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**Report of the Fifth General Meeting of the**

**Global  
Collaboration  
for  
Blood  
Safety**

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**GENEVA, 10-12 November, 2004**

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**Blood Transfusion Safety  
GCBS Secretariat  
Department of Essential Health Technologies  
World Health Organization -HQ  
Geneva**

# Executive Summary

## Introduction

Recognition of the need for a Global Collaboration for Blood Safety (GCBS) was first endorsed by 41 countries represented during the Paris AIDS Summit in 1994 and adopted by the Forty- Eighth World Health Assembly as WHA resolution 48.27 (1995), by all 191 WHO Member States prioritizing the need for Global Collaboration to improve blood safety. The Global Collaboration for Blood Safety is a voluntary partnership of internationally recognized organizations, institutions, associations, agencies and experts from developing and developed countries sharing the expertise, identifying problems, seeking solutions and working towards the common goal of global blood safety as equal collaborative partners.

Since the year 2000, four annual general meetings of the GCBS have been held. The fifth plenary meeting of GCBS was held at World Health Organization-HQ in Geneva, Switzerland on 10-12 November 2004. 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 67 participants from GCBS collaborating organizations, individual experts, WHO Regional Advisers for Blood Safety and Blood Transfusion Safety team and other staff members 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 2004

1. The Planning group and Working groups meetings (May and Nov 04) and GCBS General meeting (Nov 04) were held.
2. The GCBS 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 fourth GCBS General meeting was approved.

## Summary of discussions

It was decided that the Planning Group will continue to plan for the GCBS activities for the year 2005. The GCBS web site was finalized and has been made functional for wider public view. The process for enrolling new participants was explained and new participants were invited to present their global blood safety activities. For the financial support for GCBS, it was suggested that financial support could be sought from various organizations for smooth running of activities. It was agreed that the task group set up to examine financial requirements of activities related to GCBS. The process for the inclusion of new participants was clarified and several new participating organizations were invited to present their global blood safety activities to the GCBS.

The Working Group on Policy Process reported on successful organization of a policy makers forum on 9 Nov. 2004, which was attended by 35 participants including ministers of health, secretaries for health and other policy-makers within the health ministries from both developed and developing countries, and policy-makers or advisers to regional/sub-regional governing bodies. The main objective of the forum was sharing of experiences among policy makers and ensuring that the structured policy making conceptual framework was applicable to different economical and political settings. The final draft of the Aide memoire on good policy process was given over to WHO for consideration for adaptation and publication, as a tool for advocacy for a structured, policy making process.

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 participants 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 2005. 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 six collaborating organizations to provide an update on their international blood safety activities: Australian Red Cross, Swiss Red Cross, National Blood Services (NBS) England, EFS (French Blood Establishment), Paul Ehrlich Institute- role in relation to GCBS and Biomedical Excellence for Safer Transfusion (BEST) - role in relation to GCBS.

## Recommendations and Next Steps

- 1 The meeting encouraged GCBS participants to continue to work towards constructive collaboration, within their shared missions and goals, including commitments of support.
- 2 GCBS participants agreed to submit the Consensus Statement of the WHO-convened Forum for Good Policy Process for Blood Safety and Availability, 9 November 2004 to their respective organizations for endorsement, and advocacy of the principles of the document.
- 3 The meeting encouraged the participating organizations to advocate for increased visibility and resource commitment to blood issues at the national, regional and global levels.
- 4 The meeting noted that a number of participating organizations, including the World Federation of Haemophilia, Plasma Therapeutics Association, South African National Bio products Institute and European Plasma Fractionation Association have agreed to co-sponsor an initiative to develop constructive approaches to enhancing the availability of plasma products at affordable prices throughout the world.
- 5 The meeting agreed that the documents being developed by the GCBS Working Group on Good Policy Process should be completed, including the draft Aide-Mémoire for National Health Policy Makers: *Good Policy Process for Blood Safety and Availability* and draft guidelines on the use of formal instruments of policy and decision making. The meeting noted that a number of participating organizations have agreed to provide summaries of policy and decision making as case studies that could be integrated as examples in the aforesaid draft guidelines.
- 6 The GCBS Working Group on Quality Assessment and Access to Technology was tasked with the development of a proposed budget which could be used by the secretariat as a tool for use in the fundraising for the completion of the PAHO/WHO pilot project on Model for the Assessment of Blood Needs and for potential partnership activities with other efforts. The meeting noted the near completion of an Assessment Tool for the Situation Analysis of Blood Transfusion Services developed by WHO which would further GCBS objectives.
- 7 The meeting noted that a number of participating organizations had expressed willingness to collaborate with global initiatives to define and disseminate principles of regulatory oversight applicable to blood safety and availability.
- 8 The meeting requested the participating organizations to complete a survey questionnaire to pilot test an information-gathering exercise on resources available for technical assistance. Representatives of the American Association of Blood Banks and the Advisory Committee on Blood Safety and Availability, United States Department of Health and Human Services, volunteered to coordinate the survey and compile and report the results.
- 9 The meeting noted that the Australian Red Cross Blood Service, the Therapeutic Goods Administration, Australia, the African Society for Blood Transfusion and WHO have agreed to collaborate, and to seek additional interested collaborative parties, on an initiative to develop guidance on issues related to the health of the

blood donor, including iron status, haemoglobin levels, age limits and donation volumes.

- 10 The meeting encouraged the participating organizations to participate fully in promoting World Blood Donor Day, 14 June 2005.
- 11 The meeting noted that the English National Blood Service and the Australian Red Cross Blood Service agreed to collaborate in an initiative to develop tools that will:  
a) assist national health authorities to estimate current and future blood needs; b) encourage use of evidence-based transfusion practices. In addition, the meeting encouraged the participating organizations to publish available information on evidence-based transfusion practices.
- 12 The meeting encouraged the participating organizations to share information and documents on assessments of blood systems in various countries, the value of available resources, opportunities for direct bilateral assistance and the impact of interventions.
- 13 The meeting encouraged the participating organizations to publish existing global and regional databases on blood safety and availability.

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The meeting was opened by Dr. Jay Epstein and Dr. Jukka Koistinen as chair and vice chair of the general meeting of GCBS. The chair greeted all the participants and thanked to Dr. Steffen Groth, Director, Department of Essential Health Technologies (WHO Blood Safety programme) in WHO-HQ for his presence at the meeting. Dr. Groth welcomed all participating organizations, individual participants, observers and WHO regional representatives. He mentioned that GCBS was established as a voluntary partnership of collaborators from developing and developed countries. It promoted dialogue and initiated complementary actions to promote blood safety all over the world. GCBS identified opportunities and initiated collaboration efforts. Dr. Groth also reiterated that participants should take ownership of the recommendations and should use the available resources and involve national governments to achieve these goals, defined collectively by participating organizations.

He said that Working Groups should focus on issues of critical importance and make recommendations as how to address these. WHO recognized the role of GCBS as a driver and instrument to achieve the goals of WHO, to set priorities, identify critical issues and also identify opportunities of collaborations at global, regional and country level. Another mechanism to provide expert advice to WHO is through the Expert Committees. He mentioned that the department also identifies the role played by WHO Expert Committees, in addition to the collaborative role played by GCBS and efforts will also be directed to expand the WHO Expert Panel and constitute a WHO Expert Committee on Blood Safety. This would further crystallise and strengthen the relationship of GCBS and WHO. Recognizing the important role this forum plays in foster collaboration and partnership, WHO would continue to provide secretariat support to GCBS meetings and other activities emerging out of GCBS meetings. He also mentioned that during this period of 2 years, when the expert committee will likely be established, there is a need to develop a mechanism by the GCBS

participants including WHO for its sustainability and smooth provision of secretariat support.

The agenda and programme of work were then reviewed and adopted by the plenary group.

### **Objectives**

The fifth GCBS meeting was convened with following objectives:

1. To review relevant reports of meetings: 4<sup>th</sup> GCBS general meeting, planning and working group reports
2. To review the draft consensus statement from the Policy Makers Forum
3. To complete, review and discuss the materials produced by the following GCBS working groups
  - policy process
  - quality assessment and assistance for development
  - plasma issues
4. To review participants' reports on collaborative initiatives in the field of blood safety
5. To identify and prioritize future issues and activities to be addressed by the GCBS

## **Review of relevant reports**

### **Reports of the Planning group and Working group meetings and the 4<sup>th</sup> GCBS General Meeting**

Report of the GCBS Planning Group meeting held in May 2004 was discussed. Members acknowledged the support of Dr. K. Boukef for hosting the 4<sup>th</sup> general GCBS meeting. The financial support of the Government of Japan was also appreciated by all members. The meeting report of the plenary session was reviewed and approved unanimously.

