Report of the Fourth General Meeting of the

Global Collaboration for Blood Safety

TUNIS, 2-5 December 2003

WHO Blood safety programme
Department of Essential Health Technologies
World Health Organization
Executive Summary

Introduction
The Global Collaboration for Blood Safety (GCBS) was established following the Paris AIDS Summit in 1994. There was unanimous agreement on the need for global collaboration to improve blood safety by building on knowledge, utilizing existing expertise, promoting dialogue and suggesting realistic, effective and practical mechanisms to improve blood and blood product safety. The Forty-eighth World Health Assembly, held in May 1995, adopted resolution WHA48.27, supporting the principles of the GCBS.

The first, second and third GCBS plenary meetings were held in 2000, 2001 and 2002, respectively. The fourth plenary meeting of GCBS was held in collaboration with the National Blood Centre in Tunis, Tunisia on 2 - 5 December 2003. The meeting was convened and organized by the Blood Transfusion Safety Team, Department of Essential Health Technologies (BTS/EHT/WHO) within the Health Technology and Pharmaceuticals cluster. It was attended by 46 participants from GCBS collaborating organizations, individual experts, WHO Regional Advisers for Blood Safety and staff of the Department of Essential Health Technologies, WHO/Geneva. The meeting was chaired by Dr. Jay Epstein and Dr. Jukka Koistinen. Professor Anthon Heyns and Dr Elizabeth Vinelli were elected as Rapporteurs. The agenda and programme of work were reviewed and adopted by the plenary group.

Summary of GCBS achievements in 2003
2. The GCBS meeting met its objectives in establishing a forum to cultivate collaboration, provide scientific updates and new contacts.
3. A final draft of the Minimum Requirements for Blood Transfusion Services was developed by the Working Group on Quality and Access to Development.
4. The Aide-Mémoire: Good Policy Practice was finalized and the framework for decision making was drafted.
5. The report of the Third GCBS meeting was approved.

Summary of discussions
The process for the election of new members was clarified and several new participating organizations were invited to present their global blood safety activities to the GCBS. It was agreed that the Planning Group would continue to map the direction of the GCBS and plan the agenda of the next general meeting. The issue of the GCBS logo was resolved as being inconsistent with policies and practices of WHO and it was noted that the web site was functional but required refinements mainly in the form of additional information and links. On discussion of the financial situation of GCBS, it was agreed that the task group set up to examine financing of GCBS be urgently re-activated in order to address the problems currently being encountered.

The Working Group on Policy Process requested and obtained concurrence of the GCBS participants on several important issues being addressed by the Working Group. These included the provision of advocacy for a structured, policy making
process, improving international communication on policy making, establishing a forum for sharing of experiences among policy makers and ensuring that the conceptual framework is applicable to different economical and political settings. The participants to the general meeting expressed their support for convening a 'Policy Makers Forum' to address these issues. It was agreed that the proposed EB resolution on strengthening the WHA 28.72 through re-endorsement and enhanced implementation in all Member States” will be redrafted as a concept paper and that participants may use the mechanisms available in their respective organizations to bring this issue forward.

The Working Group on Plasma Issues reported that the Plasma fact sheets have been finalized and approved by ECBS and have also been made available through the WHO web site. The Aide Memoire for the Provision of Medicinal Products derived from Human Plasma is under development. While considering, new members and new directions for the group, it was also proposed that the Working Group on Plasma Issues would have to be made on the basis of a well-defined GCBS (strategic) Plan.

The Working Group on Quality Assessment and Assistance for Development presented the final draft of the *Minimum Requirements for Blood Transfusion Services*, and outlined its plans for the coming year. These are to address the outstanding issues of facilitation of external assessment and accreditation, stepwise audit programmes, and to develop tools for guidance on translating the *Minimum Requirements* into national standards. It was reported that the pilot study utilizing the 'Needs Assessment' Model will commence in 2004. The participants to the general meeting agreed with the statement from the group that GCBS is not constituted nor structured sufficiently to be custodian of the AABB core standards.

Presentations were made by 13 collaborating organizations to provide an update on their activities: WHO Blood safety programme, ICCBBA, Council of Europe, International Association of Biologicals, Africa Society for Blood Transfusion, Centers for Disease Control, USA, Health Canada, International Consortium for Blood Safety, Plasma Protein Therapeutic Association, European Blood Alliance, International Society for Blood Transfusion, International Trauma Anaesthesia and Critical Care Society and the World Federation of Haemophilia. The work of BTS/EHT/WHO) continued to focus on the integrated WHO strategy and was strengthened by re-focusing the Department's strategy including the development of the basic operational frameworks. The presentations from three developing countries outlined the successes and the problems encountered in these countries to improve blood safety.
Recommendations and Next Steps

1. The meeting encouraged the GCBS participants to continue to work towards constructive collaborations in support of their shared mission and goals through collective activities.

2. The meeting proposed to improve synergy between WHO, as the GCBS secretariat, and other GCBS participants by:
   - Improving dissemination of useful information and work products through enhancement of the GCBS website. The participants were requested to provide hyperlinks to the GCBS website.
   - Promoting utilization of communication tools available to NGOs, such as increasing availability and subsidized access to journals to the global blood transfusion community, particularly the resource limited countries.
   - Establishing a more stable process for funding of GCBS activities based on the annual preparation of a formal budget
   - Developing collaborative activities of GCBS participants with funding partners.
   - Re-clarifying the terms of reference and procedures of the GCBS.

3. The meeting accepted the offer of ICCBBA to participate in the ongoing development of ISBT 128 by ICCBBA

4. The meeting adopted a draft *Aide-Mémoire on Good Policy Practice* on Blood Safety and Availability and requested that the GCBS secretariat submit it to WHO for further consideration.

5. The meeting recommended that the Policy Working Group identifies a participating organization to develop a draft guideline on good policy practice to serve as an addendum to the Aide-Mémoire. The guideline should be targeted both to policy makers and to their technical experts. The guideline should:
   - Follow the model of the *Recommendations on developing national policies and guidelines on the clinical use of blood* to include brief chapters that explain the stepwise use of the elements of policy analysis and decision making;
   - Include discussion of fundamental elements of a good policy process, including use of a structured decision framework making use of formal assessment tools; transparency and accountability, and risk communication
   - Prioritize interventions in the context of public health,
   - Include a statement of the scientific, economic and social basis of the decision on national blood safety issues.
   - Take into account existing international guidelines, such as the Council of Europe's Guide to the preparation, use, and quality assurance of blood components.

6. The meeting revised and adopted the concept paper on *Strengthening WHA 28.72 through re-endorsement and enhanced implementation in all Member States*. Participants as they wish may use the mechanisms available in their respective organizations to bring this issue forward.

7. The meeting expressed its concern at the potential removal of clotting factor concentrates and immunoglobulins from the WHO Essential Medication List and encouraged its participants to comment through the appropriate mechanisms.
8. The meeting endorsed the concept to hold a special GCBS meeting (forum) with policy makers in 2004, aimed at promoting the development of a Good Policy Practice for Blood Safety and Availability. The meeting tasked the working group on Policy to develop a draft programme. The meeting suggested that the special meeting (forum) be held in temporal proximity with the meeting of the WHO Executive Board.

9. The meeting established a working group to:
   - Develop the concept and proposed mechanism for a “clearing house” function to facilitate matching of unmet national and regional needs with donor resources while eliminating overlaps in the provision of such assistance.
   - Establish all possible mechanisms and ways to promote the application of the GCBS products
   - Prepare draft recommendations on improving the availability of appropriate training and education in Transfusion Medicine.

