Report of the first meeting of the

**Global Collaboration for Blood Safety**

**GENEVA, 14–17 NOVEMBER 2000**

*Department of Blood Safety and Clinical Technology*  
*World Health Organization*
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Executive Summary

**Background**

The Global Collaboration for Blood Safety (GCBS) was established following a decision to select blood transfusion safety as a priority strategy for 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 as provided in Annex 3.

The first meeting of the Global Collaboration for Blood Safety (GCBS) took place in Geneva from 14 to 17 November 2000. Dr Roger Dodd was elected as Chairman, with Dr Rajesh Bhatia as Vice-Chairman for the period November 2000 to November 2001.

**Summary of discussions**

Several important factors were identified as key to the safety of blood products.

Participants agreed that a well-organized national blood transfusion service, with the formalized commitment and support of the government, is a pre-requisite for the safe and effective provision and use of blood and blood products.

A competent national regulatory authority is an important component for blood safety. Monitoring, evaluation and corrective measures should be established and developed within the different levels of technological advancement of the blood service. Transparent decision making processes will ensure that the public is informed and have confidence in the system. In developing countries, particular emphasis should be put on measures that can help upgrade blood programmes from simple to higher levels of technical expertise and safety, such as strengthening the effective organization and management of the programmes. Trying to implement costly systems without the necessary finances and skills will not result in improved services or safety. In developed countries many interventions for blood transfusion safety are implemented as a precautionary measure with marginal benefits that are not cost-effective and cannot be justified when compared with other pressing health care needs. Political considerations in the decision-making process often override scientific data and economic considerations.

The GCBS will play an important role for national health and/or regulatory authorities by providing a forum for exchange of information and views on how decisions are made at national and regional levels. Requirements for mutual assistance, particularly between developed and developing countries can be identified and fostered. Existing successful transfusion services have been identified and should be used as models. Coordination of all partners in multi-bilateral and bilateral assistance projects is a key to success in many resource-poor countries. Well planned, long-term projects where there is commitment and support from the national health authorities are essential ingredients for success. Appropriate accreditation mechanisms should be developed for successful and well-organized blood transfusion programmes.

Evidence on lack of blood products and the burden of disease, particularly as they relate to clinical use within a health care system, need to be better defined. The importance
of a strong interface between clinicians and transfusion services is essential since the ultimate goal is the care of the donor and the patient.

Outcome indicators are needed to measure the effective clinical use of blood products and the impact on patient care. Thalassemia and haemophilia patients exemplify existing inequities in access to diagnosis and safe treatment by blood products.

Last but not least, it was strongly stated that the cornerstone of a safe and adequate supply of blood products is the education, motivation, recruitment and retention of voluntary non-remunerated blood donors from low-risk populations. It was stressed that payment of any kind in economically restricted countries would pose a threat to the safety, affordability and adequacy of the blood supply and would hinder any attempts to implement this strategy.

The Director-General of WHO, during her intervention, confirmed to GCBS participants the commitment of the Organization to blood safety, and highlighted the importance of blood donors themselves in any advocacy effort. Dr Brundtland looked forward to the implementation of the recommendations of this international collaboration.

**Recommendations**

1. Health authorities should be encouraged to develop nationally coordinated blood programmes with appropriate regulatory systems with competent, well-trained staff. Standards, surveillance, accreditation and corrective measures should be established, for which the GCBS can provide generic guidance.

2. There is a need for a policy formulation tool whereby decision-makers can have access to information shared by others on how decisions are made. Policymakers should have this information – together with input from relevant transfusion professionals, blood donor and other relevant organizations – before decisions on major national policy changes or programmes are reached.

3. Each national health authority should be able to monitor risk assessment in the blood delivery system, including appropriate mechanisms for feedback and monitoring. The complexity of the system can vary with the relative maturity of the blood service. Models of successful national and regional alert systems, such as those in Europe and in the airline industry, should be emulated.

4. Information on blood transfusion safety, risk assessment, quality systems and other relevant material should be collected and shared and the GCBS can provide a valuable central function in this respect through the Secretariat. The global database on blood safety and the quality management project are valuable tools that should be further developed and regularly updated.

5. Developing countries should improve their blood transfusion programmes within their national context, even if such improvement is achieved gradually. Model systems, basic programme requirements and appropriate information can be obtained with the assistance of the GCBS.

6. Coordination of support activities is vital to avoid duplication of effort and conflict between programmes. The GCBS can act as a clearing house, and serve as a resource, for example in coordinating donor assistance to improve blood programmes at national level.

7. Health authorities responsible for blood programmes should support measures designed to reduce the need for transfusion, such as: training professionals in the appropriate clinical use of blood; reducing anaemia and the impact of malaria and through a strong interface between the blood programme and pa-
tient-care clinicians, public health specialists and prescribers of blood.

8. The GCBS should encourage effective measures to educate, motivate, recruit and retain voluntary, non-remunerated donors from low risk populations, using successful programmes as models (e.g. the “Club/Pledge 25” concept for adolescents).

9. Three GCBS Working Groups should be formed to elaborate a plan of action to address the key issues identified at this meeting and report back to the 2001 plenary session. A detailed summary of the discussions and recommendations in preparation for these Working Groups can be found in Annex 5 (see pp 36-44).

- Working Group on Quality Assessment and Assistance for Development. This group will gather information, in particular from the Global Database on Blood Safety, define methods to obtain further evidence, assess needs and categorize countries. It should also establish the basis of an accreditation scheme for blood transfusion services. The group will identify models that can be used for developing countries to set up national quality systems, and will provide recommendations for implementing, monitoring and improving the transfusion system.

- Working Group on the Policy Process. The group will address decision-making and policy formulation for blood safety and risk management. It will provide a forum for regular exchange between national regulatory authorities from developed and developing countries to promote a quality process for policy making related to blood safety and availability.

- Working Group on Plasma Issues. This group will discuss possible approaches to provision of plasma-derived products in various context, how to address the needs for plasma as raw material for fractionation, and the value of self sufficiency. The group will design a model to estimate needs in plasma-derived products according to the health care system level and identify justified fractionation centres on a cost effectiveness basis. It will review current material on cross border movements of plasma for fractionation and diagnostic purposes, and make appropriate recommendations for use by national authorities.
The meeting was opened by Dr Yasuhiro Suzuki, Executive Director, Health Technology and Pharmaceuticals cluster. After welcoming the participants Dr Suzuki summarized the history of the formation of the Global Collaboration for Blood Safety (GCBS) and spoke of its aim to serve as a forum for the exchange of ideas and information on international blood safety issues. He noted that WHO is committed to blood safety as evidenced by the 2000 World Health Day theme, and by the US$2.3 million efficiency savings attributed by WHO to this priority. The aim of this meeting is to build partnerships and raise awareness of key issues relating to blood safety.

After the introduction of the participants, Dr Jean C. Emmanuel, Director of the Department of Blood Safety and Clinical Technology (BCT) reviewed the history of the formation of GCBS in more detail. The impetus of this collaboration stemmed originally from the discovery of international trafficking of HIV-contaminated plasma and plasma products in 1993 in Europe. This led to a WHO informal consultation of experts in blood transfusion, plasma derivatives and medicinal products, national regulatory authorities, the International Society for Blood Transfusion (ISBT) and others. Recommendations were published, referencing existing guidelines and World Health Assembly resolutions, that pointed to the responsibility of national regulatory authorities to monitor the movement of plasma across national borders. The safety of the global blood supply thereby became a priority area, as did efforts to establish an international collaboration for blood safety at the Paris AIDS summit in 1994. The recommendations of this summit formed the basis of WHA 48.27, a resolution adopted by the Forty-eighth World Health Assembly in May 1995.

With the strengthening of the Blood Transfusion Safety (BTS) team at WHO, and the generous support of the Government of Japan, the Global Collaboration for Blood Safety has now been officially established.

**Objectives**

The aims of the GCBS are to provide a forum for participants to:

- share information, ideas and experiences;
- develop a common understanding of the challenges facing blood product safety nationally and internationally;
- increase opportunities to find solutions to these challenges;
- keep pace with developments in the field;
- establish collaborative alliances.

**Election of Chairs/Rapporteurs**

The elected chairperson of the GCBS for its first year from November 2000 is Dr Roger Dodd and the vice chair Dr Rajesh Bhatia. The rapporteurs of this meeting were Drs Albert Farrugia and Richard Davey.

Participants adopted the proposed programme for the meeting.

**General discussion**

Participants then discussed the history and rationale behind the formation of the GCBS. Dr Emmanuel underlined the cooperative focus of the GCBS for all partners concerned, with WHO fulfilling the role of Secretariat. In this way, decisions on approaches, actions and allocation of responsibilities can be reached by common agreement, as opposed to by mandate.
Other remarks made by participants included the following: Acknowledgement of past work accomplished through the Global Blood Safety Initiative? In the context of the need to assist developing countries to strengthen their regulatory systems, many different systems are in place, and each one must have a competent national authority to monitor the blood system, the import and export of blood products, and to act as an interface with other countries in blood safety decision making? Generic guidance is needed for countries that have an inadequate regulatory system? A regional approach is also relevant and fits well within the structure of WHO.

**Decision:** the overall direction of the GCBS was approved.
Global overview on blood safety

Dr N. Dhingra-Kumar, Medical Officer in the WHO/BTS team gave an overview of the Global Database on Blood Safety (GDBS). She noted that developed countries, representing 20% of the world population, have access to 80% of the global safe blood supply. The blood donation rate per 1000 population is 18 times higher in countries with a high human development index (HDI) than in countries with low HDI. In developed countries, most blood is given by voluntary, non-remunerated donors while blood in less developed countries is donated primarily by paid or family donors. Only 16% of the blood supply in developing countries is donated by voluntary, non-remunerated, low-risk blood donors.

