DEVELOPMENT OF QUALITY SYSTEMS TO IMPROVE THE CLINICAL USE OF BLOOD

Report on a WHO Regional Workshop

Groningen, Netherlands 29–31 October 2001
ABSTRACT

The meeting brought together clinicians and blood transfusion centre professionals from 20 European countries. They shared experiences and outcomes in the clinical use of blood therapy in line with recent WHO guidelines and framework policies. They also reviewed the results of a pilot pan-European quality system using a basic information sheet (BIS), which allows data contributors anonymously to assess, compare and benchmark the quality of their own transfusion practice with that of others. Government representatives were also invited to consider their policies for improving the quality of clinical blood transfusion practice. Participants were updated on the essential principles of transfusion therapy, as well as on alternative strategies to reduce as much as possible overuse and misuse of allogeneic blood and blood products. In four parallel workshops, participants made practical recommendations on three important issues: the feasibility of using a BIS for inter-European data collection to improve the quality of clinical transfusion practice; the development of common European quality indicators; and an action plan for European implementation of WHO policies and proposed quality systems to improve transfusion therapy in clinical practice.

Keywords

BLOOD TRANSFUSION
PLASMA – standards
QUALITY ASSURANCE, HEALTH CARE
QUALITY CONTROL
EUROPE
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Executive summary

The Meeting

A three-day European Regional Workshop was held 29–31 October 2001 in Groningen, Netherlands. Its main objective was to develop quality systems to improve the clinical use of blood.

The first day was mainly intended to enhance the role of national health authorities with respect to blood safety. Government representatives were invited to consider their policies for improving the quality of clinical blood transfusion practice. Representatives were introduced to WHO documents and the Regional Office for Europe initiative formulated in April 2000, entitled Rational transfusion therapy – Improving the quality of care by reducing inappropriate blood transfusions and promoting the use of alternatives: A framework for a national blood policy and guidelines.

The next two days brought together clinicians and blood bank professionals from 20 European countries. They were able to review the general situation in their respective countries and review the outcome of a pilot pan-European quality system using a basic information sheet (BIS) that permitted the participants units to assess the quality of their own transfusion practice, and benchmark their performance anonymously with other participants. The workshop ended by exploring avenues for implementation of appropriate strategies to improve the quality of European clinical transfusion practice.

Country reports

The participants described in general the situation of transfusion services in their own respective countries. They focused, in particular, on the situation of clinical and bedside transfusion practice and the efforts put in place to improve its quality standards. Six participating units gave a special report on the pan-European pilot trial to use a transfusion basic information sheet for self-assessment and benchmarking. Summaries of all these reports are included in Annex 2.

The presentations

The theme of the presentations was mainly intended to raise the general awareness of the participants to the importance of developing quality systems to improve clinical transfusion practice. Professor Cherian gave two presentations which emphasized the commitment of the WHO Department of Blood Safety and Clinical Technology to maintain and further improve the standards of appropriate clinical use of blood transfusion practice. Dr Cees Smit Sibinga highlighted the importance of establishing common safety indicators for inter-European benchmarking of the quality of clinical blood transfusion practice. Dr Smit Sibinga also reviewed the history of WHO and international initiatives for blood safety and the current, newly-established efforts to improve quality of transfusion medicine in general.

Dr Gamal Gabra introduced the European Framework Initiative for Rational Transfusion Therapy, and argued the case for urgent measures required to revise and change the prescribing habits of individual clinicians. This was followed by two presentations from Professor Philippe van der Linden, who discussed the basic physiologic principles of transfusion therapy. He described the significance and importance of the various transfusion triggers and strategies for safe, rational transfusion. In his second presentation, Professor van der Linden reviewed the available safe alternative strategies for transfusion and he supported the notion that individual prescribers should base the decision-making process on evidence and adequate clinical
assessments and information. The topic of oxygen carriers was covered by Professor D. Spahn. He specifically described his extensive clinical experience with perfluorocarbons and augmented normovolaemic haemodilution. These last three presentations were dedicated to review the pan-European self-assessment and benchmarking initiative. Dr Heidi Doughty from the United Kingdom presented the basic components of this quality system, using the basic information sheet (BIS) for case-base and aggregated data capture. She reported the results of the pilot trial and Dr David Bullock (United Kingdom) reviewed a National Quality Assurance Scheme as a model for international or inter-European data collection and comparison.

The final presentation, by Dr Isuf Kalo, was an overall vision on the quality of care development through data collection and benchmarking. Dr Kalo argued the case for the importance of data collection at a clinical care level as a system to improve the quality of transfusion practice.

The working groups and recommendations
In four working groups participants developed practical recommendations on three important issues:

1. The feasibility of using a basic information sheet for inter-European data-collection to improve the quality of clinical transfusion practice.
2. The development of common European quality indicators.
3. An action plan for European implementation of WHO policies and proposed quality systems to improve clinical transfusion practice.
1. Programme

1.1 Introduction

A European regional workshop on development of quality systems to improve the clinical use of blood was held 29–31 October 2001 in Groningen, Netherlands. The workshop was organized by the WHO collaborating centre in Groningen together with the WHO collaborating centre in Birmingham, United Kingdom and with the WHO European Regional Office. The Workshop was attended by 34 participants from 20 countries, temporary advisors from the Regional Office for Europe and WHO Headquarters, Geneva.

1.2 The programme of work

The workshop was opened by Dr Isuf Kalo, Regional Advisor, Health Systems Technology, Pharmaceuticals and Quality, WHO Regional Office for Europe on behalf of Dr Frans C.A. Jaspers, Executive Board of the University Hospital, Groningen, Netherlands. He welcomed the participants and indicated that the workshop should focus on policy of transfusion therapy and clinical use of blood. Attention should be given also to the practical use of blood and revision of existing practices in clinical blood transfusion in order to improve the quality of the use of blood.

Dr C. Smit Sibinga and Dr G. Gabra were elected chairpersons. Professor J. Koistinen, Dr A. Aquilina and Dr H. Doughty were accepted as rapporteurs of the workshop. Chairman Dr Smit Sibinga introduced the programme of work highlighting that the working groups should produce recommendations to be finalized in the plenary discussion on the last day of the workshop.

The workshop continued with the introduction of the participants. The general structure of the workshop was then discussed and agreed. The facilitators introduced each session which was then followed by discussion. The discussions and presentations were used as material for the workshops on the second day. Section 2 summarizes the presentations and discussions. Section 3 summarizes the outcomes from the workshops and their recommendations. Brief country reports are listed alphabetically in Annex 2.

2. Day 1

2.1 WHO guidelines and national policies on appropriate use of blood and blood products

Professor Meena Cherian, Blood Safety and Clinical Technology, WHO, Geneva

The mission statement of the Health, Technology and Pharmaceuticals section within the World Health Organization is “To promote the safety, quality, adequacy of blood, blood products, injections, diagnostic and clinical technologies, and medical devices which are essential for the provision of healthcare”.

The main challenges for clinical transfusion practice are: lack of access to safe blood, the hazards of transfusion, and unjustified exposure to transfusion. Access to safe blood is a major problem. Twenty percent of the global population has access to only 60% of the global blood
supply. 80% have access to 40% of the global blood supply but only 20% is safe and tested blood. Safe blood is a WHO priority.

**Clinical Guidelines**

WHO learning materials (module and handbook) on Clinical Use of Blood, distance learning material, and workshops on the appropriate use of blood should improve the safety and appropriateness of blood use globally. They bring together the developing and developed countries and will provide a forum for exchange of information and identification of issues and concerns.

The WHO guidelines on transfusion policy and appropriate clinical use of blood are based on systematic reviews of evidence on clinical effectiveness. National policies should reflect a broad consensus by physicians, blood transfusion specialists, and pharmacists on the most effective and recommended forms of treatment for specific conditions within the local context.

The key elements of the Guidelines for Clinical Use of Blood are:

1. Guidelines for the clinicians to support urgent decision-making on whether or not to transfuse a patient should be practical, comprehensive and relevant to local circumstances.
2. Standard blood request form. Ideally it should be developed by the blood transfusion service and reviewed by the National committee and be used throughout the country. The form will aid monitoring and evaluation of clinical use of blood and promote clinical transfusion practice.
3. Indications for the use of blood/blood products and alternatives to blood transfusion. Information should cover indications, dosage, and contraindications for blood and blood products and replacement fluids.
4. Blood ordering schedules. The blood ordering schedule should reflect the clinical team’s usage of blood for common procedures. It should give guidance to screen and group policy. A blood-ordering schedule saves time and expense by making it easier to analyse usage of blood. It minimizes unnecessary cross matching and reduces the wastage of blood that becomes outdated. It also makes it possible to ensure that blood is readily available for all patients who need it.
5. Standard operating procedures for:
   - ordering blood for routine and emergency procedures
   - issue of blood and blood products
   - transportation, storage and administration of blood
   - recording of all transfusions in patient records
   - monitoring patient before, during and after the transfusion
   - management, investigation and recording of transfusion reactions.
6. Indications for transfusion. Indications should include both the clinical and laboratory indications.

A national policy for the clinical use of blood is an essential component of a strategy to ensure that blood and blood products are transfused only to treat conditions leading to significant
morbidity or mortality that cannot be prevented or treated effectively by other means. The WHO guidelines for the appropriate clinical use of blood can be used as the basis for a national policy.

The implementation of a successful national policy requires a commitment by the health authorities with administrative responsibilities to health care providers and clinicians. Health authorities can support quality health systems, identify and manage conditions such as anaemia that may need transfusions. The promotion and availability of replacement fluids and pharmaceuticals/devices may also limit the need for blood transfusions.