10. As an effort complementary to the WHO Quality Management Programme, the Working Group on Quality Assessment and Assistance for Development will continue to develop a proposed framework and mechanism to achieve assessed quality status for blood transfusion services through the following steps:
   - The meeting asked the GCBS participants to provide comments of the presented final draft of the *Minimum Requirements for Blood Transfusion Services* by end of January 2004.
   - The Working Group will complete editing of the final draft by end of March 2004 and will submit the draft document through the general GCBS meeting to WHO for further consideration.

11. The development of a guideline on the preparation of regional or national standards on blood transfusion services, based on *Minimum Requirements for Blood Transfusion Services* shall continue. The Council of Europe’s Guide to the preparation, use, and quality assurance of blood components could also be used as a model ([http://www.coe.int/T/E/Social_Cohesion/Health/](http://www.coe.int/T/E/Social_Cohesion/Health/)).

12. The meeting tasked itself to clarify the terms on which GCBS participants can make use of the relevant international standards (e.g. the Council of Europe’s Guide to the preparation, use, and quality assurance of blood components, and AABB Core Standards).

13. In relation to the “Assessment of needs for blood products: theoretical framework and practical tool”, the meeting endorsed the pilot project on 'Assessing the requirements of blood and blood products' and encouraged the GCBS participants to participate in the project, subject to available funding. The meeting requested that the GCBS secretariat engage in specific fundraising for this project. The Working Group on Quality was tasked to extend the needs assessment model to include the use of plasma derivatives.

14. The meeting tasked the Working Group on Plasma Issues to develop possible strategies to improve the availability of plasma derivatives worldwide and to address the approaches that might be necessary in the settings of whole blood versus plasma collection. In addition, the group should entertain a root cause analysis of the obstacles in plasma availability and utilization.
Introduction
The Global Collaboration for Blood Safety (GCBS) was established following the Paris AIDS Summit in 1994. There was unanimous agreement at the summit on the need for global collaboration to improve blood safety by building on knowledge, utilizing existing expertise, promoting dialogue and suggesting realistic, effective and practical mechanisms to improve blood and blood product safety. The Forty-eighth World Health Assembly, held in May 1995, adopted resolution WHA48.27, supporting the declaration of the Paris AIDS Summit, including the principles of the GCBS.

The first, second and third GCBS general meetings were held in 2000, 2001 and 2002 respectively. The fourth general meeting of GCBS was held in collaboration with the National Blood Centre in Tunis, Tunisia on 2 - 5 December 2003. The meeting was convened and organized by the Blood Transfusion Safety Team, Department of Essential Health Technologies (BTS/EHT/WHO) within the Health Technology and Pharmaceuticals cluster. It was attended by 46 participants from GCBS collaborating organizations, individual experts, WHO Regional Advisers for Blood Safety and staff of the Department of Essential Health Technologies, WHO/Geneva.

The meeting was opened by Dr. Jay Epstein and Dr. Jukka Koistinen as chair and vice chair of the general meeting of GCBS with greetings to all the participants and with special thanks to Dr. Steffen Groth, Director, Department of Essential Health Technologies, WHO-HQ for his presence at the meeting. In his opening address, Dr. Groth emphasized the following points:

• WHO’s commitment to improving blood safety and that it will continue to facilitate and further global collaboration and partnerships on this issue.
• WHO’s voluntary collaboration with GCBS participants in accord with the mandate of WHO to collaborate with governments and organizations to enhance blood safety and recognizing the role that GCBS could play, particularly in developing countries.
• WHO’s continued support to any forum that works towards collaboration and that the WHO acknowledges the importance of the various partners that support this goal.

Dr. Kamel Boukef, Director of the Tunisian Blood Transfusion Service welcomed the participants to Tunisia and acknowledged the support of the Tunisian government for convening this meeting.

Professor Anthon Heyns and Dr. Elizabeth Vinelli were elected as Rapporteurs. The agenda and programme of work were reviewed and adopted by the plenary group.

Objectives
The Fourth Meeting of the GCBS was convened with the following objectives.

- Review and adopt relevant reports:
  - 3rd GCBS meeting (November 2002)
  - GCBS Planning Group meeting 2003
  - GCBS Working Group meetings
- Complete, review and discuss the materials produced by the GCBS Working Groups on policy process, quality assessment and assistance for development, and
plasma issues
- Review participants’ reports on collaborative initiatives in the field of blood safety
- Frame new issues for GCBS
- Exchange information on blood safety situation in developing countries - (obstacles/opportunities/ achievements; situation analysis) case studies on Uganda, China, India and Brazil

**Review of relevant reports**

**3rd GCBS meeting report**
The report of the 3rd meeting of the GCBS was adopted with the following revisions:
- Dr. Smit Sibinga made the following amendment to the report, Pg 15, first paragraph, last line should read: “to be used as a model for setting quality standards.”
- Pg 14. “and Pakistan and Indonesia” should replace the last sentence.

Dr Epstein noted that the process for adoption of the annual meeting report was too slow and instead suggested that it should be accepted as soon as it becomes available. He proposed that:
- The report should be circulated by e-mail, with a final date for comments established
- The report be accepted by concurrence electronically which will allow the report to be ready 3-4 months after the meeting.
- The report should then be posted on the GCBS website.

The proposal was adopted.

**Planning Group meeting**
A summary of the report of the Planning Group meeting held in Geneva in June 2003 was presented.

**Discussions**
Dr Epstein suggested forming a Working Group on Administrative Issues.
Dr. Farrugia requested clarification on the process for incorporating new participants. It was explained that interested parties should present a written statement of their global role in blood safety to the Planning Group. On agreement within the Planning Group, the interested party would be invited to attend the general meeting as guests and to present their activities. After considering this presentation, the Planning Group would accept/decline the participation of the interested party and make a recommendation to the plenary group at the general meeting. It was proposed and agreed that this process be applied during the current meeting.

Although there is a need for GCBS to be more involved in implementation of strategies, the Chairman stressed the importance and usefulness of the products generated by GCBS, and emphasized the need to improve the dissemination of these products. The Chairman suggested that the Working Group on Quality and Assistance for Development could examine mechanisms for implementation and advocacy roles.
**GCBS financial report**

Dr Neelam Dhingra, Acting Coordinator, reported that GCBS planning and general meetings had been supported over the last 4 years by the Ministry of Health, Labour and Welfare of Japan. In the current year, WHO had approached additional organizations for support namely the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration, United States of America (FDA). Total contributions from the donor agencies and organizations amounted to US $110,000. The funds were used to support:

- The attendance of 20 participants at the GCBS Planning and Working Group meetings held in Geneva on 9 – 11 June 2003. The budget was US $25,000.
- The attendance of 20 participants at the current general meeting held in Tunis, Tunisia on 2-5 December 2003. The budget for this was US $50,000.

Dr. Epstein acknowledged the substantial contribution of the National Blood Transfusion Service of Tunisia to the present meeting.

**Discussions**

On the issue of WHO providing core funding from its regular budget, Dr. Groth explained that WHO undertakes several activities that have to be covered by the core funding. All other activities usually require extra-budgetary funding.

Dr. Epstein also acknowledged the contribution and support of the Secretariat for the smooth organization of the GCBS meetings and carrying forward the tasks as recommended the GCBS meetings. Dr. Epstein also reminded the general meeting that the financial committee must be activated in order to start working on a budget and to develop fundraising ideas for 2004.

