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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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Towards better, safer blood transfusion

A REPORT FOR THE
AUSTRALIAN COUNCIL
FOR SAFETY AND QUALITY
IN HEALTH CARE

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Glossary

AIMS – Advanced Incident Management System

ANZSBT – Australia and New Zealand Society of Blood Transfusion

ARCBS – Australian Red Cross Blood Service

ASBT – Australia Society of Blood Transfusion

BTIC – New South Wales Blood Transfusion Improvement Collaborative

CME – Continuing Medical Education

CNST – Clinical Negligence Scheme for Trusts

CoE – Council of Europe

HTCs – Hospital Transfusion Committees

MRCP – Member of the Royal Australian College of Physicians

NBA – National Blood Authority

NBS – National Blood Service

NHMRC – National Health and Medical Research Council

SHOT – Serious Hazards of Transfusion

SOPs – Safe Operating Procedures

Recommendations

Future investment in enhancing the safety of transfusion must address clinical transfusion practice improvement, not just blood product quality. In 2005 the major risks from transfusion are associated with unsafe clinical transfusion practices and inappropriate blood product transfusion.

Health care professionals involved in everyday transfusion practice must receive better education and training to support safe and appropriate transfusion.

Australia should adopt a national clinical governance model for the safety and quality of blood and blood product transfusion. This should integrate organisations that currently contribute to aspects of the safety and quality of transfusion practice into a single governance framework that addresses all aspects of the transfusion 'safety chain'.

A national 'better, safer transfusion program'(BeST) should be established to promulgate transfusion practice standards, oversee monitoring of transfusion performance and lead a parsimonious core of transfusion practice improvement activities. A national BeST advisory committee should develop this program. This committee should report, via the jurisdictional blood committee, to Australian health ministers.

This national BeST program should operate through the normal accountability and responsibility channels of acute health care. Program implementation should be through jurisdictions. Jurisdictional BeST committees, with clear linkages to hospital transfusion committees, should work together on identified national transfusion safety and quality priorities.

Haemovigilance activities should be part of this national BeST program.

Hospital transfusion committees and hospital transfusion teams can only deliver enhanced transfusion safety and appropriateness if adequately resourced. This resourcing must include access to appropriately trained medical staff and, where relevant, a trained transfusion nurse (or equivalent).

The safety and appropriateness of hospital transfusion practice should be an explicit responsibility of executive managers of health services.

Definitions and status

Clinical governance:

The framework for which health organisations are accountable for continuously improving the quality of their clinical services and safe guarding high standards of care by creating an environment in which excellence in clinical care will flourish (NHS 1998).

Integrated governance:

Systems and processes by which trusts lead, direct and control their functions in order to achieve organizational objectives, safety, and quality of services, and in which they relate to the wider community and partner organisations (NHS 1998).

Transfusion practice and governance – where we are in 2004?

Despite different national consensus guidelines, several American and international multicenter studies demonstrate a substantial variability in perioperative transfusion practice. Even in a selected patient population at low risk for transfusion therapy, the percentage of patients transfused and the median number of units transfused per patient varies considerably between institutions.

The SANGUIS study evaluated blood product use in 43 teaching hospitals from ten European countries, and found that transfusion rates depend more on physicians than on type of procedure, patient population or hospital.

Similar results have been found in more recent studies involving teaching and non-teaching hospitals. Reviewing the appropriateness of red cell transfusion, based on a variety of criteria, Hébert et al. estimated that the proportion of unnecessary transfusions ranges from 4 to 66%. Reasons for the large variability in transfusion practice remain elusive, but clinicians' practice and attitude may be entrenched and slow to change.

The avoidance of unnecessary blood transfusion can be achieved by adopting a standardized blood conservation strategy, which will consequently reduce allogeneic blood use.

Van der Linden et al, 'Multidisciplinary transfusion strategy', *Canadian Journal of Anaesthetics*, 2001, 48: 9, pp 894-901.

What will occur if we do not change the way we work?

Every system is perfectly designed to achieve exactly the results it gets. Most of our systems in health care evolved over many years, rather than being designed to achieve particular objectives. It's timely to review them (Paul Batalden and Don Berwick, *IHI*).

What aspects of transfusion practice should we address?

Too much of health care performance is measured primarily through productivity and financial indicators. This could explain why safety is not listed as a primary objective in most strategic plans, and why the majority of health care providers are not directed towards (or accountable for) improving safety in performance agreements or service contracts.

When organisational management systems only focus on financial performance, the ethical requirement to improve safety is often left to individual clinicians, who are rarely empowered to effect systemwide improvements (Sue Williams, 2004, NHS).

Do we need to do anything to address transfusion safety?

Faced with the choice of changing one's mind and proving that there is no need to do so, almost everybody gets busy on the proof (John Kenneth Galbraith).

The definition of insanity is doing the same thing over and over and expecting different results (Albert Einstein).

Lessons from the UK

SHOT data provide mixed messages: the risk: benefit ratio of appropriate transfusion is high compared with other risks in life, but safety can still be improved. The United Kingdom lacks a unified body to take an overview of all aspects of blood safety, sometimes making it difficult to practice "aligning effort with risks." Technological advances such as viral genomic detection and inactivation may be mandated by regulatory authorities, but prevention of transfusion error requires local managerial commitment, "process re-engineering" and an active hospital transfusion committee. Hopefully the concept of clinical governance will focus resources in this important area (Lorna Williamson, 1999).

Summary

Like much of the developed world, Australia has invested heavily in ensuring that blood and blood products are of exceptional quality. Extraordinary measures have been embraced to minimise the risk of transfusion-transmitted infection. These measures include the introduction of central blood bank quality systems and regulatory frameworks for blood and blood products, and enhancing the applied science and technologies that support improved blood donor selection and screening, and blood product manufacture. Consequently, in Australia we have world-class blood and blood products.

Like the rest of the developed world, we now know that residual risks to the safety of transfused patients in Australia lie predominantly in the hospital environment. Transfusing the wrong blood product to the wrong patient was the dominant risk of transfusion in 2004. The literal confusion of blood sample, blood product or patient identity resulted in the unintended transfusion of a blood product into the wrong patient at an unacceptable frequency (variously estimated at somewhere between one in 3,300 and one in 20,000 transfused units). Despite the relative tolerance of the blood group antigen systems to such mishaps, these 'wrong blood' episodes occasionally produce major morbidities and even fatalities.

There were also well-intentioned, but nevertheless inappropriate transfusion of blood products, reflecting a failure of contemporary Australian transfusion practices to align with recommended best practice. These unnecessary transfusions waste a valuable community resource. They expose patients to all the risks of transfusion, without offering commensurate health benefits. They also potentially reduce the availability of that particular blood product for patients with a demonstrable need for transfusion support.

Much is known about best practice models of transfusion that offer optimum transfusion safety. These models have often been developed and predominantly discussed in environments outside where most blood product transfusion actually occurs. Much of contemporary transfusion medicine expertise lies in a 'parallel universe' from the worlds of acute medical and surgical care. As a microcosm of this 'parallel paradigm', in any individual hospital, much of the knowledge regarding optimal transfusion practice has often resided within the hospital blood bank, rather than being grounded in the clinical units and health care professional groups that commonly transfuse blood products to their patients.

In Australia, transfusion medicine expertise has largely resided within ARCBS and ANZSBT, rather than being a strong interest of the medical and nursing special interest groups that use transfusion as a common supportive therapy. Internationally, the World Health Organisation and bodies such as the EU and CoE have enthusiastically embraced transfusion safety programs, rather than the international clinical societies whose members actively transfuse blood and blood products.

Current approaches to educating and training health care professionals within the mainstream of health care delivery on the safe and appropriate transfusion of blood products are fragmented and inconsistent. This has resulted in a relative lack of expertise in transfusion safety and appropriateness within clinical environments where transfusion is an everyday intervention.

There is also a failure in governance of the transfusion process. No single agency or group manages the overall transfusion safety chain. Instead, different groups focus their oversight on one or more components of this chain. Some critical processes effectively have no review or management. These structures and processes have produced predictable consequences in transfusion outcomes in Australia. We will not improve on our current levels of transfusion performance unless we improve these governance arrangements.

Most available measures indicate that contemporary transfusion practice in Australia is performing at levels that offer significant opportunities for improvement. Risks of transmitting HIV, HCV and HBV are discussed with patients in terms of risk levels of 1:7,000,000, 1:3,000,000 and 1:1,000,000 respectively. Yet present inappropriate usage rate for FFP transfusion episodes frequently exceed 50 per cent, and typical compliance rates for 'critical' steps in the transfusion safety chain are 10 to 70 per cent below recommended best practice performance levels.

The current levels of transfusion safety and appropriateness performance in Australia are a direct and predictable consequence of the systems (or lack thereof) currently supporting the transfusion safety chain.

Some argue that systems for assuring quality in transfusion practice should reside entirely within the mainstream of health care delivery. Currently, 'mainstreaming' transfusion safety means that the responsibility for clinical transfusion safety is loosely assigned to a diverse set of clinicians, managers and scientists. There is little knowledge or interest of transfusion safety at executive management, board, regional or statewide clinical governance forums. This mainstream approach is patently inadequate, and transfusion practices are often less than desirable.

Recent projects throughout Australia (and internationally) demonstrate the capacity to improve a variety of aspects of transfusion practice.

In Australia, these projects range from focused efforts within an individual hospital, to partnerships involving small numbers of hospitals, to statewide endeavours that engaged 20 or more health services in coordinated programs of transfusion practice improvement. These projects' achievements are visible in their formal outcomes reports (examples are in the appendices). Their achievements are perhaps even more obvious when one speaks with individuals and teams engaged in the projects and seeing their data presented.

The establishment of ongoing statewide transfusion practice improvement programs has followed two of these projects (BloodSafe in South Australia and Blood Matters in Victoria). The available evidence indicates that transfusion practice typically reverts to historical norms in a relatively short time when practice improvement projects finalise. Enduring programs that set performance standards, monitor practice against these standards and implement improvement programs (where necessary) are likely to be essential to assuring sustained optimal transfusion outcomes.

There is a large improvement opportunity target in many aspects of contemporary Australian transfusion practice. Each of the approaches to transfusion practice improvement used in recent Australian projects successfully achieved their stated objectives. However, despite typically achieving significant improvement over previous performance levels, these projects often did not achieve true target performance. For example, compliance with a required step might have improved from 20 per cent to 60 per cent in the timeframe of the project, but the gold standard target for reliably safe and appropriate transfusion was actually 100 per cent compliance.

A key lesson from these recent transfusion practice improvement projects throughout Australia is that 'doing something in this area of patient safety and quality of care is infinitely better than doing nothing'.

All of these projects applied classic quality improvement methods to enhance transfusion practice. Each had a strong focus on measurement and the use of locally derived data to stimulate local changes in transfusion practice. Each used awareness raising and education to promote process improvement. However, the projects varied in their focus and scope, their approach to supporting practice changes and the membership of the clinical practice improvement teams implementing change.

All projects identified as critical the need for support from executive managers, clinical leadership by credible medical and nursing champions and adequate resourcing of expert support staff (such as QI, risk managers and transfusion scientists. The three statewide programs (South Australia, New South Wales and Victoria) effectively raised the profile of transfusion safety within their jurisdictions during their projects. They built staff capacity for clinical practice improvement, and shared ideas for improved transfusion safety and practical tools to assist organisations achieve better transfusion outcomes. The products of their endeavours deserve to be made available to the widest possible audience.

We cannot make definitive judgments, using objective criteria, about whether one approach to transfusion practice improvement used in Australia recently is better than another. Nor can we determine if a combination of approaches might deliver better outcomes. However, all successful projects require some degree of local redesign or modification of existing practice improvement methodologies and strategies to gain local ownership. Each approach was adequate for the scale of that project and the project scope. Where more than one health service participated in a project, the opportunity to share information and learn from one another was deemed invaluable. The availability of a project structure and support staff reduced the burden of design, development and implementation of change by sharing knowledge, resources (both human and physical) and tasks across the projects.

As a community, we have particular responsibilities and accountabilities for transfusion safety and appropriateness. These reflect the need to meet the reasonable expectations of blood donors, who entrust their precious gift to a collective of professionals. Blood donors anticipate that their gift will be optimally used to improve the health of people who depend on transfusion support. We also face the very high expectations of those requiring transfusion, who want a significantly greater degree of safety surrounding this supportive therapy compared to the community's typical expectations regarding safety in other types of health care interventions.

Australia has elected to move to a national governance model for blood. At present, the impact of this transition has largely been apparent in the supply side of the transfusion safety chain. This report supports the translation of a national governance model into the arena of clinical transfusion practice. This arena offers the greatest potential for changes in transfusion practice to translate into enhanced patient safety. There is merit in a national model of governance of the entire transfusion safety chain. Providing national leadership and direction for the sector would deliver far greater patient benefits than any more passive approach to transfusion practice oversight.

The governance model established for blood product transfusion must take account of existing lines of responsibility and accountability in acute health care. It is essential that all relevant players in the blood sector be engaged in the process of ensuring the integrity of the safety chain in a cohesive national governance program. The rollout of a better, safer transfusion program into our hospitals requires the active engagement of the jurisdictions that have responsibilities for acute care. This engagement must include a key role in the design of the program, and a commitment to its implementation within jurisdictions. A national transfusion practice monitoring and improvement program should bring all parties with relevant expertise and interest to a common platform for coordinating and prioritising action.

Hospital transfusion committees and hospital transfusion teams must be supported to allow meaningful monitoring and transfusion practice improvement locally. This support will include providing access to an appropriately trained human resource (including allocated time for specialist medical staff and a transfusion nurse or equivalent) to support the work program of transfusion committees.

It has been proposed that Australia adopt a haemovigilance system. 'Haemovigilance' is derived from the French, and means a program that monitors selected aspects of the safety of transfusion. Any measurement program must consciously focus on monitoring aspects of transfusion where there is known to be great potential for delivering improved patient safety. Therefore, haemovigilance measures, in an Australian transfusion context, need to include both traditional product safety and aspects of clinical transfusion practice, such as transfusion appropriateness. There must be a commitment to infrastructure that would enable transfusion practice improvement to occur if we are to embrace any national system of haemovigilance. There is little point in measuring transfusion performance if there is no system capacity to respond to identified performance concerns.

Transfusion safety is only one component of a broader health care safety and quality agenda. We need not demand that funds for better, safer transfusion be entirely 'new' monies. Negotiations between the States, Territories and the Commonwealth could resolve an agreed mix of existing and new monies for this purpose. These negotiations might deliver an agreement that meant hospital costs required for a national transfusion safety and appropriateness program were a targeted expenditure within existing, identified hospital quality and safety budgets, with the support for necessary advisory groups and working parties being identified new monies provided through the NBA.

To deliver and implement 'Better Blood Transfusion' there needs to be a heightened profile of blood transfusion practice within Trusts. It needs to be on the Governance and Risk Management agenda, with advocacy from the Chair of the Hospital Transfusion Committee.

The framework of a National Blood Transfusion Committee reporting to the CMO, linking into regional and local Hospital Transfusion Committees, is in place to aid the process.

What is needed now is an effective clinical infrastructure, including dedicated consultant sessional time and the appointment of more Transfusion Nurses/Practitioners.

(Dr Angela Robinson, NBS Medical Director, England, 2003.)

1 Background

The primary purpose of this report is to summarise the transfusion practice improvement projects undertaken in Australia between 2001 and 2004 to enhance fresh blood product transfusion safety and appropriateness. The report looks at the various approaches to improving clinical transfusion practice in these projects, their achievements and the lessons learned by those engaged in the implementation of change.

Where relevant, other national and international programs intended to deliver better, safer transfusion practice are drawn on to inform the options for consideration when contemplating future approaches to systematic enhancement of transfusion safety in Australia.

This report focuses on the safety and appropriateness of *fresh* blood product transfusion, as this is where most work has been undertaken in national and international programs. However, similar governance and systems issues apply to considerations of any other dimension of the quality of transfusion practice (including effectiveness and efficiency), and to the transfusion of plasma products, alternatives to blood and blood products, and blood conservation programs.

The authors hope that this commissioned report will consolidate knowledge on where we stand in 2004, and provoke discussion and debate on the options for evolution of a cohesive, efficient, effective transfusion safety program throughout Australia.

Patient safety has become an increasingly important issue in health care. National and international reports have emphasised that our efforts to enhance the quality of health service delivery should have a strong focus on patient safety. In Australia, national and jurisdictional groups have been launched, which are interested in patient safety and the design and implementation of a raft of strategies intended to reduce levels of iatrogenic harm.

A body of knowledge underpins successful approaches to improving the quality of health care and patient safety. An understanding of systems thinking, human error and error reduction, human factors and process improvement is increasingly common amongst those committed to the delivery of consistently safe, high quality health services in Australia.

Translating this generic knowledge base into concrete improvements in patient safety requires a move from the general to the particular. We must make practical changes to the way we do business, which translates into better, safer care. This must involve reviewing and improving specific systems and subsystems in health care delivery. While creation of a culture of safety amongst health care workers is a necessary precondition for safer care, there is also a need to work on the details to deliver safer specific care processes and component sub-processes.

Our patients will ultimately receive better, safer health care because of work done by teams of consumers, patients, health care professionals and health service and health systems managers working collaboratively to enhance every aspect of delivered care.

Efforts to realise improved outcomes for people who require blood product transfusion by ensuring better, safer transfusion practices are but one component of this broader health care safety and quality agenda. In the past decade there has been a growing recognition that there are major variations in clinical transfusion practices which cannot be explained, and that recommended best practice is frequently not reflected in contemporary transfusion practices. These practice variations have been found in every jurisdiction that has examined transfusion practice within Australia – and also internationally. There is a belief that insufficient energy has gone into ensuring that health care professionals receive adequate undergraduate and postgraduate training in clinical transfusion practice. Mechanisms for monitoring clinical transfusion practices and transfused patient outcomes, and improving clinical transfusion practice had, until very recently, been rudimentary at best.

Blood and blood products are an increasingly scarce resource. Our community bears a considerable financial burden for the provision of sufficient quantities of safe blood and blood products. Volunteer, non-remunerated blood donation creates a unique social contract between blood donors and those charged with ensuring optimal patient outcomes from this valuable community resource. Our community has extremely high expectations regarding transfusion

safety. Patients do not expect to be transfused unless there is a clearly identified, anticipated benefit. As a community, we are very intolerant of adverse outcomes from blood product transfusion.

The safety of blood products with regard to transfusion-transmitted infectious risks in Australia is outstanding. Available evidence suggests that there is a genuine need to improve current clinical blood transfusion practices.

The Stephen Review of the Australian Blood Banking and Plasma Product Sector (2001) highlighted enhanced clinical transfusion practice in Australian hospitals as a priority area.

Importantly, and contrary to public perception, the major risks of transfusion currently lie in the clinical use of blood in hospitals, rather than with transmission of infectious agents through the supply

(*Stephen Review*, 2001).

Collectively, the above influences have resulted in better, safer transfusion practice recently identified as a priority area for health care improvement efforts in Australia and internationally. This focus on clinical transfusion practice improvement is novel in terms of transfusion safety programs. The overwhelming majority of prior efforts addressed blood and blood product safety, rather than the integrity of all the interdependent processes that ultimately determine the quality and safety of clinical transfusion (the transfusion safety chain).

Momentum generated through studies of transfusion practice in Australia (such as those of Rubin et al, in Appendix 5.1.2), and the considerations of the *Stephen Review*, saw Australia generate clinical practice guidelines for the use of fresh blood components in 2001. This was a joint initiative of the NH&MRC, ASBT and the relevant specialist colleges. There was subsequent national investment in strategies to assist the implementation of these guidelines, which resulted in several different approaches to improving transfusion practice in jurisdictions introduced throughout Australia between 2001 and 2004.

Consistent application of best practice in transfusion throughout Australia would ensure that our health care system meets the reasonable expectations of people who need blood or blood product transfusion and those who donate blood. These include expectations that transfusion be as safe as humanly possible, and that the available supplies of blood and blood products enhance the health of Australians in need of transfusion support.

Lessons learned in enhancing transfusion practice should inform the design of other programs intended to improve the safety and quality of common clinical interventions in acute health care.

Mistakes in transfusing blood remain an important cause of morbidity and mortality. In 2001, the serious hazards of transfusion (SHOT) scheme, which receives reports of adverse transfusion events from the majority of United Kingdom hospitals, reported that failure in some aspect of bedside identification of the patient, the blood, or the blood component, or of the monitoring of the patient throughout the transfusion, has been the single most important cause of errors in transfusions for four consecutive years. It continues to dominate transfusion risk in 2004.

('Effect of a formal education programme on safety of Transfusions', *BMJ*, volume 323, 10 November 2001.)

2 Recent approaches to improving the safety and quality of blood product transfusion

2.1 National

2.1.1 Australian Capital Territory

The ACT ran a project titled Appropriate Use of Blood Products in 2001 and 2002 across public and private hospitals in the state. The project set out to standardise the ordering of blood products. Blood transfusion committees introduced a guide for clinical staff on the appropriate ordering of blood products for various procedures. Promulgation of best-practice guidelines occurred, and monitoring and feedback of actual performance was provided by auditing the appropriateness of blood product prescription and documentation in the two participant hospitals. The audit results were made available to the transfusion committees of these participant hospitals. These committees developed local improvement plans to enhance transfusion practice, based largely on familiarisation of medical staff with the NH&MRC/ASBT Clinical Practice Guidelines through traditional continuing medical education sessions. Calvary Health Care ran this initiative as one of its targeted Clinical Health Improvement Program (CHIP) projects.

After the release of the initial audit results, and implementation of local guidelines awareness and education strategies, a repeat audit demonstrated better documentation for all blood transfusions and improved adherence to national guidelines regarding the appropriateness of blood product prescription.

The results of the study were communicated widely to medical, nursing and scientific staff in the Canberra hospital and Calvary Health. The project won an ACT Health Quality First Award for quality and safety in health care in 2003.

Unfortunately, a re-audit of practices in 2003 demonstrated that there was a strong trend to a reversion towards prior, less adequate transfusion practices after the conclusion of the formal project phase of the initiative.

2.1.2 New South Wales

In November 1998, the Australian Centre for Effective Health Care signed an agreement with the New South Wales Health Department to conduct a project on the appropriateness of red blood cell transfusion in New South Wales hospitals. The final report on the project was presented to the Chief Health Officer and Deputy Director General, Public Health, New South Wales Health Department, and the Chairman of the New South Wales Ministerial Advisory Committee on Quality in Health Care in March 2000.

This commissioned study reported a significant non-alignment of everyday clinical transfusion practice with recommended best practice. There was a particular problem identified with inappropriate red cell transfusion in haemodynamically stable patients (that is, elective red cell transfusion).

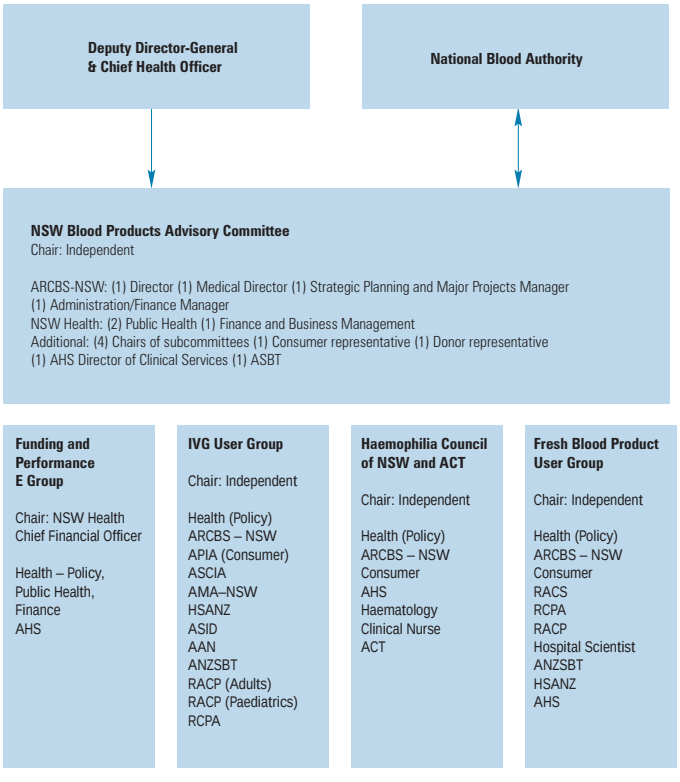
Subsequently, New South Wales Health established an additional user group to assist in the development of improved blood product usage. The New South Wales Health Blood Use Improvement Group (BUIG) consolidated all existing departmental circulars on blood and updated them to represent current best practice. BUIG complemented the existing advisory functions of the Haemophilia Council and the Intravenous Immunoglobulin User Group, who provided advice to the department on the best use of coagulation factor therapeutics and intravenous immunoglobulin. New South Wales Health also received input from an Australian Red Cross Blood Service/New South Wales Health Liaison Committee, which provided a forum for decision making on management of blood and blood products in New South Wales.

New South Wales Health, through the Institute for Clinical Excellence, commissioned a consortium based at the Northern Centre for Healthcare Improvement to undertake a 12-month New South Wales Blood Transfusion Improvement Collaborative (BTIC)

during 2002-2003, which used breakthrough collaborative methodology to focus on improving the appropriateness of red cell transfusion in haemodynamically stable patients. At the time of commissioning, the collaborative NH&MRC/ASBT guidelines for red cell use was the sole available national guideline. BTIC was seen as a first step in a structured New South Wales implementation of the NH&MRC/ASBT guidelines into clinical practice.

In 2004 New South Wales Health revised its governance structure for blood and blood products in New South Wales, incorporating a peak body at the state level to advise the department on clinical, procedural and policy issues pertaining to the supply, demand and use of blood products in the state. This governance structure is shown in the figure below.

Figure 1 Committee and reporting structure for the National Blood Authority

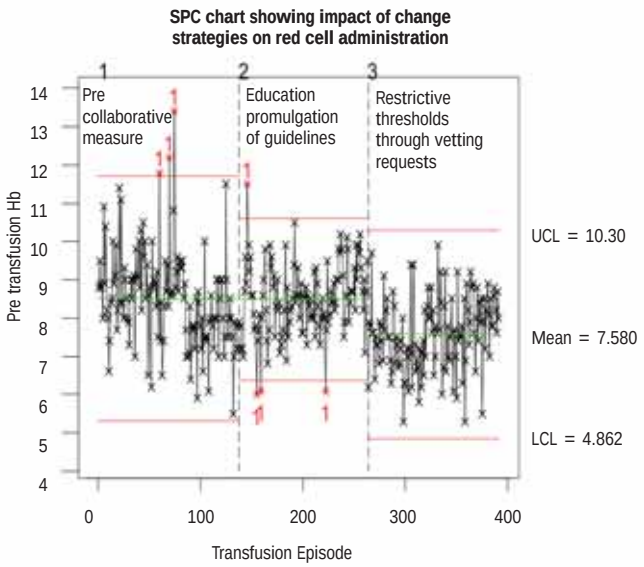


The BTIC project reported in September 2003 on their work in the 17 participant hospital teams, including a summary of their results in improving red cell transfusion practices. The report included several pertinent recommendations regarding suggested future directions for spreading and sustaining the gains identified in the project, and improving other aspects of blood transfusion practice.

BTIC demonstrated that it was feasible to deliver improved red cell transfusion practice using the breakthrough collaborative improvement methodology. BTIC noted that the largest improvements in red cell transfusion practice were achieved in hospitals where there was vetting of all requests for red cell transfusion against apparent compliance with the NH&MRC/ASBT guidelines by identified staff in hospital blood banks in addition to distribution, endorsement and education about the guidelines.

BTIC demonstrated virtual abolition of red cell transfusion in haemodynamically stable patients with a pre-transfusion haemoglobin of 100 g/L or greater in participating centres, with an overall significant reduction in pre-transfusion 'threshold' haemoglobin across participant clinical sites (shown in the chart below).

Figure 2 Statistical process control chart



The final report from BTIC emphasised that sustaining and spreading the successes of the collaborative would require improved performance measurement and governance of transfusion practice in a clinical setting at state, area health service and individual hospital levels. This improvement in measurement and governance would require the identification of statewide leadership for ongoing efforts at improving transfusion practice in New South Wales.

Key recommendations from the BTIC project included:

- strengthening local commitment to ensuring appropriate transfusion practice in hospitals
- establishment of measurement systems that can provide data on the management and use of blood
- introduction of vetting of transfusion requests including dose
- hospitals to be accountable for their use of blood and blood components issued from ARCBS
- improved education of clinical staff who prescribe and administer blood products
- increased patient and consumer education and involvement
- review of current NH&MRC/ASBT guidelines in relation to patients with chronic anaemia
- promotion of spread and sustainability of improvement, including to other blood products, using 'top-down' policy development by New South Wales Health.

The BTIC report includes invaluable resource materials and change strategies (see Appendix 5.1.1).

The BTIC report recommended additional investment in structured transfusion practice improvement in New South Wales. Some anticipated that the BTIC initiative would generate sufficient momentum to drive systemwide spread of improvements in red cell transfusion in haemodynamically stable patients and other initiatives to enhance transfusion practice in New South Wales. These expectations regarding spread and sustainability in the absence of targeted programs and investment have not been realised, perhaps understandably, given the findings in other jurisdictions and in comparable international programs.

The fresh product user group that reports to the New South Wales blood products advisory committee is currently preparing recommendations on future directions in transfusion medicine. A comprehensive strategic approach to transfusion medicine, including practice monitoring and transfusion practice improvement that takes account of the September 2003 BTIC recommendations, has been prepared for consideration by New South Wales Health.