Meeting of the three working groups were held on 8 November, 2004 and outcome of the meeting was informed to the Plenary Group. The final draft of the 'Minimum Requirement' was completed and handed over to WHO. Progress has been made in the 'Need Assessment' activity and one meeting had been scheduled to be held in 2004 in Argentina.

The group on Policy supported the organization of the Policy Makers Forum. Policy Makers forum was also attended by GCBS participants who contributed to the programme of work and facilitation. A draft Consensus statement on Good Policy Process for Blood Safety and Availability was developed by the working group for consideration by the policy maker forum.

The plasma group was concerned about the issues related to shortage of the plasma and it was suggested that there should be analysis of the root cause to address this issue.

On administrative issues, discussions were held on selection of Chair and Vice Chair, nomination phase to be done electronically.

## **Introduction of New Participating Organizations**

### **Australian Red Cross:**

Dr. Robert Hetzel, Chair of the IFRC Global Advisory Panel on Corporate Governance and Risk Management & Chief Executive Officer, Australian Red Cross Blood Service (ARCBS), informed that ARCBS has a blood donor base of more than 1.4 million. Blood donors represented diverse population in the society and there were about one million donations per year. The blood transfusion services follow the CoE guidelines. They have collaboration with International Federation of Red Cross & Red Crescent Societies, WHO, International Strategic Blood Meeting Group (ISBM), Alliances of Blood Operators (ABO), New Zealand. They also have strategic partnership with American Red Cross, Canada & England. ARC is involved in global advisory panel in self assessment scorecard and governance. Another area of ARC involvement is regional capacity building in terms of manpower development from countries like China, India, Malaysia, Vietnam, and Malaysia. The speaker expressed his support to continue this collaboration and cooperative arrangements.

#### **Swiss Red Cross:**

Dr. Guy Levy, Medical Director, Swiss Red Cross (SRC) Blood Transfusion Service informed that there were 7 million inhabitants in Switzerland and HQ of Blood Transfusion Service was located at Berne. SRC had an International Cooperation department in Switzerland; however, BTS structure is not directly linked with governance. It had 13 regional centres and more than 500,000 donations are collected every year. This organization was involved in emergencies (inside/ outside Switzerland), rehabilitation, and social development and AIDS program in Africa. SRC was committed to safe blood program of Egypt, Zimbabwe, Palestine, Eritrea.

#### **National Blood Service, England**

Mr. Steve Morgan, Project Leader, NBS International, England, presented fact, figure and activities of National Blood Services (NBS) to GCBS participants. This was one of the 5 of the British Isles where, population was 60 million. NBS, England has a donor base of 1.7 million and served 200 hospitals located in that area. The presenter highlighted that international activities of NBS were in line with GCBS goal. Out of multiple activities, NBS influences policies of EBA, EU, CoE, International Strategic Blood Group (ISBG), ABO; ISBG contributed to international blood supply; managing WHO collaborating centres (at Bristol & Birmingham), supported EBA & European School of Transfusion Medicine; participated in global manpower development program; Specialized in donor recruitment and retention techniques; established a system of appropriate use of blood and could contribute to other countries in terms of surplus equipment and visit by experts.

#### **French Blood Service:**

Mr. Jean-Francois Riffaud represented French Blood Establishment (EFS) and he informed that this organization focused on educational program for manpower development including training of trainer, advices on policies & regulations, helping functioning, equipment procurement and developing quality system of various organizations. EFS had 8500 staff and there were a team of 5 managers. There is a special department of international collaboration and they had active program with countries like Chile, Argentina, Bolivia, Morocco, Algeria, Tunisia, Macedonia, Kosovo, Iran, Iraq, Afghanistan and Francophone Africa.

#### **Biomedical Excellence for Safer Transfusion (BEST):**

Prof. John Hess presented activities of Biomedical Excellence for Safer Transfusion (BEST) which was founded as a working group of ISBT. This organization was

dedicated to improve the quality of blood components and its usage, research in platelet (storage, activation and recovery), sample collection and prevention of errors. Their main goals were for safer and better storage of blood products, stem cell therapy, and documentation, strengthening regulations, expanding in Asia, South America and Africa. BEST has several ongoing projects and one of these is red cell storage improvement.

**Paul Ehrlich Institute (PEI):**

Dr Rainer Seitz outlined the role of the Paul Ehrlich Institute, Germany. This institute helped in German regulatory affairs in terms of batch release, testing related to safety and quality of plasma derived products; GMP surveillance; medicines control laboratory and pharmaco-vigilance. About 1600 batches of plasma products were released by this institute last year. PEI made HCV-NAT testing mandatory in Germany and this had reduced the window period of HCV infection. PEI also represented in various national committees, EU and expert group in blood safety. This institute had a role to play in research in terms of viral safety, chemical inactivation of infectious agents, thromogenicity of prothrombin complex concentrates and implementation of quality control methods.

At the end of presentation of the new participating organizations, the GCBS participants unanimously approved nomination of these new organizations as GCBS participants.

**Policy working group:**

There were discussions on working of Policy Working Group. Following action taken and recommendations were presented:

1. Prepared Aide memoiré and program for the forum.
2. Aide- me moiré: went through several rounds of review and revision and a description of the policy cycle has been added.
3. Draft consensus statement was reviewed
4. Work products: developed the agenda for policy forum, final draft of the aide memoire,

**Formal tools on Decision Making:**

Mr Julius Court highlighted the importance of policy making in areas of blood safety which should be defined and evaluated. Model of the policy process were explained. It was highlighted that the principles of policy formulation should be reviewed periodically to understand outcome and evidence and transparency should be maintained. Uganda was sited as an example in this context. Strategic tools that can apply for problem solving were presented. It was opined that policy processes are critical to outcomes, they are complex, responses depend on contexts and not all of them are costly. WHO should continue to support and promote the effort to improve policy processes.

**Discussion:**

Participants expressed opinion that Aide-Mémoire was an excellent piece work and Aide-Memoire should not be more than two pages which should be used the principles and amplify with more examples. It was a very good advocacy material to the Ministers of Health. The government, regulators and blood service providers are integral part of the policy making procedures. The document could be generalized for public health instead of only for blood transfusion services. The implementation document could address the specifics for the transfusion medicine setting.

## **Follow up on the General GCBS Meeting 2003**

### **Recommendations of the General GCBS Meeting 2003:**

Dr. Koistinen recognized the role of WHO initiatives and activities in blood safety and the unique role it plays in advising MOH. It was highlighted that there is a need to develop a more detailed action plan for implementation of these recommendations and adoption and ownership of these by the participating organizations. Discussion was held on ISBT 128 however, there had been no practical implementation in developing countries. Participants informed that despite blood safety being a WHO priority, it was under resourced. It should be built into the health care system. The issue of removal of clotting factors from WHO Essential Medication List was discussed which had been responded by WFH and EPFA. Follow up on recommendations, clear guidelines was important and action line should be set to the secretariat as well as the collaborating organisations to act on recommendations.

### **Highlights of the Global Efforts and Progress on Blood Safety:**

Dr. N. Dhingra presented WHO collaboration and partnership, identifying issues and solving through expert working groups. WHO had developed many documents and guidelines BTS, decision making, standard setting at national level. The speaker presented contributions of WHO collaborating centres like Finland Red Cross Blood Service, Swiss Red Cross BTS, Singapore CTM, Sanquin Blood Supply Foundation and Shanghai Blood Centre. WHO priority in blood safety was discussed which, included implementation of quality system in member countries; development of materials; international and national quality assessment schemes; traceability and safe blood donor programme in member countries. World Blood Donor Day was taken up as an activity with partner organizations and a web site was launched. WHO was closely working on following areas like effective testing of TTIs; developing safe collection and good manufacturing practices in processing; in service training and motivating staff and collaborating training in different parts of the world.

### **GCBS Matrix of Resource available for Collaboration:**

Dr. J. Holmberg explained the objectives of this initiative through potential collaboration for sharing information with the participating organizations and assessing the possibility of collaborative activities. A draft of the matrix developed to collate this information was presented. Already available resources could be utilized and shared with countries or organizations who wanted collaborations. The speaker listed out avenues of collaborations required by GCBS to help other organizations and countries.

### **Issues in Donor Management:**

Mr. Neil Mikkelsen presented several issues for the promotion of VNRD. He highlighted that it is important to retain donors to develop a large pool and MoH should be involved at country level. Only a good quality and efficient blood service helped blood donors to come back for donations. Need to pay special attentions to take care of donor injury and informed consent a part of blood donation was recognized. Blood donor data should be confidential and all donated units should be traceable. There should be ethical guideline for the use of blood and donations should be non-remunerated without any profit. The speaker raised questions about few self sufficiency criteria, cost effectiveness of NAT testing and right to information. Voluntarism in donor recruitment and retention was stressed and it could improve blood availability.