There are also wide disparities in the extent of testing: developed countries test 100% blood for the major transfusion transmitted diseases, while 43% of the blood available to countries with a low or medium HDI is not tested for one or more major transfusion transmitted infectious agents. Whole blood is the predominant transfusion product in developing countries, while blood components are used extensively in developed countries.

Dr J. Koistinen reported on the use of labile components in developed countries. The use of red cell concentrate ranges from more than 60 per 1000 inhabitants to less than 30.

In the last 15 years, most countries have experienced an evolution in their use of red cell concentrates, whether rising or falling. France, for example, has decreased its use of red cells by more than 41%. At the present time, a group of countries using from 30 to 40 red cell concentrates per 1000 inhabitants (Australia, Canada, Czech Republic, Estonia, France, Hungary, Ireland, Italy, Norway, Slovenia, UK) may show a reasonable target for the needs of developed health care systems.

Similar variations in usage can be seen with other labile blood products. Such differences are observed not only between countries, but between regions, hospitals or even prescribing physicians. Factors affecting usage included recognition of risks, the number of major operations performed, a patient’s age when over 65, local traditions and surgical skills. It is the responsibility of the transfusionist to contribute to the appropriate use of blood products.

Mr Patrick Robert reported on plasma resources and needs in developing and developed countries alike. While distinguishing between mature, emerging and under-
served markets, he noted that the total world market for plasma products is US$5.1 billion. Thirty-three per cent of products are used in Europe, 32% in North America and the remainder in other areas of the globe. Not-for-profit organizations account for 20%. In 1999, the mean capacity of commercial fractionation plants was 2.3 times higher than not-for-profit ones.

The use of plasma products depends on a variety of factors: commercial marketing strategies, product promotion, the education of physicians, the ability to diagnose illnesses appropriately, funding and pricing, product availability and government support. Apheresis plasma accounts for 68% of the product and recovered plasma, 32%. The market is now driven by the demand for intravenous immune-globulin.

During discussion, the meeting recognized that in the United States, although blood donation is taken only from voluntary, non-remunerated donors, “source plasma donors” are paid. However, this can only exist where there is a strong and strictly regulated system with good manufacturing practice.

Dr Luc Noel, Coordinator of the BTS team, reiterated the priority that WHO has placed on blood safety, especially on the provision of quality systems in all countries. The Quality Management Programme is a long-term project to create networks – at national, regional, sub-regional and global level – to improve quality in blood transfusion. The first step in the process is a four-week course for future quality managers. Dr Noel briefed participants on the progress of BTS in developing regional or sub-regional Quality Training Centres, that will serve as reference, training and follow-up centres.

Dr Gaby Vercauteren, Scientist in the BTS team, presented the team’s budget. In 1999, 48% of the WHO regular budget contribution was allocated to staff costs, 30% for operations and lesser amounts for consultants, meetings and travel. Activities have therefore depended largely on extrabudgetary resources. For 2000-2001, additional funds from WHO efficiency savings – US$2.3 million – have been attributed to blood safety as a priority topic. The regional office share of this total will be US$1.8 million, with the remaining US$500 000 allocated to HQ. The proposed BTS budget for the biennium 2000-2001 is US$6.2 million, of which 74% is extrabudgetary contributions.
Dr Antonio Giulivi spoke on international exchanges in risk assessment for blood safety. He reviewed the Canadian experience, which stimulates the collection and sharing of blood safety data. There are many interdependent links with the agencies involved. He believed that risks must be calculated based on the individual national situation, and that the precautionary principal must be applied intelligently, if and when appropriate. The possibility of transmission of variant Creutzfeld Jakob Disease (vCJD) by transfusion of blood products was a good example of the need to balance a theoretical risk with precautionary measures.

Dr Robert Will provided an overview of vCJD epide- miology. To date, there is no data to support the possible transmission by transfusion of vCJD. Notwithstanding many uncertainties, theoretical risks must be acknowledged given the extensive bovine epidemic and widespread exportation of live cattle from the UK during the BSE epidemic.

In the discussion that followed, surveillance, modelling, science-based risk assessment and reactive regulatory bodies were considered essential components to be able to address risks and allow regular reconsideration of policies. The harmonization of risk assessment and the policy/regulatory process will optimize international exchanges. This does not preclude a country-to-country approach to rational decision-making, but should strengthen the quality of the decision.

Several participants pointed to the growing gap between rich and poor countries, where the former can implement precautionary measures, and the latter still lack resources for basic safety measures. How relevant, therefore, is the theoretical vCJD threat to developing countries? The need to improve the appropriate use of blood in any context was emphasized. Several risk assessment methods exist in developed countries, which are not feasible in developing countries for lack of resources or difference in blood donation and collection (mathematical method used in the United States and Australia). Support is needed to assist developing countries to formulate strategies for a needs assessment, including risk assessment.

Dr Strengers outlined the European concept of an alert network to identify blood transfusion threats. He contrasted the mandatory approach of France in the haemovigilance initiative to the voluntary reporting system in the UK. Six European countries have developed an alert system using pooled information, early detection, transparency, and clear links between blood centres, hos-
pitals and clinicians. This interdependence is essential for an integrated system and forms the basis for linked policy development.

During the discussion, an information base for adverse events was considered a desirable tool as a prelude to assessing risks, and a way to influence transfusion practices and optimize the usage of blood products. Dr Epstein observed that baseline data are necessary to evaluate trends, possibly in sentinel projects. Dr Lackritz spoke of the need for serum repositories in developing countries. A valuable model has been developed by the airline industry which incorporated non-punitive reporting with data analysis and feedback.

Several participants from developing countries observed that these systems may not be appropriate for the basic needs of their transfusion systems. Instead, more efforts should be placed on improved testing and on the recruitment of safe blood donors. It was also noted, however, that a basic error detection and correction system is essential for blood programmes in all countries, with the information accessible by the national regulatory authority. Transparency was considered a key aim.
GCBS for improving blood safety policy formulation

Brian McClelland summarized a consultation held in March 2000 on blood safety policy issues from an international perspective (see Annex 4). While developing countries were struggling with issues of unsafe blood, unsterile equipment, no infrastructure and poor skills, developed countries were dealing with issues of cost-effectiveness. The meeting identified the following requirements:

- a process to assist in policy development and priority setting
- a blood database to shore up the necessary knowledge base.
- cooperation between government, blood transfusion services and the health care industry
- increased sharing of information (GCBS)
- global dialogue on the impact of new initiatives in developing countries (WHO).

Dr Peterson discussed the need for a forum to discuss blood safety issues from a Canadian perspective. He commented on the need to identify the key components of the blood transfusion chain, from donor selection to recipient follow-up, to ensure collaboration and coordination among the key component parts, and the regulation of both products and practices in blood transfusion safety.

Regulatory authorities may cover product and/or establishment licenses, and accreditation by the government or a third party. Standards for accreditation are required, that may involve different levels of implementation, with a minimum level for international accreditation. Each country should determine its level of risk adversity with appropriate application of the precautionary principle. Surveillance can be passive or active, comprehensive or based on a sample, and the scope of penalties must be established.

Dr Peterson concluded that the impact of individual country decisions on others must be assessed; there must be an understanding on how decisions are made; and each country must strive for excellence in their own national context.

Professor Anthon Heyns gave a presentation on the needs of developing countries, and highlighted the following points: donor selection and questionnaires should be designed for each country’s existing system? Post-donation counselling can provide important information? Simple interventions can often yield major results as shown by South Africa’s blood donors educated through a “club” system? We must acknowledge the gulf between developed and developing countries and collaboration must be based on this reality. This includes current “not-perfect” systems and the use of family donors? Whole blood may be the primary component collected and used? Simple tests and cross-matches may be acceptable? Regional training, laboratory and fractionation networks may be useful? Programmes may gradually upgrade from simpler to higher levels rather than try to achieve the “best” system in one go.

Ms Liz Furler outlined the tools that are necessary to formulate blood safety policy. She noted that science and public policy are not the same. There is a need for evidence-
based decisions, but also a need to anticipate problems and avoid crises. Involving the public, consumers and clinicians in all major decisions should be a rule. R&D knowledge should be available to policymakers and clinicians. Politicians may regard blood safety as a money sink. Therefore, it is important to “package” policy issues for the political decision makers. GCBS should be a clearing house for information and should develop regional performance measures.

A discussion followed the above presentations on policy formulation. It was agreed that scientific, economic and political views must all be considered. The process of risk assessment and risk management needs to be defined, with each country making its own decisions. The HIV situation has eroded public trust and political decisions are often based on restoring that trust.

Discussion also focused on the possibility for the GCBS to establish a hierarchy of standards for blood transfusion centres, with a mechanism for them to upgrade as appropriate.
GCBS for improving collaborative mechanisms in blood transfusion

Dr Guy Levy described the items necessary for the success of national projects. He commented on specific problems encountered by the Swiss Red Cross in Swaziland and Egypt, and considered that extensive information should be available before country projects are initiated. Most projects take at least five years to become successful; cooperation is therefore essential at the national level, with all levels at WHO acting together.

Dr Peter Kataaaha informed the group about the experience in Uganda. Compared to the low blood donation of 600 units in 1986, the Ugandan blood service now collects 70,000 units annually, and has seen a conversion from family to volunteer donors. This is the result of extensive training and public education, with relevant external aid. Within any country, the transfusion services must be consistent and coordinated at national level, as must the various sources of international assistance. Different funding agencies, with WHO, can work productively together in a given country.

