legislative framework for phasing out paid and/or family/replacement systems of donation.

The establishment of an effective system of voluntary blood donation requires the establishment of an identifiable blood donor unit, staffed by trained donor recruitment officers and with an adequate budget for donor education, recruitment and retention, including mobile blood collection sessions.

To some extent, the safety of the blood supply is dependent on the effectiveness of wider education and control programmes on HIV/AIDS, hepatitis and other transfusion-transmissible infections (TTIs). Particular attention should be given to monitoring TTIs in the blood donor population in order to identify local sources of the most reliable, low-risk donations.

Intensive donor information and education is needed to promote the motivation and recruitment of voluntary non-remunerated donors and, equally important, the self-deferral or self-exclusion of unsuitable donors. This should be based on data from knowledge, attitude and practice studies and should build on cultural and religious beliefs favourable to voluntary blood donation. Key partners in donor recruitment and retention include the media, non-governmental organizations, voluntary blood donor organizations, patient associations, religious organizations and community-based organizations.

Particular emphasis should be placed on the valuing and retention of low-risk donors. Targeted campaigns, such as the Pledge 25 Clubs introduced in Zimbabwe and South Africa, and the use of community-based donor recruitment programmes have been effective in the recruitment and retention of donors from identified low-risk groups.

Stringent donor selection and screening procedures should be in place, with the provision of donor counselling in collaboration with, and using referral to, specialized counselling agencies and organizations.

An efficient blood donor records system or database is essential for donor recall and retention, monitoring TTIs in the donor population and updating the criteria for donor selection.

## **Screening, testing, processing and distribution of blood and blood products**

Each country should develop an appropriate, cost-effective strategy and legislative framework for the screening of blood and blood products. It should undertake a regular evaluation of screening assays in order to produce a list of approved kits and should conduct batch pre-acceptance testing before use.

Monitoring of the changing patterns of disease is essential in order to identify whether the introduction of additional tests is required. Uniformity in standards and quality and reduced costs can be achieved through the greater centralization of screening and processing and the central procurement of test kits, equipment and other supplies.

Quality assurance is essential in all aspects of the screening and processing of blood and blood products. This requires a national quality system and quality management, including the

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establishment of a national reference laboratory, external quality assessment schemes (EQAS) and the development of standard operating procedures.

Haemovigilance ‘from vein to vein’ is an essential element of a quality system. This requires a standardized reporting system, preferably computerized, and the establishment of hospital transfusion committees.

While many Member States have surplus stocks of plasma, it is not cost-effective for small countries to fractionate plasma. There is a need for effective regional collaboration to improve the quality of plasma derivatives, increase available supplies and decrease the costs of production.

An effective blood cold chain should be maintained throughout the screening, processing and distribution of blood and blood products.

### **The clinical use of blood**

While minimizing unnecessary transfusions through the appropriate clinical use of blood is a core strategy for blood safety, there are vast differences in blood usage between and within countries. Evidence from a number of countries indicates that simply raising awareness among clinicians can result in significant decreases in inappropriate blood use within short periods of time.

The appropriate clinical use of blood requires the development of national policies and guidelines, developed by clinicians with the support and facilitation of the blood transfusion service. The guidelines should be included in the curricula of medical schools and allied professions and should be distributed to all hospitals. Training should also be provided for clinicians in continuing education programmes and through in-service workshops, short courses and training days. Distance learning programmes provide an opportunity to reach staff at district hospital level who might otherwise have limited access to training.

A reduction in inappropriate use of blood and blood products requires the availability and use of alternatives to homologous blood transfusion, including intravenous replacement fluids, intraoperative blood salvage and autologous transfusion. It also requires a commitment to the prevention, early diagnosis and treatment of conditions that might otherwise lead to the need for transfusion through, for example, effective maternal and child health programmes.

An effective national system of data collection and audit is required to monitor the use of blood, including the establishment of hospital transfusion committees to facilitate an effective clinical interface between the blood transfusion service and clinicians.