## **Council of Europe**

Ms. Alina Tatarenko presented the outline of structure, working methods and ethical issues related to blood and human tissues from Council of Europe point of view. CoE adopts and celebrates World Blood Donor Day and European Day for Organ Donation and Transplantation on specified dates. The organization published recommendations on autologous cord blood banks, pathogen inactivation, and optimal use of blood and prevention of vCJD by transfusion. There were pending adaptations regarding teaching blood transfusion to nurses and optimal use of blood and blood products. The Council was also working on collection, testing and use of blood and blood components in Europe and cellular immune therapies. Assistance programmes for member European countries were being developing by the Council.

## **GCBS Working Group Reports**

### **Working group: Plasma issues:**

Dr. D Armstrong reported on the progress in the work of the group. He highlighted issues such as number of contributors, national health authorities and their different licensing/ inspection/ QC/ GMP and post market surveillance. He also stressed that plasma requirements of each country should be defined; product profile must reflect the needs of specific country and yield should be according to the local need. He presented that the national plasma fractionation program should comply with principles of self sufficiency, sustainability, optimizing blood donation and economic viability and sustainability. It was advisable to outsource to non for profit or for profit organization. In this process quality and safety management was very important. For having infrastructure for fractionation, the country might go for domestic plant or contract fractionation or purchase product or it might go for combinations of options. The Working group proposed that further discussion and guidance to countries is required on availability of plasma; availability of plasma-derived medicinal products and development of an economic model with an overview of the economic factors that influence a decision.

### **Discussion:**

Participants discussed about functions of the Working Group. Participants expressed concern over excess albumin in the developed world and surplus plasma in developing world. Partnership should be developed for optimum utilization of plasma derived factors so that these were available in economically restricted countries also. Developing countries might pool plasma for fractionation and efficient technology for harvesting small volume plasma should be developed. For developing country, contract fractionation was a better option. There had to be a balance between cost and safety. Participant expressed opinion that WHO could help with contract fractionation and work with World Federation of Hemophilia on the treatment guidelines. GCBS should address the possibility of processing of excess plasma. The problem was to deal with surplus plasma and make it a cost-effective product which might be a problem with contract fractionation. A two-tier pricing for developing and developed world was suggested. This was thought to be problematic, but could be an area for collaboration.

### **Working group: Good Policy Process:**

Dr. Albert Farrugia provided a summary of the proceedings of the Forum on good policy practice. The objectives were to review experiences, identify areas of concern,

and develop consensus statements and to identify prerequisites. In USA, the service was found to be well organized, stakeholders were involved, acceptable risks were minimised, blood safety and donor selection policy were in place. The experience in Thailand showed that there is a progression in testing which has an impact on donor selection. More cases have been detected after p24 test was implemented. The Group questioned the usefulness of universal leukodepletion considering the increase in cost of blood units. Good policy process at national level is important and commitment at national level was required. Uganda was cited as an example, which faces the serious threat of HIV and collaboration with international partners is necessary. HCV antibody testing should be adopted as a policy all over however; cost effectiveness of NAT testing should be evaluated. WHO blood safety and implementation of policy was presented. The quality management program of WHO was a success story and it should be persuaded. Dr. McClelland commented that blood is component of modern medicine and we had to decide about quantity of blood required, whether it would be evidence based whether we should aim for zero risk. The draft consensus of the forum was tabled and comments were requested from participants.

**Working group: Quality Assessment and Assistance for Development:**

Dr. A. Hynes presented the progress in the work of quality group. The recommendations of the GCBS Plenary participants submitted in 2003 had been considered and the *Minimum Requirement* document had been finalised and handed over to the WHO. The issue of informed donor consent on what tests were being performed, the implications of the test results and availability of counselling, the possible complications of donating, issues regarding voluntary non-remunerated donors were addressed and definition of incentives, taking note of the context of incentives in terms of general principles and country setting were discussed. The final publication would be a WHO publication and the contributors and the role of GCBS would be acknowledged. It was proposed that ECBS Expert Committee on Biological Standardization would be asked to review the document as a possible replacement/update of the 1994 Technical Report Series.

**Working group: Evidence based blood transfusion:**

Dr. B. McClelland emphasized the need for evidence based transfusion medicine. He discussed the scenario of assessing the need from the point of view of patients' and to transfuse only if necessary and develop transfusion medicine based on true evidence not conventional wisdom. The probability of blood transfusion depended on factors like anaemia, or drug induced bleeding or depending on operating surgeons. The patient might have a fear of contracting disease and the risk was different in different countries. The person might also have a fear of getting wrong blood. If there was a bleeding, was there a possibility of blood salvage? However, it had been observed that transfusion did not help in many cases of anaemia. So, how good did scientific evidence get?

**Priorities and Objectives for GCBS**

**Proposals of the Working Group to the GCBS General meeting:**

*A Guideline* for the preparation of regional or national Standards based on the *Minimum Requirements* be developed, this should be done after the publication/ finalisation of *Minimum Requirements*. The Guideline could include existing assessment tools to monitor progress towards implementation of national/regional

standards and mechanisms to facilitate progress towards external assessment and accreditation through national or international accreditation agencies.

**National requirement of blood and blood products:**

Dr Elizabeth Vinelli presented progress in the pilot testing of the model of the needs assessment of blood products the report and observed that there was no objective model to assess the need for blood products. It was based on usage and not on clinical needs and the data was not representative of whole population. Prof. Salmi/ Dr. McClelland model was applied as per meeting held in Buenos Aires to prepare a common protocol in PAHO/WHO-AMRO region to implement and assess the simplified model. The period of study was one year and steps outlined are protocol, questionnaire survey, databases, collection of information, implementation strategy, pilot study, improve process and readapt. During implementation in Argentina and Honduras, parameters to be kept in mind, were clinical experts, definition of major bleeders, proposed model, list of major bleeders, prevalence & percentage needing blood, average need to correct anaemia and list of data bases of patient registry. This project was completed after collection of complementary data, final meeting of experts to apply model and calculate need and preparation of report at the end. Bleeders were also to be assessed on the basis of trauma, cancer, obstetrics, cardiovascular surgery, orthopaedic surgery, GI bleed, Haematological disease.

**Discussion:**

The financial and other requirements for the next year might be presented to WHO and the work done should be in harmony with the other products that are being prepared by WHO. The need assessment investigation should be extended to Africa on malaria and HIV. There were other simpler models tested on Croatia, Africa and Arab countries and opportunities to bring these studies together should be explored. However, validation of the model was necessary and it was advisable to find an appropriate simplified model that could be used cost-effectively. GCBS should be utilized to facilitate partnerships amongst participants rather than through the working groups. The role of the Working Groups must be decided. There were also some interest groups that should be accommodated like regulators, transfusionist, and regional structures/cooperation.

**Breakout group: Sharing information and resources:**

The discussion was based on previous proposals for 'clearing house' and disseminate information to the group and then to participating organizations. It was opined that data collection should be started and there should be communication with the group via teleconference. The priorities for GCBS Working Group should be to demarcate a time frame of 6 months for finalizing Beta test, which first could be implemented in WHO regional structure than in other organization like EU etc. This tool should be web based however; language problem should be kept in mind.

**Breakout group: Management of Donor:**

Ms. S. Thomas presented the report and described three categories of donors i.e. voluntary no-remunerated donors (VNRD), paid and replacement. The Group recommended that countries should move to 100% VNRD and paid donors were not an option. Replacement donors might be acceptable as a transitory phenomenon. Donor health should be of high priority and iron status, haemoglobin, frequency of donation, donation type and volume, iron supplementation should be considered. Donor data must be handled carefully as it was sensitive data. Regarding donor age, it

was observed that ageing donor population and availability of new donors was a problem. Other important things to keep in mind were donor rights, safety implications, legal issues, donor maturity, and donor safety. It was proposed that WHO, Australian Red Cross and other interested organizations could carry out a study on adverse events related to age.

In addition to the 4 organizations currently supporting WBDD, other GCBS participants should also support. GCBS could collaborate with WHO to build recruitment capacity in developing countries to achieve sufficient supply. GCBS should develop working group for VNRBD for terminology standardisation, recruitment, incentives and issues relating to insurance. It was agreed upon that the issue of paid and unpaid donors in plasma collection should be included in the document, though there was no consensus.

### **Discussion:**

It was accepted that VNRD should be accepted as principle. This 100% goal could be achieved by a variety of means in different countries. Offering insurance should be further discussed along with continuing family replacement donors, apheresis and autologous donation.