Dr Casper Jersild noted ways in which he felt the GCBS could be effective in the field. He further hoped that expertise could be pooled, and that slow and non-uniform projects could be avoided. Dr Jersild commended training in blood transfusion safety using distance learning materials (DLM) and the quality management training (QMT), which have proven effectiveness.

Dr Roger Dodd commented on the programmes of the American Association of Blood Banks (AABB), particularly those relating to standard setting and international accreditation. He suggested that regional accreditation measures could be considered, with AABB “accrediting the accreditors.” Educational activities are given special attention at the AABB annual meeting.

Following discussion, participants proposed that policy formulation must be based on

local needs, and that the AABB cooperate with WHO in setting international standards. It was further suggested that countries and interested groups might present ideas to the GCBS, who would provide a clearance and triage function for these parties.
GCBS for improving availability and access to safe transfusion therapy

Dr Meena Cherian presented the situation in India, where there is a lack of infrastructure and public misconception about blood and blood donations. This is compounded by a lack of knowledge among clinicians. Furthermore, little guidance is available, resulting in an insufficient blood supply and misuse of resources. Guidelines, public and professional education, and advocacy for blood issues would go some way to solving the problems, as well as closer cooperation between the transfusion service and clinicians.

Dr Eva Lackritz discussed how to measure blood service needs. Distribution of test kits is not enough. Management, training, supervisory skills and back-up strategies are also needed. Dr Lackritz reported data from Kenya demonstrating that transfusions were not given in a timely fashion, and that clinicians did not use haemoglobin values or clinical signs in making transfusion decisions. Measures to prevent anaemia and combat malaria must be encouraged, as acute malaria anaemia in children is a primary reason for transfusion.

Dr Androulla Eleftheriou made some remarks on behalf of the Thalassaemia International Federation (TIF). Thalassaemia and other haemoglobinopathies are present all around the world, yet the number of patients receiving adequate transfusion therapy varies with the socio-economic status of the country. Testing of all donations for all relevant transfusion transmissible agents is essential for recipients since they depend on regular transfusions. Access to iron chelation therapy is also a source of inequity. Improving the physicians’ knowledge in the diagnosis and proper care of thalassaemia patients is a priority, but patient care is only possible if safe blood products are available.

Dr Line Robillard, on behalf of the World Federation of Hemophilia (WFH), told participants that 75% of haemophiliacs are not getting adequate care. In her presentation, she cautioned that unless the cost of recombinant coagulation factor concentrate declines, most patients will continue to rely on blood products, often on labile blood products for lack of access to virion-inactivated coagulation factor concentrates. The risk of HIV and HCV remains high in developing countries. Self-sufficiency in plasma factor production may no longer be a major priority of countries and may be
uneconomic for many countries. Suggestions to address this include the need to set standards for plasma quality, to publish guidelines for regulations in developing countries and monitor international movement of plasma products.

Mr Ashock Verma gave an overview of haemophilia sufferers in India where there is no insurance or government support for the estimated 50,000 hemophiliacs. Over 6,600 are registered with the Haemophilia Federation of India, which attempts to educate and educate patients and families, and procure Factor VIII at a low price or by donation.

In the discussion it was agreed that safe products can be made without the regulatory redundancy that exists in developed counties, although there are political and legal difficulties for developing countries to accept these products. Intermediate purity plasma products may be very useful for developing countries.
GCBS for improving efficacy of regulation and control of blood products

Professor Heyns discussed the issue of national oversight of the transfusion services in South Africa. He outlined the respective roles and responsibilities of the National Blood Committee, the government regulatory authority and the South African National Blood Service (SANBS) which is the fruit of a recent consolidation of smaller blood services.

Of interest was the two-way relationship whereby the SANBS is in partnership with several related national organizations, and blood donors are actively involved in SANBS activities. Oversight is assured through several governmental and nongovernmental organizations, although inadequate staffing and training problem for government regulators poses a problem and an inspection scheme for blood centres still needs to be initiated.

Dr Feng Gao outlined the regulatory structure in China. A National Donation Law passed in 1998 encourages voluntary donation and safety improvements. Donors are qualified by a pre-donation sample and are again screened after they have been cleared to donate. Plasma centres are monitored essentially by the 38 plasma fractionation plants in the country.

Problems include window HIV donations, training of administrators, evaluation of reagents and the development of standard protocols. A lot release policy is in place for blood screening kits since problems were encountered with the quality of imported kits. Participants posed several questions on the pre-donation qualification sample, related to donor confidentiality and retention. Dr Feng Gao acknowledged that more data must be obtained to establish the benefits of such a procedure.

Dr Rajesh Bhatia spoke about the regulatory situation in India. The national blood laws is jointly enforced by central and provincial authorities and a joint licence is issued. Inspectors are understaffed and trained. Criteria for acceptance of test kits are being developed to evaluate the 75% that are imported, for which external assistance would be helpful. The availability of standards and test panels, as well as IT and networking capacity were also identified as problems.

Dr Thérèse Hornez described the regulatory structure in France, defined by laws passed in 1993 and 1998. A single operator for transfusion services in France exists since the beginning of the year 2000. Oversight of the transfusion service is carried out by the AFSSAPS, the French Health product safety agency. AFSSAPS is responsible for inspection, evaluation and control, including haemovigilance. Inspectors of blood transfusion services need specific training. Within the inspection department of AFSSAPS, a special section deals with biological products with three subdivisions: organ tissue and cells, modified biological products and labile blood products.

The general discussion on this chapter focused on the role of blood services in public health. It was noted that blood centres engaged in public health practices such as cholesterol testing ran risks of becoming involved in clinical practice issues. Dr Heyns stated that the involvement of the
South African blood system with other public health agencies did not involve any additional screening tests on blood donors. Transfusion services are promoters of health awareness in blood donors as exemplified by reduced HIV incidence in the "pledge 25" young blood donors club. Blood donors themselves can relay health awareness in the general population. Dr Chitiyo emphasized that the initial “dry pack” donation system in Zimbabwe differs from the pre-donation sample system used in China since it offers the possibility of a preliminary test of the donor before collection for cellular components, but does not allow for any ambiguity. There was agreement that strategies have to be adapted to a specific context, i.e. incidence of viral infections, difficulties in recruiting regular donors, etc.
Mr James Reilly presented the quality and safety measures used by the Plasma Protein Therapeutics Association (PPTA) worldwide and the American Blood Resources Association (ABRA). The latter now has global membership and is considered the international authority for the source plasma collection industry. Plasma donors are paid and as such, the industry has instituted such a stringent and extensive set of standards for donors and testing that the final product is comparable to the safety levels in voluntarily donated blood.

Dr Theo Evers outlined the risk management strategy of the European Plasma Fractionation Association (EPFA). The disease marker rate and the corresponding residual risk of infectivity in the population of voluntary, non-remunerated donors is very low, while the plasma used by EPFA members is in large part recovered plasma from whole blood donations.

Mr Duncan Armstrong spoke about issues in plasma safety in developing countries. The value of country self-sufficiency in plasma products was reviewed, especially in the light of potential resources in recovered plasma and the expense of fractionating small amounts. The importance of GMP for plasma and a good process for obtaining safe whole blood for further manufacture were stressed. Importing plasma products can be dangerous and there is a need for some form of international control. He suggested the option of efficient and well regulated regional fractionation centres which can have a unique product profile for the region.

There was extensive discussion on issues related to paid plasma donors. Several speakers cautioned that the situation with paid donors in the USA cannot be applied to developing countries, where the regulatory climate may not be sufficient to maintain and review the quality of products. Competition for volunteer whole blood donors could also be damaging. Mr Armstrong reiterated comments that regulation or oversight of the international movement of plasma products was vital.
Breakout sessions

It was agreed that key issues identified by the GCBS thus far should be the focus of GCBS Working Groups, to be specially formed to address the issues and present recommendations to the next plenary session. Four breakout groups were deemed necessary on the following topics:

♦ Quality Systems
♦ Plasma Issues
♦ Assistance for Development
♦ Policy Process

The aim of the breakout sessions was to formulate terms of reference for the Working Groups and provide the outline of a plan of action based on a preliminary reflection on each issue. Working Groups will be composed of a subset of GCBS members and invited expertise as required.

The report of each breakout group as summarized in Annex 5 was presented in plenary. In the discussion that followed, the following points were raised:

♦ the Quality Systems and Assistance for Development groups would need to work together to avoid redundancy.

♦ representatives from national regulatory authorities in the work of the GCBS are essentially involved in the Policy Process group. Therefore, issues common to several groups will have to be identified and specifically addressed, such as oversight systems for blood transfusion services. Input from national regulatory authorities will be needed to address questions raised in the Plasma Issues and Policy Process groups.

The Secretariat will organize the first meetings of the working groups during the first third of 2001. Subsequent steps will be decided by the groups themselves and applied with the help of the Secretariat in order to report to the November 2001 meeting of the GCBS.
Concluding session

Intervention by Dr Gro Harlem Brundtland, Director-General of WHO

The Chairman, on behalf of all participants, welcomed Dr Gro Harlem Brundtland, Director-General of WHO, and briefed her on some of the major challenges and initiatives that had been addressed during the meeting. He congratulated WHO for its strong leadership in blood safety.

WHO was indeed committed to blood safety. Dr Brundtland commented, since World Health Day 2000 was devoted specially to this issue, in addition to enhanced international attention. She highlighted the importance of blood donors themselves in any advocacy effort, and looked forward to incorporating the recommendations of the GCBS into WHO work. Dr Dodd thanked her for her support.

