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Blood Safety and Clinical Technology

Strategy 2000-2003



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Blood Safety and Clinical Technology

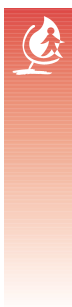
2000-2003 Strategy



*Department of Blood Safety and
Clinical Technology*



*World Health Organization,
Geneva*



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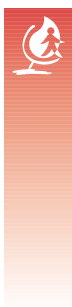
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Abbreviations

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, infections, 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



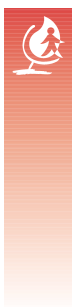
- ✓ Validated norms, standards and biological reference preparations
- ✓ Upgraded technical expertise of national regulatory authorities for the evaluation and control of blood products and related biologicals
- ✓ Knowledge and skills in the areas of blood transfusion medicine and clinical technology 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.

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.

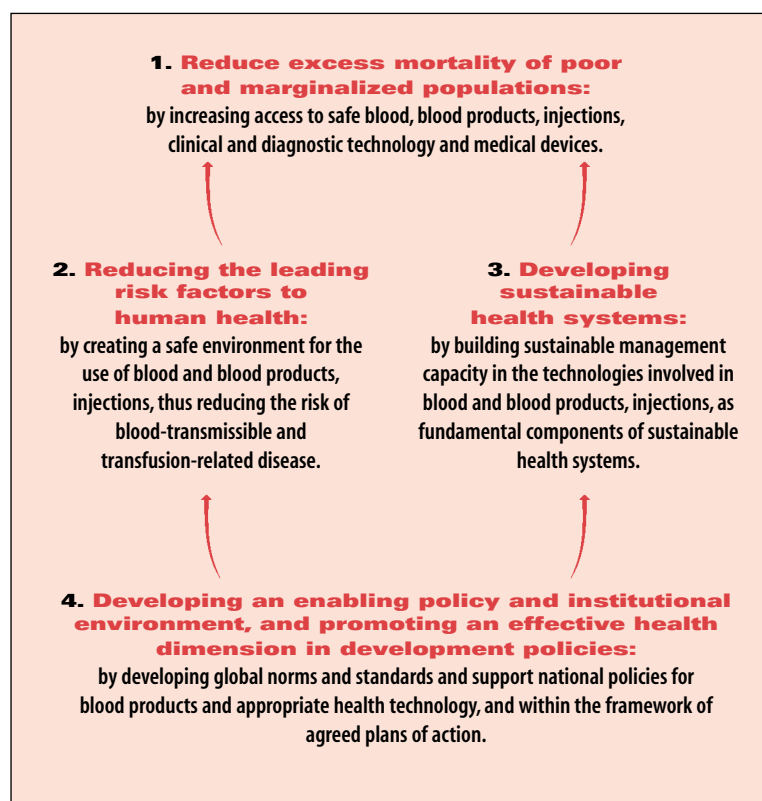
BCT contribution in WHO's four strategic directions

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



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.

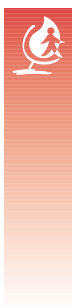
Access

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 transfusion programmes

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 an 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

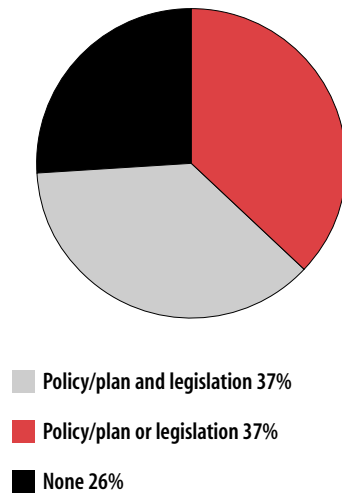
In at least one third of all patients, diagnostic imaging is an absolute requirement for proper diagnosis and treatment, and the need increases as the life expectancy of the population is improving. In several developing countries, such services are either insufficient, or not at all available, and national 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.

Biological Substances

International Standards and Reference Reagents



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 joint 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.

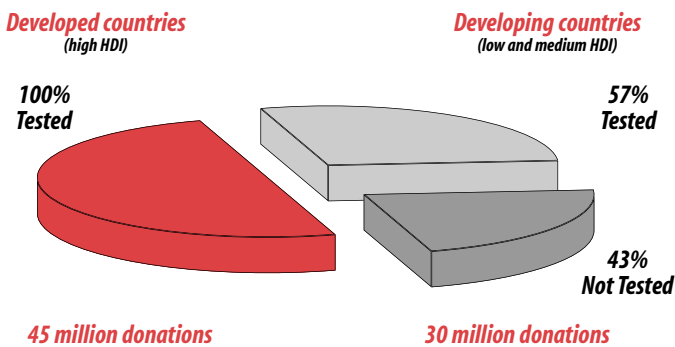
Evaluation of test kits for the detection of hepatitis B and hepatitis C

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 sero-conversion 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.