### **Breakout Group: Plasma Issues:**

Mr. T. Evers presented a SWOT analysis on plasma issues:

- *Strengths:*
  - Clotting factor surplus in 1<sup>st</sup> world
  - High level safety and quality standards available
- *Weaknesses*
  - Cost
  - Market
  - Lack of buying power
  - No global vehicle to ensure availability
  - Regulatory harmonisation
    - No global standards
  - Lack of regulatory standards
  - Maximal vs. optimal safety
  - Donor epidemiology in country of origin of the plasma and access to technology
  - Lack of skills and expertise
- *Opportunities*
  - Huge potential need
    - Albumin
    - FVIII
  - Surplus capacity
  - Availability of products/intermediates
  - Potential spare fractionation capacity
  - Potential new plasma donors
  - Technology
  - Low costs of labour
  - Recombinant products
- *Threats*
  - Vested industry interests
  - Lack of political commitment

- Consolidation of industry
- Pressure on health budgets
- Effect of recombinant products on immunoglobulins

On the basis of the above SWOT analysis, it was proposed that WHF should carry out a feasibility study for the utilisation of cryoprecipitate with the help of funding from International agencies (and foundations). WHO might consider for group purchasing of plasma-derived medicinal products with at least one year shelf life. The need assessment of plasma-derived medicinal products expected to be in surplus in coming years and transgenic model might be mentioned for future prospect.

#### **Discussions:**

Participants felt that there should be practical approach for self sufficiency in plasma (FFP). Possible source of funding should be looked out to supply of plasma derived medicinal products to developing countries. There should be practical approach in supplying these products to these countries. Cryoprecipitate should be used in absence of factor concentrate.

#### **Breakout Group: Evidence-Based Transfusion Practice:**

Dr. John Hess presented report of the break out session in improving access to existing sources of evidence and sharing information on converting evidence into practice. It was proposed that GCBS participants should join the group and participate in studies and sharing of information. It was suggested that concepts of and the need for evidence-based medicine was gaining ground and there was a need to develop and spell some narratives to support this concept

#### **Discussions:**

Possible funding for study on this topic was discussed and NBS, England BTS volunteered to support research projects financially. There were funds available from CoE its Member States. This topic should be implemented at the field of quality at hospital level.

#### **Priorities in the Developing and Developed World**

Obtaining training and expertise in Transfusion Medicine has been a major problem in developing countries. GCBS may take initiative through its participants or in their individual capacity, in man power development in these countries. Moreover, lack of manpower, funds, commitment of policy makers and lack of continuity made collaboration less efficient in long run. There should be efforts to develop National Blood Services so that success of long sustenance of blood program could be achieved. To achieve successful outcome of GCBS, participants of GCBS should find ways of how to interact with one another and what collaborators could offer.

#### **GCBS Administrative Issues:**

##### **GCBS budget:**

Dr. N. Dhingra presented the budget of the GCBS. The speaker informed the house that WHO has spent about US\$ 90,000 from its regular budget to support 24 participants. There was financial contribution from Thalassemia International Federation of € 3000 for supporting the participation of developing country participants. Moreover, WHO supported GCBS activity through allocating 10-30% time of 4 professional and two support staff along with infrastructure support. Fund

raising efforts were on continuously from the Netherlands, France and Japan. GCBS budget is mainly required for travel and meeting expenses and secretarial costs like publications, dissemination of materials, teleconferences and administrative supports.

**GCBS website:**

The GCBS web site was presented by Dr. N. Abuamin and informed that it was started working with following address: <<http://who.int/bloodsafety/gcbs/en/>>. It was discussed that the GCBS web site should be extended and it should be used for information exchange. The webpage as part of WHO/blood safety website has since been launched. Comments were invited for improvement of the WebPages.

**Election of New Chair and Vice-Chair:**

Dr Jay Epstein was elected as the chairperson and Dr Silvano Wendel as the vice-chair for the GCBS for the year 2005-2006.

**Following issues and topics were discussed:**

1. Provision of written cases studies for evidence-based Transfusion Medicine.
2. Bringing consensus statement forward through our various organizations.
3. Address a letter to the WHO Director General emphasizing the supporting blood safety activities and allocating more resources.
4. Utilization of surplus plasma and cryoprecipitate and multinational purchasing, WHO to consider reducing the shelf life of donations of blood products by companies to 6 months.
5. Requirements of blood and blood products: Need to expand the ongoing projects to other countries.
6. Information: Pilot testing of the resource database survey among GCBS participants.
7. Donor health issues: motivation vs. recruitment, medical issues, iron status of the donor and immune status of the recipient.
8. Coordination of assistance, site visit the countries in need.
9. Publishing of the resource database in a recognized journal.
10. Invite representatives from funding organizations.

Following the discussion for final recommendations Dr. N. Dhingra proposed that the recommendations be grouped into 3 broad categories:

- establishing mechanisms of ongoing communication;
- making specific recommendations to address major issues of concern
- ownership by the participants of the GCBS for implementation of the recommendations.

The Chair proposed that recommendations be made only when sponsors can be identified.

## FINAL RECOMMENDATIONS:

- 1 The meeting encouraged GCBS participants to continue to work towards constructive collaboration, within their shared missions and goals, including commitments of support.
- 2 GCBS participants agreed to submit the Consensus Statement of the WHO-convened Forum for Good Policy Process for Blood Safety and Availability, 9 November 2004 to their respective organizations for endorsement, and advocacy of the principles of the document.
- 3 The meeting encouraged the participating organizations to advocate for increased visibility and resource commitment to blood issues at the national, regional and global levels.
- 4 The meeting noted that a number of participating organizations, including the World Federation of Hemophilia, Plasma Therapeutics Association, South African National Bioproducts Institute and European Plasma Fractionation Association, have agreed to co-sponsor an initiative to develop constructive approaches to enhancing the availability of plasma products at affordable prices throughout the world.
- 5 The meeting agreed that the documents being developed by the GCBS Working Group on Good Policy Process should be completed, including the draft Aide-Mémoire for National Health Policy Makers: *Good Policy Process for Blood Safety and Availability* and draft guidelines on the use of formal instruments of policy and decision making. The meeting noted that a number of participating organizations have agreed to provide summaries of policy and decision making as case studies that could be integrated as examples in the aforesaid draft guidelines.
- 6 The GCBS Working Group on Quality Assessment and Access to Technology was tasked with the development of a proposed budget which could be used by the secretariat as a tool for use in the fundraising for the completion of the PAHO/WHO pilot project on Model for the Assessment of Blood Needs and for potential partnership activities with other efforts. The meeting noted the near completion of an Assessment Tool for the Situation Analysis of Blood Transfusion Services developed by WHO which would further GCBS objectives.
- 7 The meeting noted that a number of participating organizations had expressed willingness to collaborate with global initiatives to define and disseminate principles of regulatory oversight applicable to blood safety and availability.
- 8 The meeting requested the participating organizations to complete a survey questionnaire to pilot test an information-gathering exercise on resources available for technical assistance. Representatives of the American Association of Blood Banks and the Advisory Committee on Blood Safety and Availability, United States Department of Health and Human Services, volunteered to coordinate the survey and compile and report the results.
- 9 The meeting noted that the Australian Red Cross Blood Service, the Therapeutic Goods Administration, Australia, the African Society for Blood Transfusion and

WHO have agreed to collaborate, and to seek additional interested collaborative parties, on an initiative to develop guidance on issues related to the health of the blood donor, including iron status, haemoglobin levels, age limits and donation volumes.

- 10 The meeting encouraged the participating organizations to participate fully in promoting World Blood Donor Day, 14 June 2005.
- 11 The meeting noted that the English National Blood Service and the Australian Red Cross Blood Service agreed to collaborate in an initiative to develop tools that will:  
a) assist national health authorities to estimate current and future blood needs; b) encourage use of evidence-based transfusion practices. In addition, the meeting encouraged the participating organizations to publish available information on evidence-based transfusion practices.
- 12 The meeting encouraged the participating organizations to share information and documents on assessments of blood systems in various countries, the value of available resources, opportunities for direct bilateral assistance and the impact of interventions.
- 13 The meeting encouraged the participating organizations to publish existing global and regional databases on blood safety and availability.

### **Closing remarks:**

Dr. J Epstein, the Chairperson of the GCBS meeting offered the closing remarks and opined that the GCBS meetings provided an opportunity for all the participants to learn from each other and the organizations participating in GCBS could implement the ideas generated. There had been a number of objectives achieved which include development of Aides mémoire and need assessment model. Dr. N. Dhingra mentioned that the GCBS recommendations serve as important guiding principles for developing policies and strategies for blood safety for the participating organizations. Dr. S. Groth thanked all the participants

### **New Rapporteurs Selected:**

The meeting approved the recommendation that Dr. Jerry Holmberg and Dr. Roger Dodd be appointed as rapporteurs.