Recommendations

Members of the group provided comments, additions and modifications to the proposed recommendations of the meeting that were incorporated into final draft recommendations below:

1. Health authorities should be encouraged to develop nationally coordinated blood programmes with appropriate regulatory systems with competent, well-trained staff. Standards, surveillance, accreditation and corrective measures should be established, for which the GCBS can provide generic guidance.

2. There is a need for a policy formulation tool whereby decision-makers can have access to information shared by others on how decisions are made. Policymakers should have this information – together with input from relevant transfusion professionals, blood donor and other relevant organizations – before decisions on major national policy changes or programmes are reached.

3. Each national authority should be able to monitor risk assessment in the blood delivery system, including appropriate mechanisms for feedback and monitoring. The complexity of the system can vary with the relative maturity of the blood service. Models of successful national and regional alert systems, such as those in Europe and in the airline industry, should be emulated.

4. Information on blood transfusion safety, risk assessment, quality systems and other relevant material should be collated and shared among nations, and the GCBS can provide a valuable central function in this respect through the Secretariat. The global database on blood safety and the quality management project are valuable tools that should be further developed and regularly updated.

5. Developing countries should improve their blood transfusion programmes within their national context, even if such improvement is achieved gradually. Model systems, basic programme requirements and appropriate information can be obtained with the assistance of the GCBS.

6. Coordination of support activities is vital to avoid duplication of effort and conflict between programmes. The GCBS can act as a clearing house, and serve as a resource, for example in coordinating donor assistance to improve blood programmes at national level.

7. Health authorities responsible for blood programmes should support measures designed to reduce the need for transfu-
sion, such as: training professionals in the appropriate clinical use of blood; reducing anaemia and the impact of malaria and through a strong interface between the blood programme and patient-care clinicians.

8. The GCBS should encourage effective measures to educate, motivate, recruit and retain voluntary, non-remunerated donors from low risk populations, using successful programmes as models (e.g. the “Club/Pledge 25” concept).

9. Three GCBS Working Groups should be formed to elaborate a plan of action to address the key issues identified at this meeting and report back to the 2001 plenary session.

♦ Working Group on Quality Assessment and Assistance for Development. This group will gather information, in particular from the Global Database on Blood Safety, define methods to obtain further evidence, assess needs and categorize countries. It should also establish the basis of an accreditation scheme for blood transfusion services. The group will identify models that can be used for developing countries to set up national quality systems, and will provide recommendations for implementing, monitoring and improving the transfusion system.

♦ Working Group on Policy-making Processes. The group will address decision-making and policy formulation for blood safety and risk management. It will provide a forum for regular exchange between national regulatory authorities from developed and developing countries to promote a quality process for policy making related to blood safety and availability.

♦ Working Group on Plasma Issues. This group will discuss possible approaches to provision of plasma-derived products in various context, how to address the needs for plasma as raw material for fractionation, and the value of self-sufficiency. The group will design a model to estimate needs in plasma-derived products according to the health care system level and identify justified fractionation centres on a cost effectiveness basis. It will review current WHO material on cross border movements of plasma for fractionation and diagnostic purposes, and make appropriate recommendations for national authorities.

Perspectives for the GCBS
From the work of the breakout sessions and the discussions during the meeting, the WHO Secretariat will prepare the charge for the working groups and organize venues and future work with the Chairman of GCBS and the Chairpersons of the working groups. A first meeting of the groups should take place by April 2001.

Advocacy tools
The WHO Blood Transfusion Safety (BTS) website will lead to:

♦ increased awareness of the activities of the WHO Team, including access to country situations as assessed through the Global Database on Blood safety;

♦ information and training in an illustrated and interactive way (the development of a distance tutorial on blood safety is a logical extension of the well-established distance learning scheme);

♦ improved networking for participants in BTS projects such as the QMP and, of course, the GCBS, and enable an online discussion page and quick access to work in progress.

Closing remarks
Dr Emmanuel expressed his appreciation to the Chairman, Rapporteurs and participants for a very successful meeting. The Chairman, in turn, thanked Drs Emmanuel and Noel, and the BTS Secretariat for their outstanding work in organizing and conducting the meeting. Special thanks was given to Yolanda Cabrer as she approaches retirement after many years of dedicated service at WHO.
Annex 1: Programme of Work

**Tuesday, 14 November: morning**

Opening remarks and introduction of participants: Dr Yashuhiro Suzuki, EXD/HTP
History and Rationale for the Global Collaboration for Blood Safety (GCBS) and proposed terms of reference: Drs J.C. Emmanuel/L. Noel

Election of Chairperson and Rapporteur(s)
Questions and Discussion on GCBS and endorsement of GCBS principles: Chair
Overview of the global situation in blood safety: Dr N. Dhingra
Trends in labile component usage in developed countries: Dr J. Koistinen
A marketing view of the situation of plasma products resources and needs: Dr P. Robert
Blood safety as one of WHO priorities: Dr L. Noel
Questions and Discussion: Chair

**Tuesday, 14 November: afternoon**

**GCBS FOR IMPROVING AWARENESS OF THREATS TO BLOOD SAFETY**
The role of international exchanges in risk assessment for blood safety: Dr T. Giulivi
vCJD epidemiology and possible donor selection criteria as a precautionary move: Dr B. Will
Questions and Discussion, the role of GCBS: Chair
An alert network on blood transfusion threats: European approach, global needs: Dr P. Strengers
Questions and Discussion, the role of GCBS: Chair

**Wednesday, 15 November: morning**

**GCBS FOR IMPROVING BLOOD SAFETY POLICY FORMULATION**
Summary and outcome of the March 2000 meeting: Dr B. McClelland
International perspective on need for a forum on blood safety issues and regulation: Dr R. Peterson
Value of an international collaboration on blood safety policy, developing countries needs: Dr A. Heyns
The need for tools to share experience in blood safety decision formulations: Dr E. Furler
Questions and Discussion, the role of GCBS: Chair

**GCBS FOR IMPROVING COLLABORATION MECHANISMS IN TRANSFUSION**
Prerequisite for success in improving transfusion services: Dr G. Lévy
The Uganda Experience: P. Kataaha
Possible role for GCBS in the field: Dr C. Jersild
AABB involvement in international assistance: R. Dodd
Questions and Discussion, the role of GCBS: Chair
Wednesday, 15 November: afternoon

GCBS FOR IMPROVING AVAILABILITY/ACCESS TO SAFE TRANSFUSION THERAPY
- Meeting patient needs in cellular products: Dr. M. Cherian
- How to better measure actual needs in transfusion therapy in developing countries: Dr. E. Lackritz
- Chronic transfusion therapy, the example of Thalassemia: Dr. A. Eleftheriou
- Questions and Discussion, the role of GCBS: Chair
- Global situation of patients with haemophilia: Dr. L. Robillard
- Haemophilia in India: facts, reaction and expectation: Dr. A. Verma
- Questions and Discussion, the role of GCBS: Chair

Thursday, 16 November: morning

GCBS FOR IMPROVING EFFICACY OF REGULATION AND CONTROL OF BLOOD PRODUCTS
- Oversight of a transfusion service by national health authorities: issues in South Africa: Dr. A. Heyns
- Regulation and Control of the transfusion service in China: Dr. Feng Gao
- Inspection of transfusion services and control of labile blood product: Dr. T. Hornez
- Questions and Discussion, the role of GCBS: Chair

GCBS FOR SAFER BLOOD DONATIONS
- Quality and safety of plasma donation: Dr. J. Reilly
- Residual risks of transfusion transmitted infection the European EPFA experience: Dr. T. Evers
- The safety of plasma products in developing countries: Dr. D. Armstrong
- Questions and Discussion, the role of GCBS: Chair

Thursday, 16 November: afternoon

BREAKOUT SESSIONS: EXPECTATIONS FOR GCBS
- Introduction

Friday, 17 November: morning

BREAKOUT SESSIONS: EXPECTATIONS FOR GCBS
- Review and Discussion of outcome of Breakout Sessions: Group Rapporteurs
- Intervention of WHO Director-General: Dr Gro Harlem Brundtland

GCBS NEXT STEPS
- Issues to be further developed in working groups: Rapporteurs and Chair
- Draft recommendations: Rapporteurs and Chair

Friday, 17 November: afternoon

Discussion and adoption of draft recommendations of GCBS: Rapporteurs and Chair
- Role of Secretariat; future meetings; communications: Dr L. Noel
- Closure: Chair
Annex 2: List of participants

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Background
It is the responsibility of each national government to ensure a safe and adequate supply of blood and blood products. However, there are many parts of the world where the safety and adequacy of the blood supply is sadly lacking. Global Blood Safety is an issue that requires urgent attention, and it is only through improved collaboration between organizations and institutions involved in the area of blood safety that the safety of the global blood supply can be improved.

In December 1993, during the VIIIth International Conference on AIDS in Africa, the French Government announced its intention to convene a Summit of heads of government on AIDS in 1994. Representatives of major donor countries attended a preparatory meeting on 8 April 1994, where it was recommended that the World Health Organization (WHO) should play a key role in the preparation and follow-up of the Summit to be held in Paris on 1 December 1994, especially in view of WHO's secretariat function for the interagency working group preparing the joint and cosponsored United Nations programme on HIV/AIDS.

A pre-Summit meeting, to which ministers of health from the 42 countries were invited, took place in Paris on 17 and 18 June 1994. The participants agreed that five strategic meetings should be held to discuss the problems of HIV/AIDS in different medical and social areas, and blood safety was chosen as one of the priority areas. The meetings were held during September and October 1994 in Paris and Geneva.