2.1.3 Northern Territory

Given the population of the Northern Territory, and the concentration of transfusion practice to a relatively small number of hospitals, their Health Department has addressed the issue of improving transfusion practice and guideline implementation within existing hospital committee structures, rather than via specific projects. Blood transfusion committees (or their equivalent) exist in each hospital, and are felt to work well. Northern Territory Health also has regular 'end user' liaison meetings with ARCBS to canvass relevant blood product issues. Hospital medical scientific staff are perceived to be very diligent when it comes to vetting transfusion requests and attempting to ensure alignment of clinical practice with recommendations of current guidelines. Given the comparably lower available financial and human resources, it appears that transfusion safety and quality matters are well in hand. Should additional resources be available, there is merit in having a transfusion medicine specialist available for local CME sessions for medical staff and laboratory scientists.

2.1.4 Victoria

Studies in Victorian hospitals in the late 1990s demonstrated a significant gap between recommended best practice in transfusion and contemporary clinical practice. These discrepancies ranged from a high level of clinically inappropriate fresh product transfusion, to poor documentation and adherence to administration and monitoring guidelines, to poor inventory management, with consequent unnecessary product losses.

In 2001 the Victorian Department of Human Services funded a pilot project titled Blood Matters that used two teaching hospitals to identify and trial strategies to improve all aspects of hospital-based fresh blood product transfusion practice. A consortium of ARCBS, the centre for blood cell therapies at Peter MacCallum Cancer Centre and Melbourne Health led the pilot project. The program identified a range of practical strategies that improved aspects of fresh blood product transfusion in the pilot clinical settings. In 2002 the Victorian Department of Human Services' clinical innovation agency partnered with members of this consortium to run a 12-month breakthrough collaborative in Victoria as a key platform of the work program of the Victorian Quality Council. This breakthrough collaborative took the lessons of the pilot project and used these as the foundation for the transfusion practice improvement plans in the participant health services.

Both the pilot project and the breakthrough collaborative set out to:

- improve the handling and storage of blood products
- align clinician decision making with NH&MRC/ASBT clinical practice guidelines
- improve blood product, patient sample and patient identification, in order to prevent wrong-blood-to-wrong-patient episodes
- improve adherence to protocols and procedures for the administration of blood products, the monitoring of patients during transfusion and the traceability of blood products
- enhance patients' understanding of the risks and benefits of transfusion
- improve the capture of error and adverse events, and the use of these reports to improve transfusion safety
- develop an educational program for nurses involved in hospital transfusion teams, and assess the impact of the introduction of trained transfusion nurses into hospital practice.

Data gathered at the commencement of the collaborative demonstrated major deficiencies in health care professionals' knowledge regarding fresh blood product transfusion and hospital protocols and procedures for ordering, provision and administration, and monitoring of transfusions. The collaborative and pilot demonstrated the capacity to improve all targeted aspects of transfusion practice. The 16 participant health services in the collaborative (15 Victorian and the Royal Hobart hospital) reported their progress in enhancing transfusion practices through regular teleconferences, face-to-face learning sessions and via logging of required performance measures on a secure website. The collaborative was extended beyond the initial 12 months to 18 months, based on an interim assessment of the participant team achievements by the Department of Human Services.

The transfusion nurse education program that was developed delivered a certificate in transfusion practice distance learning course under the auspices of the Peter MacCallum Cancer Centre's department of nursing education, in conjunction with the University of Melbourne. The assessment of the implementation of the transfusion nurse role into participant hospitals was overwhelmingly positive. Most centres rated the availability of the specialist nurse as the critical success factor for their program of transfusion practice improvement endeavours. This view is repeated wherever transfusion nurses have been embraced in Australia.

A summary of some of the more significant achievements of the Blood Matters project is in Appendix 5.2.1.

In 2004-2005 the Victorian Department of Human Services established a Better, Safer Transfusion Program for Victoria, to follow the Blood Matters project. The program has an expert advisory committee that develops and oversees a program of ongoing systematic efforts to both monitor and improve hospital transfusion practice in Victorian hospitals.

2.1.5 Queensland

Queensland health has a Blood and Blood Products Advisory Committee that receives inputs from the Haemophilia Centre and the ARCBS-QLD blood products user group on blood and blood product issues, including the implementation of clinical practice guidelines. They have relied on the blood products user group and the hospital transfusion committees that feed into the ARCBS-QLD user group to implement the NH&MRC/ASBT guidelines.

Queensland Health has overseen several statewide initiatives addressing pathology and scientific services quality management, audit and staff training programs. They have not yet approached clinical transfusion practice improvement within their exemplary statewide health care improvement program. Currently, Queensland health pathology and scientific services are looking at options for introducing appropriate practice improvement strategies for blood product transfusion in the state, and are looking at using the experiences of other jurisdictions to inform their planning processes.

2.1.6 South Australia

The South Australian Department of Human Services launched its BloodSafe quality assurance program for blood products in South Australian hospitals in 2002. The project represents collaboration between the department, ARCBS, the Metropolitan and Country Clinical Subcommittees of the South Australian Hospital Safety and Quality Council and teaching hospitals and their transfusion service providers. Five major hospitals participated in the project (the Royal Adelaide Hospital, Flinders Medical Centre, Repatriation General Hospital, Queen Elizabeth Hospital and the Women's and Children's Hospital).

The project was designed to address identified key deficiencies in the (then) current system of care:

- the appropriateness of blood product transfusion, including the development of tools to measure and enhance transfusion appropriateness
- the introduction of a haemovigilance program for measuring adverse transfusion events in South Australian hospitals
- improving inventory management and reducing blood stock wastage in country South Australia.

Data gathered during the BloodSafe project demonstrated major deficiencies in health care professionals' knowledge regarding fresh blood product transfusion and current hospital protocols and procedures for ordering, provision, administration and monitoring of transfusions. In terms of clinical practice improvement, the project initially focused on surgical inpatient transfusion in participant hospitals. An essential component of the project was the introduction into these hospitals of dedicated transfusion safety officers/nurses to support the work of local transfusion teams and transfusion committees.

In the project report, the BloodSafe team found that they had delivered a significant reduction in inappropriate red cell transfusion. The initial audit revealed that red cell transfusion was inappropriate in 18 per cent (range: nine to 36 per cent) in target hospitals. After interventions, this inappropriate red cell transfusion rate fell to four per cent

(range: zero to five per cent [p<0.001]). The project report also showed significant improvements in consent for transfusion, appropriate documentation of the indication for transfusion in the medical record and adherence to recommended blood product administration procedures (Appendix 5.3.1).

BloodSafe noted that their transfusion course consultants proved themselves to be effective change agents in hospitals. This role significantly improved the safety and appropriateness of blood transfusion practices in their hospitals. The demonstrated success of the approach of the BloodSafe project and the transfusion nurse consultants prompted an initial 12-month extension of project funding by the South Australian Department of Human Services (including a state transfusion nurse educator for non-metropolitan hospitals and the private sector). More recently, the department has provided triennial funding support for BloodSafe, which covers transfusion nurses in major hospitals.

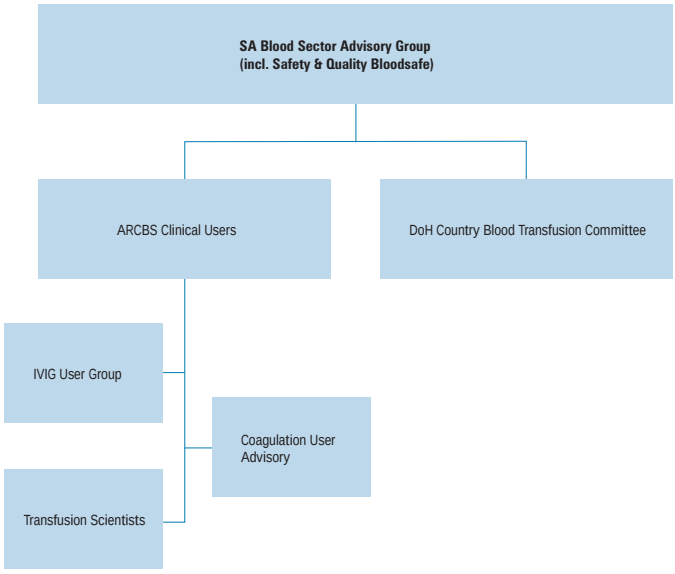
The inventory management sub-project developed several practical tools to assist small hospitals in their management of blood products. These tools help support good inventory management, minimise product expiry and assist in product-to-patient traceability.

Figure 3 Red cell audit results

	Pre	Post
Number audited		
units of red cells	664	519
transfusion episodes	357	284
patients	191	170
Percentage of episodes involving:		
planned surgery	50%	41%
autologous blood	9%	10%
Patients with a comorbidity	55%	54%
Percentage of episodes started in:		
general wards	32%	47%
theatre and recovery	36%	33%
intensive care	24%	17%

The current governance structure in South Australia includes several expert groups that provide advice to the department, in addition to the enduring practice improvement activities of BloodSafe (see figure below).

Figure 4 South Australia blood sector advisory group



The major achievements and lessons from BloodSafe are included in their reports and presentations (in Appendix 5.3.1 and 5.3.2.).

2.1.7 Tasmania

Tasmania established a Tasmanian blood and blood products management group in 2003 as a high-level policy and decision making group to ensure efficient, effective arrangements for providing blood and blood products in Tasmania. The group reports to the director of the hospitals and ambulance service division. Its terms of reference include specific roles in relation to the national blood agreement and communication with the National Blood Authority. It is also tasked with the development and implementation of best practice planning and management systems for blood products and blood related products in Tasmania, including the promotion of efficiency in use and minimisation of wastage.

Each of the three major Tasmanian public hospitals has embarked on transfusion practice improvement projects in the past three years (the Royal Hobart Hospital initially did this through participation in the Blood Matters collaborative in Victoria). These projects recorded significant improvements in various aspects of transfusion practice, including the appropriateness of requesting and use of fresh blood products. These hospital practice improvement efforts were led by their local transfusion committees, and were based on measurement of relevant aspects of transfusion practice by the transfusion committee, feedback on performance to involved clinical staff, appropriate educational interventions and repeating the relevant performance measures.

2.1.8 Western Australia

Western Australia has a long-standing blood user group (BUG) under the auspice of the Australian Red Cross blood service. BUG has representation from ARCBS, public and private hospital haematologists, hospital blood bank and pathology service scientists and the Western Australian Department of Health. The group acts as an information-sharing forum, identifies issues in blood product supply and allocation and provides advice on selected issues to the Department of Health. It has informal links back into hospital transfusion committees through shared membership.

The Department of Health in Western Australia supported two projects that used a data linkage approach to measure aspects of blood product transfusion practice. The first of these was in collaboration with ARCBS in Western Australia. This used the return of ‘bag tags’ attached to blood products issued by ARCBS which contained the name of the transfused recipient, their unit record number and the date of transfusion as identifiers. These identifiers allowed linkage of each transfusion episode with data contained in other health event registries via the Western Australia Data Linkage Project. The Data Linkage Unit of the School of Population Health at the University of Western Australia manages this project. The unit is a collaboration between the Health Information Centre in the Department of Health and the Centre for Health Services Research at the University of Western Australia, the Centre for Health Informatics at Curtin University of Technology and the Telethon Institute for Child Health Research.

The unit was established in 1995 to develop and maintain a system of linkages connecting health events for individuals across the Western Australian population. Privacy sensitive protocols, probabilistic matching and extensive clerical reviews are used to create and manage links within and between the state’s seven core population health datasets, spanning up to 30 years. This core data linkage system is further augmented through links to an extensive collection of external research and clinical datasets. These linkages are created using internationally accepted rigorous privacy sensitive protocols.

These linked datasets have enabled ARCBS in Western Australia and the Western Australian Department of Health to look at the use of blood products by age, gender, hospital and region, and by procedure, ICD10 and DRG codes. It also offers the potential to track linkages of transfusion episodes with any of the information contained in the Hospital morbidity data system, mortality records, the mental health information system and the cancer registry to the midwives notification system. This IT resource has the potential to provide comparative transfusion practice data that could underpin future such projects. Appendix 5.4 contains examples of the data derived from this linked dataset.

The Western Australian Centre for Pathology and Medical Research performed a second data linkage project, funded by the Western Australia Office for Safety and Quality in Health Care. In this project data from the hospital laboratory information system, the transfusion medicine laboratory information system and hospital records (operating room procedure codes and ICD10 codes) were linked in a relational database. This enabled reporting of the epidemiology of transfusion by clinical specialty, procedure and diagnostic category, back to health care professionals by the hospital transfusion committee.

Educational interventions on the need to reduce the cross-match-to-transfusion ratio, and the recommendations of the NH&MRC fresh product transfusion guidelines, were undertaken in targeted clinical areas. These were augmented by strict enforcement by the transfusion medicine unit of the recommendations of the hospitals Maximum Surgical Blood Order Schedule (MSBOS). These interventions were followed by re-analysis of transfusion practices using these hospital level data linkages. There were demonstrable reductions in the numbers of red cell units cross-matched and transfused in the targeted clinical specialty. A re-audit several months after the initial interventions showed that these practice improvements have been sustained.

The establishment of this linked dataset will allow easy and inexpensive monitoring of some aspects of transfusion practice over time by the hospital transfusion committee. Appendix 5.4 contains additional information on this data linkage project.

Data linkage approaches, such as those applied in Western Australia, can potentially deliver outstanding transfusion epidemiology data. While some of this might inform transfusion practice improvement, it would be even more useful for rational planning of blood product supply plans. Such systems would enable tight linkages between product planning and actual and anticipated acute care delivery planning. This would be a great improvement over current ‘historical plus a bit’ or ‘guesstimate-based’ approaches to product supply planning. Australian and international experience indicates that the costs of developing systems to collect these data are modest.

The Transfusion Medicine Unit at the Royal Perth Hospital has an active transfusion practice improvement program. The hospital transfusion committee uses a transfusion nurse as a resource to educate staff and to audit various aspects of clinical transfusion practice regularly within the hospital. When these audits identify deficiencies in transfusion practice, the transfusion committee targets interventions to improve relevant protocols and procedures and staff adherence to recommended practice.

The transfusion medicine unit believes that its success in attaining very good levels of transfusion practice throughout the hospital is largely attributable to the availability of the transfusion nurse resource, acting as both educator and auditor. Hospitals in Western Australia without this resource expressed concerns that they are limited in the scope of their transfusion practice monitoring and improvement efforts because of a lack of a similar human resource.

Patient Safety and Blood Transfusion: New Solutions

Current risk from transfusion is largely because of noninfectious hazards and defects in the overall process of delivering safe transfusion therapy. Safe transfusion therapy depends on a complex process that requires integration and coordination among multiple hospital services including laboratory medicine, nursing, anesthesia, surgery, clerical support, and transportation. The multidisciplinary hospital transfusion committee has been traditionally charged with oversight of transfusion safety. However, in recent years, this committee may have been neglected in many institutions. Resurgence in hospital oversight of patient safety and transfusion efficacy is an important strategy for change. A new position, the transfusion safety officer (TSO), has been developed in some nations to specifically identify, resolve, and monitor organizational weakness leading to unsafe transfusion practice.

New technology is becoming increasingly available to improve the performance of sample labelling and the bedside clerical check. Several technology solutions are in various stages of development and include wireless handheld portable digital assistants, advanced bar coding, radiofrequency identification, and imbedded chip technology. Technology based solutions for transfusion safety will depend on the larger issue of the technology for patient identification.

Devices for transfusion safety hold exciting promise but need to undergo clinical trials to show effectiveness and ease of use. Technology solutions will likely require integration with delivery of pharmaceuticals to be financially acceptable to hospitals.

(Walter H. Dzik, Howard Corwin, Lawrence Tim Goodnough, Martha Higgins, Harold Kaplan, Michael Murphy, Paul Ness, Ira A. Shulman and Rosyln Yomtovian. *Transfusion Medicine Reviews*, volume 17, number 3 (July), 2003, p 169-180.)

3 International

3.2.1 World Health Organisation

The Paris AIDS Summit (1994) declaration recognised the need to strengthen international collaboration for blood safety and foster the establishment and implementation of cooperative partnerships to ensure blood safety in all countries. The forty-eighth World Health Assembly, held in May 1995, in Resolution WHA48.27, welcomed the declaration of the AIDS Summit and invited governments that had not already signed the declaration to do so. The declaration and the resolution resulted in the formation of the global collaboration for blood safety (GCBS).

The GCBS operates through consensus proposals and recommendations addressed to its participants. Any proposal and recommendation does not commit the participating organisations or participating governmental agencies and institutions, but constitutes a reference for guidelines, official policy or other action. While the primary focus of the GCBS was on blood product safety, they also included in their objectives the promotion of appropriate and safe clinical transfusion practice.

GCBS participating organisations

Agence Francaise de Sécurité Sanitaire des Produits de Santé (AFSSAPS)

American Association of Blood Banks (AABB)

Council of Europe (CoE)

European Plasma Fractionation Association (EPFA)

Food and Drug Administration (FDA, USA)

International Federation of Blood Donor Organizations (FIODS)

International Consortium for Blood Safety (ICBS)

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

International Society of Blood Transfusion (ISBT)

Plasma Protein Therapeutics Association, Europe

Thalassaemia International Federation (TIF)

Therapeutic Goods Administration (TGA) laboratories, Australia

World Federation of Hemophilia (WFH)

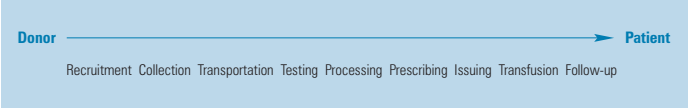
World Health Organization Collaborating Centres:

- Natal Bioproducts Institute, South Africa
- National Blood Transfusion Service Zimbabwe
- National Blood Transfusion Center, Tunisia
- Blood Transfusion Service, Finnish Red Cross, Finland
- Shanghai Blood Center, People's Republic of China
- WHO Collaborating Center and Sanquin Consulting Services, Sanquin Blood Bank Noordoost, Netherlands

The main body (plenary) of the GCBS meets once a year to discuss various issues. The collaborating parties consider the work products of GCBS for adoption and dissemination at global level.

The GCBS recognised that a continuum of processes determines the ultimate safety and quality of transfusion.

Figure 5 Donor-to-patient pathway



Working groups were established to examine specific areas of collaboration:

- policy – the group is tasked with developing a framework for quality decision making while formulating good policies for blood safety at the country level
- quality – the group is tasked with developing guidelines for quality and minimum requirements (standards) for blood transfusion, and tools for assessing implementation at country level
- plasma – the group is tasked with addressing the issues that relate to plasma and plasma-derived medicinal products.

GCBS became interested in promoting appropriate clinical use of blood and preventing unnecessary transfusions. They were amongst the first to advocate that the decision to transfuse blood or blood products must be based on a careful assessment of clinical and laboratory indications that a transfusion is necessary to save life or prevent significant morbidity. They also determined that countries should have national agreed guidelines on the clinical use of blood.

The WHO/Blood Safety and Clinical Technology/Blood Transfusion Safety (WHO/BCT/BTS) team within the cluster of Health Technology and Pharmaceuticals (HTPs) led the WHO program to enhance transfusion safety. An international workshop held in 1997 in Edinburgh was followed by the WHO/BTS publication in 1998 of *Recommendations on Developing a National Policy and Guidelines on the Clinical Use of Blood*, which supported strategies to minimise unnecessary transfusions. A meeting of experts in transfusion practice in Geneva in 1999 (Appendix 5.5) determined that these policies should be supported by the development of interactive learning materials and handbooks for the users of blood products. Appendix 5.5 includes a report of the 1999 deliberations. In 2000 and 2001 the WHO released further materials supporting better transfusion practice entitled *The Clinical Use of Blood* and reports on the first and second meetings of the Global Collaboration for Blood Safety (Appendix 5.5).

Amongst myriad excellent recommendations on approaches to safer transfusion were recommendations regarding the need to:

- raise awareness amongst clinicians of the need to minimise unnecessary transfusion
- develop national transfusion policies and guidelines
- deliver education on transfusion to relevant health care professionals
- make alternatives to blood products available, avoiding the need for transfusion
- invest in a national system of data collection, audit and transfusion practice improvement.

The Quality of Care Unit of the WHO in Europe was tasked with formulating international guidance directed at improving clinical transfusion practice in 2000. The initial output of this group was *A framework for a national blood policy and guidelines: Rational transfusion therapy* (Appendix 5.5). Although developed by the WHO, it was reviewed by a group of expert treating physicians and transfusion medicine specialists and supported as an International Society for Blood Transfusion publication by the WHO Regional Office for Europe in 2001.

3.1.1 Council of Europe and European Union

Founded in 1949, the Council of Europe is the oldest and largest of all European institutions. One of its founding principles is that of increasing cooperation between member states to improve the quality of life for all Europeans. The Council of Europe selected blood transfusion as one area to encourage cooperation among member states. From the outset in the 1950s, the activities focused on promotion of voluntary, non-remunerated blood donation, mutual assistance, optimal use of blood and blood products and protection of the donor and the recipient.

The first result of this cooperation was the adoption of the European Agreement on the Exchange of Therapeutic Substances of Human Origin (European Treaty Series, No. 26) in 1958. The European Agreement followed, pertaining to the exchange of blood grouping reagents (European Treaty Series, No. 39) and to tissue-typing reagents (European Treaty Series, No. 84) in 1962 and 1976 respectively. Around these three agreements, the Council of Europe established a blood transfusion program whose aim is to ensure good quality of blood and blood products.

Since then, the Council of Europe has adopted several recommendations covering ethical, social, scientific and training aspects of blood transfusion. While agreements are binding on the states that ratify them, recommendations are policy statements to governments proposing a common course of action to be followed. Major recommendations include Recommendation No. R (88) 4 on the responsibilities of health authorities in the field of blood transfusion; and Recommendation No. R (95) 15, which contain, in a technical appendix, guidelines on the use, preparation and quality assurance of blood components.

Work on Recommendation No. R (95) 15 started in 1986, when the Select Committee of Experts on Quality Assurance in Blood Transfusion Services published proposals on quality assurance in blood transfusion services. Based on these proposals, the select committee produced a more comprehensive guide on blood components in 1995. The immediate success and acceptability of this document was such that the committee of ministers adopted it as a technical appendix to what then became Recommendation No. R (95) 15.

Recommendation No. R (95) 15 states that its technical appendix will be regularly updated to keep it in line with scientific progress. The select committee is now charged with producing annual updates. The updates of the *Guides to the Preparation, Use and Quality Assurance of Blood Components* are currently used as foundation documents for those involved in developing regulatory controls for blood suppliers internationally. They are key source documents for the Therapeutic Goods Administration (TGA) in its approach to assessing compliance of ARCBS and CSL's procedures with the Code of Good Manufacturing Practice (CGMP).

The CoE guidance on hospitals' and clinicians' roles in the appropriate use of blood products (Appendix 5.6) is a sensible set of recommendations that are currently not embraced by accreditation agencies or regulators in the way that such authorities utilise the CoE guides on blood product manufacturing practices.

The European Union entered the arena of blood safety via the issuing of Directive 2001-83/EC in 2001, and recently updated their interest with Directive 2002-98/EC of the European Parliament and of the Council of 27 January 2003, which addresses the traceability of transfused blood products and adverse event data collection. These set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

The directives will have major consequences for blood product suppliers. They include legally binding requirements for traceability of blood components to individual recipients, and for national notification schemes for serious hazards of transfusion that relate to blood product quality and safety (Appendix 5.6). They will therefore have some impact on hospital transfusion services, but relatively little impact on clinical transfusion practices.

3.1.2 United Kingdom

Several factors have aligned in the UK in recent years and resulted in particular attention being paid to the safety and appropriateness of blood product transfusion. Experience with their transfusion error and adverse event reporting system (Serious Hazards of Transfusion, or SHOT) that first became available in 1998 suggested that there was significant patient harm resulting from blood transfusion, and that only a minority of this harm was due to the infectious hazards of transfusion. The emergence of vCJD (mad cow disease) as a potential contaminant of the UK blood supply raised real threats of consequent catastrophic impacts on the safety and sufficiency of blood products.

The UK has a long history of national and zonal blood user groups, under the leadership of blood suppliers (in recent years, the National Blood Service). These groups typically focused on blood product quality and availability. Given the evidence of patient harm in the SHOT report, and the impending crisis of confidence in the safety and sufficiency of supply, the NHS executive decided in 1998 to launch a major initiative addressing hospital transfusion practice. An initial meeting of the UK chief medical officers resulted in the launch of the better transfusion program, with the publication of the *Health Service Circular* (HSC) 1998/224 (Appendix 5.8.1). The HSC 1998/224 detailed actions required of NHS trusts and clinicians to improve transfusion practice. These were based on recommendations from the seminar held by the UK chief medical officers on better blood transfusion in London in July 1998, followed by wide consultation. This circular focused on the need for hospital transfusion committees (participation in SHOT), development and dissemination of transfusion practice guidelines and the consideration of use of transfusion alternatives. This was intended to be the first step towards safer and more effective blood transfusion in the NHS, and it was envisaged that implementation of the recommended actions would be reviewed after about two years.

New national and regional transfusion committees were established to replace the national and zonal blood user groups. The intention was to bring together a wider range of individuals and institutions than had been represented on the former blood user groups, to focus on promoting safe and effective transfusion practice within hospitals. The NBS were involved in establishing these committees and providing administrative support to them. Clinical users of blood always chair them. While they endorse the NBS-led inventory management project and other supply chain initiatives, these transfusion committees have a clear emphasis on improving the hospital end of the transfusion continuum.

The National Blood Service established the Clinical Audit and Effectiveness Strategy in May 2002 (Appendix 5.8.14). This program partnered the NBS with the Royal College of Physicians in a national program of audit of transfusion practice. In 2003 they published a *National Comparative Audit of Blood Transfusion* (Appendix 5.8.10), which highlighted several areas with demonstrated opportunities for enhancing transfusion safety through staff and patient education and improved availability and adherence to best practice procedures and protocols.

A second seminar of chief medical officers was held in October 2001. Following subsequent wide consultation, the HSC 2002/009 *Better Blood Transfusion/Appropriate Use of Blood* was issued (Appendix 5.8.2). This required the NHS to ensure that blood transfusion safety became an integral part of care, with clinical governance responsibilities for safe and appropriate transfusion practice. This circular included an action plan and an ongoing program for NHS trusts for better blood transfusion.

A recent review of the implementation of HSC 2002/009 indicates that progress is mixed. While some trusts made good progress, others demonstrated a decided lack of progress both in program implementation and observed transfusion practices (see *A Precious Gift; Better Blood Transfusion and National Comparative Audit of Blood transfusion* in Appendix 5.8.7 and 5.8.10).

The Better Blood Transfusion Program (reported on above) is essentially an initiative of professionals in England and Northern Wales. Northern Ireland, Scotland and the South of Wales have embarked on their own versions of transfusion practice improvement programs. They deliver these individual programs under the Better Blood Transfusion banner title, but each is unique and separate from the larger UK program.

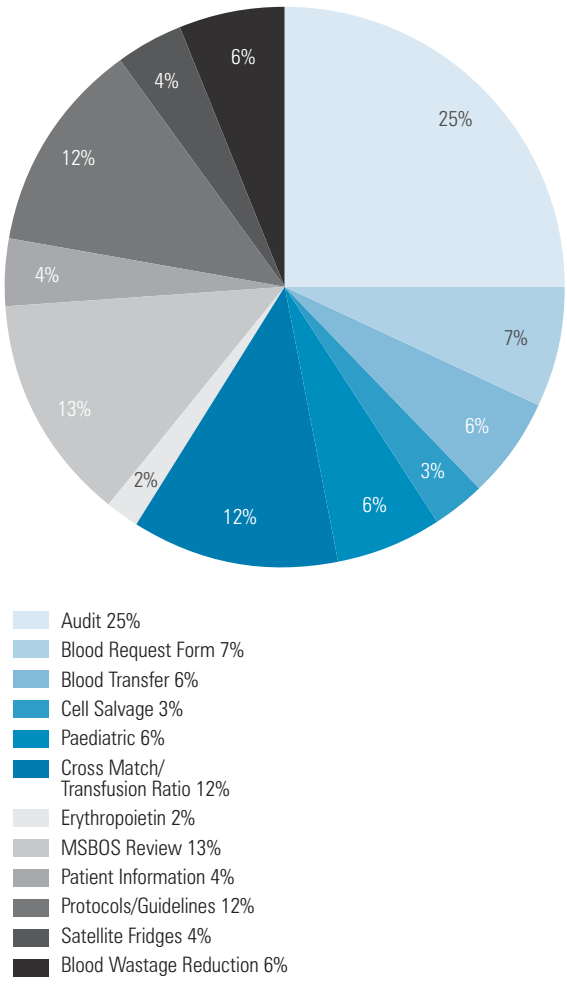
The Scottish Better Blood Transfusion Program is of particular interest, given both its organisation and the fact that it has grown out of many years of systematic endeavours in Scotland with a focus on improving hospital transfusion practice.

With leadership from health care professionals supported by the Scottish Blood Transfusion Service, several multidisciplinary programs have delivered transfusion practice guidelines, educational programs to enhance transfusion processes and development of a specialist practitioner of transfusion/transfusion nurse role. The Scots trialled the introduction of transfusion nurses into hospitals in 2001, and have reported on the successful outcomes from this initiative (Appendix 5.8.9).

The Scottish version of the Better Blood Transfusion Program differs greatly from that in England and Northern Wales. Their program, although funded by NHS trusts, is centrally managed by a specialist team of project managers, under the direction of a steering committee (Appendix 5.8.9). Transfusion practitioners employed by the central program are placed within trust hospitals, but work on the transfusion practice agenda generated by the national Scottish Better Blood Transfusion Program. The program is in its second year of operation, having spent much of the initial year recruiting and training their transfusion nurses. The program has, as one of its stated performance aims, a 10 per cent reduction in red cell utilisation in the coming year.

The central project management of the Scottish program contrasts with the approach taken in the Better Blood Transfusion Program in the remainder of the UK. There, trusts have been tasked with improving transfusion practice, but the focus of these practice improvement efforts, approaches to systems improvement and measurement of achievement are left to the individual trust. The Scottish program allows for direct comparison between hospitals, creates a team of professionals addressing common issues and facilitates knowledge transfer across the sector. There is a major concentration in the program on the delivery of relevant education to those involved in clinical transfusion and the measurement of transfusion practice using a data linkage approach essentially similar to that taken in Western Australia.