Figure 3: Blood safety



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 world-wide 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

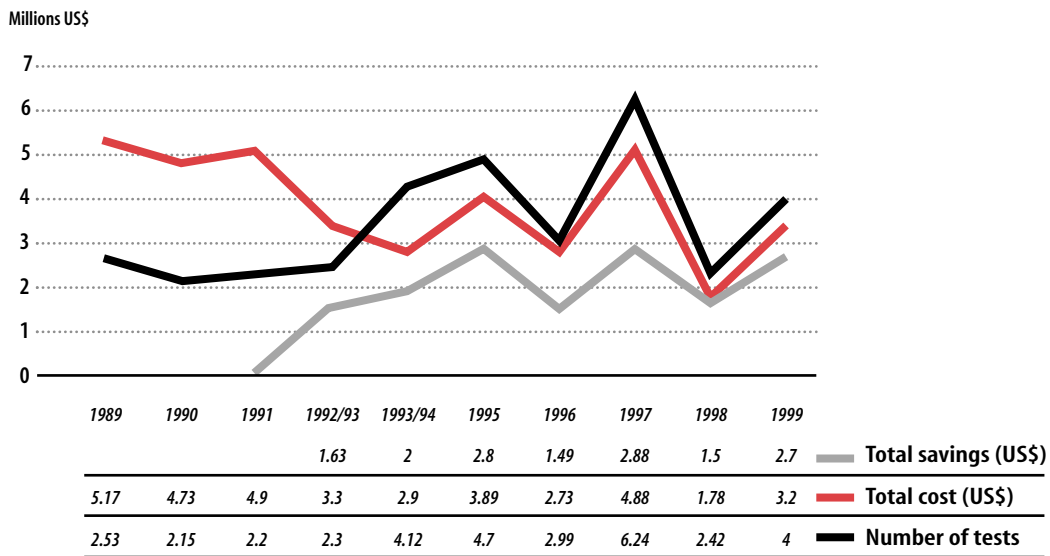
WHO bulk procurement of test kits for HIV, hepatitis B and hepatitis C

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



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 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

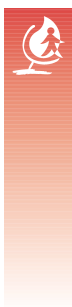
Steps in the process require a comprehensive approach and considerable resources. A global action plan for the implementation of the strategy to reduce disease burden caused by inadequate HCWM will have the following targets:

- 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).

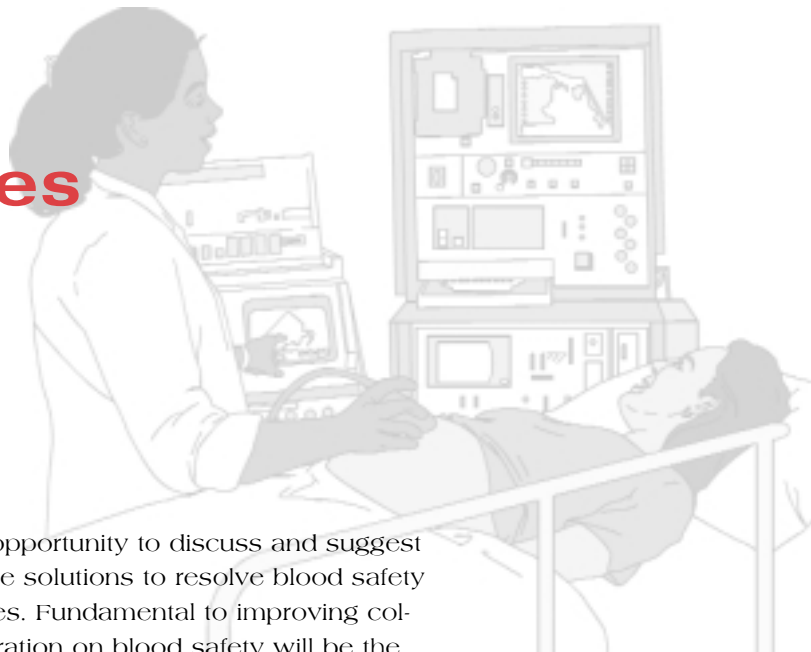
Our contribution to this activity will include: the development of literature search and a review of health impacts from microbiological hazards in health care wastes; the preparation of a guidance document for the appropriate management of blood waste and waste contaminated with blood and a primary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