**GCBS logo and GCBS website/web board**

Mrs. Shân Lloyd gave feedback on the advice from the WHO’s legal department that GCBS could have a logo, provided that in using this logo every time, it would be made clear that the GCBS is not a legal entity, but a forum hosted and convened by WHO, and that thus the WHO emblem should always be use more prominently than the GCBS logo. Considering the procedures involved in obtaining approval for an additional logo, and the feedback from another similar alliance facing problems with use of multiple logos, the matter of a separate logo for GCBS has not been further pursued.

Mrs. Lloyd demonstrated the website and gave a brief explanation on the structure and availability of the documents on the site. The structure include the GCBS mission statement, goals, objectives, a list of collaborating parties and participants and has a documentation area with all relevant reports. GCBS participants were requested to make available on the site URLs, appropriate links and relevant documentation. The web board has technical problems within WHO and will be completed later.
Reports of the GCBS Working Groups

Working Group on Policy Process
Dr. Albert Farrugia presented the objectives of the Working Group on Policy. In addition to the Aide-Mémoire: Good Policy Practice, the group will develop guidelines on good policy practice.

Aide-Mémoire and framework for decision making
Dr. Kees Groeneveld presented the latest draft of the Aide-Mémoire stressing that this was still not complete. The Working Group planned to complete the draft prior to the closure of the general meeting. Dr. Valentina Hafner presented the framework for the decision making tool on good policy practice.

The aim of this document is to provide a simple but structured self-explanatory paper that will be useful in the public domain. The document provides an overview of policy-making analysis, setting of priorities within the blood transfusion service, financial/budgetary provision, health outcomes, ethical implications, and social redistribution of resources, systems for technology assessment and priority setting, and criteria for public health spending.

Discussion
Dr. Epstein requested the concurrence of the plenary on the suitability of the proposed framework and expressed the need to include specific recommendations on this aspect. It was agreed that this tool must be kept simple and usable by policy makers.

Dr. Jerry Holmberg added that there was a need to include a risk analysis tool to the decision making process and Dr. Brian McClelland advised that the present tool should also assist policy makers to make the difficult decisions giving an opinion regarding the introduction of certain strategies/policies.

Policymakers Forum
Dr Epstein opened the discussion by expressing the fact that good policy making should not be dependent on economic development as all countries face basically the same problems. It was noted that the current decision process does not lend itself to helping countries to make the right decisions. The goals of the proposed forum are to:

- Discuss the principles underlying and provide advocacy for a structured, policy making process
- Encourage improved international communication on policy making related to blood safety
- Develop a conceptual framework for policy making on blood safety that will be applicable in different economic and political settings
- Share experiences amongst policy makers
- Discuss principles for structured policy making
- Review the draft Aide-Mémoire: Good Policy Practice
- Discuss the concept of an EB resolution to enhance national commitments and support for nationally coordinated blood transfusion services and the use of a structured process of policy making
It is planned to invite 30 senior level representatives from government and non-governmental organizations, participants of GCBS, WHO secretariat and WHO Executive Board. The invitations will be sent as per the protocol from WHO. The estimated cost of the forum is US $20,000 with the probability of self-funding from developed countries. The dates and venue are still to be decided and WHO may consider hosting the forum. It was proposed that GCBS participants could attend the forum as observers.

**Executive Board Resolution**

The aim of the resolution is to strengthen WHA 28.72 with an Executive Board (EB) resolution to highlight the need for a structured approach for a policy-making process. After much discussion it was decided the paper should be rephrased from a resolution to a concept paper for advocacy. The title and content were changed accordingly and it was clarified that participants may use the mechanisms available in their respective organizations to bring this issue forward.

**Working Group on Plasma Issues**

Dr Ana Padilla presented the report on behalf of Mr. Duncan Armstrong who was unable to attend the meeting. It was reported that the Plasma fact sheets have been finalized and approved by ECBS and have also been made available through the WHO web site. The Aide Memoire for the Provision of Medicinal Products derived from Human Plasma is under development. It was emphasised that the work plan of the WG should be revisited on the basis of a well-defined GCBS (strategic) Plan and future direction and that shift focus more to implementation issues.

Numerous efforts are carried out by WHO to strengthen national regulatory authorities through political will and commitment, and by assessing existing functions and by building national capacity to address specific risks. The Department of Essential Health Technologies has redefined its strategy and has developed basic operational frameworks that will be used to assess the situation and achieve the goals of appropriate control systems, standards, good manufacturing practice and strengthening of national control laboratories.

**Working Group on Quality Assessment and Assistance for Development**

Prof. Anthon Heyns outlined the main tasks of the Working Group:
- Develop generic “Minimum Requirements” for blood transfusion services (excluding plasma derivatives) for consideration for adoption by WHO
- Propose how the GCBS could use and maintain the AABB Core Standards
- Develop assessment tools for identifying blood needs at country level

**Minimum requirements**

At the last meeting, the Working Group was tasked with developing generic minimum requirements for blood transfusion services (excluding plasma derivatives) for consideration for adoption by WHO. The final draft of the *Minimum Requirements for Blood Transfusion Services* was developed at a meeting held in Geneva in June 2003. A small task force, Elizabeth Vinelli, Silvano Wendel, Ana del Pozo and Kenneth Clark, was constituted to refine the draft and met in Buenos Aires in July 2003. This product was formatted and partially edited by the Secretariat and further reviewed at the meeting of the Working Group on 1 December 2003. It was agreed that final
changes proposed during the Working Group meeting will be incorporated by the Secretariat and distributed to the participants at the general meeting for final comments which are to be sent by the end of January 2004. Final technical editing will be the responsibility of WHO.

The Working Group will now proceed with the task of developing a guideline on the preparation of regional or national standards based on the *Minimum Requirements for Blood Transfusion Services* for consideration for adoption by WHO.

**Discussion**

The main aim of the document is to address the identified need for countries to be able to access globally accepted standards for their national blood programme. The GCBS Working Group, by preparing this document, will support WHO in its normative work in all Member States. In addition, the document will complement WHO’s Quality Management Programme and could also be used to update similar existing WHO documents.

It was emphasized that aim of the *Minimum Requirements for Blood Transfusion Services* is to enhance and standardize the quality and safety of blood, blood products and blood services globally and to outline the requirements that are considered as basic that a blood establishment must adhere to. Health authorities should view the minimum requirements in the light of national requirements, the national legal and regulatory framework and the impact of local diseases on blood safety. The minimum requirements are globally accepted performance guidelines, based on a review of several nationally and internationally accepted documented standards and requirements related to all aspects of blood transfusion. They may be exceeded, particularly in countries where laws and regulations are already in place. In some instances, it will be necessary to institute a step-wise process to achieve the basic requirements.

It was noted that the foundation of the *Minimum Requirements* is to establish and maintain an appropriate quality management system. The document does not prescribe or define an organizational or reporting structure. It is recognized that several structures are possible. The Working Group members stressed that the document is not an “accreditation document” and should not be regarded as a checklist to measure compliance with accreditation requirements.

**Accreditation**

The Working Group had been tasked with two aspects of accreditation:

- Mechanisms to facilitate progress towards external assessment and accreditation through national or international accreditation organizations.
- Assessment tools that could be used to monitor implementation of the regional or national standards

In the discussion it was noted that tools for stepwise improvement and accreditation should be developed. This could be achieved by identifying national and international accreditation agencies and stepwise auditing programmes could be developed in conjunction with such agencies. It was noted that auditing should not be punitive but
rather supportive and educational and that many countries do not meet the minimum requirements by a large margin largely due to financial and structural constraints.