Figure 6 Improvement opportunities (Better Blood Transfusion, Scotland, 2004)



3.1.3 USA and Canada

Transfusion medicine experts in North America agree that the challenge for improving safety when patients are receiving blood product transfusions rests primarily in designing and implementing systems that augment oversight of hospital transfusion practices and seek to optimise patient safety and efficiency of utilisation of a scarce resource. They speak of 'rebuilding the hospital transfusion services paradigm', installing or reinvigorating multidisciplinary teams of professionals who monitor existing transfusion practices in their hospitals and design and oversee implementation of transfusion practice improvement programs (*Transfusion Medicine Reviews*, volume 17, number 3, July 2003, pp 169-180).

The Department of Health and Human Services Advisory Committee on Blood Safety and Availability summarised data on current problems and strategies that offer improved transfusion safety following a multi-agency workshop in 2000 (Appendix 5.9.1). Given the organisation of health services in the US, there has been no attempt at structured national programs with a focus on transfusion safety that has sought to utilise the wisdom assembled in this report.

In Canada, the National Blood Safety Council was established after the Krever Enquiry. One of its key roles was the identification of opportunities to enhance transfusion safety. Forums held in 2000 focused on hospital issues that impacted on transfusion outcomes. A large number of issues were identified in these forums, and recommendations were made that were designed to overcome some of the identified system weaknesses.

With responsibility for hospital care falling within the authority of the provinces in Canada, the ability of the federal NBSC to enact its preferred system changes was limited by the willingness of the provincial governments and hospitals to commit to common goals and strategies. Tensions arose when recommendations from this federal council required resourcing by the provinces.

A decision was made by Health Canada in July 2003 to merge the NBSC with the Expert Advisory Committee on Blood Regulation. The new consolidated committee uses the existing title and mandate of Expert Advisory Committee on Blood Regulation, and advises Health Canada on public health, ethical public policy and other issues pertaining to blood safety within the responsibility of the federal government.

This signals that hospital transfusion safety is seen as the responsibility of the provincial and territory governments by Health Canada, with their federal focus being on assuring blood product quality and safety through its regulatory systems.

Hospital and provincial/territorial involvement

In contrast to the effort, time and resources dedicated to the safety of the blood system on the supply side, Council notes that there has not been an equivalent level of concern regarding the hospitals, the sites to which blood and blood products are delivered. Council held several forums to address this concern, at which we heard many pleas for better funding at the hospital level. We identified the need for consistent standards, for data collection to improve traceability and monitoring of adverse reactions and errors, and for provision of consistent information to patients.

Efforts were made by Council to learn the positions of the provincial and territorial governments on a number of blood safety issues. While we heard about certain models, it has not been possible to secure policy views on matters involving hospitals or on plasma self-sufficiency at a national level. It is a concern to Council that with some exceptions, provincial and territorial governments generally show little interest in accepting responsibility for blood safety at hospitals.

(*NBSC Report*, Canada, 2002).

Various provincial transfusion practice improvement programs were established throughout Canada in the late 1990s and early 2000. The flagship transfusion practice improvement programs in North America are those operated by the Provincial Blood Coordinating Office (PBCO) in British Columbia, and the Transfusion Ontario programs in Canada. These both provide examples of coordinated regional practice improvement programs that have successfully monitored regional transfusion practices, have identified opportunities for improvement and have designed and successfully implemented practice improvement strategies across their regions (appendices 5.9.3 and 5.9.4).

The British Columbia Ministry of Health established the Provincial Blood Coordinating Office in 1997. The PBCO's mandate is to provide a medium for communication and consultation on provincial blood issues, to provide a forum for effective blood policy planning and program implementation, and to support the needs of hospital blood banks in British Columbia. The PBCO is funded by and reports to the British Columbia Ministry of Health Services, and works closely with Canadian Blood Services (CBS), hospitals, professional groups and public health officials. The PBCO consciously focuses on the recipient (hospital) end of the transfusion process. They run programs and projects that they characterise as information management, utilisation management and quality management activities, and operate under the guidance of two advisory groups (on blood product and transfusion medicine issues), supported by a central secretariat. The PBCO centrally develops materials and 'push' communication on relevant transfusion issues to the field through regular newsletters and forums throughout the province.

The PBCO has successfully implemented improvements in informed consent processes, introduced red blood cell redistribution plans that have reduced product expiry, rationalised and reduced utilisation of IVIG and rationalised autologous red cell use. These projects have occurred alongside program activities to capture adverse event reports, develop and distribute clinical practice guidelines, promulgate quality systems approaches to support safer hospital transfusion (through their TRAQ quality systems program) and maintain a central registry of transfused patients.

The Transfusion Ontario Program is a result of an initiative by the Ontario Ministry of Health and Long-Term Care Blood Conservation Project and the Ontario Blood System Reference Group (OBSRG) to develop and implement a province-wide blood conservation program. It is anticipated that the program will benefit hospitals, patients and the blood system in Ontario. The programs consist of individual activities in various cities throughout the province. These include quality systems programs (Quality Essentials for Safer Transfusion, or QEST); clinician education programs, and the development of an Ontario Transfusion Nurse Coordinators Program (ONTrac). There are also specific projects on the optimum use of autologous blood, the utilisation of staph columns for patients with inflammatory neuropathy and blood conservation for hip replacement.

Transfusion Ontario disseminates information on the status and outcomes of the various programs performed under its jurisdiction. The Ontario Ministry of Health funds each project under the Transfusion Ontario Programs (TOPs) project. It essentially operates as a coordinated series of projects led by individual hospitals and project leaders throughout the province, with the program acting as a clearing house for the outputs of each project.

3.1.4 Haemovigilance systems

The term ‘haemovigilance’ means many different things to different people, both within the world of transfusion medicine and without. At its simplest, the term is an evocative one that refers to the use of a measurement system to record unwanted outcomes of transfusion.

Whether it is restricted to adverse events or also embraces near-misses and errors; whether only fresh blood products should be studied or also plasma products; whether restricted to unwanted patient outcomes resulting from product quality concerns, or embracing faulty processes and procedures (such as inappropriate usage) are all matters for debate.

While strong opinion exists for all points of view on these issues, and other nuances regarded as critical by haemovigilance devotees, there is clearly no definitive, final answer to the question ‘What is haemovigilance?’ Embarking on any level of haemovigilance activity requires making some arbitrary decisions to inform the scope and nature of their program.

We typically use measurement systems to help manage some aspect of our endeavours. Decisions informing the collection of transfusion-related performance data must consider the purpose of data collection before launching into lengthy discussions and debates on the detail of the construction of any national haemovigilance system in Australia.

Ideally, the principal rationale for collecting any data on transfusion outcomes is a desire to use that data to design and implement improved systems and processes that can enhance the quality of transfusion practice and patient safety. Given that principle, haemovigilance programs should include measures of aspects of transfusion practice that, on the basis of current knowledge, are known to most significantly compromise patient safety. These include appropriateness of the decision to transfuse, the choice and quantity of transfused product and procedural safety (in particular matters that affect accurate patient, sample and product reconciliation).

If the rationale for measurement is use of data for performance improvement, there is no point embarking on programs of transfusion measures in Australia, however styled, if there is no systems infrastructure to support use of the data generated to drive transfusion practice improvement. This is a critical ‘go/no-go’ decision that must be taken initially. Appendix 5.7.1 contains a detailed recent consultants report on haemovigilance options.

The authors of this report intend to engage in major additional commentary on the details of any proposed haemovigilance program for Australia. Recent international measurement programs demonstrated that a combination of uniform reporting of stipulated adverse events and targeted collection of data on the safety and appropriateness of transfusion is feasible on a national scale. These measurement efforts provided a basis for systematic efforts to improve the quality and safety of blood and blood product transfusion.

Awaiting either evidence of a perfect haemovigilance model, or unanimous support for a model before embarking on a national haemovigilance program, is unwise. The international evidence indicates that those who embark on measuring transfusion practice and outcomes using some credible measures learn how to improve both contemporary transfusion and measurement systems in a series of action-based learning cycles. Those who stand and await perfection or complete consensus learn nothing.

Feedback from the field during preparation of this report confirmed that there is no existing Australian incident monitoring or reporting system in acute health care that adequately captures a reasonable proportion of current transfusion error and/or adverse events. Both paper-based and online incident reporting systems suffer significant underreporting of transfusion events, whenever these have been compared with alternative local transfusion safety data capture. These inadequacies probably reflect on both the culture of transfusion safety and event reporting within hospitals, and on the structural design of existing reporting systems.

Of more concern than the reported limitations on adequacy and completeness of currently captured data were consistent reports of a lack of timely, useful feedback on submitted data to those who would be expected to be accountable for transfusion performance within hospitals.

It is feasible to work with the developers of current incident reporting systems to enhance both capture and feedback on transfusion events by existing systems. An enhanced transfusion module for the AIMS reporting system currently under development in collaboration with stakeholders in South Australia and New South Wales is one example of this approach. Once the requisite minimum data required for any Australian haemovigilance program are agreed, collection of these data and the ability to export them could be inserted into the specification requirements of all adverse event and incident systems purchased for use in Australian hospitals. The focus for a national haemovigilance program should be on requiring access to specified haemovigilance data, rather than necessarily dictating one or another data collection system to jurisdictions, individual health services or hospitals.

Once there is clarity on the drivers for any national (or jurisdictional) haemovigilance program, there are several models available internationally that could be readily adapted for initial use in an Australian context. The focus for these initial haemovigilance data should be data that will help drive transfusion practice improvement efforts.

If we use essentially similar approaches to those proven to work in similar health care systems, rather than setting out to reinvent haemovigilance with a uniquely Australian accent, we are likely to get credible and relevant data at a more reasonable cost.

There would also be the added advantage of having available international comparisons to assist us in interpretation of the significance of any locally derived data.

It has been long established that there are limitations to the ability of humans to perform defined, simple tasks (however well trained and knowledgeable they are) repeatedly without committing a human error. Data from the Division of Transfusion Medicine at Mayo Clinic (Donor Center and Transfusion Service, Rochester) indicate that this limit is about 1 in 10 000 performances at best and may be considerably more frequent in situations in which personnel are tired, overworked, stressed, distracted, or harassed; are poorly or incompletely trained; or are incompetent for any other reason.

Because of the certainty of human errors, it is critical that there be systems in place to identify all errors occurring at any stage of each process involving 1 or many SOPs. If all errors cannot be analyzed, cataloged, and characterized in a consistent fashion, logic-based solutions cannot be implemented and instead, a reactive, episodic, and unplanned series of temporary approaches will be hurriedly put in place whenever a particular error or group of errors happens to attract attention, either because they get all the way to a patient who is harmed or are feared likely to do so.

There are several published and well-tried systems designed to help institutions proactively collect data on errors in ways that facilitate the regular, consistent analysis and characterization of these errors so that trends may be followed in a methodical fashion

'Error Management. Theory and Application in Transfusion Medicine at a Tertiary Care Institution', Archives of Pathology and Laboratory Medicine (*Arch Pathol Lab Med*), volume 127, November 2003.

4 Options for achieving better, safer transfusion practice in Australia

4.1 What have we learned from recent efforts to improve the safety and appropriateness of blood transfusion?

In Australia, as in all developed countries, blood and blood product quality and safety is extremely high. Indeed, the measurement of risk associated with blood product quality poses a significant challenge. Adverse events due to product quality issues are so infrequent that direct monitoring of such events is difficult, if not impossible. This places an increasing reliance on the predictions of models of risk to estimate the impact of proposed changes to donor selection and screening or manufacturing processes intended to enhance product safety.

However, the safety and appropriateness of clinical transfusion practice is very different. Each of the projects in Australia that examined contemporary transfusion practices in their jurisdictions found that clinical transfusion procedures and practices varied significantly from recommended best practice. Overuse of blood products is common and under-use is rare. With very rare exceptions, there was a greater use of blood products than recommended by available clinical practice guidelines. This is due to both a general adoption by clinicians of higher trigger points for the decision to initiate transfusion, and also because of a trend to transfuse more product than required to achieve recommended target outcomes. Protocols and procedures on blood sampling, reconciliation of identity of product and patient and product administration guidelines designed to optimise transfusion safety were also frequently absent, errant or ignored.

Contemporary transfusion practice in Australia does not differ from practices described in recent times in other developed countries. The overwhelming majority of blood product transfusion risk is now known to be associated with processes that occur closest to the patient.

Hospital transfusion practice provides an obvious target for transfusion practice improvement efforts for those interested in enhancing the safety of transfusion in 2004 and beyond.

The reasons for deviation from best practice in hospital transfusion differ between settings. Common themes are:

- a quite distinct paucity of training of undergraduate and postgraduate health care professionals in clinical transfusion practice
- a lack of awareness by relevant clinicians of the existence of transfusion clinical practice guidelines, and the detail of best practice contained therein
- uncertainty of the applicability of some current recommendations regarding transfusion best practice when such guidance is based exclusively on ‘expert opinion’
- an overall lack of monitoring of transfusion practice and feedback of relevant information to those entrusted with clinical governance responsibilities in transfusion
- the complete absence of feedback loops for clinicians regarding transfusion practice, including no sense of any negative consequences for health care professionals who fail to adhere to existing practice guidelines.

Until very recently there has been little investment in Australia in hospital transfusion safety initiatives. Transfusion safety is currently determined by a chain of individuals and organisations, ranging from those responsible for recruiting blood donors, through to those who care for patients after they have received a transfusion. High levels of overall safety would not be achieved by chance or via efforts of only some of those embedded in the safety chain.

Current levels of transfusion safety and appropriateness reflect the systems that we allow to operate in this arena of clinical practice. It is unlikely that current levels of safety and appropriateness of transfusion in Australia would meet the reasonable expectations of transfused patients, blood donors or those entrusted with purchase and provision of blood on behalf of our broader community.

Each of the initiatives implemented in Australia in recent years to improve transfusion practice has demonstrated success, despite the adoption of different approaches to enacting change. In part, these positive results will reflect a 'Hawthorne Effect', meaning that an area of clinical practice that has had a relatively low profile for many decades is suddenly put into the spotlight. Alternatively, the gap between ideal and desired practice was typically of such a magnitude that many different approaches were capable of delivering improved performance.

All approaches raised awareness of actively considering transfusion as a significant medical intervention. One program catch phrase was: 'We will have been successful if we get health care professionals to think at least once before transfusion!'

Each program educated relevant staff and patients on key issues. Each sought to introduce best practice protocols and procedures, and used measures of performance to feed information back to clinicians and managers on the progress in adherence to desired practice in their target areas.

In the larger jurisdictions (New South Wales and Victoria), more formal approaches to health care quality improvement were applied (but more particularly, a version of the Institute for Health Care Improvement's breakthrough collaborative methodology). The New South Wales approach allowed for flexibility in the make-up of participant teams, resulting in differences in team size and professional mix. Their collaborative specifically focused on red cell transfusion in haemodynamically stable patients.

The Victorian approach had a more structured team composition, with team membership defined in the requirements for participation in the collaborative. The lever of providing extra resources (including a transfusion nurse) to participating health services allowed more control of the rules of engagement in the collaborative. This uniform team membership facilitated information sharing between professionals and teams.

The Victorian collaborative had shared common aims (including the improvement of appropriateness of transfusion of any fresh blood product), and several optional aims addressing other aspects of transfusion safety, for teams to work on during their collaborative.

Given the size and complexity of these jurisdictions, and the numbers of health services embraced by their projects, some degree of project management rigor was likely to be an essential prerequisite for any project's success. The IHI breakthrough collaborative methodology clearly works. It was explicitly designed for such large-scale change exercises in health care. Experience in the Australian context, both in transfusion and elsewhere, supports its applicability in our health system. However, there is little logic in using such a methodology unless the scale of the project warrants the methodological rigor (and costs) of this approach to improving health care delivery.

The South Australian project essentially developed its own version of a collaborative from the ground up, within the life of their project. It focused on several defined areas of transfusion practice and achieved positive outcomes in each area in each participant hospital. While their collaboration methodology was less formal than the IHI's, it was well suited to the size and scope of their project. The South Australian project was also unique in its tackling of regional and remote inventory management within its program of work.

In Western Australia, two essentially similar data linkage projects developed a capacity to measure some aspects of transfusion practice patterns using information technology, and fed that data back to involved clinicians. In their experience, when this feedback occurred in an environment with an active transfusion committee, the availability of performance data and provision of education were associated with changes in clinician behaviour. The potential for long-term ease of access to these measures of transfusion performance allows for sequential tracking by both the transfusion committee and the clinicians in the targeted areas.

Similar data linkage approaches to mapping transfusion epidemiology are worthy of consideration in all jurisdictions and by the NBA. By connecting transfusion episode information with extant hospital data sets, it is possible to define blood product utilisation at relatively modest costs. The level of information derived will assist clinical governance by providing data for utilisation review, and would also inform blood product production planning and purchasing decisions.

The projects in New South Wales, South Australia and Victoria have shown the benefits that accrue when health care professionals are able to share problems and potential solutions between individual professionals, different professional groupings and different institutions. This is the true power of these collaborative methodologies. They also amply demonstrated the value of having both executive support and clinical leadership for success in performance improvement projects in health care.

It must be emphasised that these Australian transfusion practice improvement exercises have all been essentially 'demonstration projects'. They have provided 'proof of principle' that it is feasible to improve significantly on commonly accepted levels of safety and appropriateness of transfusion using several different strategies. Awareness raising, education and training and the local objective measurement of transfusion practice and feedback of measured performance are common themes in each initiative.

Each of these projects achieved improvements in targeted areas, selected wards, clinical specialties, clinical conditions or particular aspects of transfusion practice in their participant hospitals. None has achieved widespread changes in clinical practice that have been demonstrated to be sustained over time, nor could they have been expected to achieve such outcomes. This in no way points to these projects' failure.

These projects were all set up to initiate a process of building capacity. They have raised awareness, educated staff and consumers, developed practical tools and materials and generally built a capacity in participant health services for improving transfusion practice. It requires local adoption and ownership (by hospital transfusion committees or their equivalent in hospitals) of an enduring program of work designed to spread the demonstrated improvements throughout their entire hospital and sustain it locally over time.

The turnover of clinical staff (especially acute in teaching hospitals), the multidisciplinary nature of the safety chain and a strong trend to revert to historical performance over time if ignored, will obviate a continued need to focus on transfusion practice improvement in the hospital sector in the long term.

Later in this report, a key role for those beyond the hospital sector in encouraging and supporting these crucial local health service transfusion practice improvement programs is canvassed. It is essential that the health sector overall retains a sense of dissatisfaction with the status quo in Australian transfusion safety, and continues to innovate, seeking to achieve reliable excellence in transfusion practice and outcomes.

4.2 Why Australia should consider a national approach to monitoring and improving the safety and appropriateness of blood transfusion

There has been a relatively recent move, with the agreement of the Commonwealth, states and territories, to consolidate governance of the blood sector in Australia in an integrated national governance model.

We now have a national donor pool, nationally consistent products and funding agreements and blood product transfers throughout the nation to ensure that patient needs are met.

The report authors will not reiterate the rationale that led to this consolidation in this report. We agree with the architects of the current governance system that there are compelling arguments for an integrated national governance model for the blood sector. It is logical to include a nationally consistent approach to clinical governance for transfusion in this framework, including management of the safety and appropriateness of transfusion.

Without such an approach, those charged with managing the blood sector will not be in a position to know the true performance of the system, nor the degree to which system performance is in control.

One of the principles that should underpin arrangements governing blood supply is that of equity of access to required blood products. Any major variations in clinical transfusion practice between jurisdictions could generate circumstances where scarce blood product resources are consumed inappropriately in one arena, preventing their availability for transfusion to other patients with a manifest clinical need.

Key stakeholders in the field of transfusion medicine would welcome national leadership and direction for Australia's transfusion safety endeavours. There have been announcements from peak agencies involved in governance in the blood sector that have helped establish an expectation in the field that national leadership and direction for quality of transfusion practice will be forthcoming (appendices 5.10.1 and 5.10.2).

There is some concern about the apparently slow progress on these critical areas of activity after the creation of the NBA, which has hitherto focused predominantly on blood product supply issues. National systems of performance monitoring and improvement (similar to those recommended in the *Stephen Review*) are deemed by most Australian transfusion experts to be of critical importance.

If Australia is to maintain its reputation for excellence in transfusion safety, there must be timely decision making and action to implement a nationally consistent approach to transfusion safety and appropriateness.

National experts know that there is a relatively small critical mass of persons with interest and expertise in transfusion medicine and transfusion science in Australia. They are keen to see a national program leverage this limited resource to deliver the best possible outcomes for our health care system. A failure to act in 2005 to establish national clinical governance systems for transfusion would be an opportunity lost.

Health ministers, the jurisdictional blood committee and the NBA should be in a position to assure their constituencies confidently that donated blood is used safely and appropriately. This confidence needs to be underpinned by access to evidence that the system is efficiently delivering safe and appropriate blood and blood product transfusion, assuring the best possible health outcomes for people who require transfusion support.

It would appear difficult, if not impossible, to fulfil these economic and social accountabilities without some program of measurement and judgments on current transfusion performance. All stakeholders would equally expect there to be targeted improvement efforts whenever monitoring of contemporary practice indicates that we are not meeting reasonable performance expectations.

A national program would allow for the identification of particular aspects of transfusion as national priorities, effectively setting a national transfusion safety and quality agenda. It would also allow for uniform standards development and meaningful performance comparisons across jurisdictions.

Nationally consistent approaches to monitoring and improving some aspects of transfusion safety and appropriateness would reduce the development burden of transfusion practice monitoring and improvement programs. A nationally consistent approach would deliver economies of scale in terms of design of standards, performance measures and indicator development, audit tool development and the design of potential improvement strategies and tools.

Typically, health care interventions in our hospitals focus on a clearly identified clinical specialty, unit or team. Interest in monitoring the performance of the intervention and improving on current levels of safety and quality of care usually resides with these 'natural' process owners.

Interest in the safety and appropriateness of blood product transfusion embraces many important stakeholders across the hospital care sector, but also those who reside outside our hospitals. This wide range of parties with an interest in transfusion safety and appropriateness needs to be considered when designing clinical governance models for blood and blood product transfusion.

Many issues compete for the attention of health care professionals and managers in acute health care. History suggests that most clinicians and managers in our hospitals will revert to treating blood products as commodities that are simply used as and when desired in the absence of some degree of external leadership and direction, including encouragement and support for monitoring and improving transfusion practice.

The many interested parties who contribute individually to transfusion safety would benefit from some degree of orchestration of their efforts to achieve optimal transfusion outcomes. And all good orchestras need to identify a conductor to perform harmoniously and well.

There is a real need for a conductor for an Australian national transfusion safety and appropriateness score. That position must be interested in every aspect of the safety chain that determines overall safety and quality of transfusion practice to deliver optimal performance from the various players in the sector. The logical conductor is the jurisdictional blood committee.

Hospitals are largely unaware of the extent to which serious errors and near-miss events occur in blood transfusion. Even among hospitals that have identified problems, there are no established benchmarks for performance. The absence of any national performance standards for the safe process of transfusion is in striking contrast to extensive standards related to the production of blood as a product. Performance standards would reassert a commitment to patient care, would provide a strong incentive for hospitals to examine and monitor their own systems of blood delivery, and would empower laboratories to advocate for improvement within their facilities when needed.

('Patient Safety and Blood Transfusion: New Solutions', *Transfusion Medicine Reviews*, volume 17, number 3 (July), 2003, pp 169-180.)

To provide the necessary structures for the implementation of a National Programme for Transfusion Safety Improvement, it is recommended that Australia establish a National Better, Safer Transfusion (BeST) Program, reporting to the Jurisdictional Blood Committee, with Secretariat support provided by the National Blood Authority. An Advisory Committee with expertise in Transfusion Medicine and Clinical Practice Improvement should inform the work of the national BeST program.

Jurisdictional BeST Advisory Committees should support the National BeST program. These should encourage and support Hospital Transfusion Committees in their monitoring and improvement of transfusion practices. Secretariat support for Jurisdictional BeST Advisory Committees could be contracted to local Transfusion Medicine expert groups (such as ANZSBT or ARCBS). Such a 'partnership approach' would help to structurally integrate all efforts at monitoring and improving transfusion safety in a single jurisdictional program across the transfusion 'safety chain' as well as allowing for best use of our limited human capital in this arena.

How much does blood matter?

Despite the high public profile of 'Bloody Matters' through media exposure and publication of vCJD incidents, SHOT reports, the CMOs' 'Better Blood Transfusion' seminar, the EU Blood Safety Directive and CNST Clinical Risk Standards, improving hospital transfusion practice still appears to have a low profile amongst competing priorities within hospital Trusts.

(Dr Angela Robinson, NBS Medical Director, England, 2003.)

4.3 Some alternative models for a national approach to transfusion practice improvement in an Australian context

A national program might adopt several modes of operation.

The following are suggested complimentary approaches.

4.3.1 Leadership and direction

A national transfusion safety and quality program could identify opportunities for monitoring and improvement of transfusion practice and prioritise these in an Australian context. Such a program could decide upon a parsimonious set of core objectives and require that jurisdictions deliver the requisite measures and implement targeted improvement programs within explicit timeframes to achieve these agreed national objectives.

This program should be integrated into existing authority and governance structures to maximise its chances of success. A national 'Better, Safer Transfusion' Expert Advisory Committee should receive secretariat support from the NBA and report through the Jurisdictional Blood Committee to Health Ministers.

A national program would implement its program of work through replicate jurisdictional program expert advisory committees, given that hospital care is a jurisdictional responsibility.

These state and territory programs would ensure the successful delivery of national priority projects. These jurisdictional programs would also be likely to design and implement additional locally relevant projects focusing on enhancing relevant transfusion safety and appropriateness issues.

In their turn, jurisdictional program advisory committees would work with appropriately resourced hospital transfusion committees to ensure the successful delivery of both national and jurisdictional objectives. These jurisdictional expert advisory committees would also support and encourage HTCs to engage in additional relevant local activities targeting enhanced transfusion safety.

In the opinion of this report's authors, adequate resourcing of HTCs includes the availability of an appropriately trained human resource to assist the HTC achieve its monitoring and performance improvement targets.

In the absence of the availability of such a local human resource, however titled (transfusion nurse, transfusion safety officer or specialist practitioner of transfusion), the utility and potential effectiveness of any transfusion monitoring and improvement program is uncertain.

4.3.2 Funding

A national transfusion safety program could provide funds for specific initiatives aimed at enhancing transfusion safety. The potential magnitude of any investment in such initiatives is a matter for the Commonwealth and the jurisdictions to consider.

The initial investment required to engage in meaningful monitoring and improvement of transfusion safety nationally represents, at the uppermost estimate, one to two per cent of the current direct costs of blood and blood product supply. These direct product costs represent approximately one third of the overall health care costs of transfusion support.

Formal cost-benefit analyses on any such proposed investment is outside the scope of this report. However, given the evidence of current fresh blood product clinical transfusion practice in comparison with recommended best practice, there are obvious, major potential returns from even modest investment in transfusion practice improvement.

4.3.3 Clearing house

A national program should also implement a set of agreed mechanisms for gathering and sharing information about projects and programs to enhance transfusion safety and appropriateness that are occurring nationally and internationally.

National leadership and direction is required to deliver a reasonable return on investment and meet the accountability and practice improvement objectives discussed above. National leadership and direction of an agreed cohesive program of work would provide a structural reinforcement for constancy of purpose in monitoring and improving transfusion safety. It also offers an opportunity to plan a program of work over several years to achieve identified objectives.

Targeted project funding provides the opportunity for a national program to steer efforts in transfusion practice monitoring and improvement in particular directions.

The clearing house function facilitates sharing of information and knowledge regarding innovation with interested parties throughout the nation, without the requirement to directly influence the content of these activities

It is important that the objectives articulated by national transfusion practice monitoring and improvement programs wherever possible focus on the achievement of defined outcomes, rather than necessarily seeking to codify and standardise particular processes.

Each jurisdiction has characteristics that justify a degree of flexibility in their approaches to achieving set targets or particular objectives. This must be recognised.

Requests to standardise care processes should be minimised. National programs in transfusion safety should concentrate on setting objectives and targets for better patient outcomes.

Transfusion medicine is not a static field. A national program for monitoring and improving transfusion practice must have the expertise, insight and flexibility to refocus their efforts as critical issues in transfusion safety and appropriateness evolve.

A National program for better, safer transfusion (BeST) would aim to improve the quality and safety of blood transfusion in Australia. It would identify “best practices” and management and clinical innovations that: (1) yield better patient outcomes; (2) make transfusion practices more efficient; (3) reduce transfusion errors and inappropriate transfusion.

A National program would accelerate the spread of transfusion best practices and innovations throughout the health system by encouraging the replication of best transfusion practices in health care facilities through support Hospital Transfusion Committees and Transfusion Teams.

A National program would design a set of parsimonious performance measures and implement collection of data on transfusion errors and transfusion safety and appropriateness. The program would commission analyses of causes and contributory factors, sourcing of relevant safety strategies, standards and measures and improvement tools.

Linkages with international networks working on enhanced transfusion safety would be initiated to ensure timely access to state-of-the-art transfusion safety improvement practice.

Transfusion safety has received increased attention in recent years, but mostly with a focus on the epidemiology of transfusion errors and adverse events. It is important that any National program in Australia also addresses the identification and promulgation of practices that can enhance the safety and appropriateness of transfusion.

4.3.4 What might it cost to oversee transfusion practice in Australia, and who might pay for such oversight?

Unless adequate allocation of resources are made available within hospital Trusts, the NBS joint initiative with the MRCP Clinical Effectiveness and Evaluation Unit to undertake national benchmarking and comparative audit in blood transfusion will not be able to achieve its objective of improving hospitals' transfusion practice.

(Dr Angela Robinson, NBS Medical Director, England, 2003.)

There are real and potentially highly variable costs involved in transfusion practice measurement, the interpretation of performance data and feedback on performance.