### **World Health Day 2000**

The Working Groups agreed that while one of the main purposes of WHD is to promote a culture of continuous improvement in order to achieve blood safety, a principal concern should be to maintain public confidence in blood transfusion. Particular emphasis should be placed on promoting public awareness of the need for regular donation by voluntary non-remunerated donors who recognize that safe blood begins with them. The involvement of recipient groups is central to the promotion of positive messages.

### **Key audiences**

The following key audiences for World Health Day were identified:

- School children as donors of the future and the source of a regular, sustainable blood supply
- Patient groups:
  - Haemophilia

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- Thalassaemia
  - Immunodeficiencies
  - Professional organizations
  - Voluntary organizations: e.g. Rotary Clubs, Lion's Clubs
  - Religious groups

### **Activities**

The Working Groups proposed the following activities to be undertaken at international and national levels before, during and after WHD.

#### ***Before World Health Day 2000***

##### ***International***

- Identification of groups for focused activity and development of targeted messages
- Media package
- Editorial material to support media campaigns
  - Donor stories
  - Patient stories
- Generic posters, badges, stickers
- Editorial material for use in specialist professional journals
- Distribution of samples of effective donor information and education materials from different regions
- Educational material on WHO website
- International success stories in increasing blood safety
- Stamp/franking messages

##### ***National***

- Nomination of contact person/lead organization, approved by the Ministry of Health, to liaise with WHO/IFRCRCS
- Identification of partner organizations:
  - Voluntary blood donor organizations
  - Patient/consumer groups
  - Professional organizations
  - Service organizations: e.g. Rotary Clubs, Lion's Clubs
  - Community organizations
  - Religious organizations
- Fund-raising
- Media pack: good news stories and positive messages about blood safety
- Educational materials
- Advocacy to promote legislation, establishment of national blood committee, continuing medical education and research
- Media awareness programme: television, radio, press, magazines
- Launch of national poster/drawing competition for children
- Educational talks
- Press conferences/press releases
- Media workshops

##### ***Development of materials***

- Posters
- Leaflets

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- Stickers/pins
  - Publication on the history of blood transfusion in each country
  - Franking messages

### ***On World Health Day***

#### ***International***

- Launch of Global Collaboration for Blood Safety
- Launch of World Health Report on Blood Safety
- Launch of media award for the best stories or reports, to be awarded on the International Day of the Volunteer, 2001
- Global appeal for voluntary non-remunerated blood donors
- Messages of support from celebrities
- Satellite symposium

#### ***National***

- Press conference/press release
- Statements of support and blood donation by the Head of State, Minister of Health, prominent politicians and celebrities
- Donor recognition and reward ceremonies
- Messages of thanks from recipients of blood
- Release of red balloons representing lives saved by transfusion or bearing messages of thanks from recipients of blood
- Blood transfusion service open day
- Exhibitions in hospitals and public places
- National poster/drawing competition for children
- Radio phone-in
- Launch of national blood transfusion service website
- Establishment of hotline/helpline on blood donation
- Scientific/medical seminar for clinicians on the clinical use of blood
- Education programmes in schools and colleges
- Community awareness programmes
- Sports events
- Donor enrolment challenges at city, state and country level
- Runs, walks and march past to promote donor enrolments
- Donor gatherings
- Quiz programmes

### ***After World Health Day***

#### **Strengthening blood transfusion services**

- Establishment of nationally coordinated blood transfusion service
- Establishment of a National Blood Committee
- Allocation of budget for the national blood programme
- Advocacy to promote the development of legislation to strengthen blood safety
- Development of national donor database

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- Joint activities by the national blood programme, professional and patient organizations, voluntary organizations
  - Formation of a voluntary blood donor organization
  - Continuing medical education programme for prescribers of blood
  - Establishment of a national distance learning programme in blood safety
  - Research programme

### **Public education**

- Poster campaigns: health centres, hospitals and nursing homes
- Periodic press releases
- Inclusion of blood transfusion in school curricula
- Promotion of the voluntary blood donor organization.

## **Working Groups: Session I**

### **Strategies**

Participants endorsed the four core strategies for blood safety developed by WHO/BTS (see pp. 3–4). However, while recognizing that quality is integral to each of these strategies and is specifically addressed in the Aide-Memoire, they recommended that quality assurance should be given even greater prominence by being added as a fifth, separate strategy.