Hospital transfusion committees are important in producing and monitoring local guidelines for hospital practice regarding the appropriate use of blood. Education and training of clinicians and blood bank staff is essential in the implementation of such policies.

The appropriate clinical use of blood must take into consideration the following points.

1. Transfusion is only one element of management.
2. Prescribing decisions should be based on guidelines and the condition of the patient.
3. Blood loss should be minimized.
4. Effective resuscitation by IV fluids/oxygen should be used while assessing the need for blood in acute blood loss.
5. The decision to transfuse is based on clinical condition and laboratory results.
6. Awareness on the local risks of transfusion and weighing up the risk/benefit ratio.
7. Recording the reasons for transfusion.
8. A trained person should be available to monitor the blood transfusion.

**Check-lists**

There should be a check-list for the clinician to use when considering transfusion therapy. The list should help the clinician to consider whether the transfusion would really improve the condition of the patient. The check-list should prompt the use of supportive measures such as oxygen and IV fluid replacement and how to minimise the blood loss. In addition, the list could prompt the specific clinical and laboratory indications required before the use of blood and list the options if blood is not available. Monitoring and response to transfusion should be included. Finally, the clinician should consider whether he/she would be willing to accept a blood transfusion for him/herself or to his/her child in the particular clinical condition. The final decision and reasons for blood transfusion of the clinician should be recorded.

**2.2 A framework for a national blood policy and guidelines: improving the quality of blood transfusion practice in Europe**

*Dr Gamal S. Gabra, Lead Consultant, Head WHO Collaborating Centre, National Blood Service, Birmingham, United Kingdom*

**The initiative**

The European focus for the WHO World Health Day (7 April 2000) Blood Safety Initiative “Safe Blood Starts with Me” was improving the quality of clinical transfusion practice. A group of European experts met in London on the 6 and 7 April 2001 to discuss the strategies for rational transfusion therapy.
**The framework document**

The group of expert clinician prescribers and transfusion medicine specialists produced a “Framework” document. It is intended to provide national health authorities and prescribers, within Europe, with a framework to establish national policies and evidence-based guidelines to improve the quality of care by reducing inappropriate transfusion and promoting the use of alternatives.

The framework document highlighted the role of the clinician and the national health authorities and their respective responsibilities in supporting these strategies. The experts identified the basic principles for good clinical transfusion practice and the elements of appropriate haemotherapy in specific clinical situations and reviewed the range of available safe alternatives to reduce the use of allogeneic blood as much as possible. The document was published as a supplement to the International Society of Blood Transfusion (ISBT) newsletter in June 2000 and was distributed at the Regional European Meeting of the ISBT, in Vienna in July 2000.

**Quality systems**

Improvement of quality can be achieved by establishing systems for continued monitoring of the process and outcome of interventions. The system uses repeated cycles of data collection, data analysis, evaluation and comparison leading to stepwise quality improvements and setting of guidelines for best practice.

**The clinician**

The role of the clinician is crucial in taking this initiative forward. Clinicians need to understand clearly the basic and fundamental principles for transfusion practice. They need to be aware of all the potential risks of using allogeneic blood and use it judiciously to reduce morbidity and mortality, rather than to correct laboratory results. The prescribing clinician needs to consider transfusion as one element in the overall management of the condition of the patient. The decision to prescribe allogeneic blood and blood products needs to be taken by the most experienced member of the team.

**The national health authorities**

Little attention has been given to improving the quality of transfusion practice and to reducing the use of blood, in spite of the availability of effective and safe alternatives to replace the various complex activities of blood and blood products.

The framework document urges every national health authority (NHAs) to have in place a National Transfusion Policy Forum (NTPF). This body is to be responsible for establishing a National Clinical Blood Policy and National Guidelines. In addition, they should support their implementation with regular training programmes and effective information technology systems to build reliable databases to manage and improve the quality of transfusion practice and the quality of patient care.

The framework document proposes that NHAs should consider introducing a legal framework to ensure that quality systems are established and complied with as part of the risk assessment and management strategy. The assessment of risk should be based on validated data collected locally and collated and analysed centrally as in the French haemovigilance system and the British Serious Hazards of Transfusion (SHOT) scheme.
The framework document proposes several functions and responsibilities for the NTPF including the following:

- involving the clinicians in the formulation of the guidelines for the use of blood and its alternatives;
- supporting the implementation of these guidelines by education;
- establishing mechanisms to monitor the implementation and audit the patterns of blood usage;
- encouraging interdisciplinary collaboration and including patients in the decision-making process if transfusion is required;
- promoting the awareness of the potential risks of allogeneic transfusion and the benefits and role of safe alternatives;
- establishing information systems to allow clinicians to measure their own performance compared to other peers and colleagues;
- encourage the creation of hospital transfusion committees or other similar structures to monitor and improve the standards of clinical transfusion practice in health care delivery facilities;
- facilitate the creation of hospital blood safety officers;
- establish national indicators for quality and develop mandatory standardized systems to monitor them.

The framework document (Blood Safety Starts with Me) is not only a slogan but a serious initiative aiming to change the culture of transfusion practice in Europe. It aims to improve the clinical use of blood and promote the alternatives

2.3 The need for common quality indicators for inter-European benchmarking of quality of clinical transfusion practice

*Dr Cees T. Smit Sibinga, Director, WHO Collaborating Centre for Blood Transfusion, and Sanquin Consulting Services, Groningen, Netherlands*

Prevention of induction of morbidity by blood transfusion depends primarily on structure and organization, human resources (education and training, authority, responsibility and accountability) and the presence of a quality system and its management. Key elements are leadership, human resources, and awareness.

Since the United Nations Declaration of Human Rights (health, education and shelter) much has been done and achieved. However even more is still to be done. The fact is that there are astonishing differences in blood supply and clinical use, in quality (vein to vein) and in quantity, availability and accessibility. Over the late 20th century a number of important lessons have been learned:

1. Success depends on people – awareness, commitment, involvement, and ownership.
2. Soloist endeavours are bound to fail.
3. Political awareness and commitment are crucial.
4. Money and materialistic support are important but not crucial.
5. Systems only function when appropriately managed.
In achieving the primary goals of blood transfusion, such as safety, efficacy, sustainability and rational use of the blood supply, a number of major players in the field have been identified. They are WHO, the International Consortium for Blood Safety (ICBS), World Bank, Council of Europe and European Union, patient organizations such as the World Federation of Hemophilia (WFH) and the Thalassaemia International Federation (TIF), national and international professional societies and institutions such as the American Association of Blood Banks (AABB) and ISBT.

There are still major questions to be answered:
1. How to create true and sustainable cooperation and collaboration?
2. How to effectively and professionally coordinate the many projects, requests and resources to allow real action and completion of goals?
3. How to change the still ineffective pars pro toto into an effective totum pro parte?

Possible solutions are in:
1. creating a communication network
2. joint efforts – collaboration in stead of competition
3. mutual confidence, respect and cooperation
4. respecting limitations, restrictions and weaknesses
5. respecting strengths, expertise, specific knowledge and experience.

The leading factor in the prevention of morbidity through blood transfusion should be the common goal – a universal (global) safe, efficacious and sustainable blood supply, clinically rational use based on the WHO Aide Mémoire principles:
- national structures and organizations
- reliable repeat donor populations
- reliable TTI testing of all donations
- appropriate and rational use of blood and alternatives
- quality management.

In the vein to vein chain there are three major parts:
1. community involvement
2. blood banking (procurement, providing products and services)
3. clinical practice.

To allow inter-European benchmarking of quality in clinical transfusion practices common indicators need to be developed. There are various groups of indicators to be identified:
1. **Structural** – existence of clinical transfusion practice policies, medical and logistical advisory bodies, documentation and haemovigilance systems and hospital transfusion committees.
2. **Educational** – existence of curricula for transfusion medicine (all levels), written guidelines on transfusion practice.
3. **Clinical practice** – indication setting and decision-taking algorithms, compatibility testing and documentation, bedside practices, monitoring and evaluation, clinical documentation of outcomes (trace-ability).

4. **Quality system and management** – existence of a quality policy, documentation system, quality manual, quality management and audit system.

5. **Monitoring and statistics** – committee meetings, review of laboratory/bedside/clinical practices, review of errors/accidents and near accidents or adverse events, review of outcome indicators (laboratory, clinical), review of education results, review of blood usage (components and alternatives, patient categories and indications), review of standard blood ordering lists and C/T ratios.

Although one might be attempted to focus on the number 3 group of indicators related to the clinical practice *per se*, it is important to realise that this section is just one link in the chain of overall clinical practice of blood transfusion.

Regular benchmarking using these categories of indicators can be done on regional, national and international level to improve the weakest links, develop “best clinical practices” and to promote active implementation of quality systems and management to improve the clinical use of blood and alternatives.

### 2.4 Discussion

During the discussion, the delegates emphasized the importance of collaboration between different interested parties, e.g. the Council of Europe and WHO. Consensus is required to create national guidelines for quality as well as common quality indicators. Criteria for evaluation of existing guidelines are now being designed. Dr Kalo emphasized the importance of comparison between peers, which can be open or anonymized. International benchmarking only requires a limited amount of data. Examples of important measures of quality in transfusion practice are safety, appropriateness and cost effectiveness. Each country needs to decide on its own priorities since they vary depending on country and context.