There is a clear need to design and implement pragmatic practice improvement strategies that enhance current levels of transfusion quality and safety.

A national approach to enhancing transfusion safety requires the introduction of an element of quality systems into the clinical end of the transfusion safety chain. There may also be in the near future a requirement to invest in technologies to reduce wrong-blood-to-wrong-patient episodes.

It makes good sense to invest in this 'near patient' end of the transfusion safety chain at this point in time given the known current risks. In comparison with recent investments in improving product quality, the levels of investment required to enhance the safety and appropriateness of hospital transfusion practice by installing or bolstering these clinical quality systems are modest.

The blood sector must engage in reasonable quality assurance and practice improvement programs across all aspects of the safety chain to optimise the outcomes of transfused patients.

As indicated above, the programs referred to in this report would cost one to two per cent of the current cost of blood product supply. These funds would represent less than one per cent of the overall cost of blood and blood product transfusion a very small fraction of the overall national cost of acute health care.

The single most important cost in the suggested national program is the cost of providing an appropriately trained human resource to support local efforts at monitoring and improving transfusion practice in hospitals. Without this resource it is unlikely that anything of significance will be achieved in terms of enhancing transfusion safety.

The costs of operating the national and jurisdictional expert advisory committees would be modest (see Appendix 5.7.1).

Any national transfusion safety and appropriateness initiative need not be seen as requiring 100 per cent new money to commence activities. As indicated in introductory comments above, transfusion safety and appropriateness is but a subset of a broader quality and safety agenda in Australian health care, albeit a subset with certain special characteristics. Rather than requiring entirely new monies to support the implementation of better, safer transfusion practices throughout Australia, it is feasible to target some of the existing Commonwealth and jurisdictional spend on quality and safety for improving transfusion practice.

Currently, the Australian Health Care Agreements include in their objectives the desire to 'improve the focus of public hospital services and mental health services on safety, quality and improved patient outcomes'. The agreed AHCA funding formulas nominate specified funds as a 'safety and quality component' of funding for Australian hospitals. A component of these funds might be used for hospital-based transfusion practice improvement programs.

It is vital that the agreed funding arrangements to support transfusion safety and appropriateness initiatives are explicit and clearly communicated across the sector.

There would be very limited success from any approach that sees edicts issued articulating required actions, unless the resources supporting implementation of these initiatives is clearly identified in these communications.

4.4 Other issues

4.4.1 Levers for changing transfusion practice

Financial levers are often used in health care to focus executive management in hospitals on priorities identified by funding agencies. There has been considerable enthusiasm expressed by some experts for the introduction of 'price signals' into the blood product supply chain. Some believe this to be a necessary prerequisite for engaging hospitals and clinicians in changing their transfusion practices.

The precise nature of these price signals and their location in the supply chain are the subject of ongoing debate. The general tenet of discussions is that some direct awareness and/or accountability for the costs of blood and blood products by hospitals and clinicians is required to garner their interest and enthusiasm for transforming clinical transfusion practice.

The use of price signals focuses on the technical efficiency of the system (that is, the volume of products purchased). However, *allocative* efficiency might be the more important dimension for determinations of blood sector efficiency (that is, to what extent the funds directed have purchased the blood and blood products required to meet the transfusion needs of the Australian community).

The total cost to the health system of transfusion support is approximately threefold that attributable to direct blood product acquisition. The majority of avoidable costs in hospital transfusion are found in the potential avoidance of product purchase.

The quantum of money involved in blood product supply, while not insignificant, might not be sufficient to entrain executive managers' interest and enthusiasm for appropriate governance of transfusion in hospitals on purely economic grounds.

Although blood product costs are rising, they currently equate to approximately three per cent of the overall budget for acute hospitals in Australia and less than one per cent of recurrent national expenditure on health care. Put simply, for most hospitals, the need to plot strategies to save some fraction of one per cent of their overall organisational budget that could be reasonably achieved by attacking their blood budget might not keep many hospital finance managers awake at night.

Our entire national blood supply budget equals the budget allocated to two or three of our major teaching hospitals.

The ability of price signals to influence hospital transfusion practice might not be uniform across the entire blood product portfolio. Where alternatives to blood products are available, price advantages might reasonably be expected to influence product acquisition choices (for example, albumin versus saline). Where no alternative exists, pricing alone will have little impact on clinical demand and utilisation patterns.

Price signals should be used with great caution for high cost blood products that are essential for patient wellbeing (such as haemostatic factors). The use of true price signals for high cost blood products could negatively impact access to best therapy in selected patient populations dependent on access to such expensive, low-volume blood products (and alternatives). It would be unfortunate if individual hospitals chose to meet local budgetary constraints by refusing to provide such essential therapeutics.

International transfusion system experience does not support blood product pricing as having a material influence on organisational standards of transfusion practice or the success of transfusion monitoring and practice improvement programs. International comparisons of transfusion practice, such as the SANGUIS study, do not identify patterns of transfusion practice that are common to particular funding paradigms. Engagement in haemovigilance programs and transfusion practice improvement occurs equally in price signal-led and no price signal blood supply environments.

The absence of blood product price signal effects on clinical transfusion practice or transfusion practice improvement is especially clear in the UK at the

moment. Here, national systems that charge for blood products run parallel to those that provide blood products without direct hospital price signals. Trends in hospital transfusion practice and success (or otherwise) of transfusion governance and practice improvement programs are indistinguishable across these different model systems.

Some international models result in hospitals rewarded financially for engagement in transfusion safety initiatives by way of reductions in insurance premiums (or alternatively, penalties for a failure to engage in such programs). While these are not of a magnitude that would ensure executive engagement in these programs, they typically equate to the cost to that hospital of participation in transfusion practice improvement. These insurance premium levers effectively remove any financial incentive for hospitals to consider opting out of such programs.

New South Wales Health is currently in the final stages of implementation of a price signal in their model for blood product supply. There is little evidence of pre-emptive planning or actions by hospitals in New South Wales in anticipation of operating in this new funding paradigm. The authors of this report believe that it would be useful to regard the current New South Wales initiative as a 'live trial' of the introduction of price signals into practice in an Australian context. We recommend observation of the impact of this change in blood product supply policy in New South Wales on hospital transfusion practice and transfusion governance before others move down this path.

In coming years it should be possible to compare and contrast hospital transfusion practice and governance trends in New South Wales with those experiences in other states and territories. Such analyses should help to ascertain the impact of the introduction of price signals as a lever for transfusion practice change in Australia.

One of the principal drivers for change in a successful national transfusion safety program would be the availability of objective measures of comparative transfusion performance. Over time, conformance with identified minimum standards of practice would be expected. Measuring transfusion performance; provision of these measures to those involved in transfusion processes; and providing analysis and feedback on performance would be a basis for the clinical governance frameworks established for transfusion.

The available evidence from international programs would largely indicate that the success of transfusion practice monitoring and improvement programs would be dependent on executive and clinical leaders championing these transfusion safety programs.

Experience in the United Kingdom indicates that the most vulnerable link in accountability in transfusion governance lies between the agencies purchasing hospital services and the providers of health services. It would be prudent to learn from the better blood transfusion programs in the UK, and ensure that transfusion gets onto the acute health care management agenda by making the safety and appropriateness of hospital transfusion an explicit responsibility of health service CEOs.

Ultimately, effective governance for transfusion will require that blood transfusion is valued in terms that embrace both financial and non-financial input measures.

It is also noteworthy that the Clinical Negligence Scheme for Trusts (CNST) has introduced amendments to their Clinical Risk Management Standards with compliance to commence from 1st April 2002. These Standards relate to the safe administration of blood and blood products, and to meet these standards, Trusts need to have a Blood Transfusion Policy which includes protocols and training for all staff who request and/or collect blood products. The CNST will want evidence to show that appropriate systems are in place for the request, safe storage, collection and administration of human blood and blood products. Compliance with the CNST Clinical Risk Management Standards enables a Trust to claim a discount on their 'premium'. Such a discount would be sufficient to fund a Hospital Transfusion Practitioner post within a Trust.

(Dr Angela Robinson, NHS Newsletter 'Blood Matters' Issue 10 May 2002).

4.4.2 Education and training

A constant theme in the literature, and from the report authors' experience of hospitals' transfusion practitioners' experience, is the need to establish education and training programs for health care professionals and consumers that equip individuals to participate actively in safe and appropriate blood product transfusion.

The knowledge gaps evident across the nation in transfusion in an Australian context are sobering. Many health care professionals no longer acquire even the basic knowledge and skills required to deliver safe and appropriate blood product transfusion.

Consumers are not consistently able to make informed choices about transfusion, as they are rarely provided with the information that might support informed choice during their journeys through our health care system.

A nationally consistent education and training framework is needed, which ensures exposure to relevant education on transfusion practice in medical, nursing and medical science undergraduate curricula. Even more importantly, postgraduate workplace training is needed in the pragmatics of safe and appropriate transfusion, including approaches to informing patients of the risks and benefits of transfusion. Organisations like ARCBS and ANZSBT do provide educational resources within their budgetary constraints, but there clearly needs to be expansions of such programs to address adequately the needs of health care professionals involved in everyday transfusion practice.

Providing vision and practical guidance on such education and training issues would be one important activity for a national transfusion safety and appropriateness program.

4.4.3 Transfusion nurse role

There is a growing national and international experience of the use of a specially trained person within hospitals to support transfusion safety and appropriateness agendas. Systematic analysis of their impact (Franklin I: Quality Improvement Program: *Safe and Effective Transfusion in Scottish Hospitals - The role of the Transfusion Nurse Specialist* (SAET Study), June 2004) have supported the value of the role. Indeed, the experience of the pilot of the introduction of transfusion practitioners in Scotland has been followed by the national rollout of transfusion nurses as a key platform within their national better blood transfusion program.

These key individuals have various titles (transfusion nurse, transfusion nurse specialist or consultant, transfusion safety officer, haemovigilance officer, specialist practitioner of transfusion). They are usually recruited from nursing backgrounds. They act a vital bridge between the different provider groups engaged in the transfusion safety chain, in particular, those beyond the hospital laboratory. They act as educators, trainers, coordinators of data collection, project managers and change agents. They are a critical component of hospital transfusion teams, and provide invaluable support for the efforts of the hospital transfusion committee (or equivalent).

The report authors have encountered nothing but strong support for the value of this role in our discussions with jurisdictions and hospitals that have utilised such resource persons as a component of their transfusion monitoring and improvement programs. The same is true in the international literature and in personal accounts of the international experience. Typically, the availability of these resource persons and their professional competence and commitment are identified as a critical success factor for their transfusion safety program by those with experience of this relatively new hospital role.

Decisions on the quantum of resource allocated to a transfusion nurse role within any individual hospital or region needs to take account of the size of the facility served, the volume of blood products transfused and

service complexity. Few hospitals would require more than 1.0 EFT to commence this important safety and quality management role. Many would manage with much less. Smaller hospitals might choose to share a suitably trained resource across multiple sites. Jurisdictional transfusion safety programs could also employ a pool of transfusion nurses to support smaller hospitals' efforts at enhancing transfusion safety.

History indicates that, with rare exceptions, hospitals in Australia fail to self-organise and effectively deliver safe and appropriate transfusion practice in the absence of such a focused resource.

While there has been enthusiasm (and often some frustration) in hospital blood banks for transfusion safety programs, this enthusiasm has rarely translated into effective hospital-wide monitoring and improvement programs. This translation does not occur for several reasons, including financial and human resource limitations, the absence of required natural authority, and a significant cultural gap between laboratories and ward environments.

Typical hospital transfusion committees in Australia have largely floundered, in part because of the absence of someone to work on identified issues between committee meetings. These committees often sit outside any extant clinical governance, quality and safety or risk management framework, are poorly attended and lack multidisciplinary representations.

Add a lack of resource to work across the spectrum of hospital areas needed to achieve successful change in transfusion practice and it is not surprising that many HTCs are perceived as having little ability to influence transfusion practices. The availability of a suitable human resource has underpinned the success of transfusion safety programs in the few hospitals in Australia who have had access to a transfusion nurse support (however titled).

The requirement for suitable medical leadership of hospital transfusion teams is a given. These medical leaders are not the right people to deliver all of the work programs required for success in transfusion governance. The introduction of a transfusion nurse role is not an alternative to strong leadership by medical and executive management of a hospital's transfusion governance program. These key personnel have a defined bridging and implementation role that blends facilitation of education, audit and change management in the specific context of transfusion safety and quality.

Transfusion nurses have transformed the workings of HTCs when they have been installed into hospitals, either through local enthusiasm or by projects such as the BloodSafe and Blood Matters projects in Australia, the Better Blood Transfusion programs throughout the UK and the transfusion practice improvement programs in Canada.

The hospital transfusion practitioner

This article is meant to encompass appointees from various health professional backgrounds; but the most appropriate are nurses, with biomedical scientists running a close second place (some would say equal). Although pharmacists, physiotherapists, occupational therapists, etc could undertake this role after suitable further training, a nursing background has undoubted advantages; biomedical scientists (and - with luck - doctors) also have a basic understanding of the transfusion process; but those other health care professionals will probably lack experience or knowledge of the process as a whole and would need a high degree of training to make them competent and able to educate and influence the practice of others 'on the ground'.

One important aspect is to encourage awareness among patients. In the Fifth Annual Report of the SHOT group, which covers the period 2000 - - 2001, "The role of the Hospital Transfusion Specialist is explored. "While still in its infancy their contribution is just beginning to be realized. By breaking down inter-professional boundaries... and by acknowledging that the neglect of transfusion education for all professional groups can perpetuate mistakes and bad practice, the existing culture can be changed... To meet government directives... all hospitals should consider employing a Transfusion Nurse Specialist."

(Frank Boulton, NBS Southampton and Department of Haematology, Southampton University Hospitals Trust, Chair BBTS SIG on Hospital-Based, Transfusion Practice.)

Given the lack of any specific individual with responsibility for the conduct of transfusion care outside of the laboratory, it is not at all surprising that the majority of serious lapses, misunderstandings, knowledge gaps, and errors are occurring outside the laboratory.

The principal role of hospital- based TSOs is to work outside the context of the laboratory to improve patient safety regarding transfusion. TSOs bring a unique focus and responsibility for safe blood-related therapies.

('Patient Safety and Blood Transfusion: New Solutions', *Transfusion Medicine Reviews*, volume 17, number 3, July, 2003: pp 169-180.)

The mechanism for providing hospital TSOs is likely to take different forms in different institutions. Large facilities will require one or more FTEs whose focus would be devoted exclusively to transfusion delivery. Small facilities will combine the TSO focus with other hospital-wide quality assurance activities. As shown by the experience in England, some facilities may partner with their regional blood supplier for shared TSO function. With more experience, it is likely that a benchmark figure will be developed that establishes an appropriate number of TSO FTE hours per number of red blood cells distributed.

('Patient Safety and Blood Transfusion: New Solutions', *Transfusion Medicine Reviews*, volume 17, number 3, July, 2003: pp 169-180.)

In the current study, an appreciable failure to comply with the best practice in the administration and monitoring of transfusions was evident before a nurse education programme was started. In this programme, nursing instructors (trained by the local department of transfusion medicine) augmented education and there was the display of standard operating procedures for transfusion in all clinical areas. The programme resulted in noticeable improvement, as similar packages in other clinical fields have done, in all requirements for patient identification which had previously been unsatisfactory. The continuing failure to monitor vital signs properly is not easily explained, though it is of interest that most failures in this respect occurred with transfusions at night, after 10 pm. Early recognition of a haemolytic transfusion reaction is essential, as the prognosis depends on the number of cells transfused.

('Effect of a formal education programme on safety of Transfusions', *BMJ* volume 323, 10 November 2001.)

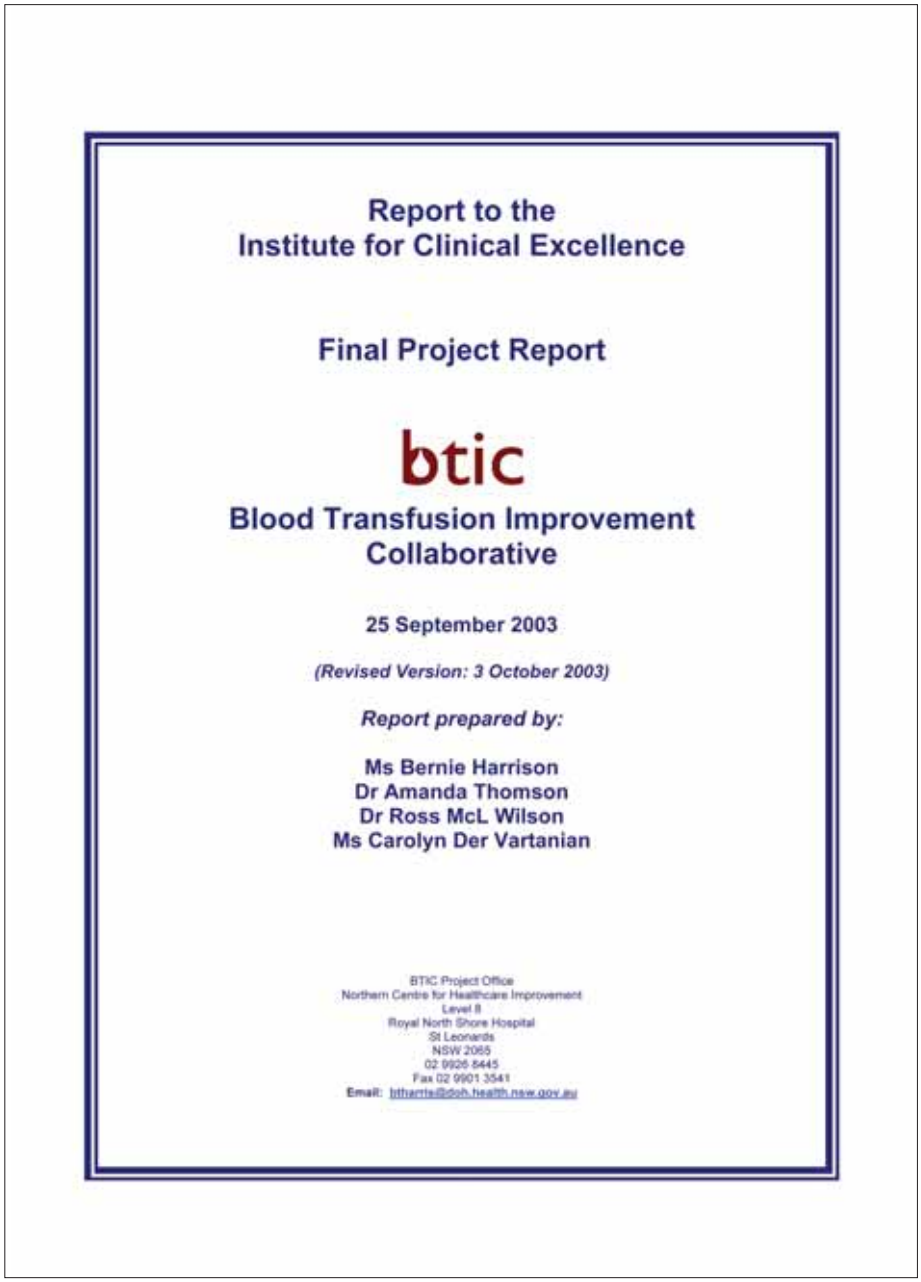
5 Appendices

Material contained in attached CD

5.1 BTIC, New South Wales

5.1.1 Project report

BTIC report



Report to the
Institute for Clinical Excellence

Final Project Report

btic

Blood Transfusion Improvement
Collaborative

25 September 2003

(Revised Version: 3 October 2003)

Report prepared by:

Ms Bernie Harrison
Dr Amanda Thomson
Dr Ross McL Wilson
Ms Carolyn Der Vartanian

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Northern Centre for Healthcare Improvement
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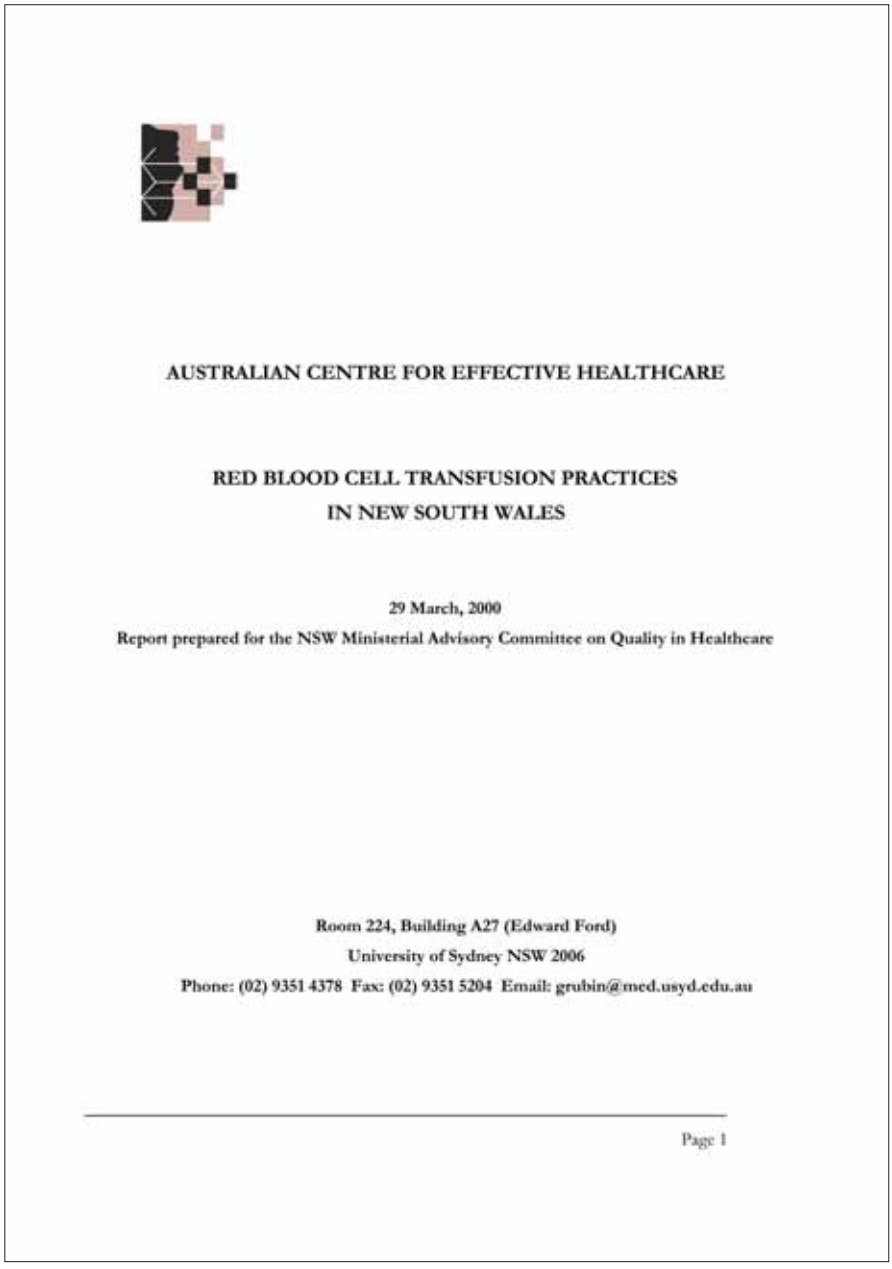
Royal North Shore Hospital
St Leonards
NSW 2065
02 9926 8445
Fax 02 9901 3541
Email: bttharris@doh.health.nsw.gov.au

5.1.2 Australian Centre for Effective Healthcare: Red Blood Cell Transfusion Practices in New South Wales

Red Cell Transfusion Practices



AUSTRALIAN CENTRE FOR EFFECTIVE HEALTHCARE

RED BLOOD CELL TRANSFUSION PRACTICES
IN NEW SOUTH WALES

29 March, 2000
Report prepared for the NSW Ministerial Advisory Committee on Quality in Healthcare

Room 224, Building A27 (Edward Ford)
University of Sydney NSW 2006
Phone: (02) 9351 4378 Fax: (02) 9351 5204 Email: grubin@med.usyd.edu.au

Page 1

5.1.3 BTIC slide set

BTIC slide set

5.2 Blood Matters, Victoria

5.2.1 Blood Matters Improvement Guide

Blood Matters Improvement Guide

5.2.1 b

Blood Matters Resources

5.2.2 Blood Matters consumer report

Blood Matters consumer report

Final Report on Survey Findings

Blood Matters Breakthrough Collaboration Consumer Study

for the Department of Human Services, Victoria

July 2003

5.2.3 Blood Matters slide set

Blood Matters slide set

5.2.4 Transfusion nurse course brochure

Transfusion nurse distance education

Entry Requirements

Applicants must meet the following requirements:

1) Hold a current practising certificate at Division 1 from the Nurses Board of Victoria or equivalent or be eligible for registration in the state of Victoria; and
2) Hold a degree or diploma in nursing or approved equivalent
3) Students will be required to work at least three days per week in an approved clinical setting

Fees

This is a fee paying course and several fee payments options are available. Course fees are set annually and may be tax deductible if the course is work related. Students are advised to consult a tax agent regarding their specific circumstances.

Application Closing Date

For the latest information on application dates, or an application kit, contact the Education Department at Peter MacCallum Cancer Centre.

The course has one intake a year commencing in February/March, with applications invited up until January. Contact the Education Department for more details.

For more information on this course please contact Fiona Hewitt, Course Administrator on +61 3 9656 3783 or e-mail Fiona.Hewitt@petermac.org

The information in this brochure is correct at the time of printing. Peter MacCallum Cancer Centre reserves the right to make changes as appropriate.