The Paris AIDS Summit took place on 1 December 1994 with the participation of the heads of government or representatives of the 42 invited countries. The Paris AIDS Summit declaration, was signed by all heads of delegation, and included the following text relating specifically to blood safety:

... undertake in our national policies to ensure the safety of blood and blood products.

... resolved to step up international cooperation through the following measures and initiatives ...:

... Strengthen international collaboration for blood safety with a view to coordinating technical information, proposing standards for good manufacturing practices for all blood products, and fostering the establishment and implementation of cooperative partnerships to ensure blood safety in all countries.

The Forty-eighth World Health Assembly, held in May 1995, produced resolution WHA48.27, which:

♦ Welcomed the declaration of the AIDS Summit adopted by the Heads of Government or representatives of the 42 States meeting in Paris on 1 December 1994;

♦ Invited governments which have not signed the declaration to do so;

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WHO, taking up the initiative of the Paris AIDS Summit calling for improved collaboration in the area of blood safety, proposed that improved collaboration would require a mechanism whereby national and international organizations involved in blood and blood product safety; manufacturers of plasma, plasma derivatives and blood devices; users and prescribers of blood; blood donor organizations, source plasma donors and recipients of blood and blood products would have a forum in which to communicate and to propose joint and complementary action. WHO submitted that the collaborative mechanism should build on existing knowledge and conventional wisdom in the area of blood safety; utilize existing expertise; promote dialogue on blood safety issues; and suggest realistic, effective and practical mechanisms to improve blood and blood product safety. The collaboration should be one of representation offering the opportunity to discuss and suggest viable solutions to resolve blood safety issues. Fundamental to improving collaboration on blood safety will be the issue of improving collaboration between the developed and developing regions of this world. Developing countries will have representation in the mechanism to help it identify and offer a realistic approach to priorities in blood safety.

The structure of a collaborative mechanism will be fundamental to its effectiveness. WHO, with its mandate as the United Nations specialized agency responsible for health issues, proposed that the WHO Blood Safety unit, should serve as the logical global organization to host the secretariat of the GCBS. WHO's Blood Safety unit, was established in October 1994, and is tasked with raising international awareness of the issues of blood and blood product safety; developing strategies and guidelines on policy, planning, legal instruments, technical and national self-sufficiency issues; assisting in identifying potential financial aid; promoting the development of clearly identifiable national blood programmes; promoting voluntary non-remunerated blood donation; advocating the appropriate use of blood and blood products; encouraging training for all blood transfusion service staff; and implementing appropriate operational research to improve blood safety.

In October 1995, WHO held the First Preparatory Meeting for the Formation of a Task Force for Global Collaboration for Blood Safety in Geneva, to prepare a proposal. The meeting involved most of the major organizations and institutions involved in the area of blood safety and it reviewed the WHO proposal and formulated recommendations for a mechanism to improve global blood safety. During discussions, the meeting agreed on a title for the collaborative mechanism and on the following recommendations:

**Recommendations for the formation of the Global Collaboration for Blood Safety (GCBS)**

1. **Goal:** Promote and strengthen international collaboration on safety of blood products and transfusion practices.

   Consistent with the declaration of the Paris AIDS Summit, 1 December 1994, the GCBS should be established with the following mission:

   To improve collaboration among organizations and institutions involved in the area of transfusion safety with a view to encouraging and facilitating information exchange, promoting standards for good manufacturing practices for blood and related products for transfusion, and fostering the establishment and implementation of cooperative partnerships to ensure donor and recipient safety in all countries. (See Definition of Blood Products attached).

2. **GCBS Structure and Functions**:

   It is recommended that to ensure an effective and efficient GCBS, it should be made up of a small number of specialists and representatives of internationally recognized organizations and institutions involved in the area of transfusion safety, as well as national representatives of different global regions.
The GCBS should ideally comprise the following organizations:

**Participants**

i) American Association of Blood Banks (AABB);

ii) European Plasma Fractionation Association (EPFA);

iii) Fédération internationale des Organisations de Donneurs de Sang (FIODS);

iv) International Federation of Red Cross and Red Crescent Societies (IFRCRCS);

v) International Plasma Products Industry Association (IPPIA);

vi) International Society of Blood Transfusion (ISBT);

vii) World Federation of Hemophilia (WFH);

viii) World Health Organization (WHO) (Blood Safety unit, Biologicals unit, Health Laboratory Technology unit);

ix) Participants from developing countries to ensure appropriate regional representation;

x) Representation of relevant health industry manufacturers/medical devices; and

xi) Representation of prescribers of blood and blood products.

**Observer Participants**

i) Commission of the European Communities (CEC);

ii) Council of Europe (CE);

iii) Food and Drug Administration (FDA), United States of America; and

iv) National Institute of Health (NIH), Japan.

2.1 Subject to sufficient funds being made available for that purpose as per paragraph 2.5 below, the **GCBS Secretariat** will be provided by the Blood Safety unit of the World Health Organization.

2.2 The GCBS will annually elect a **chairman** for a one-year term. The functions and activities of the chairmanship will be decided at the first meeting of the GCBS.

2.3 The GCBS will hold at least **two meetings per year**, with dates agreed by a majority decision of the members.

2.4 The GCBS would be expected to produce and disseminate documents which, among other things, analyze problems and advocate research to find solutions relating to transfusion safety. The GCBS will form and utilize the expertise of ad hoc **Working Groups** to debate specific issues relating to blood and blood product safety and to provide recommendations and guidance to the GCBS. In some instances, the Working Groups may need to be formally constituted and required to meet to reach consensus on particular issues. In other cases, a Working Group may be constituted less formally and carry out its task by correspondence. The GCBS will make the decision on the functions and activities of each Working Group and make appropriate provision for the costs involved in each task assigned, (i.e., a particular organization such as WHO, IFRCRCS, ISBT, etc., may be able to carry out the necessary task through its plan of work and budget for blood safety activities. In other cases a project proposal may need to be developed to seek funding for a specific Working Group activity).

2.5 **GCBS Funds**

Funds will need to be raised to support the GCBS activities, i.e., from governments, non-governmental organizations and, if necessary and appropriate, from the private sector. With regard to potential financial support from the private sector, care should be taken, however, to avoid the risk of actual or perceived conflicts of interest. Commercial donors should not seek promotion of the fact of their donations. In this regard, the participants in the GCBS will need to ensure that all fund-raising efforts are in accordance with their respective policies and principles. Under the direction of the GCBS, the WHO Blood Safety unit will administer financial contributions intended to support the activities of the GCBS through a trust fund entitled Global Collaboration for Blood Safety. This trust fund will be administered in accordance with WHO’s financial regulations, rules and practices and be subject to WHO's normal programme support costs. Periodic financial reports will be provided by the
Secretariat to the membership of the GCBS, justifying how funds designated to support the activities of GCBS have been used.

The formation of, and participation in, the GCBS may, however, dependent on how much funding is available in the above-mentioned trust fund, require financial commitments from some or all of the participants.

3. **Objectives:**

- to promote international consensus on essential principles of global blood safety;
- to promote the improvement of global blood safety and encourage governments to recognize and establish national blood programmes;
- to assist countries, upon request, to identify national blood safety priorities and prevent transfusion transmitted disease;
- to assist countries, upon request, in the implementation of appropriate and recognized transfusion practices to ensure donor and recipient safety and freedom from discrimination;
- to promote effective recruitment of safe donors through the use of appropriate selection criteria;
- to promote the appropriate preparation and utilization of blood and blood products;
- to encourage safe international practices for the collection, storage and transport of plasma and the preparation and distribution of its derivatives;
- to promote the bi-directional traceability of blood products between donor and recipient whether in-country or across national borders; and
- to facilitate the exchange and use of information by encouraging data collection, management and dissemination.

4. **Proposed activities for GCBS:**

The First Preparatory Meeting for the Formation of a Task Force for Global Collaboration for Blood Safety, Geneva, 30 October – 1 November 1995, suggested activities for consideration at the first meeting of the GCBS.

5. **Next steps for development of GCBS:**

**Secretariat tasks:**


5.2 Prepare the appropriate invitation letter for participation in the GCBS.

5.3 Organize a meeting of a GCBS Working Group comprising a limited number of GCBS participants (agreed at above-mentioned meeting) to assist the Secretariat in the preparation of the first meeting of the GCBS, i.e., identify dates, prepare a draft agenda, propose background materials.

5.4 Dependent on the availability of funds, organize first meeting of the GCBS, i.e., send out invitations, draft agenda and background materials.

Background to the Consultation
Concern about the safety of blood transfusion is shared by patients, the wider public, health policy advisers, regulators and politicians. Between 5% and 10% of human immunodeficiency virus (HIV) infections worldwide have been attributed to blood and blood products. Many more recipients are infected by hepatitis viruses, Chagas’ disease and other agents transmitted by blood.

Only about 40 million units of collected blood [53%] are donated by voluntary non-remunerated donors. About 13 million units of blood are not screened for transfusion transmissible infections (TTI).

Even in countries where the risks due to a transfusion can be shown to be minimal, many remain anxious about the small residual risks of known transfusion transmitted agents. Fear and anxiety are also sustained by the identification of conditions such as variant Creutzfeld Jacob Disease (CJD), and it is clear that current technology will lead to the discovery of more blood-borne transmissible agents. Although other risks of transfusion, such as misadministration or bacterial contamination, may have a lower public profile, they also constitute a substantial clinical risk.

New blood safety technologies are constantly becoming available and are actively marketed to professionals and, indirectly, to the public. In developed countries, many of these additional safety measures can offer only marginal gains at very high cost. Nevertheless, because there is such pressure to take any precautionary action that could reduce the risks of blood transfusion, the appearance of a new safety technology on the market poses a dilemma for the policy maker faced with competing priorities.