### **Aide-Memoire**

The Aide-Memoire was agreed to be a useful tool for advocacy and the sensitization of national health authorities to the requirements for safe and adequate supplies of blood. It also provides a useful checklist for the evaluation of the present situation and the identification of priorities for action.

The principal target groups for distribution of the Aide-Memoire were identified as:

- Decision makers
  - Political
  - Management
- Blood transfusion service staff
- Blood donor groups
- Patient groups
- Clinicians
- Financial donor agencies.

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It was proposed that the Aide-Memoire should be retained in the form of a one page, doubled-sided document but that, when the current print run is exhausted, it should be updated and revised to reflect a more explicit focus on quality as a fifth strategy for global blood safety. Other minor amendments were proposed to the text.

## **Working Groups: Session II**

### **Priorities and needs for strengthening national blood programmes**

The Working Groups recommended that WHO/BTS should give priority to the following areas to support the global implementation of its strategies for blood safety.

#### **Goals and targets**

It was proposed that regional and national goals and targets should be set in a series of regional meetings for Directors of Blood Transfusion Services, with regular follow-up meetings to evaluate progress.

#### **Quality**

The following activities were proposed to support the development of effective national quality systems:

- 1 Development of recommendations and guidelines
  - Establishing a quality management system
  - Training of the national regulatory bodies in the requirements for the production of plasma derivatives
  - Establishing an information management system ‘from vein to vein’
  - Confirmatory testing for all transfusion-transmissible infections and donor counselling for all TTIs
  - Developing national screening strategies for all transfusion-transmissible infections, including:
    - Pooling: when is it appropriate and what quality control is required?
    - Algorithms
    - Evaluation of test kits.
- 2 Organization of regional workshops and meetings
- 3 Evaluation of progress in each country.

#### **Distance learning**

High priority should be given to the wider promotion and dissemination of the distance learning materials and support for the establishment of distance learning programmes.

## **Working Groups: Session III**

### **Global Collaboration for Blood Safety**

The Working Groups endorsed the objectives and strategies of the Global Collaboration for Blood Safety. They proposed that the objectives might be expanded to include the following.

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- 1 To establish minimum standards in blood transfusion in all regions.
  - 2 To optimize the use of resources and avoid duplication through the exchange of information and technology.
  - 3 To provide a framework for national decision-making.

They emphasized the importance of regional level collaboration and the setting and regular review of targets. They proposed the following mechanisms and activities to promote and facilitate effective global collaboration

- 1 International and regional meetings to set clear targets and indicators for evaluation, including:
  - Regional meetings of directors of blood transfusion services
  - National meetings in large countries
  - Meetings of policy makers
  - Scientific meetings.
- 2 The establishment of networks to facilitate rapid, easy and appropriate information exchange to promote the optimal use of resources and avoid duplication: e.g. through WHO web site.
- 3 The strengthening of WHO Collaborating Centres.
- 4 The commitment of WHO Regional Offices to blood safety.
- 5 Collaborative training programmes.
- 6 Twinning of country programmes and activities.
- 7 International, regional and national EQAS.
- 8 Monitoring and evaluation.

In discussion, it was agreed that there is a need for regulatory control of plasma for the manufacture of plasma derivatives. However, participants felt that the quality and safety of plasma and individual products for transfusion should be assured through the application of quality systems within the blood transfusion service. A Consensus Statement prepared by Dr J. Koistinen was adopted by the Expert Group and is attached as Annex III.

### **Global Database on Blood Safety**

The Working Groups raised the following key issues during discussion.

- 1 Measurable indicators should be defined for data collection and analysis in critical areas:
  - Blood transfusion service organizational structures
  - Blood donors
  - The epidemiology of transfusion-transmissible infections
  - Quality assurance
  - The clinical use of blood and blood components.
- 2 In large and diverse countries, additional respondents should be identified at state/regional/provincial level.
- 3 In some countries, a significant proportion of blood is collected and used outside the public health sector. Additional respondents should therefore be identified, in conjunction with Ministries of Health, in order to ensure that data from these countries are accurate and

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comprehensive.