Produced by the Education Department Peter MacCallum Cancer Centre, July 2003

Transfusion Practice

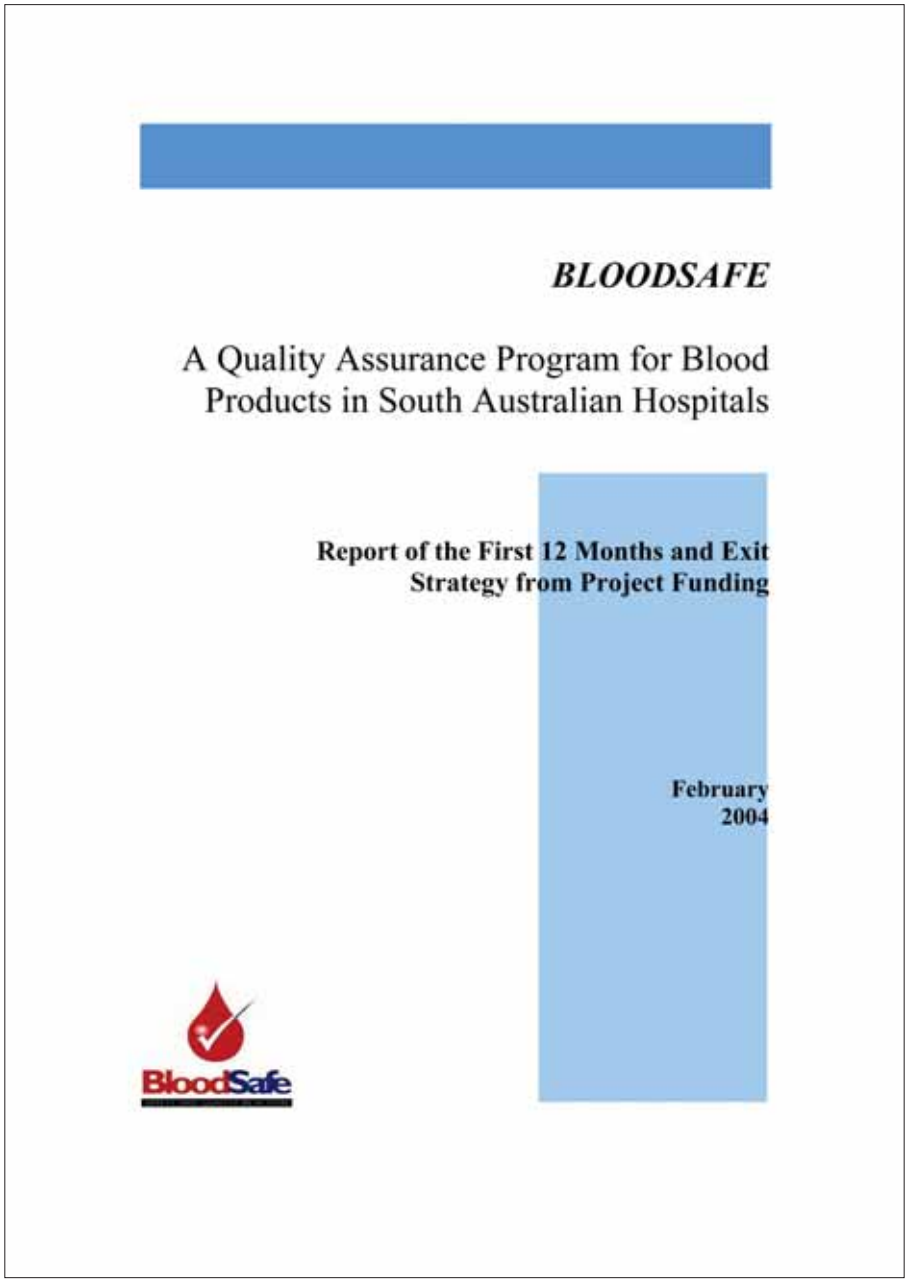
Certificate in Transfusion Practice

Accredited by the University of Melbourne as equivalent to a Graduate Certificate

5.3 BloodSafe, South Australia

5.3.1 BloodSafe Final Report

BloodSafe Final Report



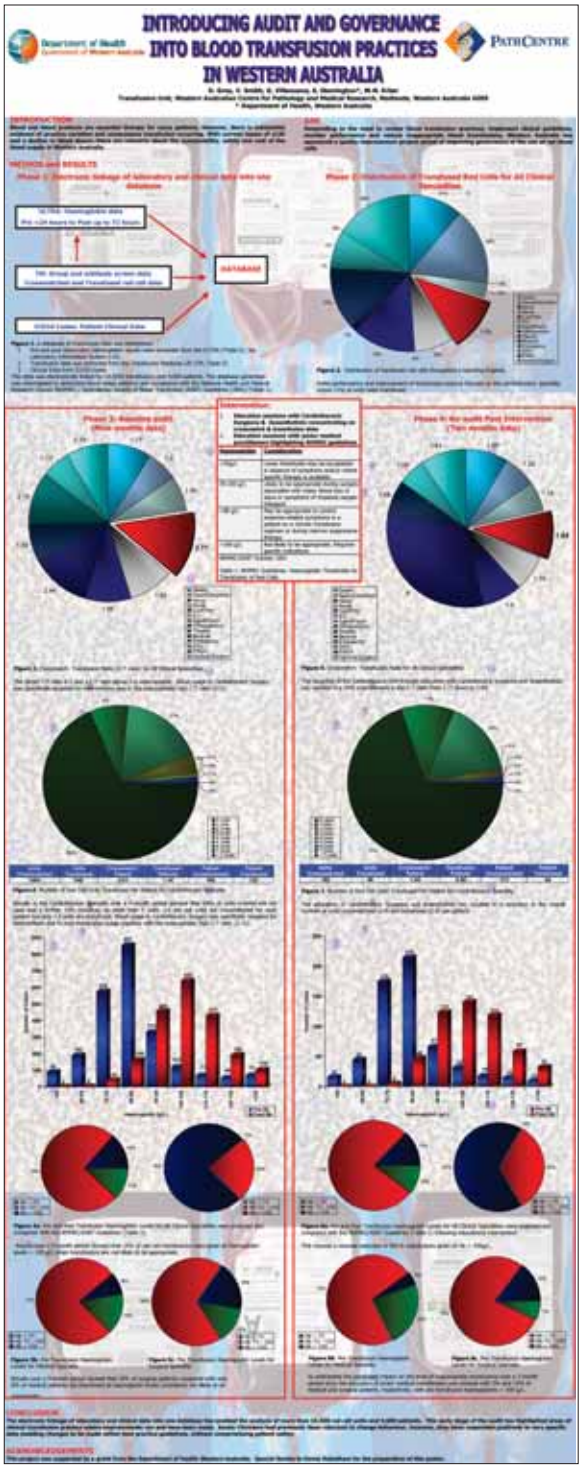
5.3.2 BloodSafe slide set

BloodSafe slide set

5.4 Western Australia

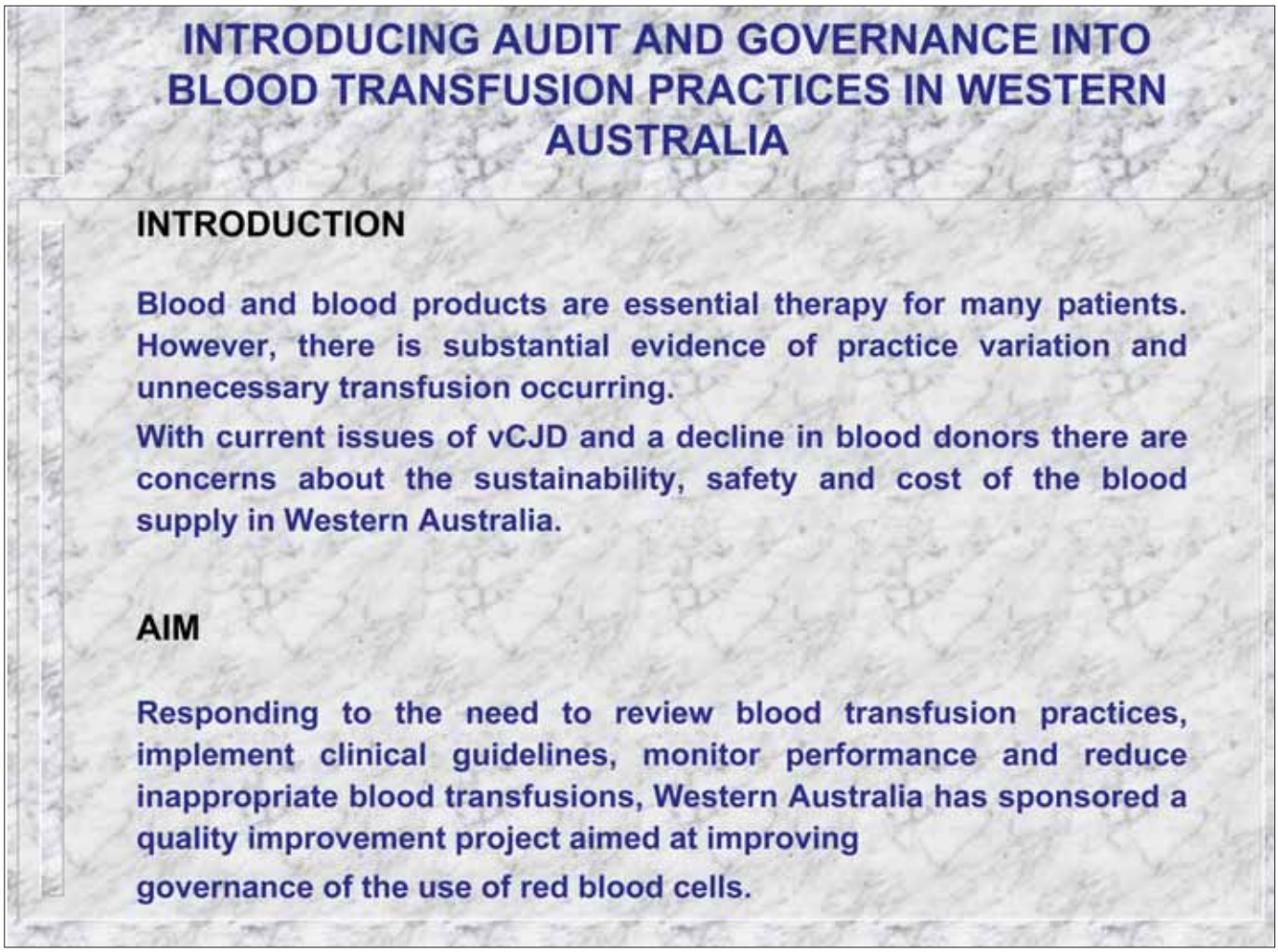
5.4.1 PathCentre poster

Western Australia poster



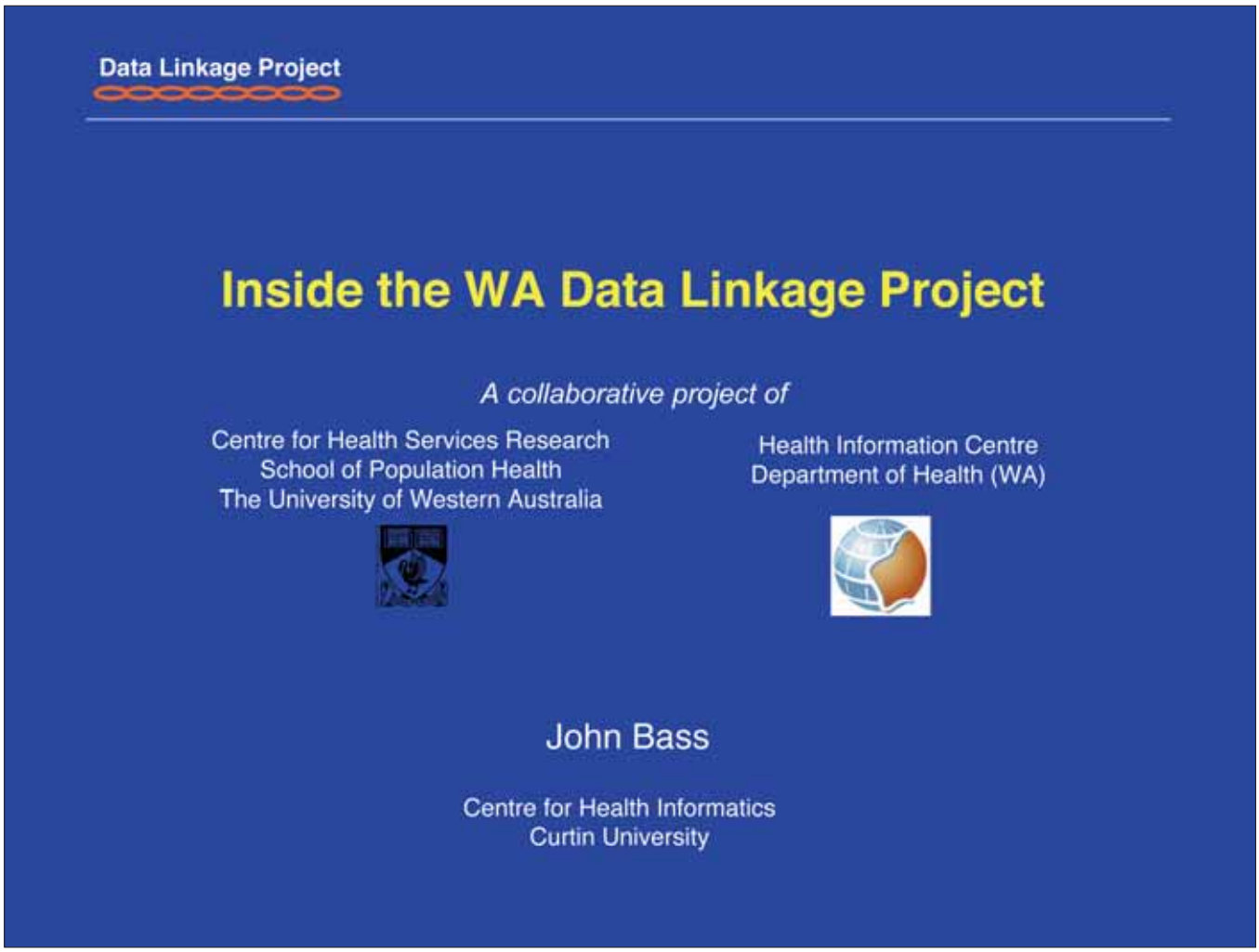
5.4.2 PathCentre slide set

Western Australia slide set



5.4.3 Western Australia data linkage approach

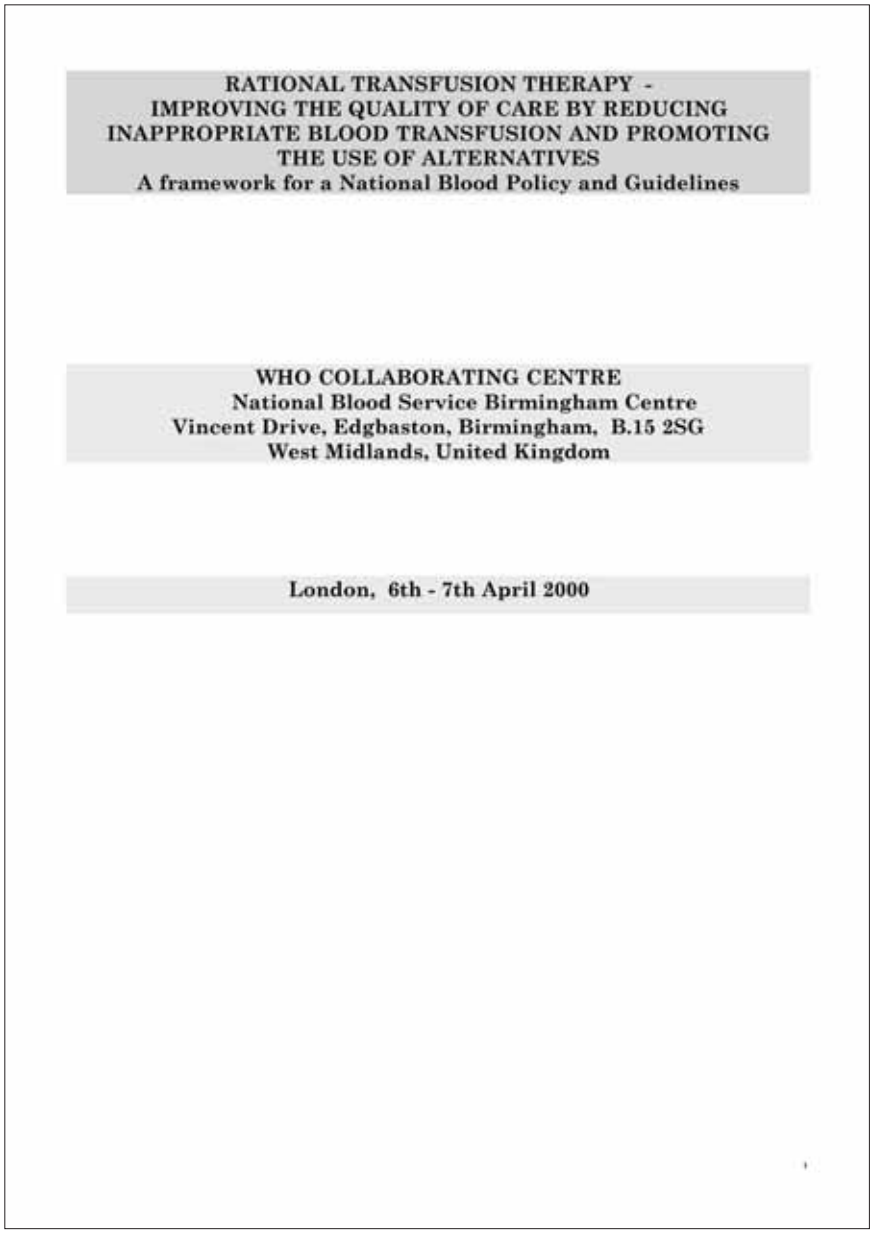
Western Australia data linkage



5.5 WHO

5.5.1 Framework for a national blood policy and guidelines: Rational transfusion therapy

Framework WHO



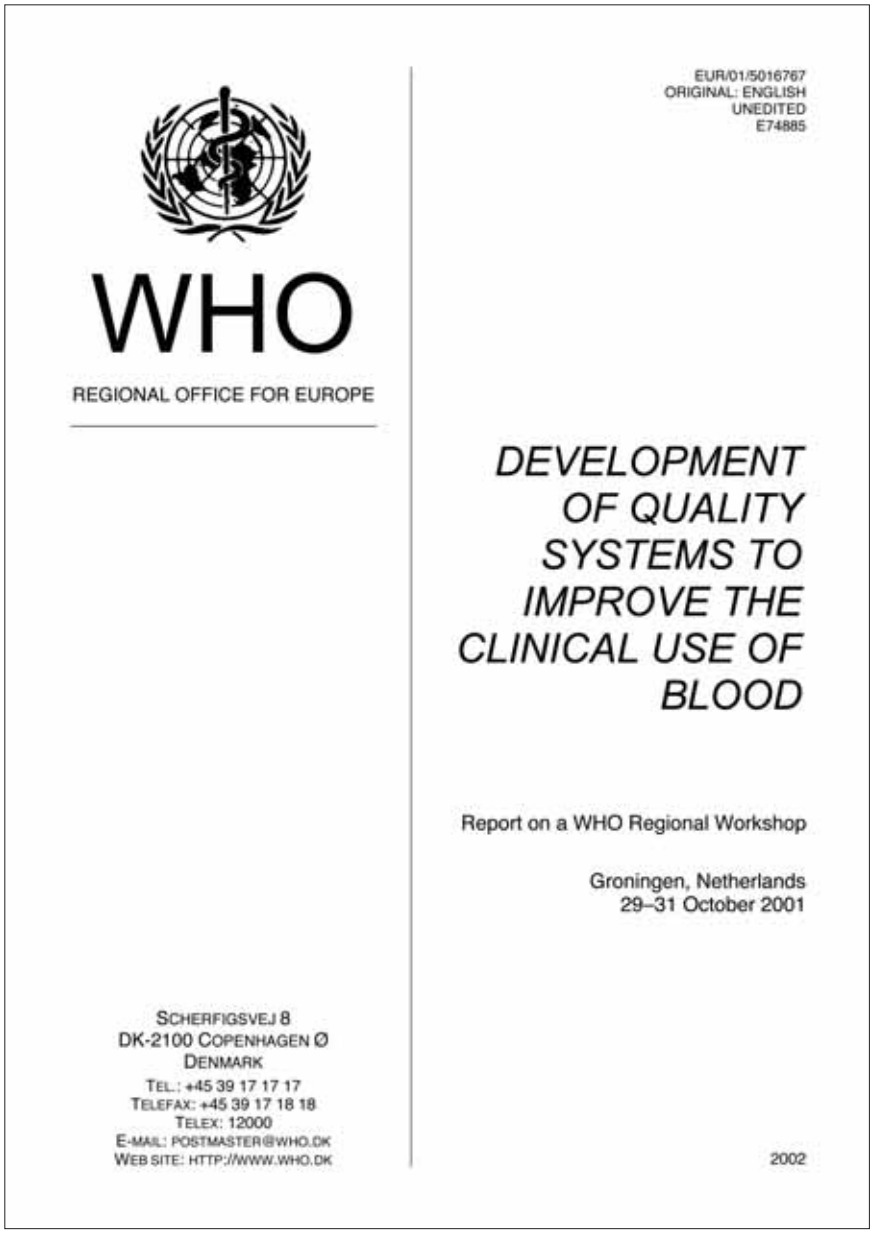
RATIONAL TRANSFUSION THERAPY -
IMPROVING THE QUALITY OF CARE BY REDUCING
INAPPROPRIATE BLOOD TRANSFUSION AND PROMOTING
THE USE OF ALTERNATIVES
A framework for a National Blood Policy and Guidelines

WHO COLLABORATING CENTRE
National Blood Service Birmingham Centre
Vincent Drive, Edgbaston, Birmingham, B.15 2SG
West Midlands, United Kingdom

London, 6th - 7th April 2000

5.5.2 Development of quality systems to improve the clinical use of blood

WHO Quality Systems



WHO

REGIONAL OFFICE FOR EUROPE

EUR/01/5016767
ORIGINAL: ENGLISH
UNEDITED
E74885

DEVELOPMENT OF QUALITY SYSTEMS TO IMPROVE THE CLINICAL USE OF BLOOD

Report on a WHO Regional Workshop

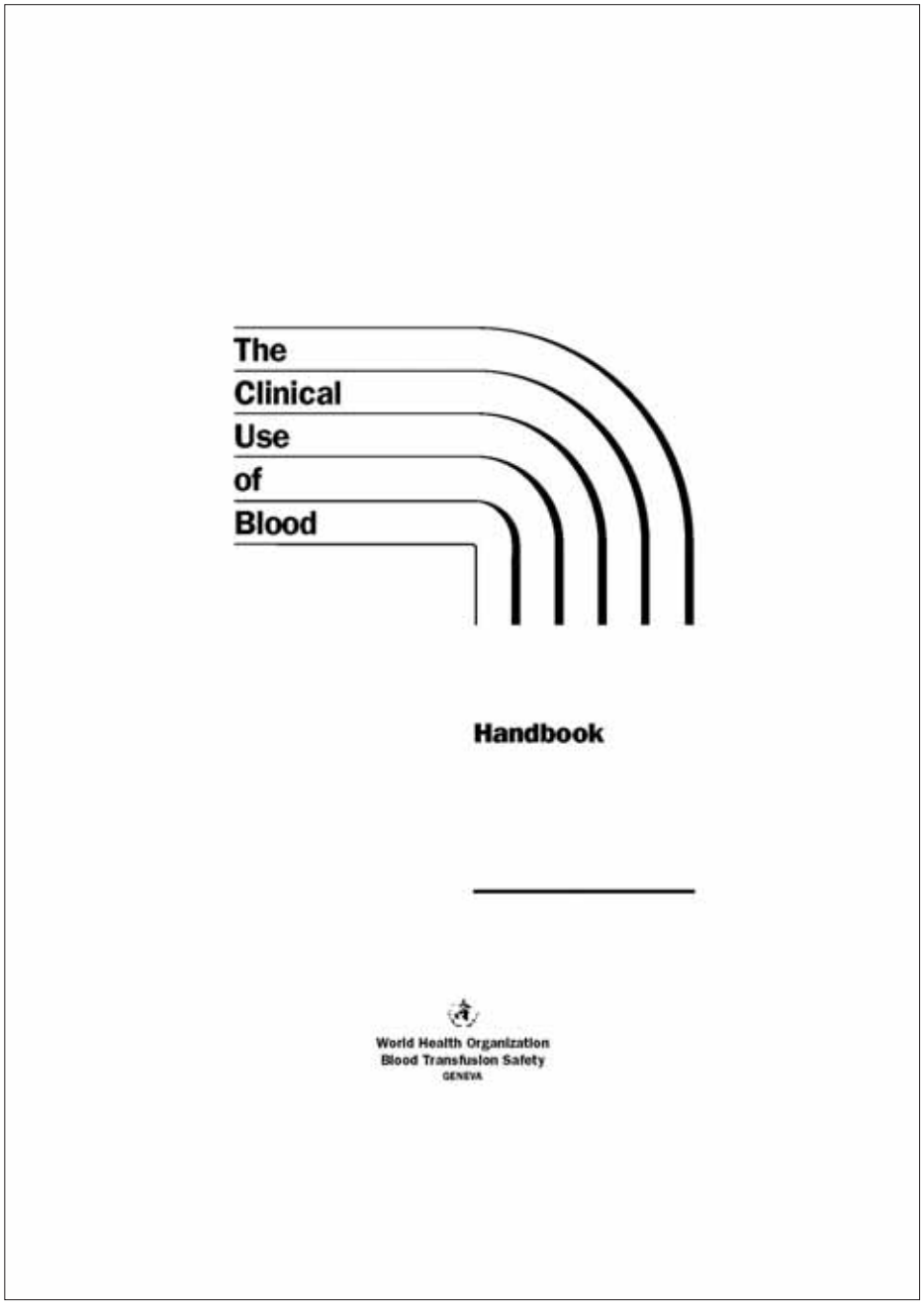
Groningen, Netherlands
29–31 October 2001

SCHERFIGSVEJ 8
DK-2100 COPENHAGEN Ø
DENMARK
TEL.: +45 39 17 17 17
TELEFAX: +45 39 17 18 18
TELEX: 12000
E-MAIL: POSTMASTER@WHO.DK
WEB SITE: HTTP://WWW.WHO.DK

2002

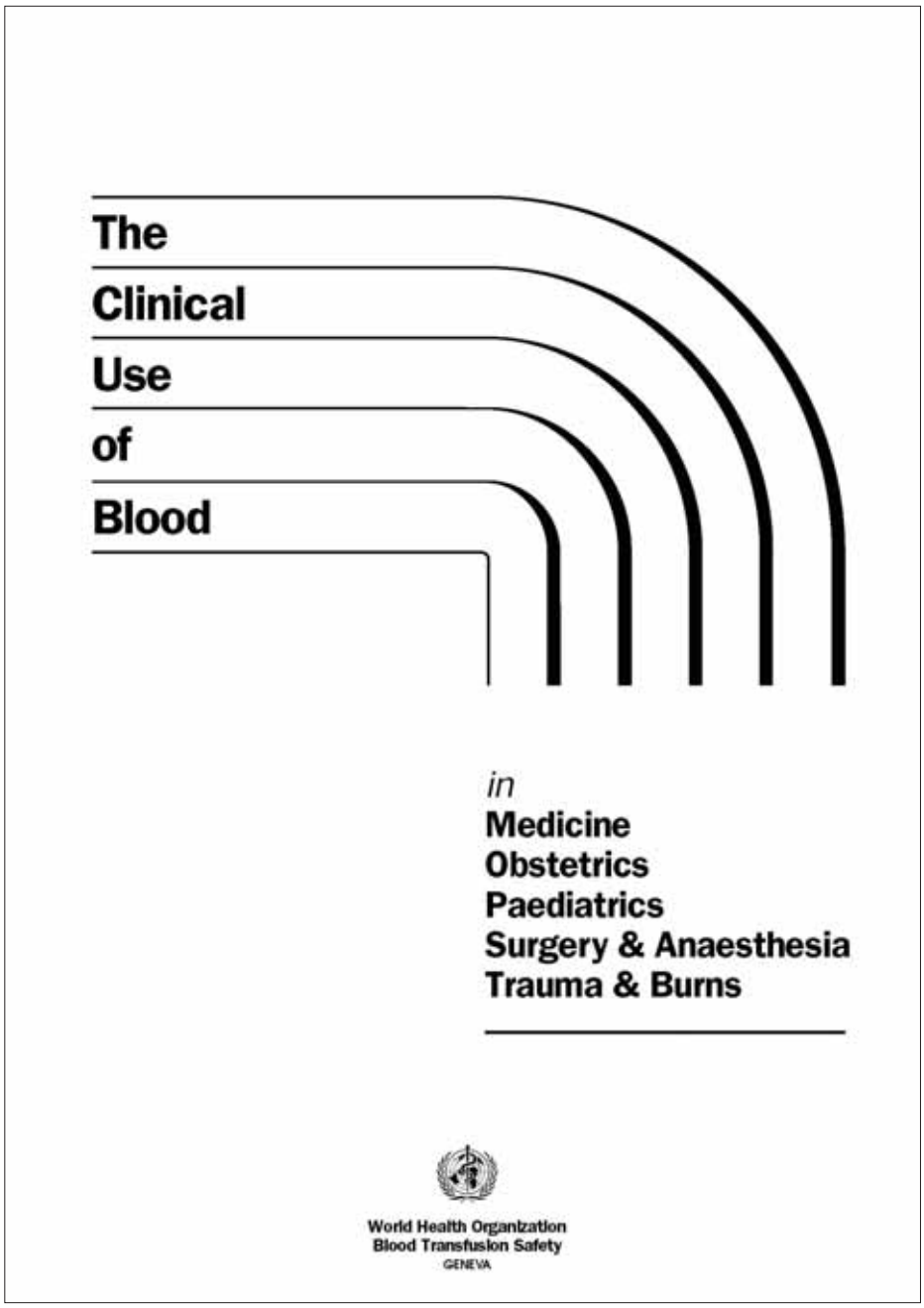
5.5.3 The clinical use of blood handbook

WHO Clinical Use of Blood



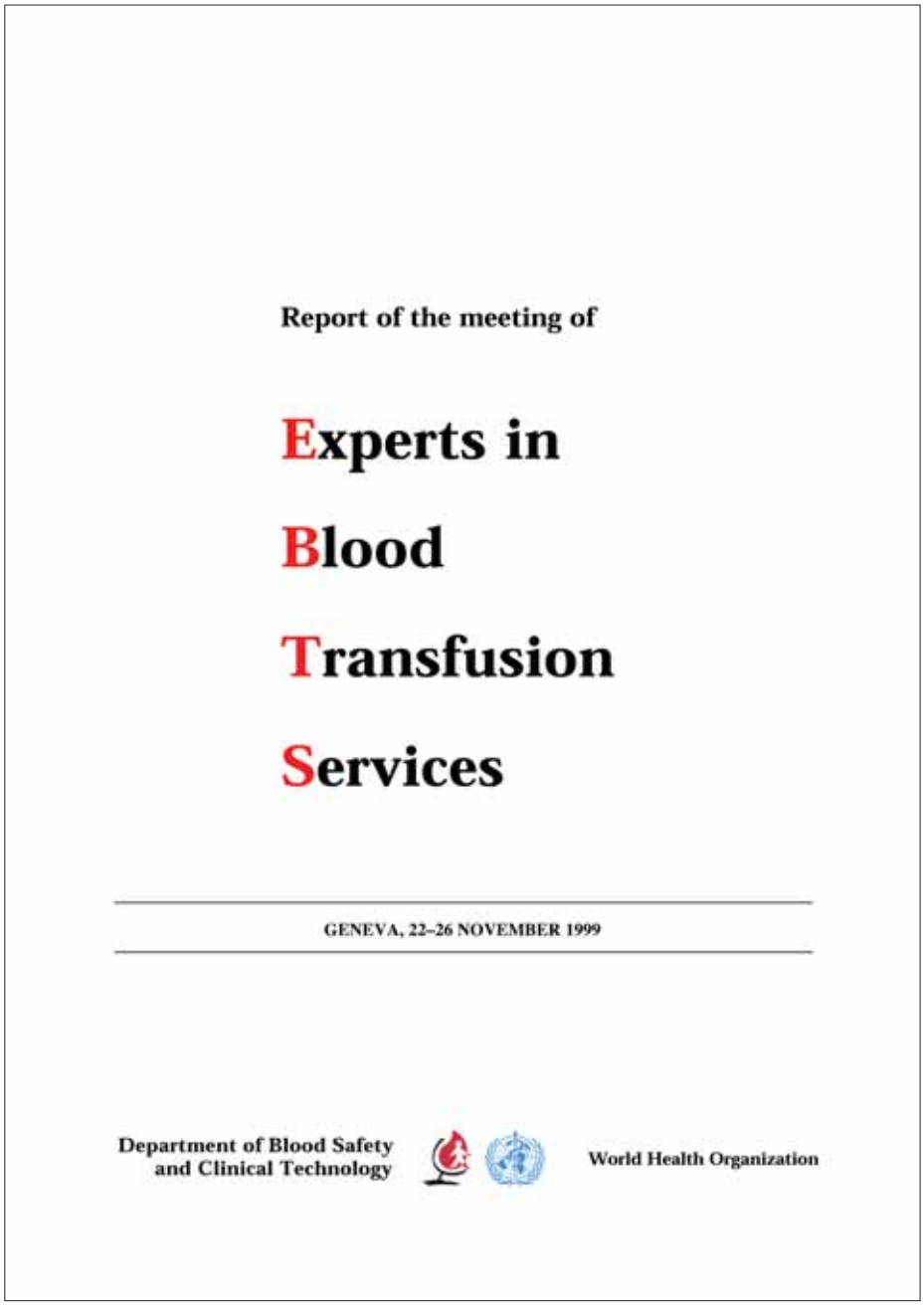
5.5.4 The clinical use of blood in medicine, obstetrics, paediatrics, anaesthesia and surgery, trauma and burns