**WORLD HEALTH ORGANIZATION**  
**ORGANISATION MONDIALE DE LA SANTE**

**5<sup>th</sup> Plenary Meeting of the Global Collaboration for Blood Safety (GCBS)**

Venue: Salle C, WHO-HQ, Geneva, 10-12 November 2004

**Programme of Work**

**Wednesday, 10 November 2004**

08.30	Registration	
08.45	Welcome and introduction of participants	Dr Jay Epstein, Chair Dr Jukka Koistinen, Vice-Chair
09.00	Welcome address from WHO	Dr Steffen Groth
09.05	Adoption of the agenda and programme of work, objectives of the meeting	Chair/Vice-Chair
09.15	Review of report of the GCBS 2004 Planning Meeting	Chair/Vice-Chair
<b>Theme 1. Introduction of New Participating Organizations</b>		
09.20	Australian Red Cross Blood Service - international blood safety activities	Ms Sally Thomas
09.30	Swiss Red Cross Blood Service - international blood safety activities	Dr Guy Levy
09.40	National Blood Service, England - international blood safety activities	Mr Steve Morgan
09.50	EFS (French Blood Establishment) - international blood safety activities	Mr Jean-François Riffard
10.00	Biomedical Excellence for Safer Transfusion (BEST) Collaborative - role in relation to GCBS	Prof John Hess
10.10	Acceptance of new participants and discussion	Plenary
10.30	Tea/coffee	

**Theme 2: Forum on Good Policy Practice**

11.00	Report on Policy Makers' Forum on Good Policy Process	Dr Albert Farrugia
12.00	Review formal tools of decision-making (risk assessment, modeling, communication, cost benefit, cost-effectiveness in the public health sector)	Dr Jay Epstein
12.30	Discussion	
13.00	Lunch	

### **Theme 3: Follow up on the GCBS plenary meeting 2003**

14.00	Discussion on the recommendations of the GCBS plenary meeting 2003: accomplishments and new initiatives	Chair/Vice-Chair
14.30	Highlights of the global efforts and progress on blood safety since 2003	Dr. Neelam Dhingra
14.55	Proposal for a GCBS matrix of resources available for collaboration	Dr Jerry Holmberg
15.05	Issues in donor management (safety, consent, medical counseling, confidentiality, ethics)	Mr Niels Mikkelsen
15.30	Tea/coffee	
16.00	Dissemination of information	Plenary discussion
16.30	General discussion	

### **Thursday, 11 November 2004**

08.30	Paul Ehrlich Institute, Germany - role in relation to GCBS	Dr Rainer Seitz
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### **Theme 4 : GCBS Working Group Reports**

#### **Working Group on Plasma Issues**

08.40	Overview and report of the group	Mr Duncan Armstrong
08.50	Feedback on Aide-Mémoire, Fact Sheets	Dr Ana Padilla
09.00	Report on plasma availability	Mr Theo Evers/ Mr Charles Waller/ Mr Duncan Armstrong
09.10	Discussion	

#### **Working Group on Policy Process**

09.30	Overview and report of the group	Dr Albert Farrugia
09.40	Feedback on Aide-Mémoire: Good policy process	Dr Neelam Dhingra
09.50	Technical guidelines on decision making	Dr Jay Epstein
10.05	Discussion	
10.30	Tea/coffee	

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

11.00	Overview and report of the group	Dr Anthon Heyns
11.05	Feedback on Minimum Requirements for Blood Transfusion Services and AABB core standards	Mrs Shan Lloyd
11.15	Progress on the pilot study on the 'Needs Assessment Model'	Dr E. Vinelli
11.30	Discussion	

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|-------|--|---------------------|
| 11.45 | Evidence-based clinical use of blood and blood products (opportunities for collaboration, critical review of evidence) | Dr Brian McClelland |
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**Theme 5: Priorities and Objectives for GCBS**

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|-------|---|---------------------------|
| 12.00 | <u>Breakout session</u><br>Defining mechanism for: <ul style="list-style-type: none"> <li>▪ Sharing of information and resources</li> <li>▪ Evidence-based transfusion practice and the need for blood components</li> <li>▪ Management of the donor</li> </ul> | 3-4 groups and moderators |
| 13.00 | Lunch   |                           |
| 14.00 | Presentations of the breakout sessions  | Session rapporteurs       |
| 15.00 | Discussion of GCBS priorities: <ul style="list-style-type: none"> <li>▪ Needs in the developing world</li> <li>▪ Needs in the developed world</li> </ul>  |                           |
| 16.00 | Focussed group discussion to foster collaborations  |                           |

**Friday, 12 November 2004**

**Theme 6: GCBS Administrative issues**

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|-------|---|--|
| 08.30 | Administrative update from the Secretariat <ul style="list-style-type: none"> <li>▪ GCBS budget</li> <li>▪ GCBS website</li> </ul>  | Dr Neelam Dhingra<br>Dr Noryati Abu Amin |
| 08.45 | Election of new Chair and Vice-Chair for 2005-2006, appointment of rapporteurs and nominations for membership of the Planning Group | Secretariat                              |

**Theme 7: Recommendations and Action Plan**

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|-------|--|----------------------|
| 09.15 | Development of draft recommendations and action plans  | New Chair/Vice-Chair |
| 10.30 | Tea/coffee   |                      |
| 11.00 | Development of draft recommendations (continued)   |                      |
| 12.00 | Strategic planning and future perspective for GCBS <ul style="list-style-type: none"> <li>▪ Identification of joint projects to address the GCBS recommendations</li> <li>▪ Funding</li> <li>▪ Meeting venues</li> </ul> | Plenary              |
| 13.00 | Next steps   | Dr Steffen Groth     |
| 13.15 | Closing remarks  | New Chair/Vice-Chair |



**WORLD HEALTH ORGANIZATION**  
**ORGANISATION MONDIALE DE LA SANTE**

**5<sup>th</sup> General Meeting of the Global Collaboration for Blood Safety**  
**Geneva, Switzerland, 10-12 November 2004**

**List of Participants**

<b>Status of participation</b>	<b>GCBS participant</b>
<b><i>Organization/Institution/Association represented</i></b>	<b><i>Nominated member</i></b>
African Society for Blood Transfusion (AfSBT)	Prof. Banji Adewuyi, President, African Society for Blood Transfusion (AfSBT) c/o Pamela Larkin (Mrs) University of Ilorin, PMB 1515 Ilorin, Nigeria Email : <a href="mailto:jowuyi@yahoo.co.uk">jowuyi@yahoo.co.uk</a> <a href="mailto:larkinp@nbi-kzn.org.za">larkinp@nbi-kzn.org.za</a>
American Association of Blood Banks (AABB)	Roger Y. Dodd, PhD Executive Director, Biomedical Safety American Red Cross Holland Laboratory 15601 Crabbs Branch Way Rockville MD 20855, USA Phone: +1 301 738 0641 FAX: +1 301 738 0495 e-mail: <a href="mailto:dodd@usa.redcross.org">dodd@usa.redcross.org</a>
Council of Europe (CoE)	Ms Alina Tatarenko Health Division Directorate General III - Social Cohesion Department of Health and of the Partial Agreement in Social and Public Health Field Council of Europe 67075 Strasbourg Cedex France Tel: + 33 (0) 3 88 41 2847 Fax: + 33 (0) 3 88 41 2726 e-mail: <a href="mailto:Alina.Tatarenko@coe.int">Alina.Tatarenko@coe.int</a>
Centers for Disease Control and Prevention	Dr Kenneth A. Clark, MD, MPH, Head International Blood Safety Team, Global AIDS Program, Centers for Disease Control and Prevention, Mail Stop E-04 1600 Clifton Road, NE, Atlanta, GA 30333 Tel: + 1 404 639 8057 fax: +1 404 639 8114 email: <a href="mailto:kjc4@cdc.gov">kjc4@cdc.gov</a> (Unable to attend)