**AABB Standards**

The Working Group reported on its deliberation regarding the AABB Core Standards. It is the opinion of the Working Group that GCBS is not an appropriate body to take custody of the AABB Core Standards because it is not structured to maintain, use, implement, supervise or monitor the appropriate use of the Standards by other international or national bodies. The Working Group therefore proposed that GCBS enters into discussion with AABB that the Core Standards not be handed to GCBS, but offered to, for instance, the WHO. WHO could then consider, adopt and utilize such Standards. The Core Standards will then be more widely available for programmes in countries that have a need for such standards.

Dr Cees Smit Sibinga clarified and confirmed the position regarding the AABB Core Standards. He stated that the Standards would remain the property of the AABB. It was not a requirement for the GCBS to maintain the Standards. The AABB has however made the Standards available to the GCBS to use and refer to in any documents or programmes that the GCBS may develop.

**Needs assessment model**

Dr Elizabeth Vinelli described the progress with the blood needs assessment model developed by Professor Salmi and Dr Brian McClelland. A pilot test of the model is being initiated in selected South American countries - Brazil at hospital level, Argentina on a provincial level, and Honduras at national level. The model of the pilot study is based on the earlier developed theoretical as well as a recently simplified model. The objectives of the pilot study are to validate the simplified model. The time frame for the pilot study is 12 months and will include steps to develop the protocol, establish appropriate databases, collect the information, and start the implementation. The feasibility of the strategies will then be evaluated. The participants will use the outcome of this evaluation to make recommendations and the model will be modified as needed. The pilot study will be implemented after the appointment and training of experts. The major users of blood will be defined. A questionnaire for the Delphi model will be prepared and the model evaluated. Implementation will start February 2004 with a site-visit from the group coordinator in July 2004. The final report will be published in January 2005.

**Discussion**

It was not agreed to incorporate the simplified model developed in Denmark due to the difficulties in validating a new model. Funding for the pilot project was to be clarified by WHO.

**Reports from Collaborating Organizations on their Roles and Activities in relation to the GCBS**

**World Health Organization**

Dr Steffen Groth informed participants of the two main approaches used by WHO/EHT to support Member States. Firstly WHO supports transfer of technologies
to countries, and secondly, develops standards, guidelines, and training materials that may be used in such countries.

The WHO has developed a ‘Basic Operational Framework’ that contains all the basic requirements for each of the technologies covered by EHT. The WHO documents that support this tool are listed and will be available on the web site by end December 2003. It was indicated that documents developed by GCBS may be included. WHO aims to complete all supporting documents for this operational framework within the next few years. These documents will give guidance on standards, norms and the level of these countries should aim at achieving.

Dr Neelam Dhingra described the activities of the WHO Blood safety programme, stressing the need for information to be able to assess the equitable availability of blood. WHO is approaching this by classifying countries into high, medium and low categories of the Human Development Index (HDI). It is shown that small amounts of blood are collected in low HDI countries (3%); and most is collected in high (61%) and medium HDI countries (36%). It is of special interest that 61% of blood collected is available to only 19% of the world population. There is a close relationship between the HDI and donations/1000 population. Reliance on family/replacement donors is still high in developing countries. Collection of blood only from voluntary non-remunerates donors is still not universal and there is a higher prevalence of markers for HIV, HBV, and HCV in developing countries that are reliant on family/replacement donors.

Similarly screening for TTI's can be related to the HDI with lower coverage more common in low and medium HDI countries in comparison to high HDI countries. 19% of developing countries do not screen for all four of the recommended TTI markers – HIV, Hepatitis B and C and syphilis. Compounding the problem is the fact that only 43% of countries have appropriate quality systems and a regular supply of reagents. Use of blood components is higher in the developed world - it is reported that usage of whole blood is 15 times higher in developing countries when compared to developed countries.

The WHO Blood safety programme has developed its strategic objectives to achieve its mission. These objectives are supported by WHA resolutions spanning the period 1975 – 2002. The goals have been achieved by support for development of national blood programmes, publications, collaborations and partnerships, the Quality Management Programme, Safe Blood Donor Programme, programmes to facilitate effective testing, collection of safe blood and appropriate manufacturing practices for blood processing. WHO has also been involved in the training and motivation of staff, the blood cold chain, equipment management, and good transfusion practice.

Discussion
It was emphasized that the WHO has initiated a programme on a major scale. GCBS Quality Assessment Working Group will ensure that work products such as the needs assessment model are linked with WHO’s programme.
ICCBBA
Dr Edwin Steane presented information regarding the role of ICCBBA in global blood safety with emphasis on ISBT code 128. Dr Steane noted the subtle but distinct difference between safe blood and safe blood transfusion, the latter of which has been ‘ignored’ to a large extent. The ISBT code 128 is a globally used donation event numbering system that has been developed over 5 years. It currently has 21 data structures that support stored tissues; blood components; stem cells; and (in draft) plasma for further processing. The system is technology independent, flexible and has a unique data identifier. The donation number, ABO/Rh group, product code, and expiry date and time, are given in four quadrants. There is provision for special testing, container manufacturer ID/catalogue number, and container lot number. There is also provision for product coding (8 characters); five for class, a modifier and added attributes. Adoption of ISBT code 128 has often resulted in reorganization of the blood transfusion service.

ICCBBA offers:
- No fee for non-computerised collection systems in developing countries
- Discounted licensing fees for developing countries
- Full participation in the further development of the ISBT 128 standard
- Assistance and help in using ISBT 128 to achieve increased safety and efficiency in blood collection and transfusion

Discussion
It was agreed that ISBT code 128 is an expensive system, but that it should be regarded as an investment in blood safety. Although it has not been implemented in non-computerised environments, this is possible. The data element has been internationally accepted therefore the system can be transported to a computerized system at a later stage.

Council of Europe
Ms Alina Tatarenko presented information on the structure, functions and activities of the Council of Europe (CoE) which represents 45 member states and has two relevant committees - Committee of experts on Blood Transfusion (SP-HM) and on Safety and Quality Assurance in Blood Transfusion Services (BTSs) (SP-R-GS). The CoE is a leading European organisation in the area of blood. It concentrates on non-commercialisation of substances of human origin, voluntary, non-remunerated blood donation, self-sufficiency, quality and safety of blood and blood products, protection of donors and recipients. These principles are implemented by studying the ethical, legal and organisational aspects of blood transfusion with a view to ensuring quality, increasing availability of blood, avoiding wastage of human substances, ensuring optimal use and analysing the possible ethical and organisational impact of new scientific developments.

The CoE uses various legal tools such as conventions, recommendations and reports. It offers recommendations on the protection of the health of donors and recipients; on the responsibilities of health authorities in the field of blood transfusion, on the preparation, use and quality assurance of blood components; on the introduction of pathogen inactivation; on the hospital's and clinician's role in the optimal use of blood; on the prevention of the possible transmission of vCJD by blood transfusion, etc. The current
work includes a study on cellular immune therapies; a draft recommendation on teaching transfusion medicine to nurses; gathering and analysis of data on collection and use of blood components in Europe, and summaries of product characteristics for the optimal use of blood.

The CoE assistance activities include training seminars, expert advice on improving/ re-structuring BTS, etc. The main CoE partners in GCBS include: 1) European Union: CoE contributed to the EU Directive 2002/98/EC on “Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components”, as well as to the Directive regarding technical requirements for blood and blood components; and 2) WHO: support, sharing data and information, joint assistance activities.

The CoE has produced a “Guide to preparation, use and quality assurance of blood components” which is updated annually (the 10th edition to be published in January 2004) and has been translated into more then 20 languages. The Guide has become a “golden standard” for blood safety in Europe. The EU Directives had been largely based on the provisions of the Guide. Moreover, it was adopted in Australia as a national legislation.