WHO Medicine, Surgery and Obstetrics



5.5.5 Report of experts in transfusion services

WHO Transfusion Medicine Experts Report



5.5.6 First report of the global collaboration for blood safety

Global Collaboration for Blood Safety

WHO/BTS/01.1
English only
Distr.: Limited

Report of the first meeting of the

Global Collaboration for Blood Safety

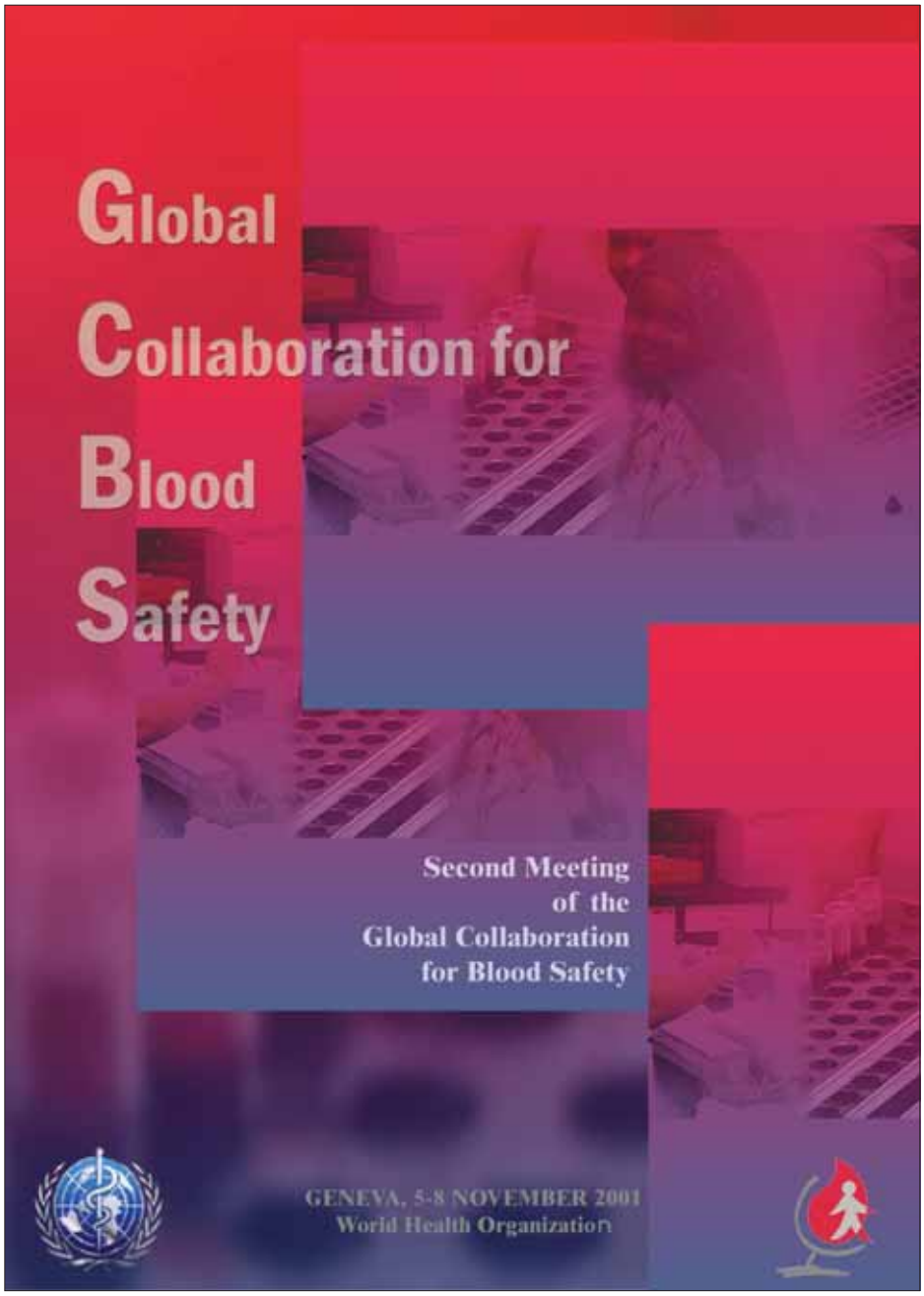
GENEVA, 14–17 NOVEMBER 2000

Department of Blood Safety and Clinical Technology

World Health Organization

5.5.7 Second report of the global collaboration for blood safety

GCBS 2



5.5.8 Aide memoir on national blood programs

Aide WHO

WORLD HEALTH ORGANIZATION

Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

A well-organized blood transfusion service (BTS), with quality systems in all areas, is a prerequisite for the safe and effective use of blood and blood products.

The HIV/AIDS pandemic has focused particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease.

The global burden of disease due to unsafe blood transfusion can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- Establishment of a nationally-coordinated blood transfusion service
- Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

Words of advice

- **Secure government commitment and support for the national blood programme**
- **Establish a blood transfusion service as a separate unit with responsibility and authority, an adequate budget, a management team and trained staff**
- **Educate, motivate, recruit and retain voluntary non-remunerated blood donors from low-risk populations**
- **Ensure good laboratory practice in screening for transfusion-transmissible infections, blood grouping, compatibility testing, blood component production and the storage and transportation of blood products**
- **Reduce unnecessary transfusions through the effective clinical use of blood, including alternatives to transfusion**
- **Establish a quality system for the BTS**
- **Train all BTS and clinical staff to ensure the provision of safe blood and its effective clinical use**

Checklist

Blood transfusion service

- ❑ Government commitment and support
- ❑ National blood policy/plan
- ❑ Legislation/regulation
- ❑ Organization with responsibility and authority for the BTS
- ❑ BTS management committee
- ❑ BTS medical director
- ❑ BTS quality manager
- ❑ Specialist BTS advisory groups
- ❑ Trained BTS administrative and technical staff
- ❑ Adequate budget
- ❑ National quality system

Blood donors

- ❑ National blood donor programme officer
- ❑ Blood donor unit
- ❑ Blood donor recruitment officer
- ❑ Standard operating procedures
- ❑ Training of staff in blood donor unit
- ❑ Low-risk donor populations
- ❑ Educational materials
- ❑ Register of voluntary non-remunerated blood donors
- ❑ Donor selection, deferral, care and confidentiality
- ❑ Donor notification and referral
- ❑ Monitoring of TTIs

Testing of donated blood

- ❑ Technical officer
- ❑ Screening strategies and protocols
- ❑ Training of laboratory technical staff
- ❑ Screening of all donated blood for TTIs
- ❑ Blood grouping and compatibility testing
- ❑ Good laboratory practice, including standard operating procedures (SOPs)
- ❑ Continuity in testing
- ❑ Effective blood cold chain

Clinical use of blood

- ❑ National policy and guidelines on the clinical use of blood
- ❑ Training of clinicians and BTS staff
- ❑ Prevention, early diagnosis and treatment
- ❑ Alternatives to transfusion (crystalloids and colloids)
- ❑ Effective clinical use of blood
- ❑ Monitoring and evaluation

5.5.9 Aide memoir on blood safety quality systems

Aide WHO Quality Systems

WORLD HEALTH ORGANIZATION

Quality Systems for Blood Safety

AIDE-MEMOIRE

for National Blood Programmes

Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

Words of advice

- **Secure the commitment and support of management at all levels**
- **Identify the need for quality in the national blood policy**
- **Develop a national quality policy and plan**
- **Secure adequate resources**
- **Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels**
- **Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank**
- **Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion**
- **Assess the effectiveness of the quality system continually**

Checklist

Prerequisites

- ❑ Nationally-coordinated BTS
- ❑ Management commitment and support
- ❑ Integration of quality in the national blood policy
- ❑ National quality policy and plan
- ❑ National quality manager
- ❑ Adequate resources

Organizational management

- ❑ Clearly defined organizational structure
- ❑ Quality manager in each blood centre and hospital blood bank
- ❑ Quality section in each blood centre and hospital blood bank
- ❑ Culture of quality
- ❑ Commitment and support of all staff
- ❑ Identification of processes and procedures and their critical control points

Standards for quality systems

- ❑ Regulatory or legislative framework
- ❑ Appropriate national or international standards
- ❑ Standards relevant to BTSs

Documentation

- ❑ Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- ❑ Complete, accurate records
- ❑ System for controlling documents

Training

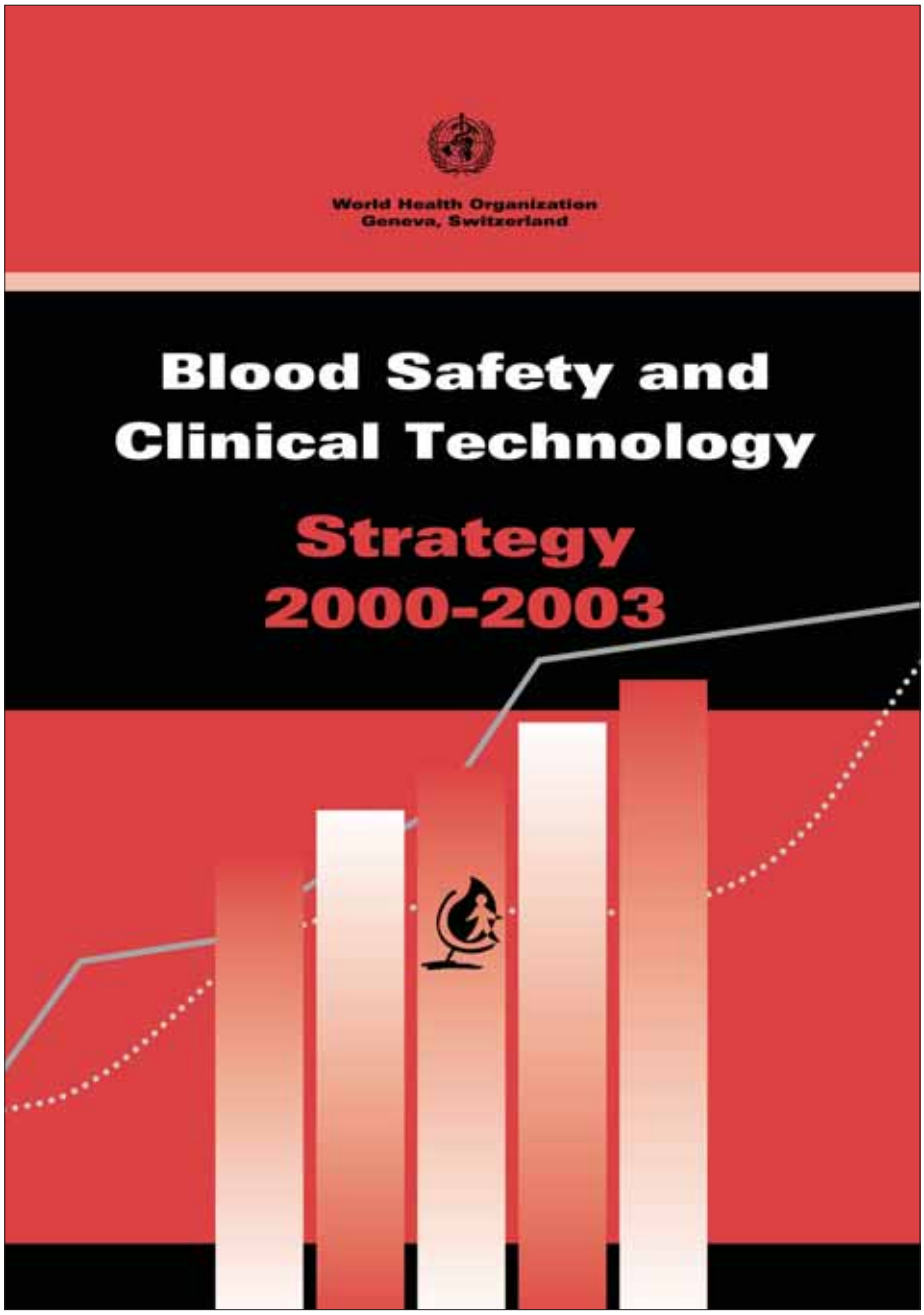
- ❑ Training policy and plan
- ❑ Training of all BTS staff in quality and quality systems
- ❑ Training of other health care professionals involved in blood transfusion
- ❑ Evaluation of training and its impact

Assessment

- ❑ Validation
- ❑ Ongoing data collection and analysis
- ❑ Haemovigilance
- ❑ Regular review of all activities
- ❑ Internal and external audits
- ❑ Error management, corrective and preventive action
- ❑ External quality assessment schemes

5.5.10 Blood safety and technology report

WHO Blood Safety and Technology Report

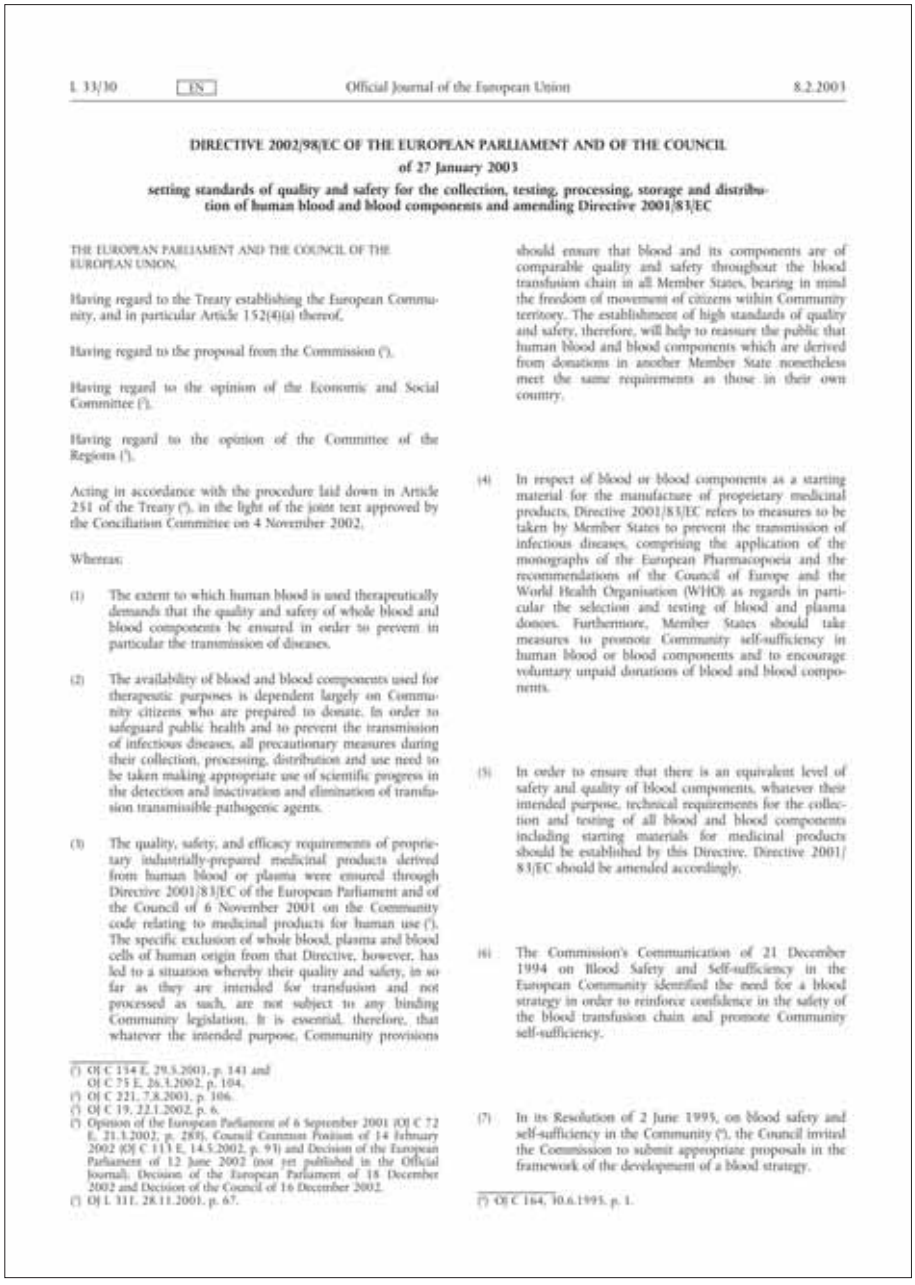


5.6 European initiatives

5.6.1 COE recommendations

COE 1

COE 2



L 33/30 EN Official Journal of the European Union 8.2.2003

DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 January 2003
setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Having regard to the opinion of the Committee of the Regions (3),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (4), in the light of the joint text approved by the Conciliation Committee on 4 November 2002,

Whereas:

(1) The extent to which human blood is used therapeutically demands that the quality and safety of whole blood and blood components be ensured in order to prevent in particular the transmission of diseases.

(2) The availability of blood and blood components used for therapeutic purposes is dependent largely on Community citizens who are prepared to donate. In order to safeguard public health and to prevent the transmission of infectious diseases, all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection and inactivation and elimination of transfusion transmissible pathogenic agents.

(3) The quality, safety, and efficacy requirements of proprietary industrially-prepared medicinal products derived from human blood or plasma were ensured through Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (5). The specific exclusion of whole blood, plasma and blood cells of human origin from that Directive, however, has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. It is essential, therefore, that whatever the intended purpose, Community provisions should ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, will help to reassure the public that human blood and blood components which are derived from donations in another Member State nonetheless meet the same requirements as those in their own country.

(4) In respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products, Directive 2001/83/EC refers to measures to be taken by Member States to prevent the transmission of infectious diseases, comprising the application of the monographs of the European Pharmacopoeia and the recommendations of the Council of Europe and the World Health Organisation (WHO) as regards in particular the selection and testing of blood and plasma donors. Furthermore, Member States should take measures to promote Community self-sufficiency in human blood or blood components and to encourage voluntary unpaid donations of blood and blood components.

(5) In order to ensure that there is an equivalent level of safety and quality of blood components, whatever their intended purpose, technical requirements for the collection and testing of all blood and blood components including starting materials for medicinal products should be established by this Directive. Directive 2001/83/EC should be amended accordingly.

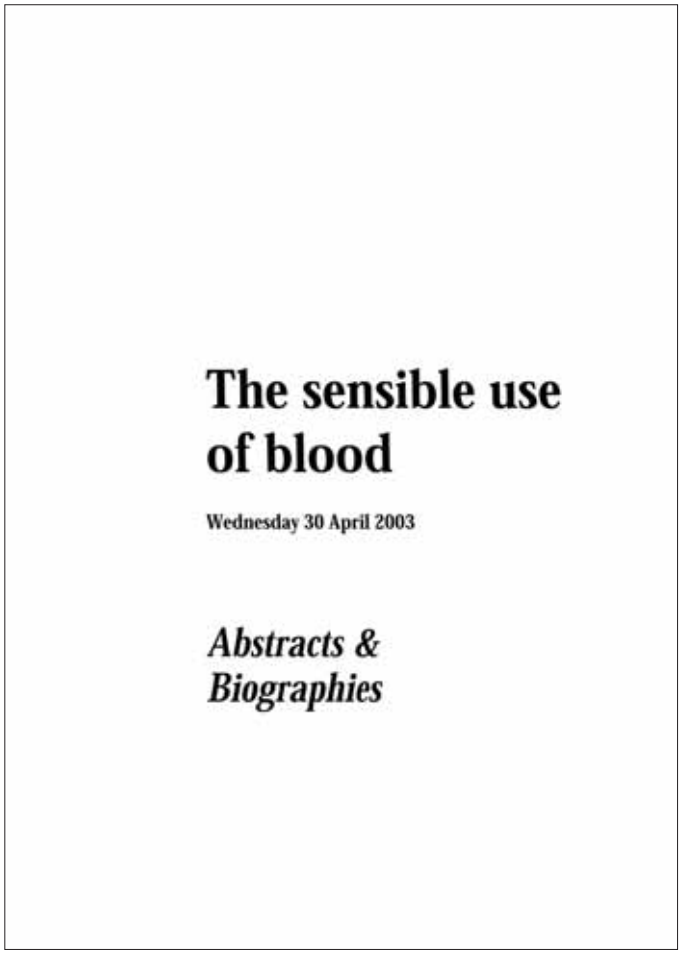
(6) The Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community identified the need for a blood strategy in order to reinforce confidence in the safety of the blood transfusion chain and promote Community self-sufficiency.

(7) In its Resolution of 2 June 1995, on blood safety and self-sufficiency in the Community (6), the Council invited the Commission to submit appropriate proposals in the framework of the development of a blood strategy.

(1) OJ C 154 E, 29.5.2001, p. 141 and OJ C 75 E, 26.3.2002, p. 104.
(2) OJ C 221, 7.8.2001, p. 106.
(3) OJ C 19, 22.1.2002, p. 6.
(4) Opinion of the European Parliament of 6 September 2001 (OJ C 72 E, 21.3.2002, p. 280), Council Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 93) and Decision of the European Parliament of 12 June 2002 (not yet published in the Official Journal). Decision of the European Parliament of 18 December 2002 and Decision of the Council of 16 December 2002.
(5) OJ L 311, 28.11.2001, p. 67.
(6) OJ C 164, 30.6.1995, p. 1.

5.6.2 European Commission directive

EU 1



The sensible use of blood

Wednesday 30 April 2003

Abstracts & Biographies

EU 2

August 2004

To: Hospital Transfusion Laboratory Managers, Consultant Haematologists with responsibility for Transfusion Laboratories, Transfusion Practitioners and Chairs of HTCs

Dear Colleague,

Re: European Blood Directive – NHS Operational Impact Working Group

I am writing to tell you that the UK Health Departments and the National Transfusion Committee have set up the NHS Operational Impact Group (OIG) to consider and make recommendations on the impact on hospital transfusion laboratories of EU directive 2002/98/EC at (www.europa.eu.int)

The group comprises representatives of hospital transfusion laboratories and Blood Services across the UK (the full membership and the terms of reference are at Appendices 1 & 2). This first letter is to alert you to the directive and to the establishment of the group. Future updates will aim to keep you informed about implementation issues and developments. The directive will also shortly feature as an item in a forthcoming Chief Executive's bulletin.

The group's job is to identify any shortfalls, and areas of improvement relating to the existing accreditation, traceability and incident reporting systems. We also aim to assess the directive's impact on Hospital Transfusion Laboratories and identify good practice to help meet its minimum requirements. In addition we will consider what practical measures might be offered to hospitals to smooth the transition to compliance e.g. guidance, training workshops, or sample document templates.

Appendix 3 is a short initial position paper from the group, minutes and papers will shortly be available at www.transfusionguidelines.org.uk

We will be consulting widely within the transfusion community. If your hospital has taken any measures in response to the directive that might be of interest to others and you are willing to share these, please contact any member of the group. Equally, if you have any ideas, or are willing to act as a communication channel for other hospitals in your area, please let us know.

Yours sincerely

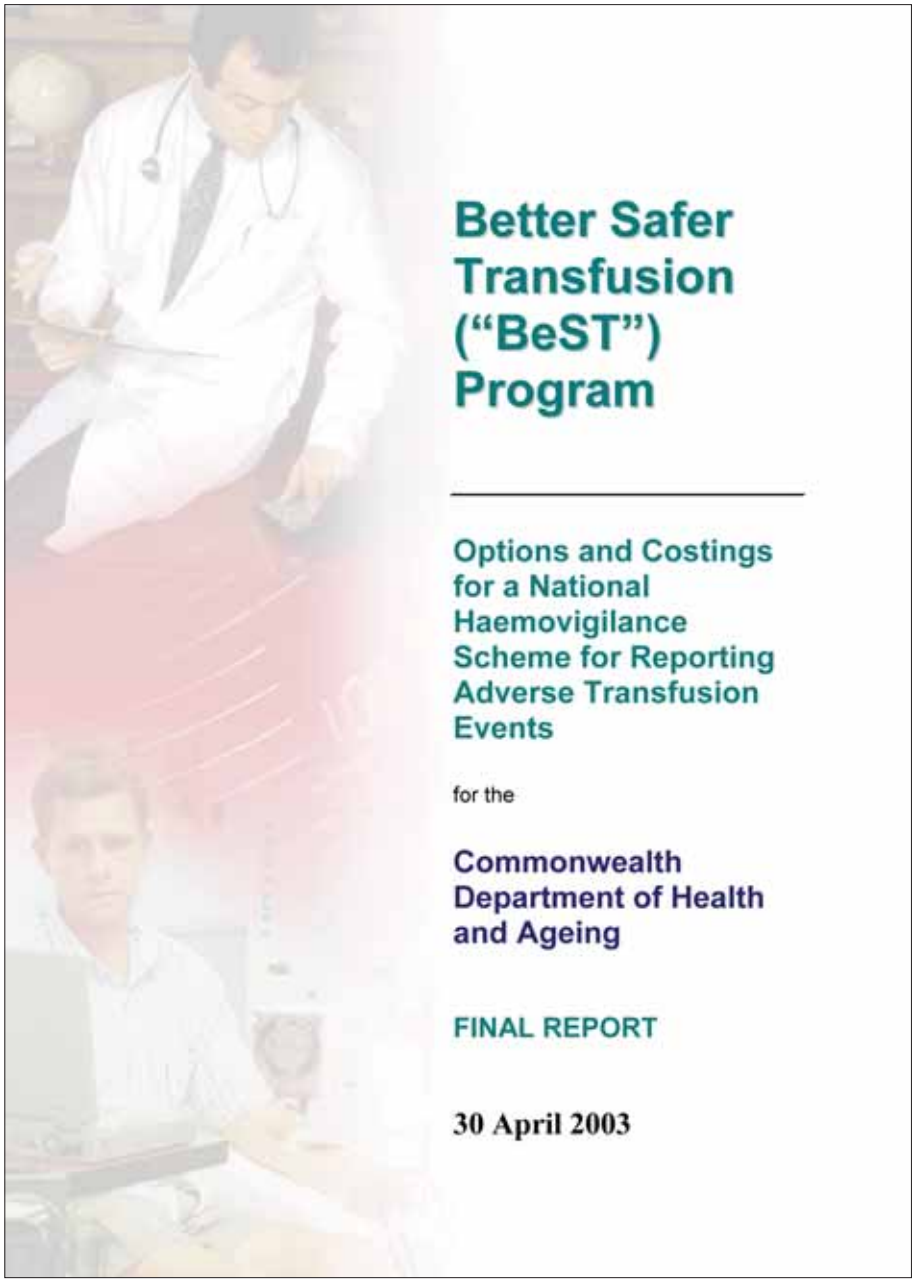
Joan Jones
Chair NHS Operational Impact Working Group

NHS

5.7 Haemovigilance

5.7.1 Consultants report

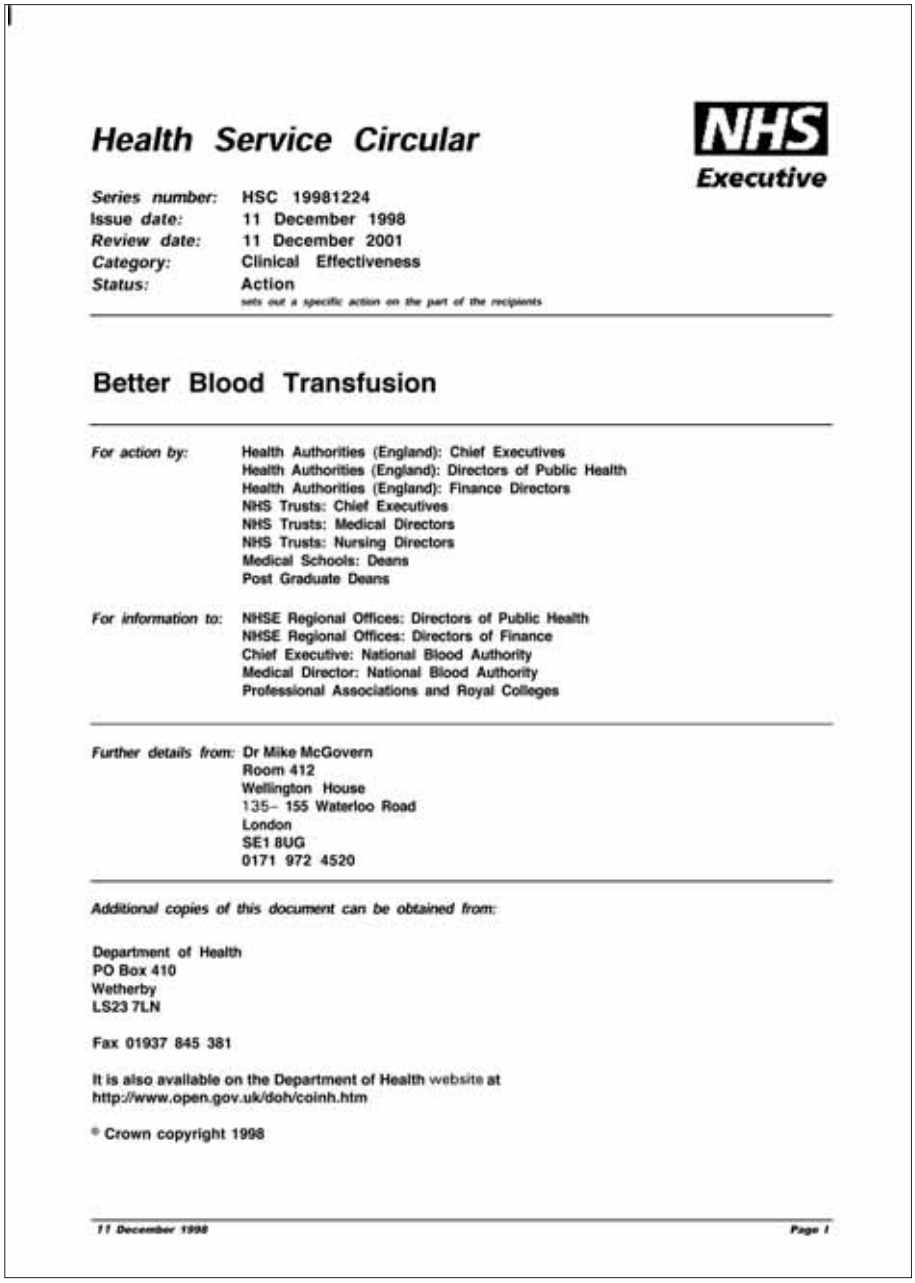
Linked Material\appendix 5.7.1.pdf



5.8 United Kingdom initiatives

5.8.1 Better Blood Transfusion 1998

Linked Material\appendix5.8.1.pdf



Health Service Circular

NHS Executive

Series number: HSC 19981224
Issue date: 11 December 1998
Review date: 11 December 2001
Category: Clinical Effectiveness
Status: Action
sets out a specific action on the part of the recipients

