



WORLD HEALTH ORGANIZATION

## MEETING OF INTERESTED PARTIES

GENEVA, 18 TO 29 JUNE 2001

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### **Blood safety and clinical technology: highlights of 2000**

#### **INTRODUCTION**

1. In most developing countries, quality management systems to ensure safety, quality, access and appropriate clinical use of blood have not been implemented in the blood transfusion systems. This is also true in the areas of diagnostic and therapeutic procedures and significantly affects patient care. Unnecessary blood transfusions expose recipients to the risk of transfusion-transmissible infections (evidenced by the high levels of HIV transmission through transfusion – 5% to 10% of all HIV cases globally), and expensive medical equipment is not utilized either because the technology provided is inappropriate, since maintenance is lacking, or because it is in need of repair.
2. However, significant improvements to the present situation are easily attainable. Four teams in the Department of Blood Safety and Clinical Technology (BCT) are addressing the following major health technology issues: blood transfusion safety; quality and safety of plasma derivatives and related substances; safety of injections; diagnostic imaging and laboratory technologies; clinical technology; and medical devices.
3. The following sections highlight specific projects<sup>1</sup> that have made a significant impact on BCT strategic areas of policy, quality and safety, access and use.

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<sup>1</sup> These projects are not a comprehensive summary of BCT activities, but examples of significant achievements in 2000.

## HIGHLIGHTS

### Policy

#### **Development of National Programme Policies and Plans**

4. **Global Collaboration for Blood Safety (GCBS)** was established as a forum to share information, identify problems, propose solutions and form collaborative alliances. At its first plenary session in November 2000 the GCBS brought together representatives from developing and developed countries in the area of blood and blood product safety, from donors to recipients of blood and blood products, transfusion service specialists, clinical prescribers of blood, national regulatory authorities and the commercial and non-commercial plasma manufacturing industry. The key recommendations of the meeting focused on: (1) the need for nationally-coordinated blood programmes with appropriate regulatory systems; (2) a flexible accreditation mechanism for blood transfusion services; (3) a policy formulation tool and monitoring of risk assessment to assist decision-makers; (4) a forum for information-sharing; (5) developing approaches to reduce the number of unnecessary transfusions and, (6) the need to increase voluntary, non-remunerated blood donations from low-risk populations, essential to the safety and availability of transfusion therapy.

5. Three working groups were formed to address these and other important issues and to prepare a draft working paper on: (1) Quality Assessment and Models for Development; (2) policy-making tool for blood and blood product safety and (3) issues in dealing with the movement of plasma and plasma-derived medicinal products and country requirements for fractionation.

6. **Global Database on Blood Safety (GDBS)** proved to be a vital tool in the production of “Facts and Figures” and the information sheets widely disseminated as part of World Health Day 2000 “Safe Blood Starts With Me”. Country data were received and analysed covering all areas involved in blood transfusion safety, from donor selection and recruitment through testing and transport to patient care. The GDBS Global Summary Report 1998-1999 was finalized and will be issued in all WHO official languages. In addition the GDBS questionnaire which was updated and expanded for the next two-year evaluation, will be used to identify problems, carry out corrective measures and form the basis of monitoring and evaluation of WHO’s strategies for improving global blood safety.

7. **Safety of Injection Global Network (SIGN)** secretariat was established in 1999. Emphasis was placed on two projects to establish an evidence base for safe and appropriate use of injection policies. First, a WHO tool for the assessment and evaluation of injection practices was drafted by experts, reviewed during an informal WHO consultation, and field-tested in eight countries in Africa, Asia and Europe. Drafts are available on the Internet and will be used in wider field testing before a final version is completed in 2001. Second, as part of the 2000 update of WHO’s Global Burden of Disease study, a comparative risk assessment was conducted to estimate the proportion of new hepatitis B and C virus and HIV infections attributable to unsafe injections worldwide. A draft of the final report is undergoing peer review before publication in *The world health report*.

### Quality and safety

8. **Quality Management Project (QMP)** is a new and innovative strategy developed by WHO to improve the quality and safety of blood. The primary objective is to build capacity in quality management of blood transfusion services in all WHO regions through a comprehensive interactive training programme at regional level through the provision of training workshops, learning materials and tools. An amount of

US\$ 2.3 million was identified for the project, reprogrammed from WHO's regular budget through efficiency savings. QMP is a collaborative and sustainable project for an initial six-year period (2000-2005). Quality Management Training (QMT) courses were planned, discussed and endorsed at a global planning meeting in August 2000 by a large number of WHO specialists in transfusion medicines from all six WHO regions. This was rapidly followed by the first four-week regional QMT course held at the WHO Collaborating Centre, the National Blood Transfusion Services, in Harare, for 12 anglophone African countries, in September 2000, using draft training materials. An evaluation of this first course was then held in October 2000 in headquarters, Geneva, in which selected participants as well as the facilitators reviewed and amended the structure and content for future courses to be held in other regions. A meeting to sensitize future facilitators for QMT courses in all six WHO regions took place in February 2001 at the WHO Collaborating Centre for Blood Transfusion in the Netherlands.