In contrast, patients – and in some cases blood donors – in many developing countries are at high risk due to transfusion of unsafe blood, or the use of unsterile equipment for both collecting and transfusing blood. In some countries, infections due to donation or transfusion contribute substantially to the overall burden of infection in the population. International travel and the movement of blood, especially of plasma and plasma derivatives, makes this a global as well as a national public health concern.

There are therefore both similarities and stark contrasts in the challenges that face the policy maker in a developed or developing country. The former is faced with pressures to introduce new safety interventions at high cost but often yielding marginal benefit. The counterpart in the developing world faces deficient infrastructure and resources, which often prevents the sustainable implementation of even low-cost interventions with proven effectiveness to increase blood safety quite significantly.

For both, the growing and widely publicised search for “State of the Art” blood safety standards poses major problems. The adoption of the latest technology, for example, even when it is unlikely to offer any material benefits, is perceived as a sign of commitment to patient safety. Conversely, a decision not to introduce such a new technology may be interpreted as inhumane or negligent, and creates the risk of litigation or public criticism. It may also be perceived as not measuring up to the dedication of altruistic blood donors.

At an exploratory meeting convened by WHO’s Department of Blood Safety and Clinical Technology in November 1999, participants from Australia, Canada, France, Japan, UK and USA, saw the need
for an international consultation on blood safety policy, within the framework of the Global Collaboration on Blood Safety.

Representatives from developed and developing countries would be invited to identify critical common problems in blood safety, propose a range of solutions, and investigate the utility of a systematic approach to assist policy makers and ministers in evaluating policy options.

Summary

Forty three blood transfusion technical and policy experts met from 27 to 30 March 2000 at WHO/HQ to identify means to assist decision-makers and their advisers in the formulation of national blood safety policies. The Programme of Work and List of Participants are attached as Annexes 1 and 2 respectively.

During this Consultation, participants shared state-of-the-art summaries from developing and developed country perspectives; round-table discussions on critical topics; and case presentations of specific safety issues and solutions.

Various models for policy development were reported, and participants used a decision formulation model specifically elaborated for the Consultation (Proposal for a method for assessing the state of knowledge on blood safety interventions-Pr R Salmi) to form initial impressions of its potential usefulness.

To achieve the development of an assessment framework or analytical tool to assist decision-makers and their advisers in the formulation of national blood safety policies, participants agreed that:

1. Such a framework should build on relevant evidence that can be identified and evaluated in a transparent manner, and where all aspects of the decision making process can be documented. Specifically, those responsible for policy formulation should be able:
   i) to demonstrate that all relevant factors have been weighed in the formation of a blood safety policy;
   ii) to communicate the policy and its basis to patients and other stakeholders;
   iii) to review and amend the policy in the light of changing conditions;
   iv) to explain, and where appropriate justify, the process through which the policy was formed, especially if it is different from that introduced by others.

2. In examining opportunities and threats for blood safety, and assessing the relative value of various interventions, blood safety policies must meet the health needs and priorities of the current situation in individual countries.

3. The outcome of this consultation on blood safety policies should feed into the forthcoming forum of the Global Collaboration on Blood Safety.

Developed and Developing Countries

The following themes were identified by the majority of participants as common to both developed and developing countries. Evidence justifying the validity of the approaches to blood safety and supply was reflected in the formal presentations, case studies and discussions, as well as in the WHO Aide-Mémoire on Blood Safety and other WHO publications.

Organization

Government commitment to and sustained practical support for a National Blood System is an essential ingredient of an effective and safe programme. Speakers emphasised that despite the claims of some countries to have national blood services, the reality is that access to a safe blood supply, in many cases, is restricted to patients in a few centres.

Management and resources

There is a lack of personnel able to perform a realistic assessment of the capital and recurring resources required to sustain the level and quality of service needed, and to set policies (and manage expectations) consistent with the anticipated sustainable level of resources.
**Professional leadership and staffing**

It was pointed out that in many countries, blood supply remains an “add on” task for hospital laboratories. As a result, there may be no medical staff with transfusion training, or clinicians with official status or career opportunities who wish to specialise in transfusion. Training for laboratory staff may be minimal, with no investment in training clinical practitioners in safe blood prescribing and procedures. In such situations, safety and quality of the blood supply and safe and effective clinical use of blood are difficult or impossible to attain.

**Product quality and quality systems**

The importance of the conventional quality system/Good Manufacturing Practice (GMP) approach was emphasised. There was a clear consensus that the principles and practices of GMP apply to both developed and developing countries. However, where resources are short, investment in Quality Management needs to be targeted where it can do most good. Participants suggested that in developed countries, it is now time to review the true costs of the “quality overhead” and examine critically which activities contribute most to patient safety. The need to explore the role of less elaborate systems was also identified.

**Regulation**

The keynote lecture on Quality Systems in Developing Countries stressed the importance of establishing a national regulatory authority, promulgating appropriate legislation, identifying quality interventions that provide most value for the available investment, and reaching firm agreements between the Blood Transfusion Service, the Government and the Regulatory Authority responsible for priorities in blood safety.

**Legislation**

Many participants stressed that a blood service must operate within a legal framework that defines responsibility and accountability for the key decisions on policy, organization and resources, and that confers the necessary powers on the appointed Regulatory Authority.

**Donors and donation**

**Voluntary Donation**

Blood for transfusion is most likely to be safe when collected only from regularly attending voluntary, non-remunerated donors. Participants reviewed numerous studies over many years and in different environments that continue to demonstrate lower risks of infection in volunteer donors.

**Family/replacement donation**

Many countries remain partly or mainly dependent on replacement donors. Participants emphasised that it may be difficult to distinguish individuals claiming this status from those who may in reality be paid donors. Data from several countries showed a high level of dependence on such donors.

**Paid or professional donors**

Many regions remain dependent on individuals whose motive for donation is purely economic. The need for government commitment, research and substantial investment to achieve the transition to a stable voluntary programme was emphasized. Several interventions emphasized that ceasing to pay donors does NOT save money, on the contrary, the establishment of a voluntary non-remunerated donor programme increases costs and safety.

**Sources of plasma for fractionation**

The continued dependence of most developed countries on plasma derivatives prepared from paid donor plasma, and the licensing of such products by national regulators, requires that countries and organizations formulate a coherent and defensible position on the voluntary vs paid donor issue.

**Selection of safe donors**

While some of the conventional selection criteria are well founded in evidence and are applicable in all environments, others require to be reviewed against current clinical knowledge and local epidemiological and social factors.
Donors should be selected from readily identifiable groups at the time of attendance, e.g. by simple questioning, and who have been shown by locally relevant epidemiological, serological and sociological data to be at low risk of exposure to transfusion transmissible infections (TTI). Evidence presented showed that such research-based local strategies are highly effective in reducing the prevalence of TTI in donating individuals. Donor motivation and recruitment methods should be designed specifically for the local situation to encourage such individuals to volunteer.

**Regular donation**

The staffing, environment, access and care at donor sessions should be such that it encourages the first time attendee to become a regular donor. Speakers reported on research leading to a range of successful strategies to encourage regular donation by suitable individuals in several countries. Essential infrastructure for a regular donor programme includes a personal identification system that recognizes each individual as much as possible, and that records their location, donating record and key laboratory data. Without reliable access to these basic data, donors cannot be recalled to donate, and donors who have been excluded due to a failed screening test may not be detected if they re-attend.

**Information Management and Technology**

Participants familiar with large complex blood collection, processing and distribution services acknowledged the importance of appropriate technology for managing all aspects of the process from donor to blood bank (and ideally to the patient’s vein). However, participants with experience of complex computerized systems emphasized the scale of the capital and continuing costs required to install, operate and maintain such systems, and the extent to which they can also cause operational, quality and regulatory problems. It was suggested that the use of simple, or non-computerized systems should be carefully evaluated before embarking on substantial IT projects.

**Donor safety and well being**

Participants emphasized the importance of securing certain basic rights and privileges for donors as part of the contract with the blood service. These include legal protection for the donor, should it be alleged that his/her donation causes harm to a recipient.

A guarantee of confidentiality, should be instituted to ensure that the blood service is prohibited from revealing, without the donor’s formal consent, any information acquired as a result of the donation that could prejudice the donor (for example a positive virology screening test result).

A clearly established procedure should guarantee that the donor will be fairly compensated for any harm that results from donating.

A commitment to complete openness with the donor should be provided by the blood service about the use that will be made of the donation and about any adverse consequences that the donor could experience as a result of donation.

**Clinical practice**

**Safe ordering and administration of blood**

Even if the blood itself is safe, there are dangers to patients if it is not stored, matched to the patient, and transfused in a safe manner. Data on such risks were presented and workshop sessions reviewed the options for improving the safety of the management of blood at the hospital level. Priorities identified are education and training of hospital clinical staff, and research and evaluation on several available technological solutions.

**Safe prescribing of blood: prevention and avoidance of the need to transfuse**

Participants identified this as a critical issue. The principles of Quality Management and Good Clinical Practice should extend to the clinical transfusion process. The importance of surveillance programmes for both clinical practice and for adverse events and outcomes was emphasised. The example of Fresh Frozen Plasma was used to illustrate the extent to which demand can be reduced by interposing a medical consultation. (*Note: the WHO Distance Learning Module on Clinical Use of Blood deals extensively with these clinical practice issues*)
Proposals for consideration by GCBS

General
There is a need for a robust and transparent process to assist the evaluation and setting of priorities among candidate blood safety interventions for the formation of policy. This process should document:

i) The scientific evidence on which the policy decision is founded, including an assessment of potential negative health effects (e.g. more stringent donor selection may result in an inadequate supply of blood).

ii) The economic factors weighed in the decision.

iii) The other social, commercial and political factors that were taken into account.

iv) The manner in which policy recommendations are developed from the above information.

v) The explicit criteria used in reaching a policy in a situation (e.g. variant CJD) where there is insufficient evidence about the magnitude of the risk and/or the impact of any intervention intended to reduce the risk.