European Blood Alliance	Dr Eila Sandborg Executive Secretary European Blood Alliance POB 9190 NL - 1006 AD Amsterdam, The Netherlands Tel: +31 20 512 3291 Fax +31 20 512 3559 e-mail: <a href="mailto:e.sandborg@sanquin.nl">e.sandborg@sanquin.nl</a>
European Commission (EC)	Ms Frances M. Delaney Health and Consumer Protection Directorate General Public Health and Risk Assessment Directorate Health Measures Unit European Commission JMO C5/73A L-2920 Luxembourg Tel: +352 4301 38215 Fax: +352 4301 33248 E-mail: <a href="mailto:frances.delaney@cec.eu.int">frances.delaney@cec.eu.int</a>
European Plasma Fractionation Association (EPFA)	Mr Theo Evers, Executive Director, European Plasma Fractionation Association (EPFA), Plesmanlaan 125, PO Box 9190, 1006 AD Amsterdam, Netherlands Tel: 31 20 512 35 61 Fax: +31 20 512 35 59 E-mail: <a href="mailto:epfa@sanquin.nl">epfa@sanquin.nl</a>
Food and Drug Administration (FDA), USA	Dr Jay Epstein, Director, Office of Blood Research and Review Center for Biologics Evaluation and Research Food and Drug Administration, HFM-300, 1401 Rockville Pike, Rockville, MD 20852, USA Tel: + 1 301 8273518 Fax: + 1 301 8273533 E-mail: <a href="mailto:epsteinj@cber.fda.gov">epsteinj@cber.fda.gov</a>
Health Canada	Dr Peter R. Ganz Director Health Canada, Biologicals and Radiopharmaceuticals Evaluation Centre, Tunney's Pasture; Building #6 Ottawa, Ontario, Canada KIA OL2 AL:0603D Tel: + 613 952 0237 Fax: + 613 948 3655 Email: <a href="mailto:Peter_ganz@hc-sc.gc.ca">Peter_ganz@hc-sc.gc.ca</a>
International Trauma Anaesthesia and Critical Care Society	Prof John Hess, Professor of Pathology and Medicine University of Maryland 5606 Oak Place, Bethesda, MD 20817 Tel: + 410 328 3834 Fax: + 410 328 6816 E-mail: <a href="mailto:jhess@umm.edu">jhess@umm.edu</a>
International Association of Biologists	Prof Jean Pierre Allain, MD, PhD University of Cambridge, Division of Transfusion Medicine Long Road Cambridge CB2 2PT, UK Phone (01223) 548044; Fax (01223) 242044; E-mail <a href="mailto:jpa1000@cam.ac.uk">jpa1000@cam.ac.uk</a>

ICCBBA	Mr Paul Ashford Executive director of ICCBBA, Inc 4117 Hillsboro Pike ; 103-307 , Nashville , TN 37215 , USA Tel : + 1 615 309 8928 Fax : + 1 615 309 8928 E-mail: <a href="mailto:paul.ashford@wbs.wales.nhs.uk">paul.ashford@wbs.wales.nhs.uk</a>
International Consortium for Blood Safety (ICBS)	Dr Mohamed El-Nageh, Executive Director, New York Blood Center, 310E 67 <sup>th</sup> Street, New York, NY 10021, USA Tel: + 1 212 570 3319 Fax: +1 212 570 3320 E-mail: <a href="mailto:Elnagehmm@aol.com">Elnagehmm@aol.com</a>
International Federation of Blood Donor Organizations (FIODS)	Mr Niels Mikkelsen, Secretary-General, Bloddonorernei Denmark, Vesterbrogade 191, 1800 Frederiksberg, Denmark Tel: +45 70 13 70 14 Fax: + 45 70 13 70 10 E-mail : <a href="mailto:mikkelsen@bloddonor.dk">mikkelsen@bloddonor.dk</a>
International Federation of Red Cross and Red Crescent Societies (IFRCRC)	Dr Robert Hetzel Chair of the IFRC Global Advisory Panel on Corporate Governance and Risk Management & Chief Executive Officer Australian Red Cross Blood Service 304 Nicholson Street, FITZROY, VIC, 3065, Australia - PO Box 2935, FITZROY, VIC, 3065, Australia tel: +61 39 412 1912 fax: +61 89 472 2020 email: <a href="mailto:rhetsel@arcbs.redcross.org.au">rhetsel@arcbs.redcross.org.au</a>
International Society of Blood Transfusion (ISBT)	Dr Paul Strengers, Secretary-General, ISBT Central Office Jan Goyenkade11, NL-1075 HP Amsterdam, The Netherlands Tel: 31 20 512 32 39 Fax: 31 20 673 7306 E-mail: <a href="mailto:isbt@eurocongres.com">isbt@eurocongres.com</a>
Plasma Protein Therapeutics Association, Europe (PPTA)	Mr Charles Waller, Executive Director, Plasma Protein Therapeutics Association Europe, Boulevard Brand, Whitlock 114/115, B-1200 Brussels, Belgium Tel: +32 2 705 5811 Fax: +322 705 5820 E-mail: <a href="mailto:ppta.eu@pptaglobal.be">ppta.eu@pptaglobal.be</a>
PPTA Source	Mr Jan Bult, President, PPTA Source 147 Old Solomons Island Road – Suite 100, Annapolis, MD 21401 USA Tel: + 410 263 8296 Fax: + 410263 2298 Email: <a href="mailto:jbult@pptaglobal.org">jbult@pptaglobal.org</a>
Thalassaemia International Federation (TIF)	Dr Androulla Eleftheriou, Scientific Director Thalassaemia International Federation 31 Ifigeneias Street, 2007 Strovolos Nicosia – Cyprus Tel: +357-22-319129 Fax: +357-22-314552 E-mail: <a href="mailto:thalassaemia@cytanet.com.cy">thalassaemia@cytanet.com.cy</a>

Therapeutic Goods Administration (TGA) Laboratories, Australia	Dr Albert Farrugia, Senior Adviser and Head, Blood and Tissue Products Group, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, P.O. Box 100, Woden, ACT, Australia 2606 Tel: +61 (2) 6232 8539 Fax: +61 (2) 6232 8635 E-mail: <a href="mailto:albert.farrugia@health.gov.au">albert.farrugia@health.gov.au</a>
World Federation of Hemophilia (WFH)	Mr Miklos Fulop, CEO/Executive Director, 1425 Rene-Levesque, Blvd West, Suite 1010, Montreal, Quebec, Canada, H3G IT7 Tel: +514 875 7944 Fax: +514 875 8916 E-mail: <a href="mailto:mfulop@wfh.org">mfulop@wfh.org</a>
World Health Organization (WHO)	Dr Neelam Dhingra A/Coordinator Blood Transfusion Safety programme (BTS) Tel: +41 22 791 46 60 Fax: +41 22 791 48 36 E-mail: <a href="mailto:dhingran@who.int">dhingran@who.int</a>
<b>WHO Collaborating Centres</b>	
<b>AFR</b>	
Zimbabwe	Dr M.E.Chitiyo, Medical Director National Blood Transfusion Service, Mazowe Street North PO Box A101, Avondale, Harare Tel: + 263 4 70 78 01/793552 Fax: + 263 4 70 78 20 E-mail: <a href="mailto:nbts@africaonline.co.zw">nbts@africaonline.co.zw</a>
<b>AMRO</b>	
Brazil	Dr Marcia Otani Fundação Pró Sangue Hemocentro de São Paulo Av. Dr Eneas de Carvalho Aguiar 44, B. Sangre CEP 05403.000 São Paulo Brazil Tel: 55 11 3061 55 44 ext. 353 Fax 55 11 3088 8317 email: <a href="mailto:otanimarcia@uol.com.br">otanimarcia@uol.com.br</a>
<b>EMR</b>	
Tunisia	Pr Kamel Boukef, Director, National Blood Transfusion Centre, Ministry of Public Health, 13 rue Djebel Lakhdar, Bab Saadoun, Tunis, 1006 Tel: +216 71 568 903 Fax: +216 71 562 957 E-mail: <a href="mailto:kamel.boukef@rns.tn">kamel.boukef@rns.tn</a>
Jordan	Dr Janiet Niquir Merza, Director, National Blood Bank, P.O. Box 10058, Al Ashrafieh, Amman <i>tel:</i> +962 (6) 474 91 23 <i>fax:</i> +962 (6) 474 91 23 <i>e-mail:</i> <a href="mailto:nbbam@moh.gov.jo">nbbam@moh.gov.jo</a> (Unable to attend)
<b>EUR</b>	