- 4 Respondents should be given an explanation of the purpose of the database and the benefits of contributing to the collection of data.
- 5 Data should be collected, analyzed and reported on an annual basis.
- 6 Adequate time should be allowed for respondents to collect data and complete the checklist.
- 7 Questions on the database checklist should be unambiguous, with explanations, where appropriate.
- 8 A comparative analysis (longitudinal study) should be undertaken and reported at national, regional and global levels.
- 9 Higher priority should be given to the needs of respondents in the analysis and reporting of data. In addition to global and regional reports, country reports should be provided to:
  - Assist in needs assessment
  - Provide comparative indicators of performance on a regular basis
  - Provide benchmarks
  - Strengthen and maintain motivation.
- 10 Reports should be distributed to respondents, directors of blood transfusion services, national health authorities, World Health Representatives and WHO Regional Offices.
- 11 Data should be made available on the WHO web site and reported in publications such as 'Transfusion Today'.

## **Working Groups: Session IV**

### **Review of WHO/BTS materials**

The Working Groups reviewed all materials produced by WHO/BTS and its predecessors and made the following recommendations.

- 1 The following publications are now out-of-date and should be removed from the publications list.

#### **Books**

- Guidelines for the Organization of Blood Transfusion Services
- Management of Blood Transfusion Services
- Blood Grouping Reagents
- Blood Transfusion and Blood Components

#### **Documents**

- Essential Consumables and Equipment for Blood Transfusion Services
- Use of Plasma Substitutes and Plasma in Developing Countries
- Essential Blood Components, Plasma Derivatives and Substitutes
- Minimum Targets for Blood Transfusion
- Guidelines for the Appropriate Use of Blood
- Consensus Statement on Accelerated Strategies to Reduce the Risk of Transmission of HIV by Blood Transfusion

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- Consensus Statement on Screening of Blood Donations for Infectious Agents through Blood Transfusion
  - Costing of Blood Transfusion Services
- 2 The following materials should be removed from the publications list in their existing form, but should be updated and produced in a new format.
- i) Guidelines for Quality Assurance Programmes for Blood Transfusion Services  
High priority should be given to the development of:
    - Guidelines on establishing a quality system
    - Establishing a quality system and quality management in blood transfusion services (DLM).
  - ii) Autologous Transfusion in Developing Countries  
This should be revised in the form of guidelines on the use of autologous transfusion.
  - iii) Recruiting, Educating and Retaining Safe Blood Donors  
This document should be included as an addendum to Module 1: Safe Blood Donation in the series of distance learning materials, *Safe Blood and Blood Products*.
  - iv) Viral Inactivation of Blood and Blood Products  
This document should be updated and revised.
- 3 New documents should be produced on the following topics:
- Establishing an information management system for blood transfusion services (manual or DLM)
  - Information technology in blood transfusion services
  - Establishing a cost recovery system for blood transfusion services (supplement to *Costing Blood Transfusion Services*)
  - Strategies for the recruitment and retention of voluntary non-remunerated blood donors (guidelines and DLM)
  - Counselling blood donors (guidelines and DLM)
  - Legal and ethical issues in transfusion practice in relation to blood donors and the recipients of blood (short document)
  - Strategies/algorithms for screening strategies for transfusion-transmissible infections (guidelines)
    - update screening strategies, I, II and III
    - include all other TTIs
    - include repeat testing of initial positives
    - include guidelines on pooling
  - Guidelines on the selection, evaluation and validation of screening assays
  - Waste management
  - Component preparation (DLM)
  - The procurement and maintenance of equipment
  - The assessment of training needs and establishing training programmes in blood safety (may be incorporated in the new material on quality assurance)
  - The management of blood waste

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The Working Groups also made the following additional recommendations.

- 1 Short documents should be placed on the WHO web site.
- 2 All old documents that are removed from the publications list should be archived and made available on the WHO web site and CD-ROM, with clear links and instructions on retrieval.
- 3 The distance learning materials, *Safe Blood and Blood Products*, do not need to be revised. Where updating is required, new material should be provided in the form of supplements.
- 4 The distance learning materials should be produced in an electronic form, such as CD-ROM and/or diskettes.
- 5 All materials should be subjected to regular review to identify any need for revision or updating.