Figure 5: GCBS – WHO Secretariat

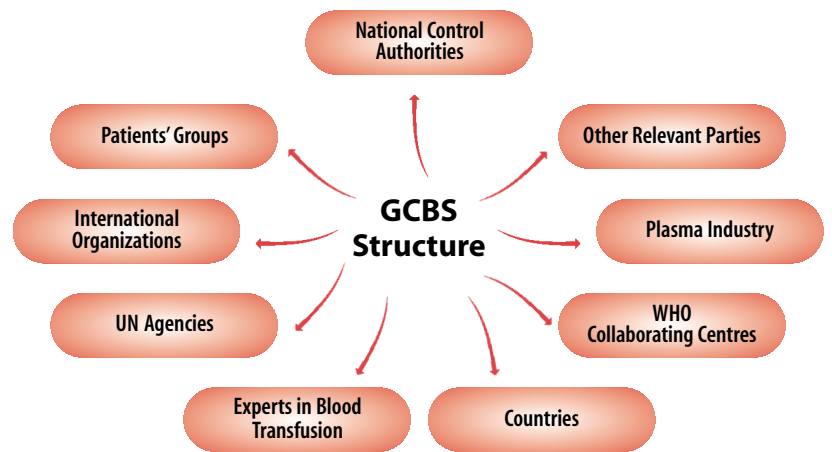
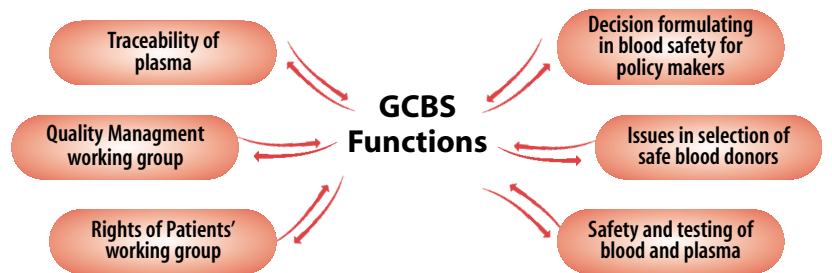


Figure 6: GCBS – Partners and WHO Secretariat



- 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;

- 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.

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 ill-

Figure 7: SIGN Associates and SIGN Secretariat

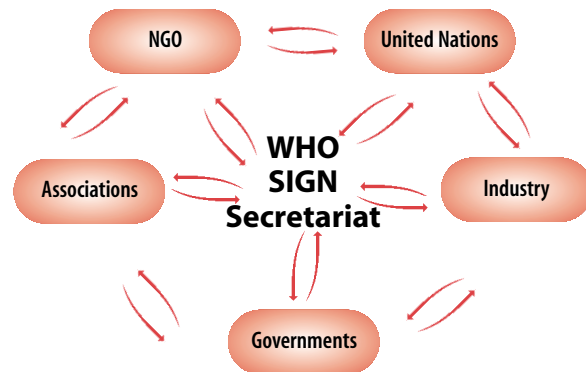
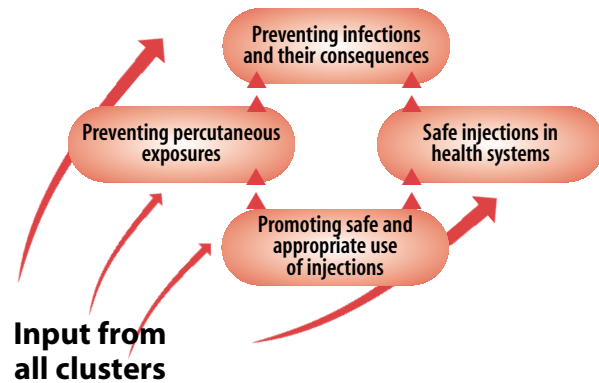


Figure 8: Cross Cluster Collaboration within WHO



nesses 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.

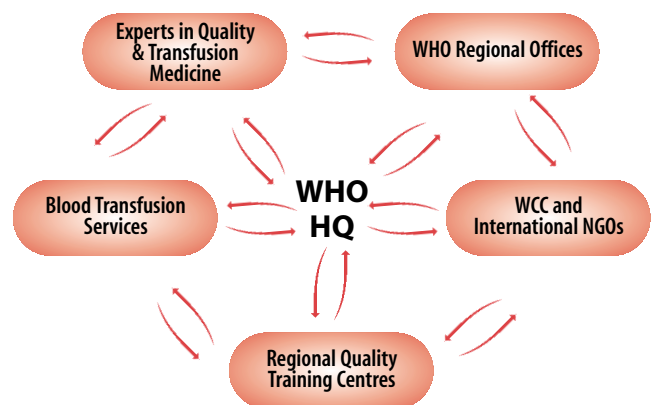
WHO has developed the **Quality Management Project (QMP)** as a new initiative to be carried out in all regions starting from 2001 as a part of a strategy for building capacity at global level. The project addresses the need to adopt the principles of quality management in all areas of the blood transfusion 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.