Finland	<p>Prof Jukka L.K. Koistinen  Deputy Director, Blood Transfusion Service, Finnish Red Cross,  Kivihaantie 7, Helsinki, 00310  Tel: +358 9 580 12 60  Fax: +358 9 580 1233  E-mail: <a href="mailto:jukka.koistinen@bts.redcross.fi">jukka.koistinen@bts.redcross.fi</a> and  <a href="mailto:Jukka.Koistinen@veripalvelu.fi">Jukka.Koistinen@veripalvelu.fi</a></p>
Netherlands	<p>Prof Cees Th. Smit Sibinga, Director WHO Collaborating Center,  Academic Institute for International Development of Transfusion  Medicine (IDTM), University of Groningen, and Sanquin  Consulting Services, Sanquin Blood Bank Noordoost, Post Bus  11085, Groningen, 9700 CB  Tel: +31 50 361 00 61 / +31 6 2223 4325  Fax: +31 50 361 90 39  E-mail: <a href="mailto:sibinga@wolmail.nl">sibinga@wolmail.nl</a> or <a href="mailto:c.smitsibinga@sanquin.nl">c.smitsibinga@sanquin.nl</a>  <a href="mailto:consulting@aabb.org">consulting@aabb.org</a></p>
<b>SEAR</b>	
Thailand	<p>Dr Rachanee O-Charoen, Director, National Blood Centre, The  Thai Red Cross Society, Henri Dunant Road, Bangkok, 10330  Tel: +662 251 3111  Fax: +662 255 5558  E-mail: <a href="mailto:rachanee@redcross.or.th">rachanee@redcross.or.th</a></p>
<b>WPR</b>	
Singapore	<p>Dr Diana Teo, Director, Centre for Transfusion Medicine  Health Sciences Authority, 1 Outram Road  Singapore 169078  tel: +65 229 06 05  fax: +65 223 86 82  e-mail: <a href="mailto:Diana_TEO@HSA.gov.sg">Diana_TEO@HSA.gov.sg</a></p>
China	<p>ZHU Yong Ming  President, Shanghai Blood Center  Director, WHO Collaborating Center for Development and  Research for the Services of Blood Transfusion  #1191, Hong Qiao Rd. Shanghai 200051, China  Tel +86 21 62956974  Fax +86 21 62958414  E-mail: <a href="mailto:ymzhu@sbc.org.cn">ymzhu@sbc.org.cn</a></p>
<i>In individual capacity as an expert</i>	
<b>AFR</b>	
Côte d'Ivoire	<p>Dr Seidou Konate, Medical Adviser, Centre National de  Transfusion Sanguine, KM4 Boulevard de Marseille 18 BP, 898,  Abidjan 18  Tel: +225 22522666/ 07 07 91 11  Fax: +225 21358060  E-mail: <a href="mailto:plasma@avisoci.ci">plasma@avisoci.ci</a>  (Unable to attend)</p>

South Africa	<p>Dr Anthon du P. Heyns, Director, South African National Blood Service, Private bag X14, Weltevreden Park, 1715          Tel: +27 11 761 91 11          Fax: +27 11 761 91 13          E-mail: <a href="mailto:aheyns@inl.sanbs.org.za">aheyns@inl.sanbs.org.za</a></p> <p>Mr Duncan Armstrong, Executive Director, Natal Bioproducts Institute, 10 Eden Road, Pinetown 3610, Private Bag X9043, Pinetown 3600          Tel: +27 31 719 67 89          Fax: +27 31 708 56 14          E-mail: <a href="mailto:armstrongd@nbi-kzn.org.za">armstrongd@nbi-kzn.org.za</a></p>
Uganda	<p>Dr Peter K. Kataaha, Senior Medical Consultant, Ministry of Health, P.O. Box 1772, Kampala          Tel: +256 41 259 195/257 155 / 25677431880          Fax: +256 41 257 484          E-mail: <a href="mailto:director@ubts.go.ug">director@ubts.go.ug</a></p>
<b>AMR</b>	
Argentina	<p>Dr Ana Emilia del Pozo, National Coordinator of Clinical Use of Blood Commission, International Affairs Secretary, Asociation Argentina de Hemoterapia e Immunohematologia          c/o Chacabuco 824, CP 1069, Buenos Aires          Tel: +54 11 43620645          Fax: +54 11 43085325          E-mail: <a href="mailto:adelpozo@speedy.com.ar">adelpozo@speedy.com.ar</a> <a href="mailto:anaemiliad03@yahoo.com.ar">anaemiliad03@yahoo.com.ar</a>          (Unable to attend)</p>
Brazil	<p>Dr Silvano Wendel, Medical Director, Blood Bank, Hospital Sirio Libanes, Rua D. Adma Jafet 91, 20 Andar, Sao Paulo, 01308-050          Tel: +55 11 3255 7746          Fax: +55 11 3257 1290          E-mail: <a href="mailto:snwendel@uninet.com.br">snwendel@uninet.com.br</a></p>
Honduras	<p>Dr Elizabeth Vinelli, Medical Director, National Blood Programme, Cruz Roja Hondureña, 2a Avenida, Entre 6a y 7a calle, Comayagüela, M.D.C.          Tel: +504 237 18 00          Fax: +504 238 0185          E-mail: <a href="mailto:cenasa@honduras.cruzroja.org">cenasa@honduras.cruzroja.org</a></p>
<b>EMR</b>	
Iran	<p>Dr Ali Akbar Pourfathoullah          Managing Director          Iranian Blood Transfusion Organization          IBTO bldg Hemmat EXP. Way, Teheran          Off: 009821 8288582/3          Fax: 009821 8288581          E-mail: <a href="mailto:pourfa@ibto.ir">pourfa@ibto.ir</a></p>
<b>EUR</b>	
Denmark	<p>Dr Casper Jersild, M.D., DMSC, Consultant, Jagtvej 3          DK-9000 AALBORG, Denmark          Tel: +45 (98 16) 38 18          Mobile Phone: +45 (23 29) 47 50          E-mail: <a href="mailto:jersild@dadlnet.dk">jersild@dadlnet.dk</a>          (Unable to attend)</p>

The Netherlands	Dr Kees Groeneveld, Scientific Officer, Health Council of the Netherlands, P.O. Box 16052, 2500 BB Den Haag., The Netherlands Tel: +31 70 340 56 88/75 20 Fax: +31 70 340 75 23 E-mail: <a href="mailto:K.Groeneveld@gr.nl">K.Groeneveld@gr.nl</a>
Russian Federation	Professor Evgueni Selivanov, Director, Russian Institute of Haematology and Transfusiology 2 <sup>nd</sup> Sovestskaya Street 16, St Petersburg, 193024 Russia Tel: + 7 812 274 56 50 Fax: +7 812 274 9227 e-mail: <a href="mailto:evgsell@mail.wplus.net">evgsell@mail.wplus.net</a> (Unable to attend)
United Kingdom of Great Britain and Northern Ireland	Dr Brian McClelland, Regional Director, Edinburgh and South-East Scotland Blood Transfusion Service, 41 Lauriston Place, Edinburgh, EH3 9HB Tel: +44 131 536 53 51 Fax: +44 131 536 53 52 E-mail: <a href="mailto:brian.mcclelland@snbts.csa.scot.nhs.uk">brian.mcclelland@snbts.csa.scot.nhs.uk</a>
<b>SEAR</b>	
India	Dr Zarin S. Bharucha, Transfusion Medicine Expert, 4/40 Wadia Baug, G D Ambekar Road, Mumbai, 400033, India Tel: +91 22 24710214 Fax: +91 22 24714927 E-mail: <a href="mailto:zsbharucha@rediffmail.com">zsbharucha@rediffmail.com</a> (Unable to attend)
India	Dr Nabajyoti Choudhury, Medical Director Prathama Blood Center, Behind Jivraj Mehta Hospital, Vasna, Ahmedabad-380007, India. Phone:+91-79-26600101 (O); 79-26851228 (R); Fax: +91-79-26611850; Mobile:9825414251. Email: < <a href="mailto:nc@prathama.org">nc@prathama.org</a> >; < <a href="mailto:nabajyoti_2000@yahoo.com">nabajyoti_2000@yahoo.com</a> >
<b>WPR</b>	
Japan	Dr Masatoshi Kanai, Director, Blood Safety Division Medical and Pharmaceutical Bureau, Ministry and Health, Labour and Welfare, 1-2-2 Kasumigaseki, Chiyoda-ku, 100-8916, Tokyo, Japan E-mail: <a href="mailto:kanai-masatoshi@mhlw.go.jp">kanai-masatoshi@mhlw.go.jp</a> (Unable to attend)
Malaysia	Dr Yasmin Ayob, Director, National Blood Centre, Jalan Tun Razak, Kuala Lumpur, 50400 Tel: +603 26 95 55 55 Fax: +603 269 258 26/80362 E-mail: <a href="mailto:yasminpd@tm.net.my">yasminpd@tm.net.my</a> (Unable to attend)