The group felt that most government authorities do not currently require reporting on quality. Therefore, it is important to identify who should collate data on the quality of transfusion practice. The development of institutional and organizational quality should be seen as a professional issue.

Dr Letowska reported that Poland has started a programme for quality in transfusion practice and this is now being introduced at a national level. Problems have been seen during the collection of information on the number of blood units used and those wasted. Hospital liaison between the blood transfusion services and hospitals is now receiving special attention. In the United Kingdom, hospital transfusion committees (HTCs) and hospital liaison staff provide the liaison between hospitals and the blood transfusion services. The HTCs report to regional transfusion committees, which in turn report to the newly formed national committee. In the Netherlands, the Health Inspectorate is now looking for ways to audit the clinical practice in hospitals.

There was a lively discussion on quality indicators. Dr Kalo reminded the participants that the expectations of the population also need to be considered. Quality is measured differently by different interest groups and these should be brought together. The traditional yardstick QALE
(quality adjusted life expectancy) is nowadays often replaced by DALE (disease adjusted life expectancy) as a measure of success in clinical practice.

2.5 Summary of the first day

Following an introduction to the theme for the workshop, Professor Cherian reviewed the WHO guidelines and national policies on appropriate use of blood and blood components. Dr Gabra reviewed and discussed the strategies to improve the clinical use of blood proposed in the Regional Framework Document. The workshop then discussed the implications of the WHO guidelines for Europe.

Dr Smit Sibinga guided the participants through the historical developments to achieve safety of blood supplies. He described the activities of the various international organizations involved in this endeavour and identified five groups of important quality indicators: structural, educational, clinical practice including indication setting, decision taking and bedside practice. The final two groups of indicators deal with monitoring and statistics and benchmarking to improve the weakest links and to develop best practice and promote active implementation of the quality systems and management set in place.

The discussion explored the ways to streamline the international guidelines and welcomed the efforts of the regional office to establish systems for the evaluation of guidelines, the criteria of setting guidelines and how to measure quality. In addition, who should be involved in this system of comparison between peers and how to generate the need for improvement? The discussion emphasized that data collection is not primarily for administration but to provide indicators for quality improvement. Such indicators must meet the needs for the three parts of Europe with their very different conditions.

Day 2

2.6 The WHO initiative on quality in transfusion medicine

Dr Cees T. Smit Sibinga, Director, WHO Collaborating Centre for Blood Transfusion, and Sanquin Consulting Services, Groningen, Netherlands

The World Health Organization is actively promoting a Quality Management Project (QMP) for Blood Transfusion Services. This constitutes the backbone of WHO strategy for global blood safety. QMP covers all aspects of blood transfusion practice, from the structure of the service, voluntary non remunerated donors, testing of blood and the appropriate and rational use of blood and blood products.

QMP also involves an integrated approach to training and assessment of blood transfusion practices. The aim is to reach a certain level of uniformity in standards in all member states and a significant element of regional cooperation.

QMP involves various components. Training in QMP (QMT) requires the availability of training materials and courses. QMP is a dynamic process of learning and practice. Regional quality training centres and external quality assessment schemes are also necessary. WHO headquarters should be the central point linking Blood Transfusion Services, Experts in Quality and Transfusion Medicine, WHO Regional Offices, and regional training centres.
The WHO objectives are to assist member states in improving safety of blood, to upgrade national capacity, knowledge and skills in QM in blood transfusion, to develop external quality assessment schemes for blood group serology and transfusion transmissible infections, and to establish regional training centres. At a national level the aim is to establish a sustainable National Quality System and to upgrade facilities.

The objectives of QMT are to develop and improve knowledge and skills in quality management, and to assess the current status of quality systems in Blood Transfusion Services. As a result a plan of action for the effective implementation of Quality systems in the respective blood banks can be developed.

Regional QMT courses covering all aspects of transfusion science are being proposed. These should promote active learning through participation. The courses should be aimed at policy makers at regional, national and local levels. The courses should lead to mechanisms for implementing, monitoring and evaluation of QMP. Monitoring and evaluation are crucial to assess effectiveness and to identify necessary modifications required in implementing QMP.

2.7 The WHO initiatives for guidelines and national policies on the appropriate use of blood

Professor Meena Cherian, Blood Safety and Clinical Technology, WHO, Geneva

WHO initiatives in this area are Policies and guidelines; Education and training; and Monitoring and evaluation. The steps and key elements required to initiate policies are:

**Policies and guidelines.** National policies based on WHO guidelines should cover the appropriate use of blood, standard blood request forms for national use, information regarding availability and use of appropriate blood substitutes and practical and comprehensive guidelines to help clinicians in urgent situations. Standard operating procedures covering all aspects of clinical transfusion practice from ordering, issuing, transportation, recording of transfusion and patient monitoring are also very appropriate. The implementation of a blood ordering schedule will help in the management of blood availability, besides reducing unnecessary cross matching.

**Establishment of hospital transfusion committees.** HTCs should be multidisciplinary with representation of both clinicians and the blood transfusion service, nursing staff, pharmacists and hospital administrators. The role of the committee is to monitor safety, adequacy, reliability and alternatives to blood transfusion. The committee monitors the use of blood components, reviews the transfusion incidents of adverse reactions, takes corrective action and promotes effective implementation, education and training.

**National workshops.** National workshops should be organized to plan and draft national guidelines. The workshop should involve both clinical specialists and senior officials of the blood transfusion service.

**National committee on clinical use of blood.** The National Committee on Clinical Use of Blood should regularly review guidelines and alert the Ministry of Health and other national authorities to the need for further update of national policy and guidelines. The National Committee on Clinical Use of Blood should submit guidelines and policies to the Ministry of Health for approval, endorsement, and support. The National Committee on Clinical Use of Blood disseminates the national policy and guidelines to the providers and prescribers. The
National Committee on Clinical Use of Blood ensures effective implementation, reviews and updates the guidelines and monitors and evaluates the effectiveness of blood usage and training programmes.

**Education and training.** WHO learning materials on the appropriate Clinical Use of Blood can be disseminated in special workshops, during conferences and introduced in medical journals. Transfusion medicine should be included in the medical curricula of medical and nursing schools. Education helps to modify clinical practice and improves practice among members of the clinical team.

## 2.8 Why do we need to review and change our prescribing habits?

*Dr Gamal S. Gabra, Lead Consultant, Head WHO Collaborating Centre, National Blood Service, Birmingham, United Kingdom*

Quality development in clinical care is a concept which aims at establishing systems for continued monitoring of the process and outcome of clinical care. It relies on repeated cycles consisting of data collection, analysis, evaluation comparison, intervention and repeating data collection for a second cycle and so on, leading ultimately to stepwise quality improvement.

The management of this approach to quality improvement depends on standardized data collection tools built around validated quality indicators which could be measured against evidence-based benchmarks. The outcome of this strategy is to develop guidelines and policies which ultimately promote best practice, resulting in improvement of the quality of care given to patients. Feedback to and involvement of the clinicians in formulation of resulting consensus guidelines are the pre-requisites of the success of this strategy. These efforts to improve the quality of decision-making process of physicians will also depend on the close application of the guidelines to the point where the request is made and the decision is then taken, for example, to give a transfusion.

Guidelines have maximum effect when generated and implemented at local level, highlighting the concept of ownership as a crucial factor for its success, particularly when the implementation is supported by education.

### Why are some guidelines difficult to enforce?

In theory, guidelines should be evidence-based. However, many are produced by panels of experts and consensus views based on global assessment and secondary observations or retrospective hospital records with suspect validity removed from patient/physician encounter. The constraints leading to non-compliance must be examined carefully and measures taken to promote debate and introduce innovative and creative approaches to facilitate the adoption and implementation by clinicians.

### Why do we need to reduce the use of blood and blood products?

National audit figures in some countries show that at least 20% of transfusions are unnecessary. Blood transfusion saves lives, but this benefit has to be measured against the risks involved in using blood and blood products. A recent report in the United Kingdom confirms, for the third year running, that over 50% of the incidents reported to the haemovigilance scheme are “the wrong blood being given to the wrong patient”. Even when we exclude these human errors, transfusion of allogeneic blood has major immunological hazards, including: acute and delayed transfusion reactions, acute lung injury and graft-versus-host disease. The other major group of
hazards are the transfusion-transmissible infections, in spite of all the measures introduced for screening. The risk depends on the residual risks in the blood donor population. Unnecessary transfusions constitute a substantial financial cost and a waste of resources. The cost of management of the complications, litigation and the loss of human life can effectively be controlled by promoting the use of alternatives.

The role of the individual prescriber

The basic principle of rational transfusion is to provide the factors needed to correct the impaired functional properties of the patient’s circulating blood, and not simply to correct the figures and values as assessed and measured by laboratory means. This is best achieved when the decision to transfuse is taken by a senior, experienced member of the treating team. The reasons for the decision should be documented in the patient’s notes. The clinician should be aware of the risks of transfusion-transmissible infections and prescribe blood where the benefits are likely to outweigh the risks and only when no other alternatives are available.

Transfusion practice continues to be unrelated to clinical outcomes. Evidence suggests that transfusion can often be reduced without compromising clinical outcome. Experience also shows that the mere requirement to document the reason for transfusion can reduce the use of transfusion. Clinicians will often reduce blood consumption when they are provided with feedback on their performance in comparison with others.