9. **Transmissible Spongiform Encephalopathies (TSEs)** include bovine spongiform encephalopathy (BSE), Creutzfeldt-Jakob disease (CJD) and sheep scrapie, among others. The appearance in humans of variant CJD (vCJD) in the United Kingdom, France and Ireland increased the profile of this disease as a risk to human health. In response to this concern, BCT collaborated in a meeting with the cluster of Communicable Diseases (CDS) and international experts on the possible risk of vCJD transmission through blood transfusion. In addition, international reference materials to be used for comparing the sensitivities of new diagnostic procedures for TSEs are being developed with the utmost urgency and WHO has established a forum involving specialists, international medicines regulatory agencies and industry to exchange current knowledge and expertise in this field of work.

## Access

### **Infections transmitted by transfusion**

10. **Diagnosis of infections that can be transmitted through blood (transfusion-transmissible infections (TTIs)).** A total of 43% of countries with low or medium Human Development Index (HDI, as classified by UNDP) do not reliably test all donated blood. Thus 80% of the world's population has access to only 20% of available blood that is safe.

11. WHO has strategies to meet the challenge to develop appropriate, affordable tests, without compromising the quality and reliability of the test results. In addition, evaluation of these tests has been completed for HIV and is nearing completion for hepatitis B and C virus. In 2000, Regional External Quality Assessment Schemes (REQAS) were organized which have improved the capacity of national blood transfusion services and reference laboratories to test donated blood. WHO International Standards have also been developed to ensure the comparability of diagnostic assays.

12. **Clinical laboratory services are vital for national health services.** A workshop was held in Dakar in December 2000 on Quality Assurance in Clinical Laboratories. The workshop, co-sponsored by the Regional Office for the Eastern Mediterranean and REMED (*Réseau des Médicaments*) brought together laboratory managers from French, Spanish and Portuguese-speaking countries in the African Region to develop recommendations on appropriate strategies for access to laboratory technology.

## Use

13. **Haemoglobin Colour Scale**, developed by WHO following five years of improvement and field trials, will be ready for commercial production and distribution by May 2001. The Colour Scale will be of assistance in the detection and management of anaemia, especially in those most at risk, the

disadvantaged and the poor. The device will not compete with existing laboratory techniques, but will enhance the capacity of peripheral health services and resource-poor settings where equipment and technology are lacking. It will also be used as a tool for developing countries for rapid screening for anaemia in clinical settings.

14. The clinical utility of the Scale has been demonstrated in a large-scale study involving more than 14 000 subjects from the screening of potential blood donors, malaria management, antenatal and child health programmes, iron therapy control in hookworm infection to screening of patients for further referral for hospital treatment. This inexpensive test will cost almost 100 times less than any other conventional laboratory photometric analysis and will enable screening to assess anaemia for appropriate prevention and management of anaemic patients, especially women, children, trauma victims and the disadvantaged.

15. **Learning materials** to promote the appropriate clinical use of blood were produced and will be used to educate physicians and health care workers so that the right blood is given to the right patient for the right reasons. This will reduce unnecessary transfusions and the risk of infections and make blood available for those who are in need.

16. **A Global Steering Group for Education and Training in Diagnostic Imaging** has been established as a collaboration between WHO and the major international and regional scientific societies for diagnostic imaging. WHO and the Global Steering Group have established the first of six regional Centres of Excellence for Education and Training in Diagnostic Imaging as a pilot project at the University of Nairobi. The centre acts as a focal point for educational activities and development of training material for district and peripheral level hospitals in Kenya and anglophone countries in the region. The first three of a series of 15 manuals were completed and are being printed as WHO documents for free distribution.

## Priority projects

### World Health Day 2000

17. A document on the highlights of the year 2000 would not be complete without a record of the global impetus and motivation created around World Health Day "Safe Blood Starts With Me". There is a need to build on this momentum over a five-year period to ensure that all countries have nationally-coordinated blood transfusion services with quality management systems; that blood donations take place only from voluntary, non-remunerated donors from low-risk populations; that screening of all donations is carried out for all relevant infectious agents; and that clinicians are educated in the appropriate clinical use of blood.

18. The impact of all these activities will lead to the improvement of the safety and quality, access and use of blood and blood products.

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