Such a method for assessing the state of knowledge on blood safety interventions, developed for the Consultation, was reviewed by participants and judged to be potentially valuable and to merit further development. Other policy formation and priority setting approaches were also presented.

An efficient means of sharing and developing the international knowledge base on transfusion safety must be developed.

Similarly, there is a need to share and develop the knowledge and skills needed to assemble, analyse and evaluate information on blood safety interventions so that it can feed effectively into the policy forming process.

There is a need for cooperation between governments, blood transfusion services, the health care industry and WHO to accelerate the availability of effective and affordable blood safety technologies for developing countries.

It is proposed that the recommendation of this consultation should be submitted at the next meeting of the GCBS and that support should be received for the establishment of a working group to take forward the development and evaluation of the appropriate instruments for national blood policy formulation. Developing guidance on national blood policy formulation will thus become a key strategy of the work of GCBS.

- A system and process to facilitate international sharing of information on existing or candidate blood safety policies, and their underlying scientific, technical, operational and economic bases should be developed.

- Development and maintenance of the existing WHO Global Database on Blood Safety could be one way of building a key information source.

WHO should take steps to identify, develop and disseminate the expertise required to assist countries to evaluate relevant evidence on the performance of blood safety interventions, and to prepare the scientific, economic and social analyses required to inform their policy formation processes. Countries with special expertise in health economics, technology assessment and clinical epidemiology should be invited to support the development of these skills in countries where they are not well developed.

WHO should continue to promote a global dialogue about the impact on developing countries of new, precautionary blood safety measures introduced by the developed countries with the intention of ensuring that such decisions take account of the global as well as the national perspective.

WHO should facilitate discussions with governments, the health care industry and other stakeholders, with the specific objective of accelerating the availability of effective, low cost blood safety technologies.
ANNEX 5: REPORTS OF GCBS BREAKOUT GROUPS

Working Group on Quality Systems

Chair: Richard Davey  
Rapporteur: Silvano Wendel  
Participants: Rajesh Bhatia, Kamel Boukef, Meena Nathan Cherian, M. E. Chitiyo, Ana del Pozo, Roger Dodd, Basma Khraisat, Eve Lackritz, Evgueni Selivanov, Gaby Vercauteren

Objective
The aim of this Working Group will be to establish criteria for a mechanism(s) that can identify countries’ needs and recognize achievements, notably through the promotion of accreditation schemes.

Areas of Work

Gathering appropriate information
- The WHO Global Database on Blood Safety (GDBS) is an essential tool that should be further developed and regularly updated. It should remain evidence based, and the information it generates should be accessible through all WHO communications systems to ensure its availability globally. The Working Group will base its work largely on GDBS data and will contribute to its improvement.

- Assessment of risks – each country has to assess the risks related to transfusion based on local or regional epidemiological parameters, since risks vary widely and depend on a multitude of factors.

- Assessment of needs in blood products – Discussion focused mainly on:
  a) Requirements – are there enough blood products to supply country demand?
  b) Availability/accessibility – if the requirements are met, are all products available to the general population, or only in certain cities/hospitals, leaving gaps in the service provided in the country?
  c) Affordability – is the cost and price for all blood components and/or services reasonably set so that the country system can afford it?
  d) Safety – is the blood supply safe enough to guarantee that the population served will face no hazardous effects? Are the safety parameters in line with those observed in other countries?

- Educational needs – since education is one of the mainstays of a safe blood supply, all countries should encourage and distribute WHO educational material such as that on the Distance Learning Materials (DLM), the Quality Management Project (QMP) and the
Clinical Use of Blood (CUB). In addition, educational material released locally or via any other transfusion organizations (ISBT, AABB, IFRCRCS, etc.) should be encouraged.

- Standards/Guidelines – every country should produce and apply standards and/or guidelines focused on donor care, good laboratory practice and good manufacturing practice, blood products and clinical practice of transfusion medicine. In addition, commonalities and differences between countries should be identified by the Working Groups when they are formed.

Identification of different developmental stages (categories) of blood systems
- The Working Group will extend its work in the identification of different developmental stages (or categories) among all countries, in order that a standard and general classification could be applied globally. The group will have to define criteria to classify countries within three main groups: basic, intermediate and advanced. This may produce initially some constraints; however, once countries become fully aware of the level they are facing compared to other countries, this will promote incentives to increase their blood supply safety, if necessary. Assessment can either be external, or via self-assessment in the initial phase of the process.

- Certification or accreditation of transfusion services will be a valuable way to acknowledge progress. Since it is expected that some countries may face great variation of development within certain regions, accreditation may be either regional, national or international. The Working Group will examine parameters for existing accreditation schemes and propose parameters to be applied.

- Monitoring and evaluation: all data obtained must be linked to the GDBS so that it improves continuously. In addition, key indicators shall be defined and applied to validate improvement.

Working Group on Assistance for Development

Chair: Anthon du P. Heyns
Rapporteur: Lawrence McMurtry
Participants: Yasmin Ayob; Zarin S. Bharucha; Neelam Dhingra; Mohamed El-Nageh; Androulla Eleftheriou; Casper Jersild; Peter.K. Kataaha; Paul McCurdy; Rachanee O’Charoen; Konate Seidou; Jean-Baptiste Tapko

Objective
Develop a model or template to assist developing countries in establishing a successful and sustainable Blood Transfusion Service (BTS). More specifically, the Working Group should:

- identify, from an analysis of base-line data, two or three “successful” BTS models that can serve as a template for developing countries;
- provide guidelines on how to graduate from an embryonic BTS to the optimum model stage, including a financial and organizational resources structure;
- identify methods to monitor and improve the BTS;
- provide orientation to countries requesting assistance.
Areas of Work

Government commitment

A basic premise for the formulation of recommendations is that the model or template would be applicable to countries that do not currently have a successful BTS. Integral to the success of any BTS is the involvement and full support of the government, who should accept responsibility for the BTS. Another prerequisite to success is the formulation of a national blood programme, incorporating a blood policy and/or plan. It must be clear whether this policy or plan will be government-operated or if it will be delegated to an outside entity such as the Red Cross/Red Crescent (a confirmed example of an NGO operating the BTS). There are advantages for a BTS to be autonomous, e.g. parastatal, with a board of directors and a permanent chair.

A starting point for a specific country should be established based on the type of approach described by the Quality Systems Working Group. The commitment of the government should be assured early on, in an ex officio capacity, i.e. independent of individuals and change of the government. A critical component of government involvement is financial support, preferably with a budget dedicated to and accessible by the BTS. Government involvement should also involve some form of regulation, oversight and inspection that can assure patient safety and the availability of a safe blood supply. The government should also provide some type of human resource development. This could be training for employees, the provision of facilities in which to work or similar services.

A national blood transfusion service should, ideally, be an actual part of the nation’s health structure and be closely associated with – if not physically located within – the headquarters of the national health service.

The BTS should consider donors, the medical/technical aspects of the operation and the patients or recipients of the collected blood.

Blood product safety through blood donor recruitment

It was agreed that the BTS should have clear selection criteria. The Service should examine the blood collected to determine if it comes from a replacement donor, a paid donor or a non-remunerated donor, with the aim of attaining 100% repeat non-remunerated donors. Questions to be addressed include whether there are staff specifically trained in the recruitment of donors; and whether the BTS collects data on its donors and, if so, whether the data is analysed and used to improve the process.

The BTS should have an established infrastructure operated by trained personnel. It should provide support, and specifically counselling, to donors. The group noted that blood transfusion services often become successful as a result of an active donor base. This is sometimes the result of the vision of individuals who are dedicated to blood donation and can motivate the government, donor groups, and volunteers.

Blood product safety through adequate processing and testing

A successful BTS should ensure the safety of blood products and have medical and technical standards of practice, including reliable testing for at least HIV-Ab, HBs-Ag, HCV-Ab and syphilis. The BTS must be aware of the appropriate clinical use of blood products and possess some form of guidelines on this. An internal operating system should assure to the greatest extent possible a stable team that is periodically and appropriately trained. The facility should
be adequately equipped, have a reliable supply of test kits and reagents and an appropriate and adequate storage system. The facility should also have a quality assurance programme.

The BTS should have an established system – either regionalized or hospital-based – justifying investment in instruments, automation of processing and use of information technologies as appropriate.

One critical element regarding the establishment of a successful BTS is international and regional support, since one country sharing its experience with another provides invaluable benefits.

**Implementing WHO’s Aide-Mémoire on Blood Safety**

The WHO Aide-Mémoire for Blood Safety outlines the basic premises to set up a transfusion service. The Service would benefit from the vision of a highly motivated person or donor group, who should negotiate with government for support to a national blood plan or policy, and for a dedicated and adequate budget. This may be the Medical Director or the Manager (who might also function as the BTS Budget Officer). The organization should also have a Donor Programme Officer and a Recruitment “specialist”.

The development of the BTS should occur in stages, e.g. be set up in one location such as a hospital and, when successfully operational, replicated elsewhere in the region or country, rather than attempt an overly large operation and fail.

However, the BTS should not start without “system thinking”: the establishment of the donor base, the medical and technical aspects and its finances. Financing of the BTS should be either on a cost recovery basis or by government subsidy.