2.9 The principles of transfusion therapy: triggers and strategies

Professor Philippe van der Linden, Department of Cardiac Anaesthesia, CHU, Charleroi, Belgium

Professor Philippe van der Linden from the Department of Cardiac Anaesthesiology at the University of Charleroi in Belgium, highlighted in his first lecture the basic pathophysiologic principles that affect the decision to consider transfusion. The increasing awareness of transfusion-transmissible infections and other transfusion hazards has stimulated an earnest review of our transfusion prescribing habits.

Knowledge of the physiology responses to acute anaemia and of the factors that limit or improve the body to maintain adequate tissue oxygen delivery will allow the clinician to define the transfusion-triggers for each individual patient. In healthy individuals, the acute reduction of red cells triggers compensatory mechanisms at the systemic and microcirculatory levels. These compensatory mechanisms include an increase in cardiac output and in peripheral oxygen extraction.

Maintenance of ample circulating blood volume is essential to allow the body to increase its cardiac output and maintain tissue oxygen extraction. The magnitude of the increase of cardiac output is closely related to blood viscosity. It is essentially related to increase in the stroke volume and the heart rate. Decreased viscosity increases the venous return and reduces the peripheral vascular resistance and prevents peripheral pooling.

The second compensatory mechanism attempts to optimise the relationship between \( O_2 \) delivery and oxygen demand by allowing improved oxygen extraction at the microcirculatory and tissue levels. At the systemic level, there is redistribution of blood flow to organs with high \( O_2 \) demand, e.g. brain and heart, which depends on neurogenic control. At the microcirculatory level, there is increased capillary red cell velocity and increase in the ratio of microcirculatory to systemic haematocrit allowing improved tissue \( O_2 \) extraction.
A decrease in the affinity of haemoglobin for oxygen, related to a rise in 2,3-diphosphoglycerate has only been demonstrated in chronic anaemia. These mechanisms allow systemic oxygen uptake to remain constant until haematocrit falls to about 10–12%. Tolerance of anaemia will depend, not only on the ability of the organism to mount these compensatory mechanisms, but also on the level of tissue metabolic demand. Any clinical factors that alter the cardiac output response or the ability of the tissues to extract oxygen will decrease the tolerance of the patient to anaemia.

The essential first step is volume replacement using crystalloids and/or colloids. This is essential to maximize the cardiac output. The concomitant reduction of haematocrit further reduces the blood viscosity and improves the blood flow. The rheologic effects of the fluid used for volume replacement therapy did not seem to influence tolerance of the body to severe acute anaemia, providing that normovolaemia is maintained. Increasing the inspired fraction of oxygen might also improve the tolerance of the body to acute anaemia, as the contribution of plasma dissolved oxygen to tissue oxygen delivery increased markedly in these situations. However, as high oxygen partial pressure could have deleterious effects on the brain and the lung, administration of high inspired fraction of oxygen can be recommended for only short periods of time.

Decreasing metabolic rate reduces the tissue O₂ demand. This can be achieved by moderate hypothermia. Decreasing central core temperature to 30–32° will indeed decrease O₂ consumption by about 48%. However, hypothermia also alters regional blood flow distribution and increases haemoglobin affinity for oxygen. The real effect of hypothermia on the tolerance to acute isovolaemic anaemia remains to be determined. The same is true for anaesthesia which, on one hand decreases tissue oxygen demand, but on the other hand, blunts the cardiac output response associated with isovolaemic anaemia.

2.10 Alternatives for blood transfusion

Professor Philippe van der Linden, Department of Cardiac Anaesthesia, CHU, Charleroi, Belgium

Professor van der Linden gave the second lecture in this session, on “Alternatives for Blood Transfusion”. In this presentation, he gave a comprehensive review of the various alternative strategies to reduce blood transfusion. These strategies cover three different approaches.

The first aims at increasing the patient’s red blood cell mass. It involves the administration of erythropoietin and the use of pre-operative autologous blood donation. The second strategy aims at decreasing peri-operative blood loss. It includes the use of specific anaesthetic and surgical techniques and the use of pharmacological agents like aprotinin, a serine protease inhibitor, and tranexamic acid, an anti-fibrinolytic lysine analogue. The third strategy aims at re-evaluating the transfusion trigger based on better knowledge and understanding of the principles affecting the decision of the need to use allogeneic blood.

Experience has shown that the use of blood can be brought down by audit and practice of guidelines and by standardized blood transfusion strategy. Professor van der Linden has used this approach and documented a 50% reduction in blood use.
2.11 Clinical experience with oxygen carriers

Professor Donat R. Spahn, Institute of anaesthesiology, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland

Professor Spahn gave a review of the role of fluid O2 carriers, namely haemoglobin solutions and perfluorocarbons. He explained the function and the role of O2 carrying fluids and the role of O2 dissolved and carried in plasma to improve O2 delivery at the cellular level.

One problem with the acellular Hb solutions as oxygen carriers is the high affinity of oxygen to haemoglobin. Vasoconstriction and pancreatitis have been seen as complications and the nature of these complications is not clearly understood. An Hb solution, polyHeme is in phase III studies and 20% reduction in the need of red blood cells (RBCs) has been reported in one of the studies. A product called Hemapure (by Biopure) has been approved in 2001 for clinical use in South Africa. Studies by Baxter were recently prematurely terminated due to higher mortality in trauma victims in the Hemapure group than in controls. Replacement of erythrocyte concentrates by the oxygen carriers is not in sight in the near future.

Modified Hb solutions and perfluorocarbon (PFC) emulsions are the most promising oxygen carriers being tested. Perfluoro-octyl bromide (C\textsubscript{8}F\textsubscript{17}Br) is a droplet with less that 0.2 um in diameter. It was in phase III clinical studies in USA (in cardiac surgery), but the studies were stopped in January 2001 due to adverse neurologic outcome in the PFC group and lack of the same in the control group. The off-loading of oxygen by the perfluorocarbon is linear and differs considerably from that of the haemoglobin molecule giving a proportionately lower capacity.

Professor Spahn described in detail, the clinical experience with a novel perfluorocarbon which was used in a large, multi-centre controlled trial in non-cardiac surgery, with anticipated blood loss > 20 ml/kg. A total of 492 patients were prospectively randomized in two groups: a standard care group and a second arm where patients were deliberately haemodiluted pre-operatively and tissue oxygenation was maintained by infusions of the new modified perfluorocarbon based oxygen carrier perfluorocarbon emulsion; a procedure he described as “Augmented Acute Normovolaemic Haemodilution” (A-ANH). The procedure allowed normovolaemic haemodilution to a haemoglobin level below 70 g/l. Tissue oxygenation was maintained by administration of perfluorocarbon and O2 instead of red cells. Avoidance of the transfusion and reduction in blood usage were significant in the group managed by A-ANH compared to the group that received standard care. The difference remained statistically significant through the monitoring period of 21 days.

2.12 The basic information sheet (BIS) for transfusion – a new tool for data collection: Interim report from pilot trials

Dr Heidi A. Doughty, Consultant Haematologist, WHO Collaborating Centre, National Blood Service, Birmingham, United Kingdom

Dr Doughty reported on this WHO Regional Office activity developed by the Birmingham Centre. The purpose of the project was to develop a tool for collecting basic information for transfusion and managing clinical practice. In addition, the project sought to develop indicators for measuring the quality of the use of blood and alternatives in different clinical settings and to assist in the establishment of an Internet server for information collection. A basic information sheet (BIS) was created to serve as a clinical performance management tool and a tool for case based data. It consists of a core data set and is made up of indicators that are used as data fields. The data collection may be either paper based or electronic.
Preparation for BIS included considering the different influences on transfusion practice and a review of other data collection projects. The other projects reviewed were OBSQID/ObsCare Project, Development of quality of care in Armenia programme (QCT); BIS for diabetes and complications; Monitoring of transfusion practice – a computerized procedure (Odense, Denmark); and various non-WHO data collection forms.

Seven centres participated in the first field trial after which the BIS was reviewed. Nine centres participated in the second field trial after which the study was reviewed and IT solutions considered. The aim of this workshop is to review the use and design of the BIS.

The current contents of the BIS form are demographics, context, pre-transfusion data, transfusion targets, treatments, transfusion management, post-transfusion data, performance review, and authorship. The draft form of the BIS used in the second trial is shown in Fig. 1.

**Study feedback**

Each centre recorded five to ten unselected consecutive transfusions for the study and returned the BIS by fax or mail. The data was entered into Microsoft Access/Excel. The forms were reviewed for completion and for feedback from users.

Comments received on the BIS included:

- It was good for the prescribing clinician to specify a transfusion target.
- More clinical data should be collected.
- One form should be for a single episode of transfusion rather than for each unit transfused. The use of hospital registration numbers/Unique Identifiers may be difficult if these numbers changed within the hospital. This is not a problem if a national identity number is used.
- It was useful to include post transfusion coagulation tests.
- The complications of transfusion should be included.
- Consideration should be given to including the volume of components used.

Feedback from the second trial included:

- A reminder to involve the patient/family by inclusion of a patient consultation field.
- Use age rather than date of birth.
- Use of ratios for coagulation results.
- Include fields for different methods of autologous transfusions.
- International Statistical Classification of Diseases and Related Health Problems (ICD) codes were often not available for the users.
- Estimation of non-surgical blood loss was found to be difficult.
- The transfusion assessment should be fixed, e.g. 48 hours after the transfusion.
Fig. 1. The draft BIS used in the second trial.
Use of the BIS

The 10 centres returned 125 BIS during the six-month period (49 from the first trial and 76 from the second). The clinical context included emergency and routine situations. The BIS had been used in a variety of surgical, medical and obstetric situations but had not been used in paediatric practice. The sex and age fields were completed.