**Discussion**

It was pointed out the CoE provides guidelines and not directives to its members. The CoE expertise is not limited to Europe and can be shared and applied globally. The GCBS, WHO, and any interested countries and organisations are invited to use the CoE recommendations (and the Guide in particular) which contribute to assuring the blood quality and safety.

**International Association of Biologicals (IABs)**

Dr Girish Vyas reported on the IABs, a scientific society established in 1955 with its headquarters based in Switzerland. The aim of the society is to promote research, development, characterisation, standardisation and quality control of medical biological products. IABs also sponsors scientific meetings, and facilitates development of new technology. It publishes the journal: “Biologicals” and issues a regular newsletter.

The IABs Committee on Blood addresses the following areas:

- Blood group serology
- Screening for infectious disease
- Plasma fractionation
- Coagulation factors
- Components
- Pathogen inactivation

**Discussions**

During the discussion particular reference was made to training and academic education and role of IABs in offering structured training courses. Information was also given by Dr Cees Smit Sibinga on an institute which has been established at the University of Groningen for the education and training of the leadership in blood transfusion. The programme culminates in a Masters degree after two years and a
dissertation - Management of Transfusion Medicine. The programme is e-learning based and comprises 15 modules.

African Society for Blood Transfusion and Blood Safety (AfSBT)
Dr Banji Adewuyi presented the objectives of the AfSBT as follows:
- Promote the highest level of blood transfusion in Africa
- Facilitate exchange of information
- Advocate safe blood programmes in Africa
- Resource organization for policies on blood transfusion practice
- Promote regional collaboration in Africa

The structure of the organisation is a general assembly, council, executive council and officers, financial management team, and a general membership. AfSBT was formed in response to several factors that contribute to poor blood safety in Africa:
- No nationally organized blood programmes
- Absence of strategy for regular voluntary non-remunerated blood donors
- Insufficiency of the blood supply
- High prevalence of TTIs
- Poor technical capacity to detect TTIs
- Poor facilities for component preparation
- Inappropriate use of blood

The role of ASBT in promoting blood safety as being primarily:
- Advocacy to government
- Exchange of information
- Education
- Setting standards
- Training
- Research

There are however many constraints to achieving this mainly lack of finances, poor communication and a harsh operational environment.
Dr Adewuyi urged participants to consider attending the up-coming AfSBT congress in Lagos, Nigeria in September 2004 and the co-hosted ISBT Congress to be held in Cape Town in 2006.

Discussion
In the discussion it was noted that national economy and the general health care infrastructure such as available hospital beds have a clear relationship with the amount of blood required and even prescribed. It was noted that language diversity in Africa made collaboration difficult, and although the African Union was active this was more on a political rather than health front.

Centers for Disease Control and Prevention (CDC)
Dr Kenneth Clark outlined a new programme, the Global AIDS Programme (GAP) of the CDC. The programme is the contribution from the United States of America to the international partnership against HIV/AIDS. The budget allocated to GAP is US$ 35 million per annum which will be mostly dedicated to country budgets with priorities determined by the country offices in collaboration with ministries of health.
Blood safety activities of the CDC include the following areas:

- Infrastructure of blood transfusion services
- Low-risk donations
- Decrease in the demand for transfusion
- Quality assurance
- Training for physicians

CDC country projects on blood safety include Cambodia, Democratic Republic of Congo, India, Kenya, Uganda and the United Republic of Tanzania.

Recently announced is the *Emergency Plan for AIDS Relief* of President George W. Bush. The plan includes rapid strengthening of blood transfusion services in 14 designated countries in Africa and 2 in Caribbean. The total funding is $52 million for 5 years. The programme will also support experienced organizations to provide technical assistance to these countries. The focus of the strengthening will be on infrastructure, collection and processing, testing, and clinical use of blood.

The programme is based on a cooperative agreement and was announced on 1 December 2003 with applications being open for 3 months, and an award date of 25 March 2004. Country-specific submissions must be by the national blood transfusion service or the Ministry of Health. Public or private organizations and universities are also eligible to compete for grants to provide technical assistance. The CDC will assist in refining operational plans. The details of the programme are available in the US Federal Register and application instructions are available online.

**Discussion**

It was noted that the current CDC emergency programme has limited availability. There, however, may be additional support for infrastructure building. Twinning between countries will be encouraged. Long-term sustainability of programmes would be considered favourably.

**Health Canada**

Dr Peter Ganz outlined the history and structure of the Canadian blood system. The Canadian Blood System was restructured because of the slow response to the AIDS epidemic. The Krever Commission clearly stated the responsibility for blood safety and the role of the regulatory authority. A new national blood authority was established in 1996, based on the 50 recommendations, 17 of which were to the regulatory authority that emanated from the Krever Commission. The public health branch is responsible for surveillance, identifying vulnerable populations, risk assessment and conducting outbreak investigations. The Service is structured to function on the basis of risk management and recognizes the importance of external relationships with stakeholders.

In its work in the international field, Health Canada has been involved in:

- Training
- Providing expertise in policy and regulatory framework development
- Development and use of risk management tools
- Development of international standards for components and blood products
- Novel safety initiatives to reduce risks

Health Canada have a long history of partnerships to foster blood safety. Canada therefore can share its experience with many of the challenges faced by other countries. The Service is currently cooperating with Australia, Cuba, United States of America, and countries in Asia, Latin America and the Middle-East.

Discussion
During discussions, Dr Ganz pointed out that the system is not 100% national which is hampering the development of national minimum requirements. However, the system is in a sense national as products with similar standards can be exchanged. In addition to changes in the structure of the blood supply system, a decrease in the blood donor base was observed following various HIV incidences/episodes. In response to a query from the floor, Dr Ganz reported that the cost of providing blood is about $1 billion to collect and process about a million units of blood.

International Consortium on Blood Safety (ICBS)
Dr. Mohammed El-Nageh reported on how the ICBS, founded in 1998 and with funds received from the Gates Foundation, facilitates the availability of a sustainable supply of affordable, high quality reagents for developing countries, avoiding duplication and maximizing resources. ICBS activities complement national and international efforts. The current projects involve establishing master panels (HCV, HBV and HIV, if deemed necessary) and the supply of reagents for the countries. The panels are used with reagents that are purchased from the market to ensure end-product results. Country projects are undergoing in India, Indonesia, Vietnam, Paraguay, and countries in Africa and Central Asia. The projects are phased out over the course of 3 years with signed memoranda of agreement with the government.

Plasma Protein Therapeutic Association - SOURCE (PPTA)
Mr. Jan M. Bult reported on the PPTA Source, an association founded in 1974 to provide advocacy and standards setting for source plasma collectors. Its membership includes 350 collection centres in the United States of America and 50 collection centres in Europe, with a donor population between 750,000 – 1,000,000 each year. There has been a decreasing trend of collections over the last two years. The aim of PPTA is to foster the collection of safe and high quality plasma from healthy donors. This is done through a strict international quality programme which includes qualified donor standards (first time donors are not used), on-going training for the participating centres, a national donor deferral registry for US donors, screening for drug abuse, a fully compliant quality, facility standards, monitoring of viral marker rates and quality assurance standards (verified through inspections). PPTA believes emerging diseases are a real risk to the availability of plasma world-wide; self-sufficiency is an understandable concept for blood for transfusion but an unrealistic concept for plasma for fractionation.