## **Working Groups: Session V**

### **Developing a databank of WHO blood transfusion consultants**

The Working Groups agreed that WHO/BTS should respond positively to requests by individual countries or regions for consultancy and recommended that panels of consultants should be established in the following areas:

- The organization and management of blood transfusion services
- The education, motivation, recruitment and retention of voluntary non-remunerated blood donors
- The screening and processing of blood
- The clinical use of blood
- Quality management and quality systems
- Training
- Monitoring, evaluation and audit.

Where appropriate, consultancy may be required from non-BTS specialists, such as accountants, sociologists and media personnel.

Consultants should assist in:

- Needs assessment
- Training
- Technical support and problem-solving
- Workshop facilitation
- Support for WHO Regional Office activities.

The criteria for the selection of consultants should include:

- Relevant, specialist expertise in the consultancy area: e.g. policy making, audit
- Active in the field of expertise
- Communication skills
- Experience in developing countries
- Knowledge of regional issues
- Professional credibility
- Availability and commitment.

WHO/BTS should provide active support for consultants, including:

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- Briefing and debriefing sessions
  - A comprehensive information package, including:
    - Briefing on the country situation, its health systems, policies and blood programme
    - Country report from the Global Database on Blood Safety
    - Relevant WHO policies, guidelines and learning materials
    - Guidelines on the reporting format
  - Support from the World Health Representative
  - The identification of a national counterpart.

A mechanism should be established to provide consultants with feedback on the outcomes of their activities.

It was recommended that WHO/BTS should give consideration to organizing a meeting for the training of consultants.

## **Working Groups: Session VI**

### **Strategies and mechanisms to strengthen inter- and intra-regional collaboration in transfusion medicine**

In the final Working Group session, participants identified the following aspects of transfusion medicine that might benefit from collaboration within and between regions:

- Needs assessment/situation analysis
- Policy development
- Preparation of guidelines
- Regional meetings and workshops with specific goals and targets and continued evaluation of progress
- Training, with particular emphasis on:
  - Training of medical directors of blood transfusion services
  - Organization and management of blood transfusion services
  - Quality assurance
  - The recruitment and retention of voluntary non-remunerated blood donors
  - Counselling blood donors
  - Evaluation of screening assays
- Technical cooperation and assistance
- Networking and information exchange
- Sharing of resources
- Transfer of technology
- Evaluation and critical review of:
  - New technologies: e.g. Haemoglobin Colour Scale, autologous transfusion device
  - Training materials
  - Test kits
- Development and analysis of the Global Database on Blood Safety
- Implementation of EQAS
- Production of reagents
- Joint research programmes: e.g. rare donor panels, HCV genotypes
- Contract plasma fractionation.

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They emphasized that effective collaboration cannot be achieved without adequate budgetary support.

### **The role of stakeholders**

The Working Groups identified the following activities that might be undertaken by the various stakeholders in collaboration in transfusion medicine.

#### ***WHO/BTS***

- Advocacy
- Develop policies and strategies
- Fund-raising.
- Provide direction
- Prepare recommendations and guidelines
- Develop training materials
- Disseminate information through WHO web site
- Coordinate inter-regional training activities
- Support regional initiatives
- Provide consultants
- Monitoring and evaluation

#### ***WHO Regional Offices***

- Provide feedback on regional needs and priorities to WHO/BTS
- Coordinate activities within the region
- Support country activities
- Organize regional meetings and workshops

#### ***WHO Representatives (WRs)***

- Define country needs and priorities in relation to blood safety
- Advocacy
- Coordinate activities between WHO Regional Offices and national health authorities

#### ***WHO Collaborating Centres***

- Regional reference centres
- Training
- Research
- Evaluation of test kits and medical devices

#### ***Nongovernmental organizations***

- Identify areas and issues that would benefit from collaboration
- Actively support collaboration through technical and financial assistance.