Nine of the ten centres completed the diagnosis field, but only three used ICD codes. Eight of the ten centres completed the procedure field, but these were often surgical procedures and not medical and only one centre used ICD codes for procedures. Of the pre-transfusion laboratory results, thrombin time (TT) was not used and was therefore removed from later versions of the BIS. Respiration was often not used in the pre-transfusion clinical data. Targets were set by most clinicians. Clinical targets were highly variable whereas laboratory targets were often standardized. The Hb was often higher than is currently recommended in the framework document. The performance review fields were completed. Performance against targets showed considerable variation between intended and actual endpoints. Platelet transfusion targets were usually more carefully monitored than the targets for other components. In 85% of cases, the clinicians indicated that they had achieved their clinical targets. Most indicated that they had achieved their laboratory results, however, review by the collation centre, found that 22% of those who said that laboratory targets were met, did not actually meet them.

Summary

Many clinical issues arose from the field trials, such as:

- What is the best way to audit clinical care.
- Which clinical parameters should be used.
- When should each patient be reviewed – after the transfusion or prior to discharge.
- How can patients and their carers be involved.
- Should ICD 10 codes or free text be used?
- How to minimize the duplication of data collection.
- The need for benchmarking.

The biggest problem is that BIS monitors transfusion whereas non-transfusion may be the marker of success.

The findings of the field trial were: The trial of the draft transfusion BIS has been completed; the BIS was successfully used in a variety of clinical settings; there was a wide variation in treatment targets; Hb targets used were higher than recommended; All blood components need monitoring; and 22% of laboratory reviews were found to be incorrect.

Discussion

At the hospital Santo Antonio in Porto, Portugal the field trials led to the start of a local haemovigilance and audit programmes and a training programme on clinical use of blood.

In Malta the feedback received from clinicians was inadequate and another attempt will be made later. In Slovenia it was also difficult to motivate the clinicians to participate in the BIS field study. Apparently the schedule for the study was too tight and more information is needed about the aim of the study. No Norwegian centre participated in the trial but Norway has excellent
experience in reducing blood loss. Professor Solheim presented an example of the difference in clinical transfusion practice due to the local policies of an institution. He described the use of blood in cardiac surgery in two different hospitals in Oslo. The same senior surgical staff worked in the two hospitals. In one, only 4% of the operated patients received red cell transfusions. In this hospital, most patients were undergoing elective cardiac surgery for the first time, only senior surgeons operated, attention was paid to preoperative correction of anaemia, the procedure was carefully evaluated and the blood was ordered only by a senior surgeon. In the other hospital, some 60% of operated patients received a transfusion. The difference in this hospital was that 30% of procedures were emergencies, 25% had previously undergone cardiac surgery, attention was not given to correction of preoperative anaemia, junior physicians performed the operation, no written procedures for transfusion existed and blood was often ordered by a less experienced clinician.

2.13 The United Kingdom national external quality assurance scheme: A model for international data collection and comparison

Dr David Bullock, UK NEQAS for Clinical Chemistry, Wolfson EQA Laboratory, Birmingham, United Kingdom

The United Kingdom National External Quality Assessment Scheme (NEQAS) at Birmingham covers clinical chemistry and immunoassays for thyroid and steroid hormones. It also serves as a WHO collaborating centre providing international external quality schemes (EQASs) for clinical chemistry as well as and providing education, training, consultation and support for other WHO quality-related projects. It is part of a NEQAS network, which in the year 2001 has more than 20 schemes in all laboratory disciplines including histopathology.

To be effective, an EQA must be accepted and seen as useful. This requires effective quality assurance and internal quality control, full and regular EQA participation, specimens treated as routine patients’ specimens, remedial action to be taken when needed and confidence in scheme design. In the scheme design, there must be sufficient recent data, an appropriate basis for assessment, and an effective communication of performance data. Information must be fed back to the laboratories within 2–3 days, it must be structured, informative, and the reports must be intelligible to all participants who will have different needs. Graphical content is important in the reporting. All reports start with a summary page and a detailed report is given for each analyte. Comparison with other laboratories is provided. Median, 25–75% performance and 5–95 percentiles are given as well as performance over time. An electronic report is provided in the same format as the paper one. Annual reviews are available through the website.

Assessment of the impact of EQAS has shown that it results in improved performance, elimination of poor techniques, appropriate use of reagents and technology, change in practice and instigation of new and updated guidelines. Transfusion laboratory practice has improved with reduction of errors in ABO grouping, Rhesus typing, and antibody identification. Comparison of the EQAS results with those of the central haemovigilance system (SHOT) programme show that NEQAS performance mirrors clinical reality.

WHO-sponsored international EQAS (IEQAS) may be the only EQAS schemes available to many of the participants. It may be a model for introducing own national EQAS. It gives educational information in the reports and raises awareness of accepted standards and guidelines. Problems have been encountered in receipt of samples, quality of samples, appropriate exercise design, communication and limited access to full range of EQAS services.
2.14 Proposals for quality information systems using the transfusion BIS for case-based and aggregated data

Dr Heidi A. Doughty, Consultant Haematologist, WHO Collaborating Centre, National Blood Service, Birmingham, United Kingdom

A quality information system is a system, which gathers processes and assesses information relevant to quality. The outcome of the assessment may be used to determine policy/benchmarking or as an input into a quality management system. A common data set acts as a checklist to encourage consistent care of a high quality, supports shared care between departments, assists local analysis and multi-site audit. Common transfusion targets should be set (e.g. Hb 9g/dl); performance must be actively monitored against the targets. The outcome must be reviewed as soon as appropriate and treatment adjusted as required. It is recommended that case based data should be reviewed with colleagues. Such cases can serve as the basis for teaching. Patterns of performance (Fig. 2) should be identified, as a part of training needs analysis. Training needs can then be addressed using common educational material and training with an emphasis on the areas of poor performance.

Fig. 2. Patterns of performance

The figure shows the results from a single centre. Each point represents a single transfusion episode showing the intended final haemoglobin on the x-axis and the difference between that and the actual final haemoglobin on the y-axis. This figure shows the use of two transfusion targets, 9, and 10 g/dl. It also shows an over transfusion of 2 g/dl associated with the lower target on one occasion (circled).

Application of the transfusion BIS gives case based data for immediate review by the decision-maker. BIS based information can also be used for measurement of performance against local guidelines, for comparison of practice, benchmarking and for re-evaluation of local guidelines and for improving performance. The information provided by BIS should be utilized not only for feedback to guide decision making of the individual physician or clinical team but also on the institutional (hospital) level and nationally as well as internationally. National data protection acts must be adhered to if exchange of data is undertaken for external quality schemes involving case based data. An approach to this is to aggregate the data using smaller data sets. Aggregation of data is best undertaken locally before central collation. After collation, the aggregated data for individual units can be compared and feedback given.
There are some challenges still to be addressed on the use and utilization of the BIS. These include the method of data entry, for example paper, electronic or both and should the data from hard copies be entered manually or by optical character recognition. How should feedback be communicated (by paper reports or via WHO home page). What extra resources are required to implement this activity and what benefits should be demonstrated in order to justify investment?

2.15 Quality of care development through data collection and benchmarking at a clinical level. Can this be applied to transfusion therapy?

Dr Isuf Kalo, WHO Regional Office for Europe

Quality means degree of excellence and should be evaluated as what is best in relation to what is achievable. The health system goals measure goodness (quality) and equity. Measurement of the quality of care must be structured, there has to be a process and a process of measuring the outcome. Improvement comes then through a change in the process. Quality and validity of the data must be good. Quality information system (QIS) tools include Quality indicators; Basic information sheets; Database; Software/hardware; and resources. There are challenges in measuring, data transfer, comparison, and resources. The collected data has to be used and acted upon.

Data collection in clinical care should be an integral part of the daily work. It is the responsibility of the professionals and is based on self-assessment and self-regulation. Action to be taken is based on the gathered information. For instance in the use of the BIS on neonatal care or on pregnant women, the wellbeing of the patient is also included in the outcome. Feedback is given to each institution and anonymous comparison is done. WHO has developed automatic systems to record data from BISs. The most relevant indicators are collected and the compiled data can be sent to national health authorities, e.g. fetal death during delivery. Comparison between individual countries or institutes can be used to highlight centres of best practice.

Data collection, collation, and monitoring of standards at a national level require national resourcing. The United Kingdom has a newly formed National Institute for Clinical Excellence, which creates clear standards of service for the National Health Service. It is hoped that this should lead to monitoring performance against these standards and result in dependable local services.

- Prerequisites for the quality development in transfusion therapy and quality of care are: Agreed assessment measures.
- Commitment from Health Care Professionals (leadership, ownership, clinical governance).
- Common definitions of data items (data sets, forms, quality indications).
- Adequate information systems for data transfer, analysis, benchmarking and feedback Policy and measures for quality development (commitment of key players).

Challenges for quality development in clinical transfusion therapy are:

- different clinical expectations
- different users
- various number and definition of data items
- time for data collection
3. Working groups

There were four parallel working groups, which worked on the following topics.
1. Generic BIS – with Dr Doughty as facilitator.
2. Aggregated Data – with Dr bullock as facilitator.
3. Development of Quality Indicators – with Dr Smit Sibinga as facilitator.
4. Implementing the WHO policies – with Dr Gabra as facilitator.

3.1 Generic BIS

The participants considered that the Basic Information Sheet (BIS) is a tool to help the individual prescriber to improve the quality of their clinical practice. It is neither a tool for epidemiology nor a tool for haemovigilance.