Hong Kong	Dr Lin Che Kit, Hospital Chief Executive Hong Kong Red Cross, Blood Transfusion Service 15 King's Park Rise, Kowloon Hong Kong Tel. no.: 852 2780 1862 FAX: 852 2780 1862 e-mail: <a href="mailto:cklin@ha.org.hk">cklin@ha.org.hk</a>
<b>Invited Organization/Speakers</b>	
Individual Expert	Dr Jerry Holmberg, Ph.D. Senior Advisor for Blood Policy and Executive Secretary Advisory Committee on Blood Safety and Availability Department of Health and Human Services 1101 Wootton Parkway, Suite 250 Rockville, MD 20852, USA Tel: + 301-443-2331 Fax: + 301-443-4788 E-mail: <a href="mailto:JHolmberg@osophs.dhhs.gov">JHolmberg@osophs.dhhs.gov</a>
Individual Expert	Mr Julius Court Research Fellow Overseas Development Institute (ODI) 111 Westminster Bridge Road London SE1 7JD, UK Tel: +44 20 7922 0368 Email: <a href="mailto:jcourt@odi.org.uk">jcourt@odi.org.uk</a>
Agence Francaise de Sécurité Sanitaire des Produits de Santé (AFSSAPS)	Dr Jean-Hugues Trouvin 143/147, Bd. Anatole France, 93285 Saint Denis CEDEX, France tel: +33 1 55 87 40 37 fax: +33 1 55 87 40 32 e-mail: <a href="mailto:Jean-Hugues.TROUVIN@afssaps.sante.fr">Jean-Hugues.TROUVIN@afssaps.sante.fr</a> (Unable to attend)
Australian Red Cross Blood Service	Ms Sally Thomas Australian Red Cross Blood Service tel: +61 39 412 1912 fax: +61 89 472 2020 email: <a href="mailto:SThomas@arcbs.redcross.org.au">SThomas@arcbs.redcross.org.au</a>
Biomedical Excellence for Safer Transfusion (BEST) Collaborative'	Prof John Hess, Professor of Pathology and Medicine University of Maryland 5606 Oak Place, Bethesda, MD 20817 Tel: + 410 328 3834 Fax: + 410 328 6816 E-mail: <a href="mailto:jhess@umm.edu">jhess@umm.edu</a>
Establissement français du sang, France	Mr Jean-François Riffaud Director, Communications and International Affairs Tel: +33 (1) 44 49 65 71 Fax: +33 (1) 44 49 66 01 French Blood Establishment (Establissement français du sang) E-mail: <a href="mailto:jean-francois.riffaud@efs.sante.fr">jean-francois.riffaud@efs.sante.fr</a>

Paul Ehrlich Institute	Prof. Dr Rainer Seitz, Head. Dept. Haematology and Transfusion Medicine Paul Ehrlich Institute 51-59 Paul Ehrlich Strasse, 63225 Langen Tel: 0049-6103-772600 Fax +49-6103-771250 E-mail: <a href="mailto:seira@pei.de">seira@pei.de</a>
Swiss Red Cross Blood Transfusion Service	Dr Guy Levy Medical Director Blood Transfusion Service SRC Gutenbergstrasse 14 Postfach 5510 3001 Bern, Switzerland Tel : +41 31 380 81 86 Fax: +41 31 380 81 80 Mail : <a href="mailto:guy.levy@redcross.ch">guy.levy@redcross.ch</a>
UK NBS	Mr Steve Morgan Project Leader, NBS International New Address:2440-2430 The Quadrant Aztec West, Almonsbury Bristol BS32, England Telephone: 01454-841401 07711-447415 (Mobile) Fax 01454 84 1630 E-mail: <a href="mailto:steve.morgan@nbs.nhs.uk">steve.morgan@nbs.nhs.uk</a>
<b>Observers</b>	
Establissement français du sang, France	Dr Maurice Chassaigne Etablissemnt français du Sang 29 rue du Chemin Blanc France +33 2 47 65 90 48/33 68 999 55 90 +33 2 47 65 90 48
International Association of Biologicals	Dr Girish Vyas Professor Dept of Laboratory Medicine, 513 Parnassus Avenue; Room S-561, UCSF School of Medicine, San Francisco, USA Tel: + 415 476 4678 Fax: + 415 476 6322 Email: <a href="mailto:vyas@itsa.ucsf.edu">vyas@itsa.ucsf.edu</a>
International Federation of Red Cross and Red Crescent Societies (IFRCRCS)	Mr Peter Carolan, Senior Officer, Case Postale 372, 1211 Geneva 19, Switzerland. tel: +41 22 730 42 22 fax: +41 22 733 03 95 e-mail: <a href="mailto:carolan@ifrc.org">carolan@ifrc.org</a>

Iran	Dr. Ahmad Gharehbaghian Deputy of managing director of IBTO for research & education affairs Department of research & education IBTO bldg, Next to the Milad tower Hemmat exp way Tehran-Iran Tel: (+9821) 8288501-20 Fax: (+9821) 8288555 <a href="mailto:gharehbaghian@ibto.ir">gharehbaghian@ibto.ir</a>
Marketing Research Bureau	Mr Patrick Robert President The Marketing Research Bureau, Inc. 284 Racebrook Road Orange, CT 06477 USA <a href="mailto:mrb_ibpn@earthlink.net">mrb_ibpn@earthlink.net</a>
<b>WHO REGIONAL OFFICES</b>	
<b>Dr Jean-Baptiste Tapko , Regional Adviser,</b> Blood Safety, WHO Regional Office for Africa (AFRO)	<i>tel:</i> +47 2 41 39250 <i>fax:</i> +47 241 39511 <i>e-mail:</i> <a href="mailto:tapkoj@afro.who.int">tapkoj@afro.who.int</a>
<b>Dr Jose Cruz, Regional Adviser,</b> Laboratory, WHO/PAHO AMRO, Regional Office for the Americas (Unable to attend)	<i>tel:</i> +1 202 974 3230 <i>fax:</i> +1 202 974 3663 <i>e-mail:</i> <a href="mailto:CRUZJOSE@paho.org">CRUZJOSE@paho.org</a>
<b>Dr Nabila Metwalli, Regional Adviser,</b> Laboratory, WHO Office for Eastern Mediterranean Region (EMRO)	<i>tel:</i> +202 670 5314 <i>fax:</i> +202 2765416 <i>e-mail:</i> <a href="mailto:metwallin@emro.who.int">metwallin@emro.who.int</a>
<b>Dr Valentina Hafner, Medical Officer</b> WHO Regional Office for Europe (EURO)	<i>tel:</i> +45 39 17 1265 <i>fax:</i> +45 39 18 18 <i>e-mail:</i> <a href="mailto:IKA@who.dk">IKA@who.dk</a>
<b>Dr Rajesh Bhatia,</b> WHO Office for the South East Asian Region (SEARO) (Unable to attend)	<i>tel:</i> +11 23370804 <i>fax:</i> +11 332 7972 <i>e-mail:</i> <a href="mailto:kumaris@whosea.org">kumaris@whosea.org</a>
<b>Dr Yu Jungping, Blood Safety Specialist,</b> WHO Office for the Western Pacific Region (WPRO) (Unable to attend)	<i>Tel</i> + 632 528 9848 <i>fax:</i> +632 521 1036 <i>Email:</i> <a href="mailto:yuj@wpro.who.int">yuj@wpro.who.int</a>
<b>WHO SECRETARIAT</b>	
<b>Dr Steffen Groth</b> Director, Essential Health Technologies	<i>tel:</i> +41 22 791 4387 <i>fax:</i> +41 22 791 48 36 <i>e-mail:</i> <a href="mailto:groths@who.int">groths@who.int</a>
<b>Dr Neelam Dhingra</b> <b>(Project Leader, GCBS Secretariat)</b> A/Coordinator Blood Transfusion Safety (BTS)	<i>tel:</i> +41 22 791 46 60 <i>fax:</i> +41 22 791 48 36 <i>e-mail:</i> <a href="mailto:dhingran@who.int">dhingran@who.int</a>
<b>Mrs Shân Lloyd</b> Technical Officer Blood Transfusion Safety (BTS)	<i>tel:</i> +41 22 791 33 41 <i>fax:</i> +41 22 791 48 36 <i>e-mail:</i> <a href="mailto:lloyds@who.int">lloyds@who.int</a>

<b>Ms Jan Fordham</b> Technical Officer Blood Transfusion Safety (BTS)	<i>el:</i> +41 22 7913644 <i>fax:</i> +41 22 791 48 36 <i>e-mail:</i> <a href="mailto:fordhamj@who.int">fordhamj@who.int</a>
<b>Dr Noryati Abu Amin</b> Medical Officer Blood Transfusion Safety (BTS)	<i>el:</i> +41 22 7913948 <i>fax:</i> +41 22 791 48 36 <i>e-mail:</i> <a href="mailto:abuaminn@who.int">abuaminn@who.int</a>
<b>Dr Luc Noel</b> Coordinator, Clinical Procedures	<i>Tel:</i> +41 22 791 3681 <i>Fax:</i> +41 22 791 4836 <i>E-mail:</i> <a href="mailto:noell@who.int">noell@who.int</a>
<b>Dr Ana Padilla</b> Scientist, Quality and Safety of Plasma Derivatives	<i>tel:</i> +41 22 791 38 92 <i>fax:</i> +41 22 791 48 36 <i>e-mail:</i> <a href="mailto:padillaa@who.int">padillaa@who.int</a>