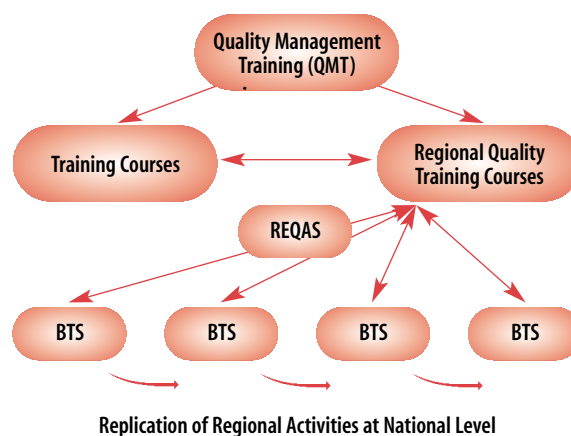
Activities

- 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



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 man-

agement 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

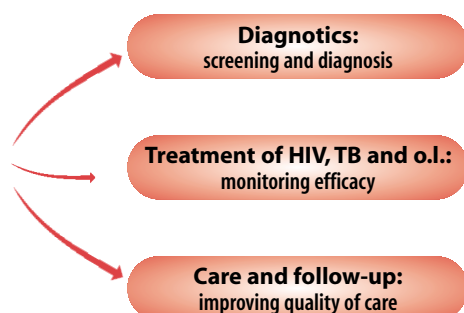
- Number of training courses held as per plan
- Quality of the training course developed
- Participants' satisfaction with the course
- Use of the centre as a resource
- Improvement in quality of work at the BTSS of the participants' after 6 month/1 year of training
- Number of centres participating 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.

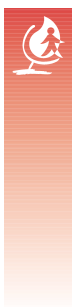
BCT aims to ensure that the diagnostic technologies used in diagnosis and screening meet the highest stan-

dards, 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.

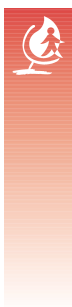
BCT's activities have largely been funded by WHO's regular budget and the department has historically had only a few government donors such as Belgium, Italy, Japan, Luxembourg, Netherlands and United Kingdom, providing extrabudgetary support.

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

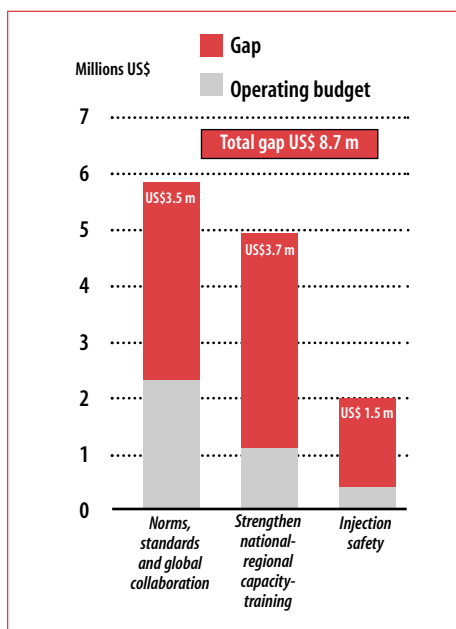


Figure 13: Income expected and unfunded priorities

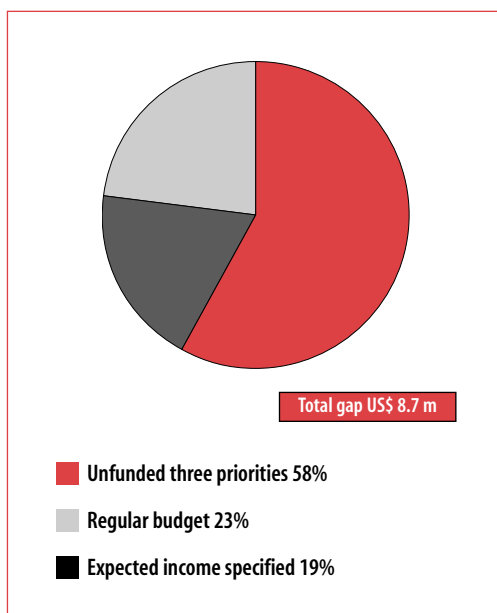


Table 1: Planned cost, core budget and unfunded priorities by objectives and target, and by source of funds, 2000-2001, as at January 2000 (all amounts in US\$ thousand, inclusive of programme support cost on voluntary contribution)

<i>Objective • Target</i>	<i>Planned cost (a)</i>	<i>Total core budget (b)</i>	<i>Unfunded priorities (c = b - a)</i>	<i>WHO regular budget allocation (d)</i>	<i>Voluntary contributions (e = f + g)</i>	<i>Unspecified (f)</i>	<i>Specified (g)</i>
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	523	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
Programme support cost on unfunded area	1 423		-1 423				
Total BCT – objective target	19 169	6 801	-12 368	3 751	3 050	0	3 050
Departmental management, advocacy and coordination		2 209		685	1 524	0	1 524
Grand total BCT	19 169	9 010	-12 368	4 436	4 574	0	4 574