The BIS is a simple tool that can be used as a paper based system. However, any recommendation to use the BIS should emphasise the implication for resources at the local level. Resources should include paper, information technology and staff time for implementation, which includes adaptation for local needs.

The participants also recommend that:
1. A generic BIS should be trailed rather then separate BIS for surgery and non-surgery. It should be noted that the group was divided in their opinion on this and that the generic BIS should be kept under review.
2. Measurements should be given when they are specified in the targets, e.g. normal clotting, Hb.
3. Different fields should be used accordingly to clinical assessment of the patient needs, e.g. platelet counts are important when monitoring the use of platelet transfusions but is not a routine requirement in surgery.
4. Individual vital signs should be measured, e.g. blood pressure, pulse, rather than global assessment of shock.
5. Ratios are used for reporting coagulation results, i.e. the ratio of the test sample/control result.
6. The use of the respiration rate as a vital sign varies between countries should be removed from the BIS. Approximate blood loss and inclusion of urine output (where applicable) were also discussed.
7. Cryo-poor plasma should be removed and replaced with albumin as an option on the list of components.
8. Only life threatening and immediate reactions need to be listed as complications in the section for post-transfusion reactions.

9. A third trial is to be started. Units that are interested should contact the Birmingham centre to indicate their willingness to participate.

### 3.2 Aggregated data

**The participants agreed that:**

- The Basic Information Sheet (BIS) is a constructive clinical tool to improve appropriate use of blood. The tool should support resource utilization and risk management and enhance communication between clinicians and blood bank professionals. Cost savings may follow the increasing effective utilization of resources and reduced.
- Member States implement data aggregation using the BIS, at local (and if appropriate later at national) level, in a stepwise manner, reflecting local and national issues and priorities.
- Input of full BIS data to European level aggregation should be preferably by web-based procedures, or alternatively by file transfer with defined structure.

**The participants recommend that the WHO Regional Office gives all possible assistance to:**

1. Finalize the BIS (or set of BISs), maintaining its simplicity, both as a bedside clinical tool and as a basis for data aggregation.
2. Support aggregated data to be passed electronically to a higher level as a reduced dataset with defined content and structure (preferably XML).
3. Establish, when appropriate, a European level server to receive aggregated national data.
4. Establish, as a priority, a European level system for aggregation of full BIS data, for BIS validation and for European interim benchmarking (using sample data) and continuing specialized studies, compliant with data protection and other ethical considerations.

**The participants also recommend that:**

1. Each country may need to customise the BIS, for language and/or descriptions (e.g. to identify blood components used.
2. Confidentiality of data must be respected, to maintain patients’ and clinicians’ trust and to assure the validity of entered data as well as to satisfy data protection legislation.
3. Data aggregation at any level carries a responsibility to feed back information, including professional input and commentary.
4. Data aggregation is useful at local level (e.g. individual clinician, clinical team, hospital), to influence clinical practice and blood utilization, ideally including data from every patient considered for transfusion.
5. Implementation of local and national aggregation systems should use and complement existing and planned processes and systems (including information technology), with support from national advisory mechanisms.
6. Data aggregation may be useful at national level, to identify best practice and enable benchmarking.
7. Data aggregation is useful at European level, to identify best practice and enable benchmarking.
8. Data aggregation is useful for specialized clinical situations at European level, to identify best practice and enable benchmarking.
9. Input of full BIS data to European level aggregation be preferably by web-based procedures, or alternatively by file transfer with defined structure.

3.3 Development of quality indicators (QIS)

The participants recommend that:

1. Structurally the quality indicators are developed for local purposes as well as for the blood transfusion services (BTSs) and hospital systems.
2. Local level working groups are organized to draft the indicators, to write guidelines and standard operating procedures (SOPs) as well as blood order forms.
3. Doctors, nurses, and technicians must be educated both at the BTSs and hospital. Education must be regular and continuous and must be assessed.
4. SOPs should cover the blood order form, patient identification, clinical and laboratory parameters, cross matching and product identification, clinical and laboratory outcome of the transfusion and traceability of the components.
5. Infrastructure, based on aggregated data system, must be developed to monitor and assist the development of the quality indicators.
6. Establishment of a working party is recommended for the development of the indicators and of the operational structure.

3.4 Implementing the WHO policies

It was recommended on the first day of the meeting that the implementation of the WHO policies, along the lines proposed in the various WHO documents prepared, should follow a clearly defined action plan with dates for completion and dates for review and monitoring.

The participants considered that the Initiative of this meeting to be good advocacy to sensitize the health authorities to support action to implement the WHO policies. It is recommended that a comprehensive report of this meeting be circulated as soon as possible to all ministries of health for action (no later than January 2002).

1. It is recommended that a National multidisciplinary working group (Clinical Policy Forum) be established in every participating country according to the criteria proposed by WHO (within three months from the date of this meeting). WHO is urged to bring this to the attention of the various governments via the respective WHO representatives.
2. The workshop acknowledges that policies constitute the background for the guidelines. It is recommended that at national level and based on the WHO/BCT Handbook on the Clinical Use of Blood\textsuperscript{1,2} a first set of guidelines should be prepared for:

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\textsuperscript{2} The Clinical Use of Blood in Medicine, Obstetrics, Paediatrics, Surgery & Anaesthesia, Trauma & Burns. Module WHO/BCT 99/2, Geneva (Learning Material).
the use and indication for specific blood products, including; red blood cells, platelets, FFP and cryoprecipitate;

specific clinical situations, including obstetrics, massive bleeding, planning for elective surgery, paediatrics, intensive care and others if required;

the use of volume expanders and safe transfusion alternatives.

3. It is also recommended that the participants of this meeting should be responsible for ensuring that the above set of guidelines are completed, based on revision of existing local guidelines as well as on the current and proposed WHO guidelines.

4. It is recommended that the draft guidelines be completed for presentation to their respective national clinical policy forum within three months from the date of this meeting to adopt the clinical guidelines before submission to the ministry of health.

5. It is recommended that the participants of this meeting review:

- the request form for the standard procedures on clinical transfusion;
- clinical blood ordering schedules.

Participants should submit their review to their clinical policy forum. The proposed timeframe is within three months from the date of this meeting.

6. It is recommended that the clinical policy forum or working group should establish a strategy for dissemination and training of the guidelines so that this is achieved by one year from the time the guidelines are adopted. Assistance from the WHO Regional Office may be required to achieve this goal.

7. The clinical policy forum should seek assistance from the health authorities to ensure that all facilities using blood have a “transfusion monitoring committee”, which:

- audits the patterns of blood usage;
- provides data on the prevalence of the markers for transfusion transmissible infections;
- provides data on the prevalence of other complications and transfusion reactions.

8. It is therefore recommended that the National Health Authorities encourage the establishment of such transfusion committees in all health care facilities (within one year of this meeting).

9. The main goal of this meeting is the development of quality of clinical transfusion practice. It is recommended that a quality system to improve the clinical use of blood be established in the European Region. The system should be based on the principles demonstrated in the Basic Information Sheet project. National Authorities should provide the necessary resources and training facilities. It is recommended that participation should start immediately.

10. The WHO learning materials on clinical use of blood (module and handbook) should be translated into the respective languages of the Region, implemented and utilized at the country level. Promotion of these materials should be directed toward anaesthetists as well as other clinicians, and clinical specialists should collaborate with blood transfusion specialists in raising awareness of these materials.

11. The communication between transfusion medicine specialists and WHO representatives (WR) is vital to support the implementation of the WHO policies and guidelines. The workshop recommends that the WHO Regional Office and the WRs are sensitized to
support the activities of the national health authorities required for implementation of the proposed action plan.

12. The participants recommend that a follow up workshop is facilitated by the Regional Office in one year’s time, to review the progress achieved as indicated in the action plan. In this meeting there should be a representative of the ministry of health, the head of the transfusion service and a clinician to represent the national clinical policy group. It is possible that this large meeting may be replaced by more than one meeting in order to respond to the diverse needs of the various regions in Europe.

4. Discussion

4.1 Working group on quality indicators

A draft of forms to be utilized for creating the QIs. A working group consisting of Smit Sibinga, Solheim, Doughty, Fruhwald, Letowska and Jevtic will be created for QIs and it will work through e-mail.

4.2 Time frames

Time frames are good to give, but they should be realistic. The time frames given by group IV should be from the time the report comes out and not from the date of the meeting. The aim is to complete the report of this workshop by the end of the year (C. Smit Sibinga, G. Gabra and H. Doughty).

4.3 Representation

It was noted that only 20 countries of the 51 in the Region were represented in the workshop. It was felt that a core operative group is needed to take concrete steps to implement the recommendations of the workshop. Such a group would be working with Dr Kalo’s programme and the two collaborating centres. It is recommended that a small advisory group be formed under a contract with the Regional Office to take this initiative further.

4.4 Closing comments

In his final comments, Dr Kalo thanked the participants from the 20 Member States for their active participation. He thanked also the hosts, chairmen and volunteer rapporteurs as well as the staff of the Regional Office, who had contributed to the proceedings of the workshop. He stated that the visible measures of the outcome of the workshop are the report and the recommendations. Invisible measures of the outcome are the impact on all the participants, their thinking, reflections, and motivation. Above all, the outcome is our common understanding of issues discussed that has developed during this workshop.
Annex 1

SCOPE AND PURPOSE OF THE MEETING

The World Health Organization devoted World Health Day, 7 April 2000 to raising awareness of the importance of safe blood, voluntary blood donation and the rational use of blood.