European Blood Alliance (EBA)
Dr. William Murphy reported that the EBA was formed as a result of legislation in the European Union in 1996. Its objective is to address the issues that are important to the national blood transfusion centres in the operating states including:
- Advocate medical and ethical principles
- Support human and technical resources
- Establish joint positions and foster information exchange (networking) between the executive membership

EBA has worked in line with its members respect for the principle of voluntary non-remunerated blood donation, to ensure that the Blood Directive incorporates the principle of voluntary non-remunerated blood donation, is centred on core directives and fundamentals and that the technical details were left in a separate procedure to avoid inappropriate detail. Its main achievements have been to be recognized and accepted as a force by the European Union in the development of the Blood Directive, its growing membership, establishing an effective network co-operation and international cooperation. EBA sees its major challenges for the future is to help European countries, including non-EU members, to implement the Blood Directive, and streamlining the alliance.

International Society for Blood Transfusion (ISBT)
Dr Paul Strengers reported that the main aim of the ISBT is to establish mutually beneficial working relationship with relevant international and national professional societies, and with intergovernmental and non-governmental organizations, in order to disseminate knowledge of how blood transfusion medicine and science may best serve the patient. Education and training is also an important component of ISBT activities, including round table conferences, a database of potential facilitators, support for European School of Transfusion Medicine and working parties on several topics. A “Friends of ISBT” Foundation is being formed in 2004 in order to obtain additional funding for its activities. Funding will be dispensed on budget proposals and there will be annual auditing. The focus for the future is the study of transfusion medicine as a science, the promotion of voluntary non-remunerated blood donation, increasing its membership and the collaboration with WHO and other partners in the implementation of educational programmes.

International Trauma Anesthesia and Critical Care Society (ITACCS)
Dr. Maureen McCunn reported on the ITACCS which is an international non profit scientific foundation and professional association that is active in more than 40 countries. In response to the fact that road traffic accidents will become the third cause of death over the next decade, the ITACCS aim is to issue multiple publications, books and journals, in addition to the information and materials available on its web site (www.itaccs.com). A guideline on the management of patients with massive trauma can be downloaded from the web. Dr. McCunn presented strategies and data on the management of patients with severe trauma including survival rates according to number of blood components. It was stressed that alternatives to transfusions are being developed and assessed. In line with the concern over road traffic accidents and in keeping with World Health Day 2004, Dr McCunn added “both airbags and blood-bags save lives!”

World Federation of Haemophilia (WFH)
Mr. Miklos Fulop reported on the WFH which is a non-profit organization with 101 member associations and its headquarters in Montreal, Canada. Its mission is to introduce, improve and maintain care for people with haemophilia and related
bleeding disorders around the world. WFH indirectly represents at least 105 thousand males with Haemophilia A and 28 thousand with Haemophilia B. Activities include country programmes, medical training fellowships, twinning medical centres, twinning patient organizations, humanitarian aid, haemophilia organization development, supporting availability of products, medical congresses and a Global Alliance for Progress. Some of the challenges that the organization is helping to overcome are unavailability of diagnosis, low priority for haemophilia as seen by governments, and the high cost of replacement therapy. New programmes of care will be implemented in Egypt, Georgia, Mexico and the Philippines. Preparatory work has been initiated in Armenia, Jordan, People’s Republic of China, Russia Federation, Saudi Arabia and Thailand. Improved programmes of care will be achieved through training, data collection, product donations, fostering government and support to patient organizations and clinicians. Safety and supply issues were discussed including emerging diseases, inhibitors and cost issues. A possible setback has been identified by the organization in that WHO is considering removing Factor VIII and Factor IX from the list of essential medications.

Framing new issues for GCBS
A breakout session was held to develop new issues for possible consideration by GCBS participants. The participants, and particularly the Working Groups, were asked to consider what recommendations should emanate from this general meeting. It was suggested that:

1. Consideration should be given to how work products should be used and materials disseminated.
2. GCBS participants should consider the issue of “injury to blood donors” as an important topic that has been neglected.

In addition to the planned break-out groups, it was proposed and agreed upon to have a further group to review mechanisms that may foster international collaboration.

Reports were received from the breakout groups as follows:

New Technologies to Improve Blood Safety
The group was tasked with examining the subject:
Approaching new technology to improve blood safety: cost-effectiveness
- Pathogen inactivation
- NAT
- Leukocyte reduction

The current pathogen reduction technologies make available suitable procedures for platelets and plasma labile components (subject to the country’s regulatory authority). However, the technology is not yet available for red cell products and it is anticipated that this will only be introduced in about 5 years. Thus despite some test procedures, such as NAT, which potentially could be dropped after the introduction of pathogen reduction methods, since these methods are not fully available and licensed to all laboratories for all components, this will result in no change in current practice.

It is also a consideration of the breakout group that probably new emergent technologies e.g. radio frequency identification (RFID) chips may be available in the
next 5 years, will justify countries to hold on a little until a dramatic and effective change is perceived that will impact significantly on the safety of the blood supply. There is still some doubt whether the technology should be implemented for selected recipients.

Different leukocyte reduction processes are available (buffy coat products, leukocyte filters, both in-line and bedside) providing variable benefits for febrile reactions, platelet allo-immunisation and refractoriness, or removal of cellular associated viruses e.g. CMV and HTLV I/II. There are, as yet, unknown and unproven benefits for immuno-modulation effects on recipients and prion transmission prevention.

Managing the Interaction of Blood and Plasma Collection
Several issues were addressed by the group including:

**Needs assessment; clinical use, dynamics of health care development.** The process begins with the identification of needs usually beginning with calculations for cellular needs. This should then assist with calculations for the need for source plasma. This is based on diagnosis e.g. the need for factor VIII can be calculated or the need for red cells for Thalassaemia patients, and the improvement in quality of care as affordable. The decision that needs to be made consequent to improved diagnosis is at what level the response should be for the treatment that is required such as use of cryoprecipitate versus use of recombinant factor. What ever decision is made, the product used must be safe.

One other important consideration is the driving force behind the collection of plasma e.g. factor VIII or IgG or albumin. Once the decision is made, strategies for raising yield of either recovered or source plasma must be initiated. The important issue to decide on in this case is that of deciding whether or not the programmes for the collection of blood cells and plasma are run independently. In addition, there must be a concurrent improvement in utilisation of the plasma and of blood cells.

**Infrastructure; procurement system, donor system.** It is important to examine the impact of the current blood system infrastructure on the availability of plasma and cells. It is also essential to insure the necessary logistics and planning and storage capacity. This will include aspects such as building or renovating your own fractionation plant. Alternatively purchasing products from abroad may be the best solution.

**Quality issues.** Various issues need to be examined such as the problems with recovered plasma because of the lack of correct and controlled procedures in the blood banks. In addition, there is a need to develop standards and regulatory competence. Quality is related to the ownership of blood banks, and the coherence of national legislation for both plasma and cell collection including assurance of no direct competition about the donors.

**Education.** It is essential that all involved in the supply and use of plasma are well-educated and trained.

The group also examined various priorities for different HDI categories of countries with particular emphasis on the economical situation in each individual country. It was proposed that:
• Low HDI countries should focus on whole blood collection.
• Medium HDI countries although well-equipped for the separation of whole blood into components encounter the problem of having excess plasma which may not be of sufficient quality or quantity for further processing.
• High HDI countries can select any of the options provided they are self sufficient.

**Other aspects to consider:**
• Risk assessment with particular reference to the type of donors and the consequent impact on product quality.
• Property issues and pricing of end products -- might lead to decrease in use?
• International exchange of plasma and blood.
• Documentation, batch sizes. Number of (new) products.