#### ***National blood transfusion services***

- Actively participate in the collaboration
- Assist in the identification of needs
- Coordinate national programmes

#### ***Universities and training institutions***

- Provide continuing professional education in all aspects of blood transfusion medicine
- Provide trainers and training facilities for short courses and workshops

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- Assist in the validation and accreditation of training activities.

## Recommendations

The Meeting of Experts in Blood Transfusion Services endorsed the key strategies for blood safety developed by WHO/BTS, as outlined in the *Aide-Memoire: Blood Safety*, and made the following recommendations.

- 1 WHO/BTS should continue to promote and facilitate the effective implementation of its strategies for global blood safety at global, regional and national levels through:
  - Advocacy
  - Technical support.
- 2 WHO/BTS should promote a positive public image of blood transfusion, including collaboration in global, regional and national activities on World Health Day and beyond.
- 3 WHO/BTS should expand its four core strategies for blood safety to include a fifth strategy: the establishment of a quality system
- 4 WHO/BTS should promote and facilitate the development of quality systems for national blood transfusion services through the development of guidelines, learning materials and training activities.
- 5 WHO/BTS should promote and facilitate the strengthening of systems for the recruitment, retention and counselling of voluntary non-remunerated blood donors.
- 6 WHO/BTS should assist Member States to determine appropriate strategies for screening for transfusion-transmissible infections and to develop national guidelines on the selection, evaluation and validation of screening assays.
- 7 WHO/BTS should provide guidance on health legislation and the ethical aspects of blood transfusion.
- 8 WHO/BTS should continue to promote and support the Global Collaboration for Blood Safety which should facilitate technology transfer, technical cooperation and information exchange.
- 9 WHO/BTS should promote continuing monitoring and evaluation of blood safety through the Global Collaboration for Blood Safety and the Global Database on Blood Safety.
- 10 WHO/BTS should strengthen the reliability of data held on the Global Database on Blood Safety by identifying sources of information on non-governmental organization and private sector blood programmes, particularly in large and diverse countries.
- 11 WHO/BTS should assist in the development of tools to support the development of evidence-based, transparent decision-making practice in blood transfusion.
- 12 WHO/BTS should promote the expansion of training for blood transfusion service personnel and clinical personnel through the continuing development of learning materials and support of regional activities for the training of trainers.
- 13 WHO/BTS should promote and fully utilize the expertise and experience available at global,

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regional and national levels from WHO Collaborating Centres, blood transfusion specialists and all other available means.

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## **Annex 2: PROGRAMME OF WORK**

**Monday, 22 November 1999**

09.00	Opening session by Dr Michael Scholtz, Executive Director, HTP	
09.10	Election of chair, vice-chair and rapporteurs	
09.15	WHO Department of Blood Safety and Clinical Technology: Structure and functions	Dr Jean C. Emmanuel
09.25	Introduction	Dr Luc Noel
09.35	Objectives of the meeting	Dr Jean C. Emmanuel
09.45	Country reports	Participants
10.30	Coffee/Tea	
10.45	Country reports (continued)	Participants
13.00	Lunch	
14.00	World Health Day 2000 (WHD 2000): Overview of objectives/products of WHD 2000 and theme	Dr K. Behbehani
14.10	Discussion/Working Groups on WHD 2000 activities and follow-up	Mrs Danièle Letoré
14.20	Working Groups	Participants
15.30	Coffee/Tea	
15.45	Working Groups (continued)	Participants
16.00	Reports by rapporteurs	Rapporteurs
17.00	Discussion and summary	