The Regional Office for Europe chose to focus its World Health Day activities on promoting the rational use of blood. A group of experts was convened in London in April 2000 to formulate stringent recommendations which would bring down blood overuse and misuse while promoting alternatives. This document, entitled A framework for a national blood policy and guidelines: Rational transfusion therapy – Improving the quality of care by reducing inappropriate blood transfusions and promoting the use of alternatives was published as a supplement to the June 2000 issue of the International Society of Blood Transfusion’s Newsletter, “Transfusion Today”. Early in 2001, WHO launched two excellent documents (a module and a handbook) on the clinical use of blood.

On 29 October 2001, the WHO Regional Office and the Ministry of Health of the Netherlands held a meeting on this topic in Groningen, Netherlands, to which were invited representatives from the ministries of health and medical associations of WHO’s European Member States. This was followed by a two-day workshop for expert clinicians from Member States who reported to what extent the guidelines and recommendations of the above documents have been implemented and what impact they may have had on the continued development of quality and safety of blood transfusion therapy.

The expected outcome of this seminar was the commitment of the European Member States’ health authorities and medical associations to reviewing or designing policies for improving the quality of blood transfusion therapy and promoting the use of alternatives in line with the WHO documents.

Participants were also introduced to the new WHO policy and role in the promotion of the quality of health systems, where the rational use of blood and transfusion alternatives may be used as a model. The possibilities of dissemination of the quality development approach in transfusion practice from WHO to a country level was discussed.
Annex 2

PROVISIONAL PROGRAMME

Monday 29 October 2001

08.00–09.00   Registration and coffee
09.00–09.30   Welcome and introduction. Dr I. Kalo
               Opening address. Dr Frans C.A. Jaspers, Executive Board, University Hospital, Groningen
               Election of Chairperson and Rapporteur
               Adoption of provisional programme
09.30–09.45   Introduction of participants
09.45–10.15   WHO guidelines and national policies on appropriate use of blood and blood products. Professor M. Cherian
10.15–10.45   Coffee break
10.45–11.15   A framework for a national blood policy and guidelines: improving the quality of blood transfusion practice in Europe. Dr G.S. Gabra
11.15–11.45   The need for common quality indicators for inter-European bench-marking of quality of clinical transfusion practice. Dr C.T. Smit Sibinga
11.45–12.30   Questions and discussion
12.30–13.30   Lunch
13.30–15.00   Country reports by health systems representatives on national policies for rational use of blood and blood products
15.00–15.30   Questions and discussion
15.30–16.00   Summary and provisional recommendations

Tuesday 30 October 2001

09.00–09.30   The WHO initiative on quality in transfusion medicine. Dr C.T. Smit Sibinga
09.30–10.00   The WHO initiatives for guidelines and national policies on the appropriate use of blood. Dr M. Cherian
10.00–10.30   Why do we need to review our prescribing habits? Dr G.S. Gabra
10.30–11.00   Coffee break
11.00–11.30   The principles of transfusion therapy: triggers and strategies. Professor Ph. van der Linden
11.30–12.00   Alternatives for blood transfusion. Professor Ph. van der Linden
12.00–12.30   Clinical experience with O₂ Carriers. Professor D.R. Spahn
12.30–13.00   Summary of morning lectures and discussion (Chairperson)
13.00–14.00   Lunch
14.00–14.30   The United Kingdom National External Quality Assurance Scheme: A model for international data collection and comparison. Dr D. Bullock
14.30–15.00 The Basic Information Sheet (BIS) for transfusion – a new tool for data collection: Interim report from pilot trials. Dr H.A. Doughty

15.00–15.30 Reports (10-minute presentations) Theme: Quality development in transfusion practice – examples of failure and success at a clinical level.
- Dr M. Amil Dias, Portugal
- Dr A. Aquilina, Malta
- Dr G. Özet, Turkey
- Dr M. Potocnik, Slovenia
- Dr V. Rehacek, Czech Republic
- Professor B. Solheim, Norway
Moderators: Dr G.S. Gabra and Dr C.T. Smit Sibinga

15.30–16.00 Coffee break

16.00–16.30 Reports, continued

16.30–17.00 Discussion

Wednesday 31 October 2001

09.00–09.20 Quality of care development through data collection and benchmarking at a clinical level. Can this be applied transfusion therapy? Dr I. Kalo

09.20–09.50 Proposals for quality information systems using the Transfusion BIS for case-based and aggregated data. Dr H.A. Doughty

09.50–10.00 Introduction to working groups. Dr G.S. Gabra

Each working group will have a chairperson and a rapporteur and will prepare draft recommendations

10.00–10.30 Coffee break

10.30–12.30 Parallel Working Groups:
1. Generic BIS – facilitator: Dr H.A. Doughty
2. Aggregated data – facilitator: Dr D. Bullock
3. Development of: quality indicators (QIs) – facilitator: Dr C.T. Smit Sibinga
4. Implementing the WHO policies – facilitator: Dr G.S. Gabra

12.30–13.30 Lunch

13.30–14.30 Reports from Working Groups

14.30–15.00 Questions and discussions

15.00–15.30 Summary and Recommendations. Dr G.S. Gabra and Dr C.T. Smit Sibinga

15.30 Closure of the meeting. Dr I. Kalo
Annex 3

COUNTRY REPORTS

1. Albania

Population: 3.5 million. Albania has legislation covering blood transfusion and the prevention of HIV/AIDS. There is a National Blood Transfusion Service. National regulation now exists for donor selection criteria, blood collection criteria, blood testing, blood products, and the distribution of blood products from blood banks to the hospitals. Guidelines cover the import and export of human blood and its derivatives for therapeutic and diagnostic use. A national policy on blood transfusion is being developed and a National Blood Transfusion Service Committee has been established. Guidelines on the safety of blood and blood products have also been developed. A national blood request form is in use.

Blood donors include autologous, paid and family replacement donors. The proportion of voluntary non-paid donors is increasing. The short-term goals of the blood transfusion service are: promotion of the principle of voluntary, non-remunerated blood donation; reduction of the number of blood banks; strengthening of quality assurance and quality control systems; promotion of policies for the rational use of blood and blood products; and harmonization of blood services standards in Albania with Council of Europe Guidelines.

Long-term goals are: achievement of self-sufficiency in blood components based on voluntary, non-remunerated donations; development of a haemovigilance system; establishment of external quality control; computerization of data collection; postgraduate training for physicians in transfusion medicine.

A workshop on rational use of blood was organized in collaboration with WHO, the Ministry of Health and the Albanian national blood transfusion service. A conference of surgery has also produced recommendations for the clinical indications of the use blood components. Standard operation procedures have been written for the clinical transfusion process. There are currently two studies being undertaken on the use of blood, one on the use of blood in general surgery and the other on the use of blood substitutes in open-heart surgery.

2. Armenia

Population: ± 2.0 million. No report presented.

3. Austria

Population: 8.1 million. Guidelines and algorithms for blood transfusion have been developed and are available on the Internet. This enables those who do not have their own algorithms to learn from the national one. For instance it is “forbidden” to order blood for some operations.

The bloodstocks at the hospitals are run by the anaesthesiologists. Workshops on appropriate use of blood were organized five years ago for senior hospital staff resulting in a reduction in the outdating of blood components from 40% to 6%.

4. Belarus

Population: 10 million. There are 67 blood banks, which are located in the hospitals. Blood products are free for the hospitals. The number of whole blood collections has remained the same for some time, but the number of aphaeresis procedures has increased. In 2000, some 420,000 units of blood were collected and 98% were given as components. The proportion of new blood donors used to be some 45%, but this has decreased to 20% in year 2000. In the year 2000 0.45% of donors were HBsAg positive, 0.75% HCV positive and 3 donors were found to be HIV positive. The cumulative number of HIV positive persons in Belarus is 3020. Elevated ALT values in blood donors are mainly due to alcohol use.
Fresh frozen plasma is cheaper than colloids and crystalloids and its use varies from 3000 to 7000 ml/1000 inhabitants. A quarantine programme for apheresis plasma was started two years ago to increase safety. The use of platelets is 15 units/1000 inhabitants and that of albumin is 182 g/1000 inhabitants.

5. Belgium

*Population: 10 million.* The Red Cross runs the blood transfusion system. The country collects approximately 750 000 blood donations annually. The number of individual blood banks, besides the two main ones, has been reduced from 38 to 8. The two main blood services (Flemish and French) and eight blood centres take care of 95% of the production of blood components. The blood transfusion services have a close connection with the universities. The national social security system reimburses the blood transfusion services for products. All donations are voluntary and non-remunerated.

There is no national blood policy or national structure, but the Flemish and French parts of the country have their own systems. The law on blood transfusion was revised in 1994 and it gives prices for blood components but does not regulate the use of blood.

A traceability system for blood components and transfusions has been created. Reporting on transfusion complications is on voluntary basis. A consensus conference on albumin resulted in a decrease in the use of albumin, in which Belgium used to be the leading country in Europe! Transfusion Committees are expected to become mandatory in the hospitals in the near future.

6. Bosnia and Herzegovina

*Population: 3.9 million.* No report presented.

7. Czech Republic

*Population: 10 million.* Traditionally the hospitals had their own blood banks, but recently there has been some centralization. There has been a law on blood banking since 1997, which classifies blood and cellular components as medicinal products. The regulators of medicinal products control the activities of the blood transfusion service. The Ministry of Health has issued a recommendation on the optimal use of blood. The hospital blood transfusion committees are expected to give the practical guidance on the indications and contra-indications of the use of blood.