**Education and training in blood banking and transfusion medicine**
The group recognized the need for training in this area with particular reference to formal training programmes. Several steps in this process were identified:
• Need assessment should be done to establish the audience and topics.
• Resources (human, financial, facilities, materials) need to be secure.
• Identification of leadership and motivation to initiate the strategy.
• Securing government support to ensure the appropriate participants are selected, development of curricula and the overall implementation of the training programme.
• Training capacity such as development of curricula and formal courses need to be established. Links could be made with universities, training institutions and WHO Collaborating Centres.
• Web based training programmes as well as twinning should be considered.

The group made the following recommendations:
• Authorities need to be sensitised to education in blood transfusion
• Develop a comprehensive database for teachers, teaching institutions, training courses
• Mechanisms of training: workshops on training needs and assessment, national level courses, international collaboration

It is necessary to improve dissemination and awareness of the materials already available and to separate the strategies that address education and training.

**GCBS strategic issues**
This break-out session dealt with GCBS strategic issues. It was recognised that a strategic plan is needed, but that such a plan could, of course, not be developed in a short break-out session. Instead, the group defined following gaps in the strategic activities of the GCBS:
• Lack of mechanisms of effective support to countries in addition to existing WHO mechanisms
• Need for a role as a clearing house to matcher of needs and “donors”. It is necessary to establish what resources are available and to minimise duplication of efforts.
• Deficiencies of communications including electronic and non-electronic. NGOs provide tools for communications through their publications.
• GCBS does not collaborate with funding organizations who should also be invited
to participate in GCBS meetings.
- Insufficient mechanisms for self-evaluation. There is no way to document the collaborations that happen outside of the GCBS forum.
- Clinical use of blood has been left behind. It is important to improve the engagement with the users in the process of identifying good clinical practice.
- The possibility of creating unrealistic expectations with regards to GCBS work products.

**Selected Reports on Blood Safety in Developing Countries**

**Uganda**

Dr Peter Kataaha presented information regarding blood safety in Uganda.

**Situation Analysis**

A current process relating to safe blood started in 1989. At this stage there was no coordinated blood service and no voluntary donor programme. Blood was not tested for HIV, hepatitis or syphilis. The blood programme was initiated by WHO and funded by the European Union and the Government of Uganda.

Currently the BTS has been reorganized and has been rehabilitated to a large extent. The Headquarters is at the Nakasero Blood Bank and there are 5 regional blood banks supplying blood to 150 health units in the country. About 103,000 units are issued per year; 95% blood procured from voluntary non-remunerated blood donors. Replacement donors have been phased out gradually. All blood is tested for HIV, HCV, HBV and Syphilis. Prevalence for HIV ranges from 0.7%-6.6%, which contrasts to prevalence of 15% in 1989. Prevalence for HBsAg ranges between 2-13%.

**Achievements**

- Effective nationally coordinated and organized BTS
- Effective well-organised departments including blood donor recruitment, laboratory services and support services.
- Blood donor pool provides over 100,000 units per year
- All units are tested prior to transfusion
- HIV seroprevalence amongst blood donors has been lowered from 15% to 2.6%
- Quality assurance programme has been initiated

**Opportunities**

- Government commitment and existing policies are conducive to safe and sufficient blood
- Community supports voluntary blood donation
- Good international collaboration with EU, American Red Cross, CDC and others
- The BTS is a recognized essential institution for the provision of services for patients
- Good public image
- Service in the process of being made autonomous, an Interim board is already in place
- An international training programme is made available to the BTS
Obstacles and threats
- Periodic blood shortages
- Expanding health care system
- Lack of infrastructure
- Old, broken down equipment
- Difficulty of BTS to retain key staff due to unfavourable conditions of service
- End of funding and no assurance of full government support
- High HIV prevalence indicating high residual risk
- Endemic infections especially Malaria and HIV, AIDS
- No HCV testing

The possibility of introducing screening for HCV is slim, even if screening for syphilis could be dropped; this would however be bad practice because the prime value for syphilis serological screening is its value as a surrogate maker.

Efforts are being made to increase repeat donors, which currently total only about 25% of total donors.
- Most funding is coordinated through the Health Secretary
- There is no cost recovery system and long-term sustainability is uncertain. Cost of a unit of blood ranges $35-$40
- EU donates approximately 700,000 Euro/year, but this may not be continued

India
Dr Zarin Bharucha presented information regarding blood safety in India.

Situation Analysis:
Blood is considered a drug and is regulated through the Drugs and Cosmetics Act, 1940. The blood system in India is a decentralized, fragmented, and hospital-based system. About 45% of the blood banks are governmental, 12% voluntary, 20% private, and 23% commercial. There are approximately 1800 blood banks in the country, only 18% have computerized systems. About 3.5 million units are collected annually. About 3.5/1000 of the population are donors; of these only 5-10% are repeat donors. The blood is obtained mostly from a replacement system, autologous donations are rare, and directed units are preferred because these are viewed safer by patients and physicians. Only 20% of blood units are separated into components. There are no standardized donor selection or self-exclusion procedures.

Officially 100% of donations are screened for transmissible disease but little is known of what happens in rural areas; it is evident that there are several problems with screening of blood. Unnecessary use of blood transfusion is prevalent. Records are incomplete and incorrect.

In January 1998 paid donation became illegal and it became law that all blood banks must be licensed. State and National Councils were formed and in 2003 an action plan to identify priorities and objectives was formulated. Programmes to increase voluntary blood donation have been launched and universal and uniform blood donor screening is to be introduced.
The middle class is the major source of blood; males predominate and most donors are aged 18-30 years. The prevalence of HIV ranges from 0.04 – 1.4%; HBsAg 0.2 – 5.9% and HCV 1 – 1.4%.

Thalassaemia is a major problem and it is estimated that there are 30 million carriers. Awareness for safe blood has increased. Haemovigilance programmes are poorly accepted and understood. Transfusion-associated AIDS cases as a percentage of all AIDS cases have decreased steadily from 8.85% in 1996 to 3.27% in 2001.

Achievements:
- Quality management training has been introduced, licensing of blood banks has been strengthened, and a standardized donor history questionnaire is in place.
- All blood banks will be linked with centres that will provide confirmatory testing and counselling to seropositive donors.
- Clinician awareness programmes on the appropriate use of blood have been initiated and hospital transfusion committees are being organized.
- There has been one plasma fractionation plant in India and this recently has been closed due to administrative problems. The country is now dependent on imported plasma derivatives.
- Transfusion medicine is a recognized medical specialty.
- Punitive actions for masquerading paid donors are being considered.

Despite all these achievements and the introduction of appropriate programmes, there are still enormous challenges.

Brazil
Dr Silvano Wendel outlined the problems and challenges in a country with a population of 177 million, some 6400 hospitals, 620 blood collection sites, and the collection and processing of 4 million donations per year. Brazil is classified as a medium HDI country. There are huge differences in the living standards: from highly developed centres to population groups with almost no access to any health service. Some 59% of health expenditure is in the private sector. There is a non-equitable distribution of health care.

Overview of the blood services
- National guidelines are available but should be revised,
- The Government is responsible for 56% of BTSs.
- There is a national blood committee, a national quality system, a designated budget for blood transfusion, and the system of stock control is inadequate.
- Some 47% of donations come from voluntary non-remunerated donors; there are no paid donors.
- Counselling services for blood donors and confidentiality must be strengthened.
- Basically 100% of units are tested for HCV, HIV, HBsAg, anti-HB core, syphilis and Chagas disease.
- NAT testing has been introduced only in 7 BTSs (approximately 100,000 units/year total).
- Discard rate after testing is 8.3%.
- Of all the blood banks in the country: 26% are regional, 45% hospital based and 29% are collection units. There are 64 collection facilities in the Amazon region.
Prevalence and incidence of transfusion hazards is unknown but over the last two years a haemovigilance programme has been started. Monthly reports are sent to the Ministry of Health every month. Transfusion-transmitted HIV has decreased dramatically over the last decade; in 2002 only 2 cases were reported.