Better Blood Transfusion

For action by:
Health Authorities (England): Chief Executives
Health Authorities (England): Directors of Public Health
Health Authorities (England): Finance Directors
NHS Trusts: Chief Executives
NHS Trusts: Medical Directors
NHS Trusts: Nursing Directors
Medical Schools: Deans
Post Graduate Deans

For information to:
NHSE Regional Offices: Directors of Public Health
NHSE Regional Offices: Directors of Finance
Chief Executive: National Blood Authority
Medical Director: National Blood Authority
Professional Associations and Royal Colleges

Further details from: Dr Mike McGovern
Room 412
Wellington House
135– 155 Waterloo Road
London
SE1 8UG
0171 972 4520

Additional copies of this document can be obtained from:

Department of Health
PO Box 410
Wetherby
LS23 7LN

Fax 01937 845 381

It is also available on the Department of Health website at
http://www.open.gov.uk/doh/coinh.htm

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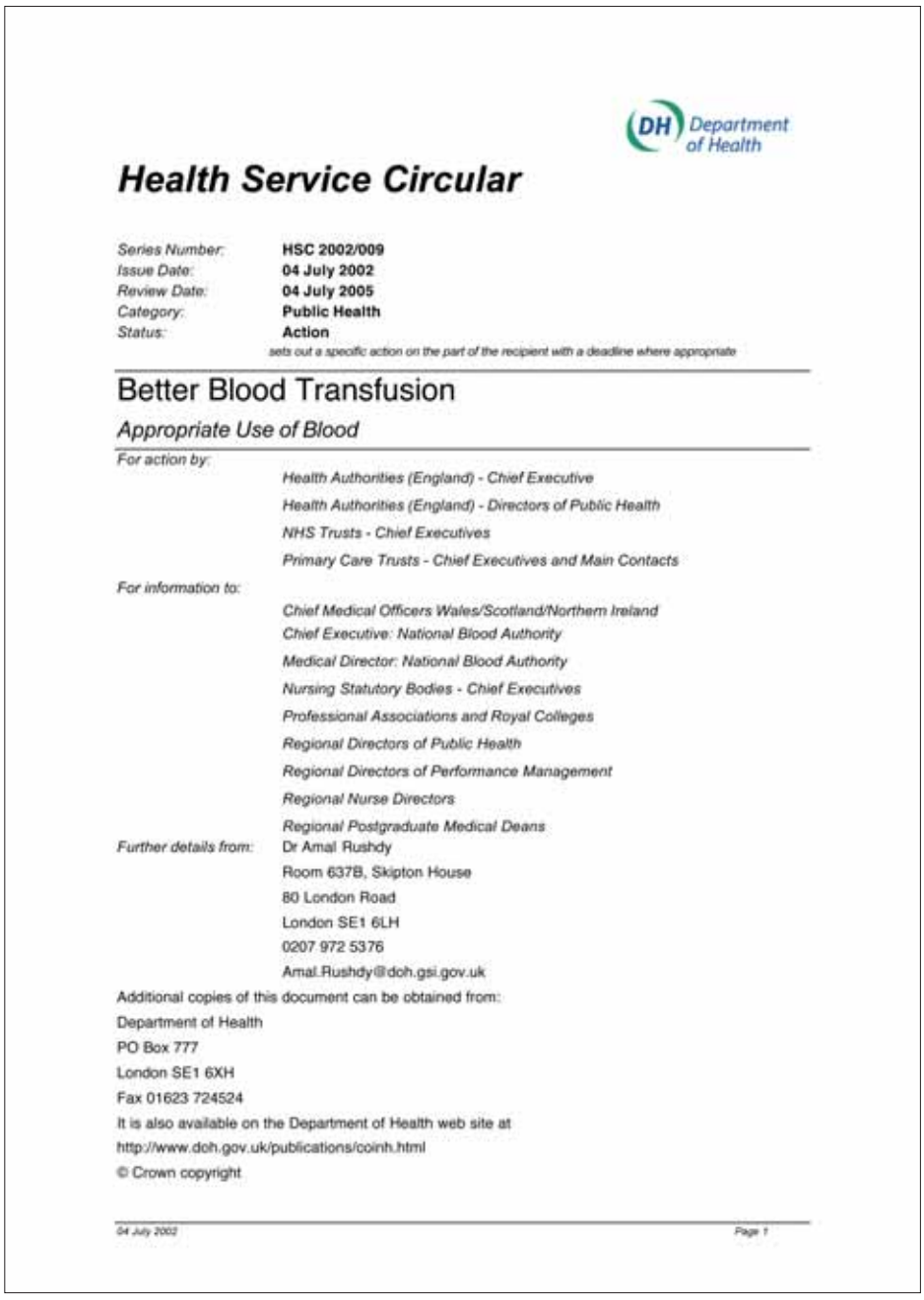
11 December 1998 *Page 1*

5.8.2 Better blood transfusion 2002

Linked Material\appendix 5.8.2.pdf



DH Department of Health

Health Service Circular

Series Number:	**HSC 2002/009**
Issue Date:	**04 July 2002**
Review Date:	**04 July 2005**
Category:	**Public Health**
Status:	**Action**

sets out a specific action on the part of the recipient with a deadline where appropriate

Better Blood Transfusion

Appropriate Use of Blood

For action by:

Health Authorities (England) - Chief Executive
Health Authorities (England) - Directors of Public Health
NHS Trusts - Chief Executives
Primary Care Trusts - Chief Executives and Main Contacts

For information to:

Chief Medical Officers Wales/Scotland/Northern Ireland
Chief Executive: National Blood Authority
Medical Director: National Blood Authority
Nursing Statutory Bodies - Chief Executives
Professional Associations and Royal Colleges
Regional Directors of Public Health
Regional Directors of Performance Management
Regional Nurse Directors
Regional Postgraduate Medical Deans

Further details from:
Dr Amal Rushdy
Room 637B, Skipton House
80 London Road
London SE1 6LH
0207 972 5376
Amal.Rushdy@doh.gsi.gov.uk

Additional copies of this document can be obtained from:
Department of Health
PO Box 777
London SE1 6XH
Fax 01623 724524
It is also available on the Department of Health web site at
http://www.doh.gov.uk/publications/coinh.html

5.8.3 Better Blood Transfusion 2002 resource requirements

Linked Material\appendix 5.8.3.pdf

RESOURCES REQUIRED FOR THE IMPLEMENTATION OF BETTER BLOOD TRANSFUSION HSC 2002/009

The resources required to implement Better Blood Transfusion 2 will be quite variable depending on the size of the hospital and the level of transfusion dependent activity undertaken. It is expected that many organisations will have already managed to achieve some of the objectives outlined and that fewer additional resources will be required. However, a complete programme is described to achieve the ideal, to give an overview of the potential complexity of the process. The importance of this is that it is clear that any examination of transfusion related procedures commonly raises issues that have not been previously contemplated, therefore this paper covers all areas that should be considered. In particular, medical and nursing knowledge is frequently overestimated and this can impact on all aspects of transfusion practice.

The resources can be categorised into five headings. It is unrealistic to assume that all items will be in place by April 2003 but the list, by describing the ideal, will permit a hierarchy of goals to be planned, which can be worked toward. Aside from the equipment, all expenses will be recurring. *Appendix 1* tables a proposed hierarchy of need with attendant costs.

STAFF

Transfusion Practitioner

This role is vital for the organisation and provision of staff training, implementation of safe practice and assessment of appropriate usage. The postholder may be from a medical, biomedical scientist or nursing background and there are pros and cons attached to each. Depending on the size of the hospital there may need to be one or several people in post and in the larger Trusts the post should work in tandem with an Audit Coordinator (see below) . In this instance, consideration should be given to the advantages of individuals from complementary disciplines e.g. nurse and biomedical scientist or audit co-ordinator and nurse. Pertaining to nurses, each Trust has it's own

1

5.8.4 Better blood transfusion. Progress reports 2003

Linked Material\appendix 5.8.4.pdf

ORIGINAL ARTICLE

Survey of the implementation of the recommendations in the Health Services Circular 1998/224 '*Better Blood Transfusion*'

M. F. Murphy,*† C. Edbury* and C. Wickenden*

SUMMARY. This report describes a questionnaire survey on the implementation of the recommendations of the Health Services Circular (HSC) '*Better Blood Transfusion*' 1998/224 for improving transfusion practice. The survey was carried out to inform a second UK Chief Medical Officers' symposium on '*Better Blood Transfusion*' in October 2001. Sixty-nine percent of hospitals where blood is transfused in England participated. The results show that, by 2001, most hospitals had established Hospital Transfusion Committees (HTCs), developed protocols for the process of transfusion and were participating in the Serious Hazards of Transfusion (SHOT) scheme. However, there was limited compliance with other recommendations, including the provision of training for staff involved in transfusion and information to patients, the development of protocols for the appropriate use of blood, the performance of audits of transfusion practice and the introduction of peri-operative cell salvage. The survey did not determine the reasons for this limited compliance. New initiatives including the issue of a further HSC on '*Better Blood Transfusion*' are aimed at enabling hospitals to improve their transfusion practice in a more systematic way than that was found in the results of this survey.

Key words: blood transfusion, questionnaire survey, transfusion practice.

Attention has focused on blood transfusion practice in recent years for several reasons. These include the recommendations arising from the Serious Hazards of Transfusion (SHOT) scheme, concerns about the risk of transmission of variant Creutzfeldt–Jakob disease (vCJD) by blood transfusion, the increased costs associated with new safety measures such as leucocyte-depletion of blood components, and documented variations in transfusion practice (The Sangstar Study Group, 1994; Murphy *et al.*, 2001). The Health Services Circular (HSC) 1998/224 '*Better Blood Transfusion*' detailed the action required of National Health Service (NHS) Trusts and clinicians to improve transfusion practice; its recommendations were based on presentations and workshops at a symposium held by the UK Chief Medical Officers' on *Evidence-Based Blood Transfusion* on 6 July 1998 in London (NHS Executive, 1998).

Limited information was available on the implementation of the recommendations of the HSC 1998/224 as its review date of December 2001 approached. A survey, carried out in 1999 by the UK Blood Transfusion Services/National Institute of Biological Standards and Controls Joint Guidelines Committee's Standing Advisory Committee on Information Technology, found that 84·5% of 317 hospitals indicated that they had a Hospital Transfusion Committee (HTC) (Serious Hazards of Transfusion (SHOT) scheme, 2000) and 305 of 426 (72%) hospitals surveyed participated in the SHOT scheme in 1999/2000 (Serious Hazards of Transfusion (SHOT) scheme, 2001). This report describes a questionnaire survey on the implementation of the recommendations of the HSC '*Better Blood Transfusion*' 1998/224 that was carried out to inform the second UK Chief Medical Officers' symposium on '*Better Blood Transfusion*' in October 2001.

METHODS

A questionnaire survey agreed by the Department of Health about the implementation of HSC 1998/224 '*Better Blood Transfusion*' was sent by the National

Correspondence: Dr M. F. Murphy, National Blood Service, John Radcliffe Hospital, Oxford OX3 9DU, UK.
e-mail: mike.murphy@nbs.nhs.uk

Linked Material\appendix 5.8.4b.pdf

5.8.5 CMO's Better Blood Transfusion Committee - Terms of Reference

Linked Material\appendix 5.8.5.pdf

THE CMO'S NATIONAL BLOOD TRANSFUSION COMMITTEE AND REGIONAL TRANSFUSION COMMITTEES

TERMS OF REFERENCE

1. BACKGROUND

1.1 The National Blood Service Zones were integrated into the new national management structure for the National Blood Service in 2000, and the Zonal Blood User Groups (ZBUGs) were disbanded. A formal mechanism for interaction of the National Blood Service with blood users needs to be maintained and developed, and it was proposed that Regional Transfusion Committees should be established.

1.2 It was also proposed that a National Transfusion Committee be established to replace the National Blood User Group (NBUG) along the lines of recommendations by the WHO Blood Safety Unit for a National Committee on the Clinical Use of Blood.

1.3 An Interim National Transfusion Committee was set up with the objective of establishing the Hospital, Regional and National Transfusion Committee structure by September 2001. Its membership included the ex-Chairmen and Blood Bank Members of the NBUG/ZBUGs to provide a link with the previous User Group structure.

1.4 The primary purpose of this initiative is to promote safe and effective transfusion practice in hospitals. The National Blood Transfusion Committee will be accountable to the Chief Medical Officer (CMO), and the Chairman appointed by the CMO.

1.5 The name of the National Transfusion Committee will be the 'CMO's National Blood Transfusion Committee'.

1.6 This initiative was highlighted at a second CMOs' Seminar on 'Better Blood Transfusion' in October 2001.

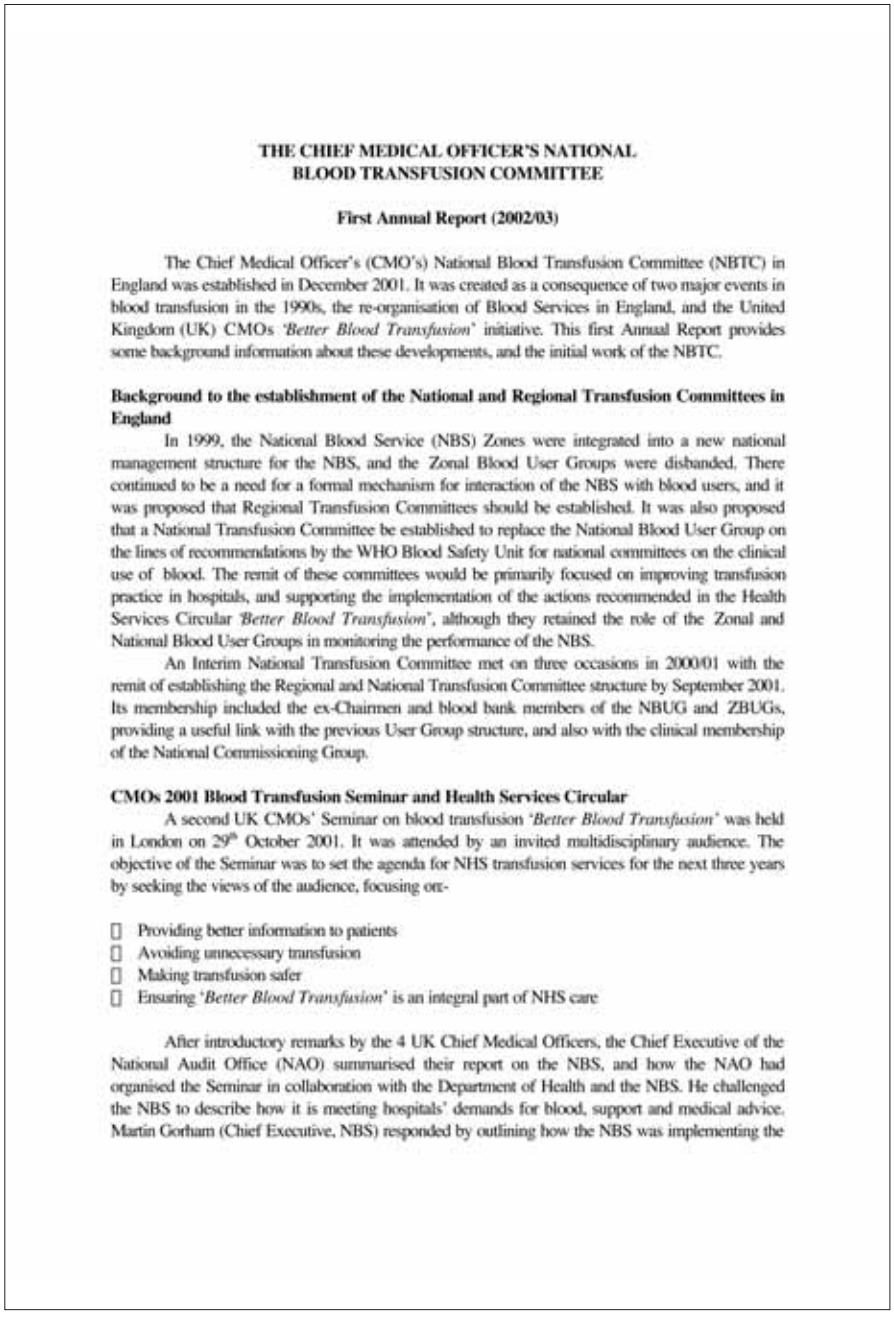
1.7 A two-way flow of information between Hospital Transfusion Committees and the Regional and CMO's National Blood Transfusion Committees should encourage good local blood transfusion practice and the implementation of national transfusion guidelines in accordance with the recommendations in the HSC 2002/009 *Better Blood Transfusion – Appropriate Use of Blood.*

1.8 In addition, the identification of problems in any aspect of blood transfusion including the delivery of services by the National Blood Service remains within the remit of the CMO's National Blood Transfusion and Regional Committees.

Revised June 2003

5.8.6 CMO's Annual Report on Better Blood Transfusion 2002-2003

Linked Material\appendix 5.8.6.pdf



THE CHIEF MEDICAL OFFICER'S NATIONAL BLOOD TRANSFUSION COMMITTEE

First Annual Report (2002/03)

The Chief Medical Officer's (CMO's) National Blood Transfusion Committee (NBTC) in England was established in December 2001. It was created as a consequence of two major events in blood transfusion in the 1990s, the re-organisation of Blood Services in England, and the United Kingdom (UK) CMOs *'Better Blood Transfusion'* initiative. This first Annual Report provides some background information about these developments, and the initial work of the NBTC.

Background to the establishment of the National and Regional Transfusion Committees in England

In 1999, the National Blood Service (NBS) Zones were integrated into a new national management structure for the NBS, and the Zonal Blood User Groups were disbanded. There continued to be a need for a formal mechanism for interaction of the NBS with blood users, and it was proposed that Regional Transfusion Committees should be established. It was also proposed that a National Transfusion Committee be established to replace the National Blood User Group on the lines of recommendations by the WHO Blood Safety Unit for national committees on the clinical use of blood. The remit of these committees would be primarily focused on improving transfusion practice in hospitals, and supporting the implementation of the actions recommended in the Health Services Circular *'Better Blood Transfusion'*, although they retained the role of the Zonal and National Blood User Groups in monitoring the performance of the NBS.

An Interim National Transfusion Committee met on three occasions in 2000/01 with the remit of establishing the Regional and National Transfusion Committee structure by September 2001. Its membership included the ex-Chairmen and blood bank members of the NBUG and ZBUGs, providing a useful link with the previous User Group structure, and also with the clinical membership of the National Commissioning Group.

CMOs 2001 Blood Transfusion Seminar and Health Services Circular

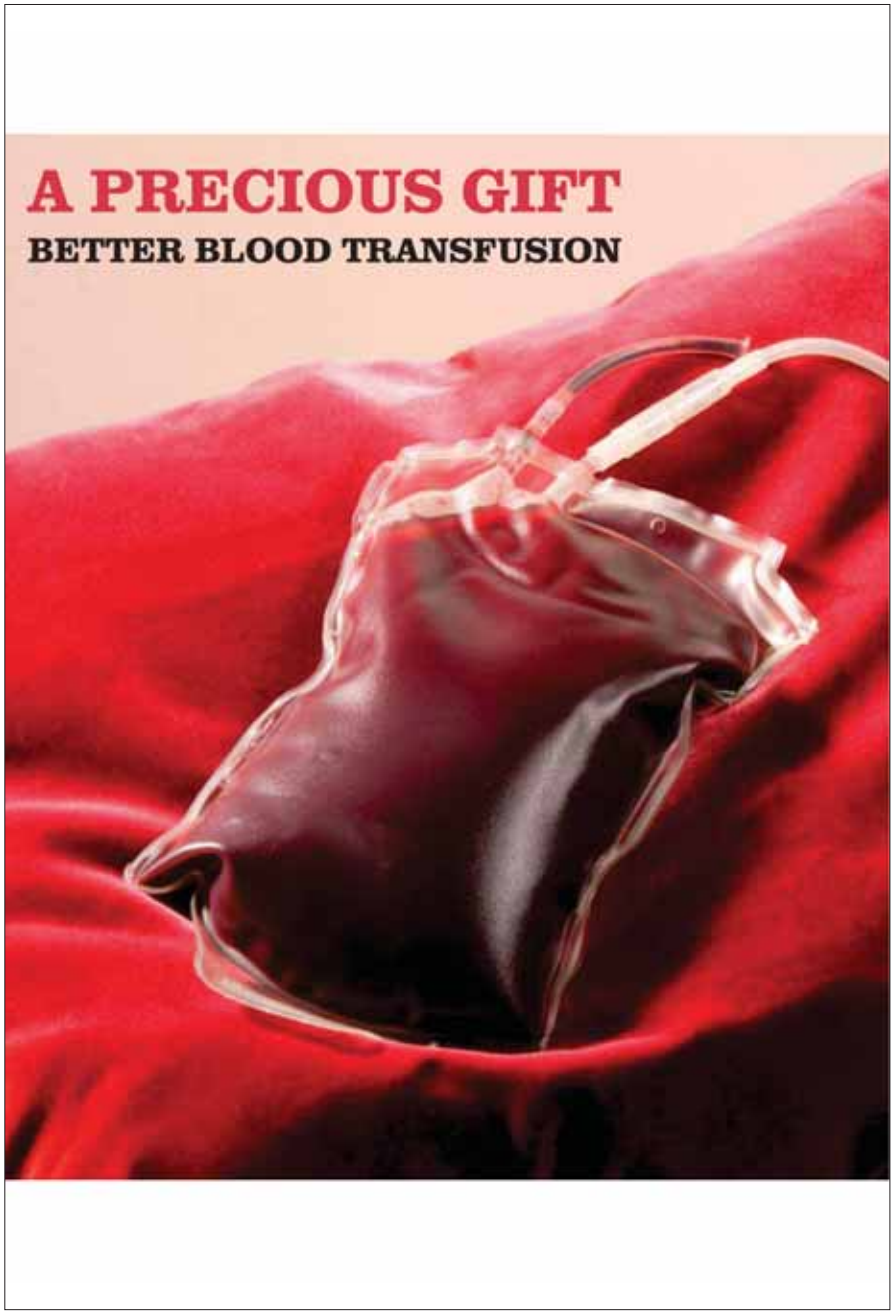
A second UK CMOs' Seminar on blood transfusion *'Better Blood Transfusion'* was held in London on 29th October 2001. It was attended by an invited multidisciplinary audience. The objective of the Seminar was to set the agenda for NHS transfusion services for the next three years by seeking the views of the audience, focusing on:-

- Providing better information to patients
- Avoiding unnecessary transfusion
- Making transfusion safer
- Ensuring *'Better Blood Transfusion'* is an integral part of NHS care

After introductory remarks by the 4 UK Chief Medical Officers, the Chief Executive of the National Audit Office (NAO) summarised their report on the NBS, and how the NAO had organised the Seminar in collaboration with the Department of Health and the NBS. He challenged the NBS to describe how it is meeting hospitals' demands for blood, support and medical advice. Martin Gorham (Chief Executive, NBS) responded by outlining how the NBS was implementing the

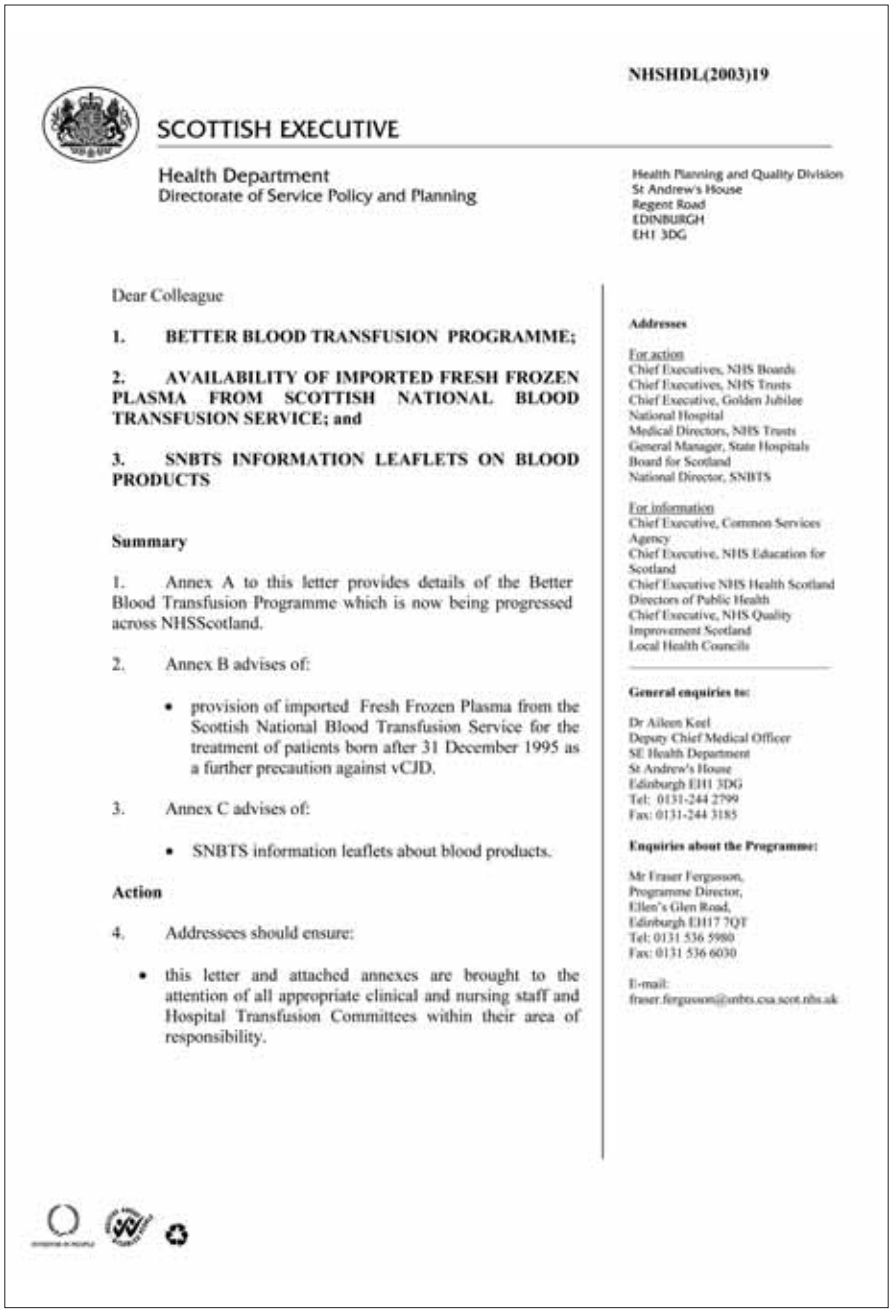
5.8.7 CMO's Annual Report on Better Blood Transfusion 2003-2004

Linked Material\appendix 5.8.7.pdf



5.8.8 Scottish Better Blood Transfusion 1998

Linked Material\appendix 5.8.8.pdf



NHSHDL(2003)19

SCOTTISH EXECUTIVE

Health Department
Directorate of Service Policy and Planning

Health Planning and Quality Division
St Andrew's House
Regent Road
EDINBURGH
EH1 3DG

Dear Colleague

1. **BETTER BLOOD TRANSFUSION PROGRAMME;**

2. **AVAILABILITY OF IMPORTED FRESH FROZEN PLASMA FROM SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE; and**

3. **SNBTS INFORMATION LEAFLETS ON BLOOD PRODUCTS**

Summary

1. Annex A to this letter provides details of the Better Blood Transfusion Programme which is now being progressed across NHSScotland.

2. Annex B advises of:

- provision of imported Fresh Frozen Plasma from the Scottish National Blood Transfusion Service for the treatment of patients born after 31 December 1995 as a further precaution against vCJD.

3. Annex C advises of:

- SNBTS information leaflets about blood products.

Action

4. Addressees should ensure:

- this letter and attached annexes are brought to the attention of all appropriate clinical and nursing staff and Hospital Transfusion Committees within their area of responsibility.