There are some 100 district hospitals, of which 60 collect and some also process blood. Haematologists are available for guidance on the use of blood. Ten regional hospitals (university hospitals) collect and process blood and are directed by full time experts in blood transfusion. It is felt that sometimes the collaboration between the blood bank and clinicians is not as good in the regional hospitals as in smaller ones.

8. Croatia

*Population: 4.7 million.* The number of annual donations is 160 000. Blood is collected by the blood service consisting of the national institute and 22 blood banks. The country is self-sufficient in red blood cells and platelets but not in F VIII.

A Committee on Transfusion Medicine has been created, but there is no officially agreed national transfusion policy. There are regulations concerning hospital blood transfusion committees, but they are not yet active in all hospitals. Guidelines on blood transfusion have been created and training in transfusion medicine in medical schools has been started.

9. Finland

*Population: 5 million.* The Finnish Red Cross has one Blood Transfusion Service (FRC/BTS), which is in charge of running the activity in the country through its National Blood Transfusion Service Centre, four Regional Blood Transfusion Services and 16 local blood collection centres. The number of annual
collections is about 330,000, of which some 30% is collected in mobile donations. The number of blood donors in year 2000 was 195,000, of which 11.6% were new donors.

Finland is self-sufficient in all blood components. The use of red cells decreased in 2000 by 1% from the previous year. The use of platelets increased by 10% and that of albumin decreased by 12%.

A law on blood collection and blood transfusion services came into effect in 1995, but there is no official blood transfusion policy. The clinicians in the hospitals are in charge of the blood use. National statistics on the collection of blood and consumption of red cells, platelets, and other components are kept by the FRC/BTS. Statistics for the use of blood components by the hospitals are available for the blood transfusion service on an annual, monthly and weekly basis.

Guidance on the appropriate use of blood is given in a textbook published by the Union of Communities, which is the organization that owns the hospitals. The personnel of the FRC/BTS participate actively in training of students in medical schools, nursing schools and in the hospital and other training courses. The experts of the FRC/BTS have also published textbooks on blood components with active participation.

The FRC/BTS influences the clinical use of blood by providing information on the products and by publishing statistics, surveys and research on the use of blood components. Information to hospitals on the use of blood is regularly given through consultants, in seminars, meetings, and discussions with the hospitals, regulatory agencies, and Ministry of Health. A catalogue of the blood products provided by the FRC/BTS is published regularly and it gives also instruction on appropriate use of the products.

10. Hungary

Population: 10 million. The blood transfusion services are hospital based, but the concept of national centralization was introduced in 1999. Centralization has now been achieved. Besides the headquarters there are 6 regional centres, 18 local blood transfusion services and hospital based transfusion departments, which also collect whole blood.

Thirty-two percent of the blood is collected in Budapest, but shortages of blood supply are experienced. There is a central dispatch office in Budapest, which operates 24 hours a day. Data on blood is collected during the night and, for example, red cell concentrates can be delivered the day after collection. With every product the hospital gets a reporting form of the blood transfusion, in which the side effects of the transfusion are also registered. Ratio of FFP vs. RBC usage is analysed. There is no national law on blood transfusion services or blood banks, but recommendations exist for the use of blood.

11. Latvia

Population: 2.3 million. The country has one Central blood transfusion service, one regional BTS, and 18 hospital blood banks. Council of Europe standards in blood components are followed. Training programs in transfusion medicine for physicians and nurses have been created. In the year 2000, a 100% usage of blood components was reached.

12. The former Yugoslav Republic of Macedonia

Population: 1.8 million. No report presented.

13. Malta

Population: 0.4 million. The only blood bank and three other blood collection sites are associated with hospitals. So far, there is no blood transfusion committee. Policies on the use of blood components are created by experts as required and implemented by the laboratory trained scientists of the blood transfusion service. The blood transfusion service audits the hospital use of blood and can identify those, which do not have appropriate usage of the components.
14. **Netherlands**

*Population: 16 million.* A new law on blood supply became effective in 1997 and since then the national blood transfusion service system (Sanquin) has been reorganized. The leading principles are self-sufficiency, safety by using non-paid donors and not-for-profit principle. At present, the blood transfusion services in the country are in nine regions.

A law on quality of health care institutes came into effect in 1996 and according to its principles, attention is given to reducing the unnecessary use of blood. A study on the efficient use of blood products has been initiated and local initiatives on reduction of the use of blood are encouraged. A 6% decrease in the use of cellular products was recorded in 2000 when compared to the previous year.

An organization (TRIP foundation) for haemovigilance with advisory bodies and Council of Blood Users is to be established.

15. **Norway**

*Population: 4.5 million.* The 58 blood banks are run by the hospitals. A considerable centralization is expected soon especially with respect to processing of blood, partly because from the beginning of 2002 the state will take over the running of the hospitals. There is no national blood policy. However, guidelines for the use of blood and blood components have been published by the Health Directorate. Since 1996, the hospitals have been obliged to have blood transfusion committees. The Department of Health and Social Affairs recently established a committee for quality assurance in blood transfusion services, the secretariat of which is at the National Institute of Health. The Committee had its first meeting in September 2001 and decided to create a national haemovigilance system.

National statistics on blood transfusions are collected by the Society for Immunology and Transfusion Medicine of the Norwegian Medical Association. The Society has also taken the initiative of holding consensus conferences on rational use of blood and blood products.

Blood collection figures are at 45 000/million inhabitants from 22 000 blood donors/million inhabitants. Some 99% of the blood collections are based on the SAGM multi-bag system and all red cell concentrates as well as platelets are leukodepleted by filtration. Plasma is sent to Octapharma for fractionation from the 54 blood banks. Consumption of blood components per million inhabitants is: 38 000 units of red cell concentrates (171 000 units), 6000 units of platelets (27 000), 7000–8000 units of S/D treated FFP (36 000 units of 0.2 l), 140 kg of albumin (total 630 kg), and 3.1 million units of F VIII, of which 30% is recombinant.

A type and antibody screen principal is generally implemented and it has been noticed that it reduces the need for preoperative requests for blood products. Salvage of blood is used in cardiovascular and orthopaedic surgery and some acute normovolemic haemodilution is used in cardiac surgery.

16. **Poland**

*Population: 39 million.* Poland has a centralized blood transfusion service system. In 1997 a law on blood transfusion was given. The blood transfusion services are part of the national public health service. There is a National Blood Transfusion Service, 21 Regional Blood Centres and 274 hospital blood banks. The hospital blood banks belong administratively to the regional blood centres. The blood transfusion service system is a national monopoly and it has a uniform organization and has had a central budget since 1999. When the hospitals had to start paying for the blood components the usage fell by 25% and is now about 10% less than when there was no payment for the components.

The National Blood Transfusion Service has expert supervision through the Institute of Haematology and Blood Transfusion and National Centre for Transfusion Medicine. It gives guidelines, supervises the quality assurance and good manufacturing practice, conducts inspections and provides training and lectures in the field.
The number of hospital blood banks has decreased. The number of mobile blood collections has increased and the paid donor system has been changed to a non-paid one. A guidebook on blood components and use of blood has been published and recently new guidelines of the use of blood for the hospitals have been given out. It has also a unified form for cross matching and for recording the side effects of blood transfusion.

17. Portugal  
Population: 10 million. A national blood network has been created. It includes the Portuguese Blood Institute, three regional blood centres, and 50 hospital-based blood banks. Regional blood centres audit the hospital blood banks. Portugal is not self-sufficient in blood and blood products. There are no official criteria for the use of cellular components however, a consensus conference has agreed upon appropriate use of blood. The results of conference will be published in the near future and distributed to the hospitals.

18. Turkey  
Population: 65 million. The Ministry of Health arranges training for blood bank directors. The Red Crescent Society provides 60% of the blood and blood components in the country. Whole blood is still used, but component production is increasing. Turkey has no domestic plasma fractionation.

Blood order forms provide indications for blood usage. Blood transfusion forms are filled by the wards and returned to the blood transfusion services, which makes it possible to gather information on the use of blood components.

19. United Kingdom  
Population: 60 million. The United Kingdom has 3 blood services. The National Blood Service (NBS) of England and Wales has the task of coordinating the blood supply through 13 regional centres in England and one in Wales. Scotland and Northern Ireland have their own transfusion services. The NBS collects approximately 2.2 million units of blood a year supporting self-sufficiency in cellular blood components. All blood is processed into components. In addition, the United Kingdom imports plasma for fractionation within a central plasma processing facility. The number of blood donors is approximately 1.8 million, which represents 6% of the population. The NBS is a part of the National Health Service and reports to the Department of Health. The NBS is subject to all the quality initiatives designed for the health services.

Each regional centre directly supports a geographical area for reference work, donor, and patient care. Most the 350 plus hospitals served has a blood transfusion laboratory but do not collect blood. Blood collection is a nurse led activity organized by the regional centres using a combination of mobile collection team and static collection sites. The blood service has been managerially reorganized along into functional lines to continually improve quality and to allow staff to develop expertise.

There are no laws concerning the use of blood but guidelines are regularly published and distributed to the hospitals. The performance of the hospitals against these guidelines should be monitored locally by the Hospital Transfusion Committee. There is no system for central collation of data except for the central haemovigilance system (SHOT), which is providing valuable feedback on blood safety. The NBS has developed closer links with the hospitals using a variety of liaison posts and web-based data sharing. The hospital liaison function has initiated a number of national audits to allow comparison of practice.
Annex 4

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