**Major Obstacles:**
- Lack of political continuity, limited human resources, and the blood budget is allocated by funds that become available in an environment of low per capita health expenditure.
- A huge amount of resources (83 million in local currency) are spent on imported plasma derivatives, and 90% of locally procured plasma is discarded.
- The situation is similar to that faced by other developing countries: the government contributes both to the solution and to the problem. It is recognised that identifying the appropriate model for future development of the blood system is a key element to make it possible to successfully improve the Brazilian blood system.

The meeting closed at 1400 hours 5 December.
WORLD HEALTH ORGANIZATION  
ORGANISATION MONDIALE DE LA SANTE  

4th Plenary Meeting of the Global Collaboration for Blood Safety (GCBS)  
2-5 December 2003, Tunis, Tunisia  

Programme of Work

Tuesday, 2 December 2003

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<tr>
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<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>08.45</td>
<td>Registration</td>
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</table>
| 09.00 | Welcome and introduction of participants | Dr Jay Epstein, Chair  
         | Dr Jukka Koistinen, Vice-Chair |
| 09.15 | Welcome address from WHO | Dr Steffen Groth |
| 09.25 | Welcome address from National Blood Centre, Tunisia | Dr Kamel Boukef |

**Theme 1: GCBS Administrative Issues**

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<tr>
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<tr>
<td>09.30</td>
<td>Adoption of the agenda and programme of work, objectives of the meeting</td>
<td>Chair/Vice-Chair</td>
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<tr>
<td>09.50</td>
<td>Adoption of report of the GCBS plenary 2002 meeting</td>
<td>Chair/Vice-Chair</td>
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<tr>
<td>10.10</td>
<td>Review of report of the GCBS planning 2003 meeting</td>
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<td>10.30</td>
<td>Coffee/tea break</td>
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<tr>
<td>11.00</td>
<td>GCBS finances</td>
<td>Dr Neelam Dhingra</td>
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<tr>
<td>11.15</td>
<td>GCBS website and logo</td>
<td>Mrs Shân Lloyd</td>
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**Theme 2: GCBS Working Group Reports**

**Working Group on Policy Process**

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<tr>
<td>11.30</td>
<td>Overview and report of the group</td>
<td>Dr Albert Farrugia</td>
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<tr>
<td>12.00</td>
<td>Aide-Mémoire: Good policy practice</td>
<td>Dr Kees Groeneveld</td>
</tr>
<tr>
<td>12.15</td>
<td>Framework for decision making</td>
<td>Dr Valentina Hafner</td>
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<tr>
<td>12.30</td>
<td>Progress towards a policymakers’ forum</td>
<td>Dr Jay Epstein</td>
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<tr>
<td>13.00</td>
<td>Lunch Break</td>
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<td>14.00</td>
<td>EB Resolution: concept paper</td>
<td>Dr Jay Epstein</td>
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<tr>
<td>15.00</td>
<td>Discussion</td>
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<td>15.30</td>
<td>Tea/Coffee</td>
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**Working Group on Plasma Issues**

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<th>Speaker(s)</th>
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<tr>
<td>16.00</td>
<td>Overview and report of the group</td>
<td>Dr Ana Padilla</td>
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<tr>
<td>16.30</td>
<td>Work Products: Aide-Mémoire, Fact Sheets</td>
<td>Dr Ana Padilla</td>
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<tr>
<td>17.00</td>
<td>Discussion</td>
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Wednesday, 3 December 2003

Working Group on Quality Assessment and Assistance for Development

08.30 Overview and report of the group Dr Anthon Heyns
09.00 Work product: ‘Minimum Requirements for Blood Transfusion Services’ Dr Silvano Wendel
09.20 AABB core standards Dr Anthon Heyns
09.40 Pilot scheme of the 'Needs Assessment Tool' Dr E. Vinelli
10.00 Discussion
10.30 Coffee/tea break

Theme 3: Reports and Workplans of Collaborating Organizations/Institutions/Agencies

11.00 WHO Blood Safety Programme Dr. Neelam Dhintra
11.40 Role of ICCBBA in developing countries Dr Edwin A. Steane
12.20 CoE - role in relation to GCBS Mrs Alina Tatarenko
13.00 Lunch
14.00 Role of International Association of Biologicals Dr Girish Vyas
15.20 Coffee/tea break
15.50 Role of African Society for Blood Transfusion in improving blood safety (AfSBT) Prof. Banji Adewuyi
16.30 CDC - international blood safety activities Dr Kenneth Clark
17.10 Health Canada - role in relation to GCBS Dr Peter Ganz
17.50 Discussion

Thursday, 4 December 2003

08.30 ICBS - role in relation to GCBS Dr Mohamed El-Nageh
09.10 PPTA source - role in relation to GCBS Mr Jan M Bult
09.50 EBA - role in relation to GCBS Dr William Murphy
10.30 Tea /coffee
11.00 ISBT- working together for developing countries Dr Paul Strengers
11.40 Blood needs in the treatment of vehicular injury - International Trauma Anaesthesia and Critical Care Society Dr Maureen McCunn
12.20 WFH - role in relation to GCBS Mr Miklos Fulop
13.00 Lunch
14.00 Discussion on identification of joint projects and activities amongst participating organizations/agencies/institutions Plenary
15.30 Coffee/tea break
Theme 4: Framing New Issues for GCBS

16.00 Breakout groups
1. Approaching new technology to improve blood safety: cost-effectiveness
   • Pathogen Inactivation
   • Nucleic Acid Testing
   • Leukocyte Reduction
2. Managing the interaction of blood and plasma collection
3. Education and training in blood banking and transfusion medicine: Obstacles and opportunities

Moderators
Dr Brian McClelland
Dr Cees Smit Sibinga
Dr Neelam Dhingra

17.00 Presentations of the breakout session
17.45 Discussion

Friday, 5 December 2003

Theme 5: Blood Safety in Developing World

09.00 Blood safety in Uganda (obstacles/opportunities/achievements; situation analysis)  Dr Peter Kataaha
09.30 Blood safety in India (obstacles/opportunities/achievements; situation analysis)  Dr Zarin Bharucha
10.00 Blood safety in Brazil (obstacles/opportunities/achievements; situation analysis)  Dr Silvano Wendel
10.30 Coffee/tea break
11.00 Discussion

Theme 6: Recommendations and Next Steps

11.30 Development of draft recommendations  Plenary
13.00 Lunch
14.00 Future perspectives and plans  Plenary
14.30 Summary and Conclusions  Chair/Vice-Chair
14.35 Next steps for WHO as the GCBS secretariat  Dr Neelam Dhingra
15.00 Closing remarks  Chair/Vice-Chair
### List of Collaborating Parties

<table>
<thead>
<tr>
<th>Status of participation</th>
<th>GCBS participant</th>
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<tbody>
<tr>
<td>Organization/Institution / Association represented</td>
<td>Nominated member</td>
</tr>
<tr>
<td>Agence Francaise de Sécurité Sanitaire des Produits de Santé (AFSSAPS)</td>
<td>Dr Olivier Balland, Chef du Département de Sécurité sanitaire, 143/147, Bd. Anatole France, 93285 Saint Denis CEDEX, France</td>
</tr>
<tr>
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