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Tuesday, 23 November 1999

09.00	Key messages from Country Reports	Rapporteurs
09.30	BTS Team structure/functions, Global Collaboration for Blood Safety (Blood Science Conference); Aide-Memoire: Blood Safety	Dr Luc Noel
10.00	Discussion	
10.30	Coffee/Tea	
10.45	Ensuring quality testing of donated blood Evaluation of test kits EQAS Workshops	Dr Gaby Vercauteren
11.15	Discussion	
11.45	BTS/Quality and safety of plasma derivatives (QSD) Reference preparations National control authorities Quality and safety of plasma	Dr Ana Padilla
12.15	Discussion	
13.00	Lunch	
14.00	Safe blood and blood products Distance Learning Materials (DLM) Translations Workshops Guide for programme coordinators	Ms Jan Fordham
14.20	Distance learning programme: Argentina	Dr Ana del Pozo
14.50	Distance learning programme: China	Dr Feng Gao
15.00	The Clinical Use of Blood Learning materials Pocket handbook Policy and plans for the clinical use of blood	Dr Brian McClelland Dr Jean C. Emmanuel
15.20	Discussion	
15.45	Coffee/Tea	
16.00	External Relations: Projected Strategies for BCT/BTS and potential improvement	Ms Renia Coghlan Dr Luc Noel
16.30	Discussion	
17.30	Reception	

**Wednesday, 24 November 1999**

09.00	Summary and review of previous day's discussions	
09.30	Global Database for Blood Safety	Ms Shân Lloyd Dr Gaby Vercauteren Ms Bronwen Van der Wal
10.00	Discussion	
10.30	Coffee/Tea	
10.45	WHO Haemoglobin Colour Scale and Medical Devices	Mr Gerald Verollet

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11.15	The Blood Cold Chain Developing specifications/evaluation/field testing Learning materials for managers/users of blood cold chain equipment	Mr David Mvere  Dr Elizabeth Vinelli Ms Jan Fordham
11.30	Discussion	
12.00	Working Groups: Session I Theme: <u>Aide Memoire - Strategies</u>	
13.00	Lunch	
14.00	Discussion/Report from Working Groups	
15.30	Coffee/Tea	
16.00	Working Group Session II Theme: <u>Priorities and needs for strengthening national blood programmes</u>	
17.00	Discussion/Report from Working Groups	
<b>Thursday, 25 November 1999</b>		
09.00	Reports from Working Groups: Sessions I and II	
09.30	Safe Injection Global Network (SIGN)	Dr Yvan Hutin
09.40	Discussion	
09.50	Working Groups: Session III Theme: <u>Global Collaboration for Blood Safety and Global Database on Blood Safety</u>	
10.30	Coffee/Tea	
10.45	Reports from Working Groups: Session III	
12.00	Working Groups: Session IV Theme: <u>Review of BTS materials</u>	
13.00	Lunch	
14.00	Reports from Working Group: Session IV	
15.00	Working Group Session V Theme: <u>Developing a Databank of WHO Blood Transfusion Consultants</u>	
15.30	Coffee/Tea	
15.45	Reports from Working Groups: Session V	
16.15	Working Group Session VI Theme: <u>Identification of strategies and mechanisms to strengthen inter- and intra-regional collaboration in transfusion medicine</u>	
17.15	Reports from Working Groups: Session VI	
<b>Friday, 26 November 1999</b>		
09.00	Summary of workshop discussions	
09.30	Discussion and development of draft recommendations	
10.30	Coffee/Tea	
10.45	Discussions (continued)	
12.30	Lunch	
14.00	Summary and agreement on recommendations	
15.30	Coffee/Tea	
15.45	Closing	

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### **Annex 3: Consensus statement on the regulatory control of plasma for the manufacture of plasma derivatives**

The integration of the team of Blood Transfusion Safety (BTS) and Quality and Safety of Plasma Derivatives (QSD) within the Department of Blood Safety and Clinical Technology provides WHO with a unique opportunity for discussion on the regulatory control of plasma for the manufacture of blood products and plasma derivatives. The production of plasma-derived medicinal products is dependent on supplies of plasma by blood transfusion services.

In the developed world, there is a tendency for blood transfusion medicine to move towards a pharmaceutical approach. However, quality systems in pharmaceutical production deal with the batch control of products, unlike the production of labile blood components.

The same rules and regulations cannot be applied to all blood products. Excessive regulation of labile blood products may have unfortunate outcomes.

In transfusion medicine, emphasis should be placed on the regulation and inspection of processes rather than products. The clinical benefits of transfusion can still be achieved even where deviations occur in labile blood products.

WHO should promote the introduction of quality systems and quality management of transfusion services and promote education and training of national regulatory authorities.