The BTS should establish outcome indicators in collaboration with users of blood products, actually collect and measure data, and react to the results.

**Outcomes (Measures)**

The relevance of the models will be demonstrated by outcome indicators showing the success of the BTS from government involvement (budget, national blood policy or plan), donor selection and blood product safety (as increase in blood donors and donations, evidence of a risk management system particularly with regards to HIV, adequacy of blood product supply, percentage of donations tested, participation in an external quality assessment programme, percentage of whole blood used vs. components, severe transfusion reactions, etc.).

**Proposed modus operandi of the working group**

Members should represent successful programmes in all six WHO regions and include decision makers, blood transfusion specialists, administrative/financial officers, WHO Secretariat and funding organizations. The Working Group should meet three times over the course of six months. The first meeting would be a plenary session of all members; the second, to be held in each WHO region by members of that region, to observe and gather information; and the third meeting of all members to compile the information gathered, formulate the model/template and deliver the product to the next meeting of the GCBS.
Working Group on the Policy Process

Chair: Jay Epstein
Participants: Karl-Friedricc Bopp, Liz Furler, Feng Gao, Antonio Giulivi, Thérèse Hornez, Jukka Koistinen, Brian McClelland, Stephen Nightingale, Michihiro Nishida, Luc Noel, Robert Peterson

Objectives

i) Define the principles of good policy-making for national blood systems; codify best practices; clarify the necessary content of international communications;

ii) Seek international endorsement of policy-making principles for national policy makers

More specifically, the Working Group should:
♦ define a process for policy formulation;
♦ identify three or four significant new threats/challenges to global safe blood and engage policy makers to test the defined policy process;
♦ define a method to forecast new threats/challenges in developed and developing countries alike, giving consideration to technology and the cost/benefit of possible strategies for progress involving a technology leap;
♦ develop the concept of “public health wellness” as the measure of appropriate policy-making;
♦ make suggestions to the GCBS Secretariat for inclusion in a WHO Cabinet paper on quality principles for national policy-making and international communications.

Description of key areas of work

i) Define principles of good policy making for blood systems

Public health and safety come first
The overarching goal of a quality policy process for the blood system should be decision-making that serves the overall needs of national public health and safety. Processes should be developed that foster this aim.

Communication of risk
In order to maintain public confidence and trust, there should be transparency in risk management for all stages of the process, including risk identification, assessment and reduction. Risk communication is thus essential, as well as a review of outcomes of decisions and the possible revision of policy based upon scientific, economic, technological and other developments. Communication should target the public, health care professional and policy makers, and address all aspects of the issue, including scientific and technological aspects, cost/benefits, politics, etc.

An orderly and structured process of decision-making is essential
Well-codified best practices are a premise to progress. These practices should be based on external scientific expertise, input from advisory committees and a situation assessment, and be published to seek stakeholder input. Appropriate use of analytic tools such as risk assessment models should be promoted, as well as the use of a defined decision framework. Additionally, the outcome of decisions needs to be monitored to provide feedback necessary for policy improvement. Decisions should be re-examined in the light of emerging scientific data and new assessments.
**Define necessary international communications**
Policy makers nationally are affected by decisions made in other countries. A process is needed that will assure that national policy makers have available any input needed from other countries. Such interactions should be designed to maximize the freedom to make decisions that are best in each local setting. Towards this end, practices that make clear the scientific, social, economic and political bases for decisions should be encouraged.

**Develop tools for international communication**
Options should be considered to enhance international communication on policy development through periodic meetings on focused issues, use of a web site and use of media instruments.

i) Obtain international endorsement for policy-making principles and international communication

**Concept paper on blood safety**
The GCBS Working Group on the Policy Process should assist the WHO/BTS Secretariat to develop a WHO Cabinet paper on the need for a quality process for policy-making related to blood product safety and availability, as a prelude to the potential consideration of a resolution by the World Health Assembly in 2002. The Policy Process Group made the following suggestions to the Secretariat for inclusion in such a Cabinet Paper.

**Suggestions for inclusion in a WHO Cabinet Paper**
There is a need for an internationally recognized quality process for policy-making related to blood product safety and availability.

**Background**
Donated blood is a unique national and international resource.

Availability of safe blood products is essential to modern health care and is cost-effective within the overall context of public health.

Globally, the needs for establishing and maintaining blood safety and supply are seriously underserved, resulting in profound human cost.

Blood availability and safety are fragile, requiring strong national and international support and protection as a fundamental human right.

The challenges of addressing emerging threats and technologies relevant to blood safety and availability require an international framework of decision-making due to the movement of blood products between nations and the international impact of national decisions, even in the absence of such trade.

The limited resources to promote a safe blood supply can be misdirected through shortcomings in the policy-making process within individual nations.

A quality process for policy-making related to blood safety and availability would assist all nations in making decisions that would enhance rational use of resources and promote the availability of products most adapted for actual needs.

**Proposal**
The following areas of concern need to be addressed to protect and enhance blood safety and availability:
Quality process for policy-making
- Rapid and complete international communication of newly recognized threats to safety and availability of blood and blood products
- A structured process of decision-making including scientific risk assessment, risk management strategies, and risk communication
- Clear communication of policy decisions and action plans including independent statement of the scientific, economic and social/political rationale underlying the decisions
- Communication of outcomes and impacts, including public acceptance
- Endorsement of policy decisions affecting risks and costs by political leaders at high levels

Quality product management including national development assistance

Working Group on Plasma Issues

Chair: Duncan Armstrong
Rapporteur: Lenka Walterova
Participants: Reinhard Burger; Jean Emmanuel; Theo Evers; Albert Farrugia; Katsutoshi Komuro; Ana Padilla; James Reilly; Patrick Robert; Ashok Verma; Charles Waller;

Objective
The task of this Group is to propose which direction of work should be taken in the setting of standards for plasma as a source material, for self-sufficiency and in relation to cross-border movements of plasma and plasma-derived blood products.

Areas of Work

Standards
The present reference point is the WHO Technical Report Series 840, 1994 “Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives”. More than one standard for industry would not be acceptable. Blood products used as source material for the plasma industry are not a mere surplus to whole blood donation. Plasma for fractionation should be clearly differentiated from therapeutic plasma. Plasma for fractionation encompasses a range of blood products defined according to specifications (labile coagulation factors activity, antibody specificity and titer, etc.). Requirements should be based on the implementation of quality systems and not just laboratory limits, and make reference to pharmacopoeia. The quality of plasma starts with its collection. The status of plasma collection for fractionation should therefore be determined, particularly in developing countries.

A plasma master file is a requirement for plasma fractionation. Pooling of individual plasma must take into consideration epidemiological data as it may result in unacceptable viral load in plasma pools.

There is a need to remove constraints to the free movement of blood products and plasma as source material to assure the availability of safe products everywhere.
In summary, the Working Group will develop ways to meet safety requirements that should be endorsed by the principal internationally recognized regulatory authorities (overseeing manufacturers). This measure is intended to ensure protection of public health while enabling free movement of plasma and plasma products.

**Use of component therapy**
There is a need to evaluate the interest of moving from whole blood to component therapy in transfusion practice, taking into account the pros and cons of producing plasma for fractionation and the advantage of better purified cellular components.

The Working Group should design a model and prepare guidelines for such a potential transition, and even for the setting up of a plasmapheresis programme for source plasma. This model should take into consideration contract fractionation, the building of separate fractionation facilities, and the economics of purchasing compared to producing plasma-derived blood products. This will guide regulators when making decisions in national programmes.

**Self Sufficiency**
The working group will clarify the definition of self sufficiency. A difference should be made between cellular and small pool products and plasma derivatives (large pool products).

For cellular products and other labile components
Self sufficiency should be encouraged for cellular products and labile components. This should not be a legal requirement, but an objective of work. The Working Group should revisit issues of surplus cellular components (facilitation of export of excesses) taking into account the risks of blood donor exploitation.

For plasma-derived components
The working group will use the WHO Essential Drug List (EDL) as a minimum requirement. Self sufficiency may not be applicable to all plasma products (e.g. Anti-D) that may also run a risk of donor exploitation. Unnecessary surpluses must be avoided, and self sufficiency must not result in lower safety or inequity of access.

A model to estimate the need for plasma-derived products based on the national level of health care, hospital facilities, etc. will have to be designed. Such a model should make provision for equitable access to a safe an adequate supply and involve patient health care groups such as the World Haemophilia Federation on minimum requirements for effective treatment.

Fractionation capacities should be considered from the point of view of their cost effectiveness in a given setting (amount of plasma for fractionation and potential market for products). The acceptability of plasma for contract fractionation within existing fractionation centres will have to be investigated and an inventory of existing channels for plasma elaborated.

**Legal/illegal international trade in blood products**
WHO should assist departments of health with procedures for the legal cross-boundary movement of blood products. In order to provide assistance in prevention of illegal trafficking of plasma and plasma products, the Working Group will update relevant WHO background material, particularly the document “Safety of Blood and Blood Products”, published following the WHO Expert Consultation in Copenhagen in November 1993.
The group should design a decision tree of approval for the import and export of well-defined blood products (diagnostic and therapeutic) in order to clarify the key responsibility of regulatory authorities. This process will involve both the health as well as the trade and customs authorities. Whilst the control of the import and export of blood products remains undeniably the responsibility of the national authorities, WHO’s role will be to facilitate the introduction of such a system and provide guidance on the mechanisms proposed by the group.

The group will investigate and may make recommendation on specific customs codes for blood products to draw attention to this category of products. A plasma master file will be part of the minimum requirements for the import/export of plasma derivatives.