Addresses

For action
Chief Executives, NHS Boards
Chief Executives, NHS Trusts
Chief Executive, Golden Jubilee National Hospital
Medical Directors, NHS Trusts
General Manager, State Hospitals Board for Scotland
National Director, SNBTS

For information
Chief Executive, Common Services Agency
Chief Executive, NHS Education for Scotland
Chief Executive NHS Health Scotland
Directors of Public Health
Chief Executive, NHS Quality Improvement Scotland
Local Health Councils

General enquiries to:

Dr Aileen Keel
Deputy Chief Medical Officer
SE Health Department
St Andrew's House
Edinburgh EH1 3DG
Tel: 0131-244 2799
Fax: 0131-244 3185

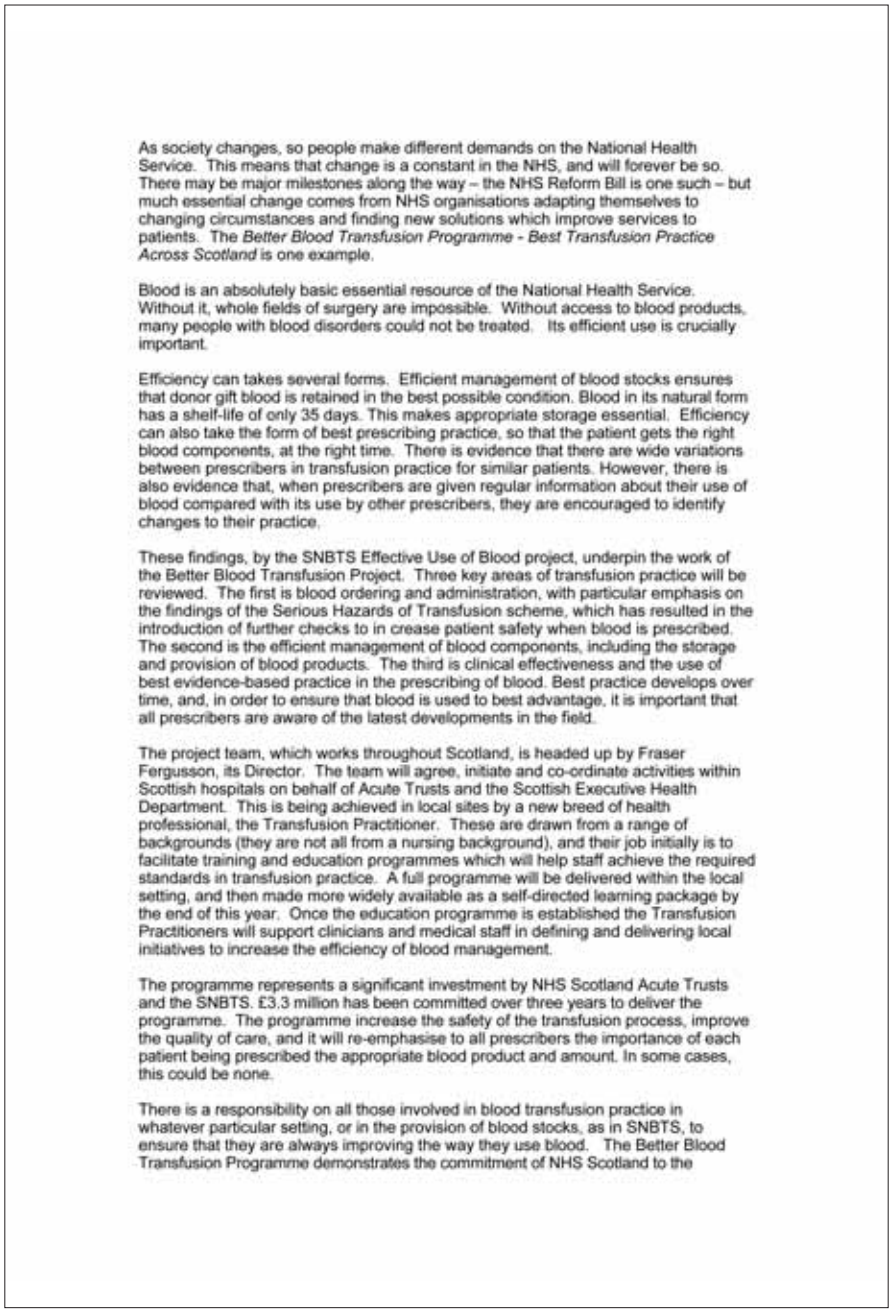
Enquiries about the Programme:

Mr Fraser Fergusson,
Programme Director,
Ellen's Glen Road,
Edinburgh EH17 7QT
Tel: 0131 536 5980
Fax: 0131 536 6030

E-mail:
fraser.fergusson@snbts.csa.scot.nhs.uk

5.8.9 Scottish Better Blood Transfusion Program 2004

Linked Material\appendix 5.8.9.pdf



As society changes, so people make different demands on the National Health Service. This means that change is a constant in the NHS, and will forever be so. There may be major milestones along the way – the NHS Reform Bill is one such – but much essential change comes from NHS organisations adapting themselves to changing circumstances and finding new solutions which improve services to patients. The *Better Blood Transfusion Programme - Best Transfusion Practice Across Scotland* is one example.

Blood is an absolutely basic essential resource of the National Health Service. Without it, whole fields of surgery are impossible. Without access to blood products, many people with blood disorders could not be treated. Its efficient use is crucially important.

Efficiency can takes several forms. Efficient management of blood stocks ensures that donor gift blood is retained in the best possible condition. Blood in its natural form has a shelf-life of only 35 days. This makes appropriate storage essential. Efficiency can also take the form of best prescribing practice, so that the patient gets the right blood components, at the right time. There is evidence that there are wide variations between prescribers in transfusion practice for similar patients. However, there is also evidence that, when prescribers are given regular information about their use of blood compared with its use by other prescribers, they are encouraged to identify changes to their practice.

These findings, by the SNBTS Effective Use of Blood project, underpin the work of the Better Blood Transfusion Project. Three key areas of transfusion practice will be reviewed. The first is blood ordering and administration, with particular emphasis on the findings of the Serious Hazards of Transfusion scheme, which has resulted in the introduction of further checks to in crease patient safety when blood is prescribed. The second is the efficient management of blood components, including the storage and provision of blood products. The third is clinical effectiveness and the use of best evidence-based practice in the prescribing of blood. Best practice develops over time, and, in order to ensure that blood is used to best advantage, it is important that all prescribers are aware of the latest developments in the field.

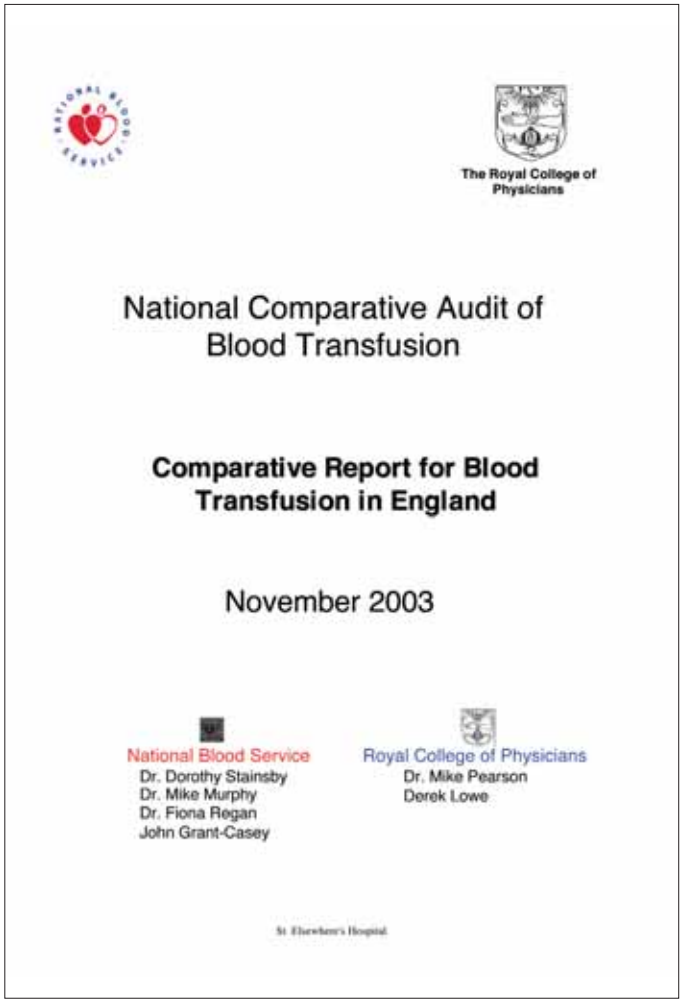
The project team, which works throughout Scotland, is headed up by Fraser Fergusson, its Director. The team will agree, initiate and co-ordinate activities within Scottish hospitals on behalf of Acute Trusts and the Scottish Executive Health Department. This is being achieved in local sites by a new breed of health professional, the Transfusion Practitioner. These are drawn from a range of backgrounds (they are not all from a nursing background), and their job initially is to facilitate training and education programmes which will help staff achieve the required standards in transfusion practice. A full programme will be delivered within the local setting, and then made more widely available as a self-directed learning package by the end of this year. Once the education programme is established the Transfusion Practitioners will support clinicians and medical staff in defining and delivering local initiatives to increase the efficiency of blood management.

The programme represents a significant investment by NHS Scotland Acute Trusts and the SNBTS. £3.3 million has been committed over three years to deliver the programme. The programme increase the safety of the transfusion process, improve the quality of care, and it will re-emphasise to all prescribers the importance of each patient being prescribed the appropriate blood product and amount. In some cases, this could be none.

There is a responsibility on all those involved in blood transfusion practice in whatever particular setting, or in the provision of blood stocks, as in SNBTS, to ensure that they are always improving the way they use blood. The Better Blood Transfusion Programme demonstrates the commitment of NHS Scotland to the

5.8.10 National audit of blood transfusion practices

Linked Material\appendix 5.8.10.pdf



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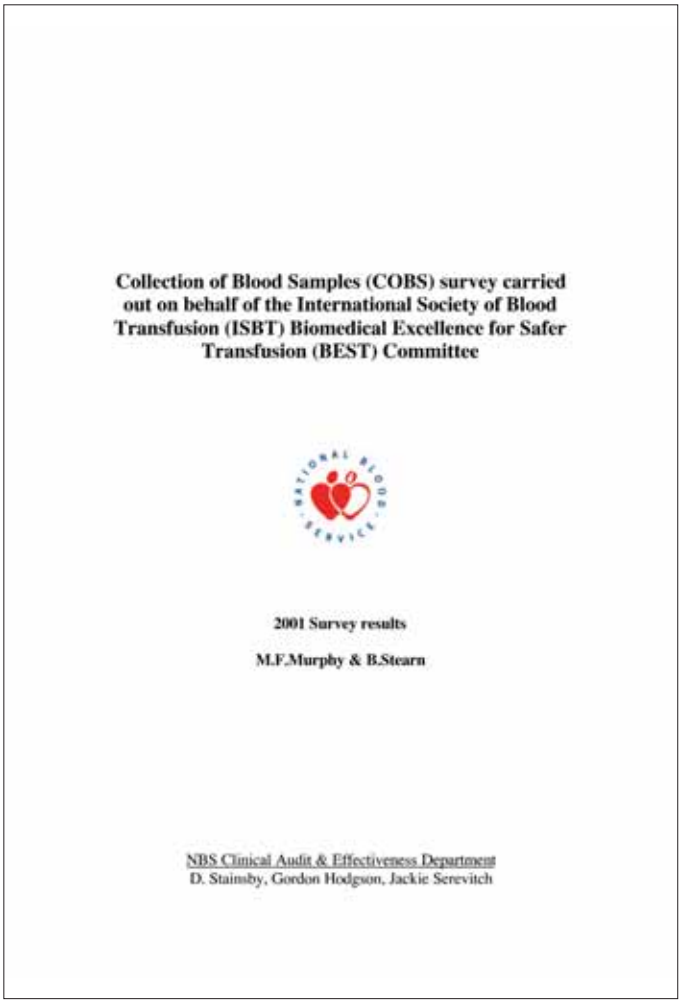
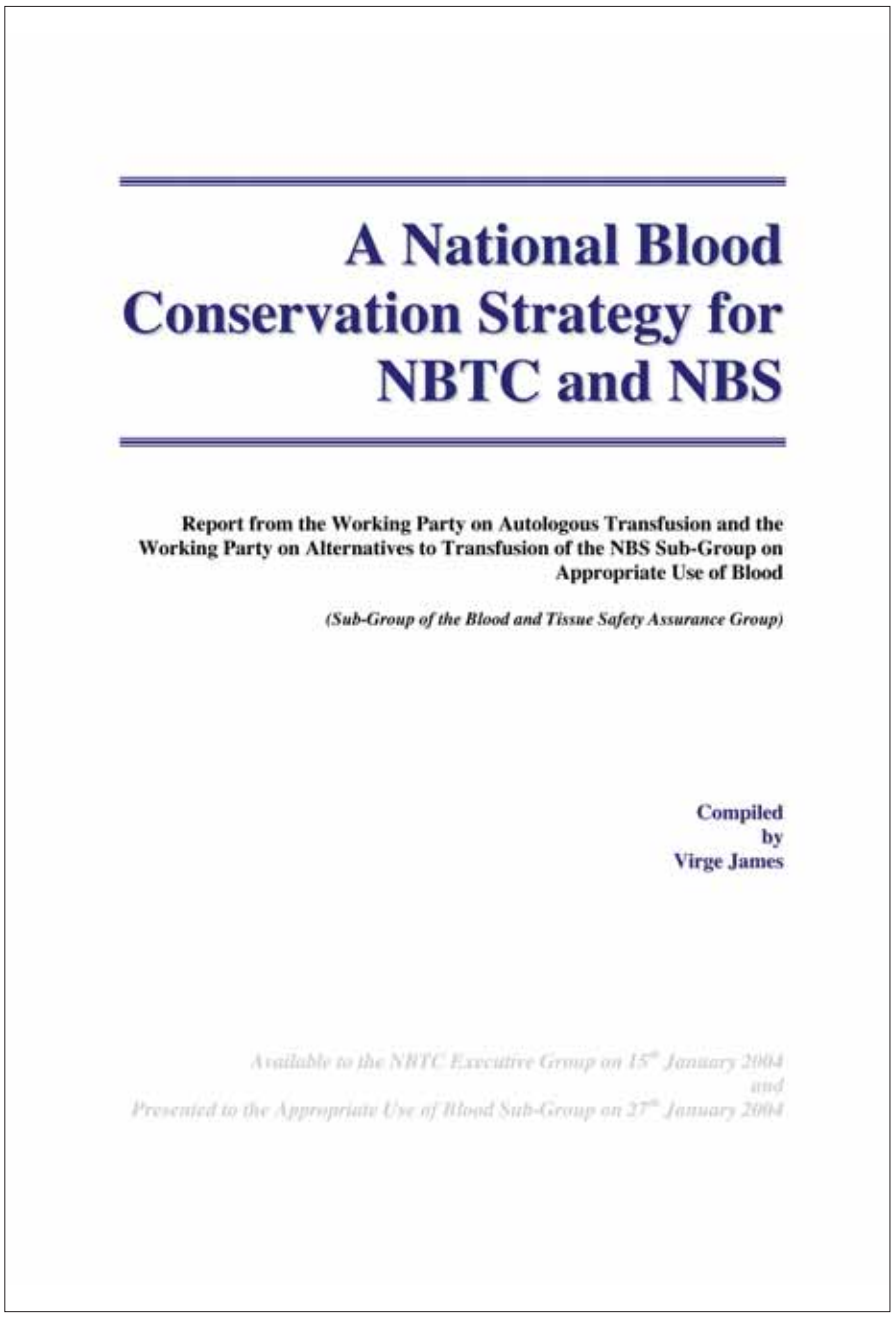


5.8.11 Blood conservation strategies for the NBTS and NBA

Linked Material\appendix5.8.11.pdf



A National Blood Conservation Strategy for NBTC and NBS

Report from the Working Party on Autologous Transfusion and the Working Party on Alternatives to Transfusion of the NBS Sub-Group on Appropriate Use of Blood

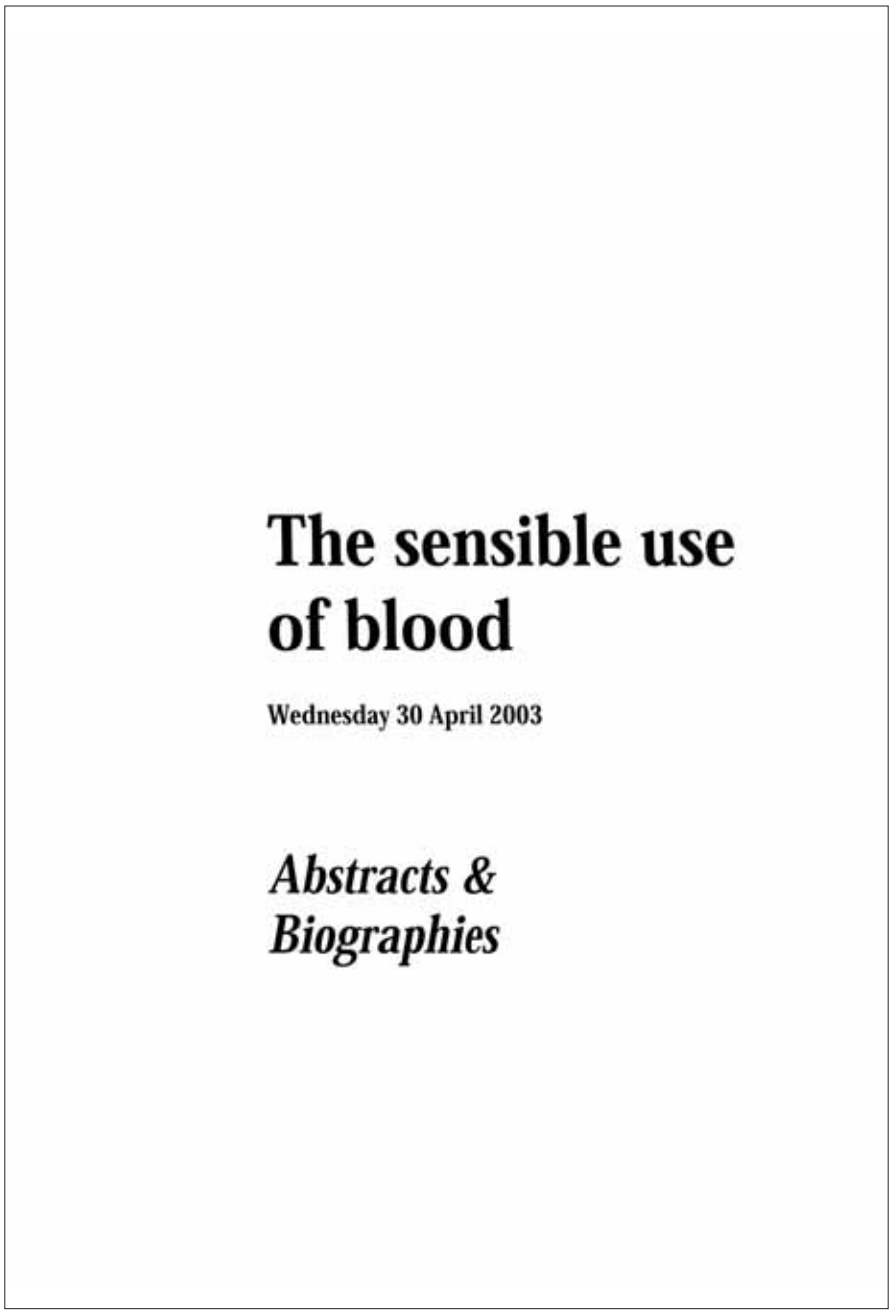
(Sub-Group of the Blood and Tissue Safety Assurance Group)

Compiled by Virge James

Available to the NBTC Executive Group on 15th January 2004 and Presented to the Appropriate Use of Blood Sub-Group on 27th January 2004

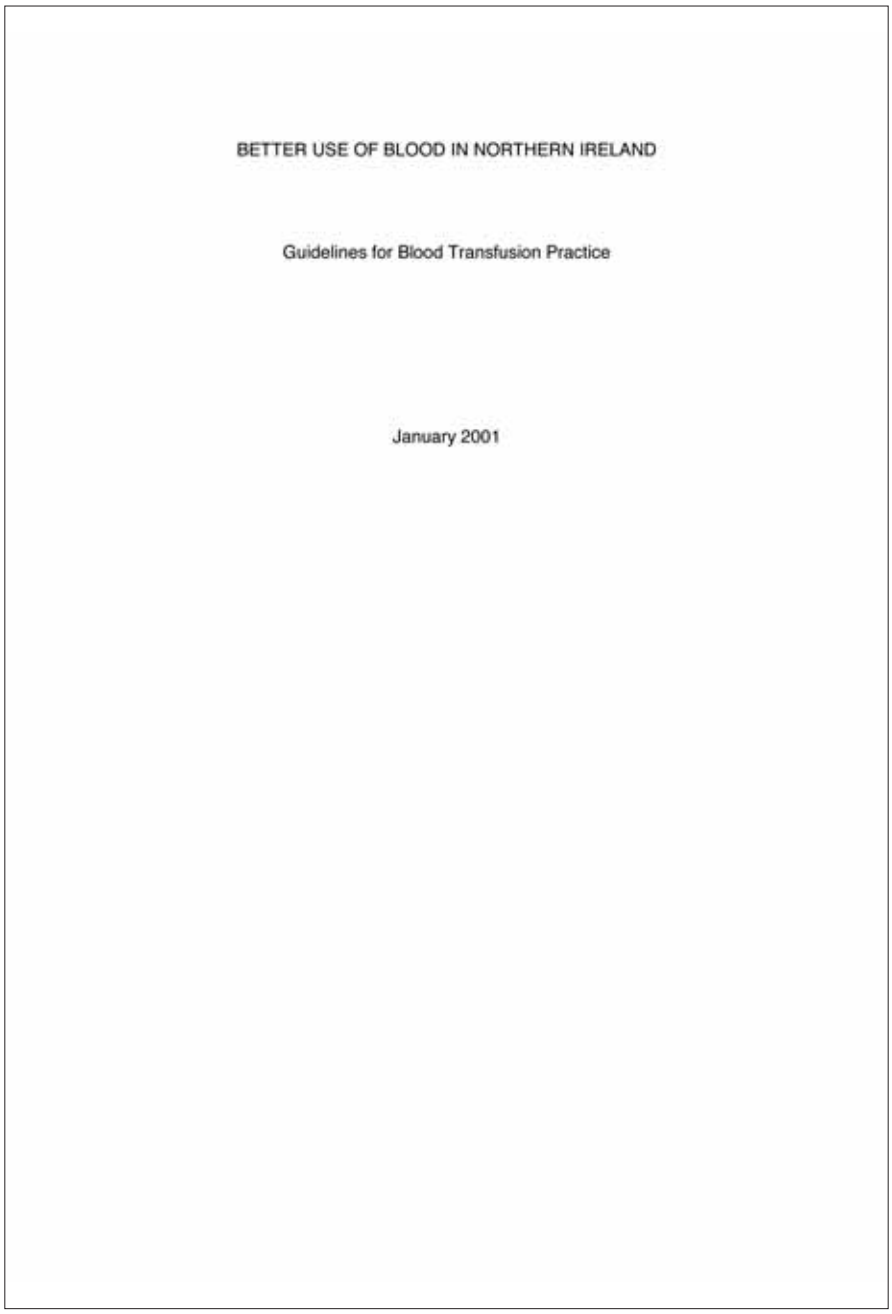
5.8.12 The Sensible Use of Blood 2003

Linked Material\appendix 5.8.12.pdf



5.8.13 Better use of blood in Northern Ireland

Linked Material\appendix 5.8.13.pdf



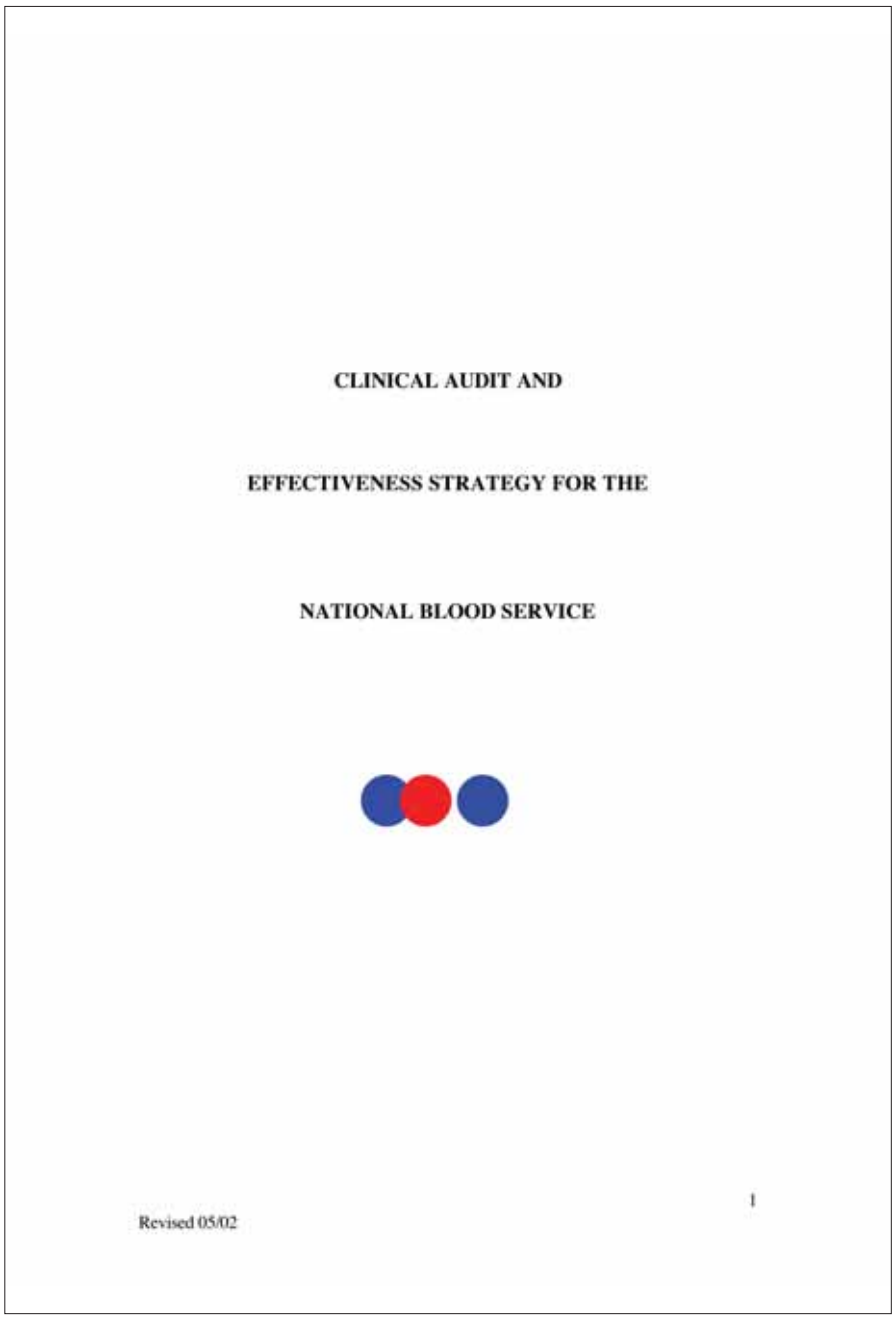
BETTER USE OF BLOOD IN NORTHERN IRELAND

Guidelines for Blood Transfusion Practice

January 2001

5.8.14 Clinical audit and effectiveness strategy for the National Blood Service

Linked Material\appendix 5.8.14.pdf



CLINICAL AUDIT AND

EFFECTIVENESS STRATEGY FOR THE

NATIONAL BLOOD SERVICE

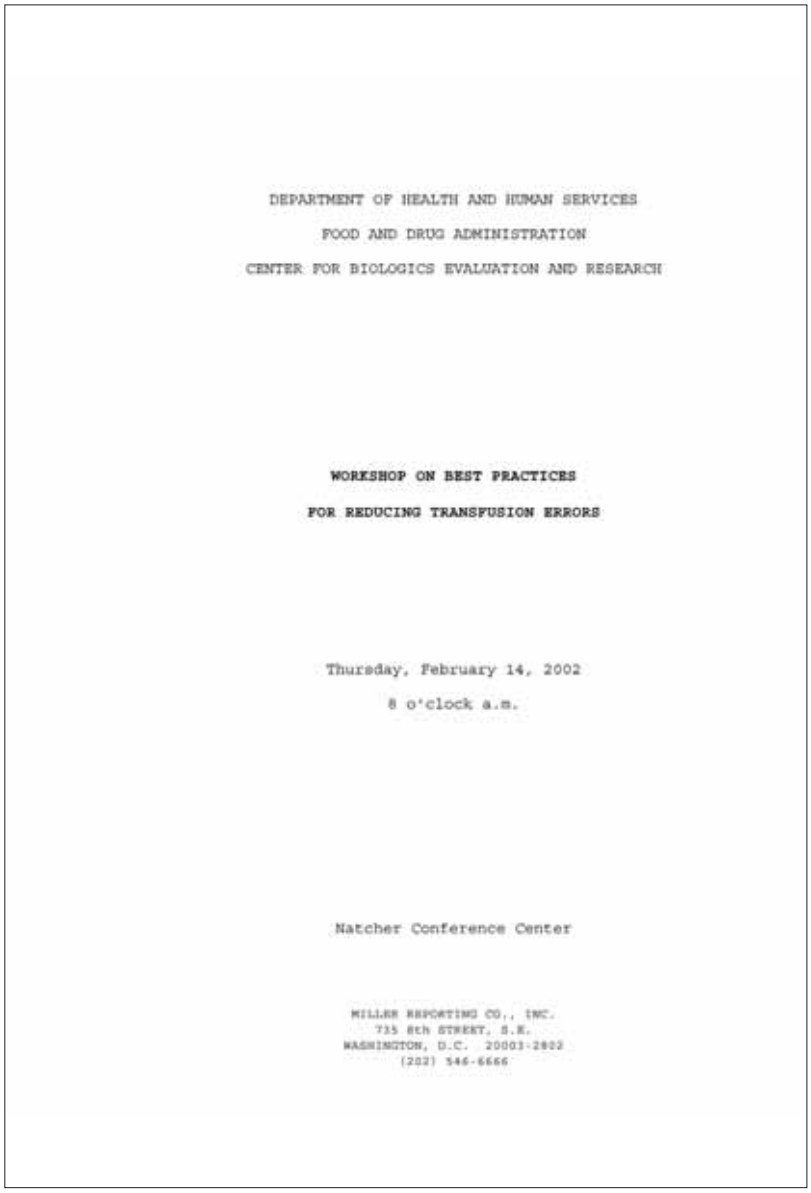
Revised 05/02

1

5.9 North American initiatives

5.9.1 Department of Health and Human Services, Food and Drug Administration and Center for Biologics Evaluation and Research: Workshop on Best Practices for Reducing Transfusion Errors

Linked Material\appendix 5.9.1.pdf.pdf



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

WORKSHOP ON BEST PRACTICES

FOR REDUCING TRANSFUSION ERRORS

Thursday, February 14, 2002

8 o'clock a.m.

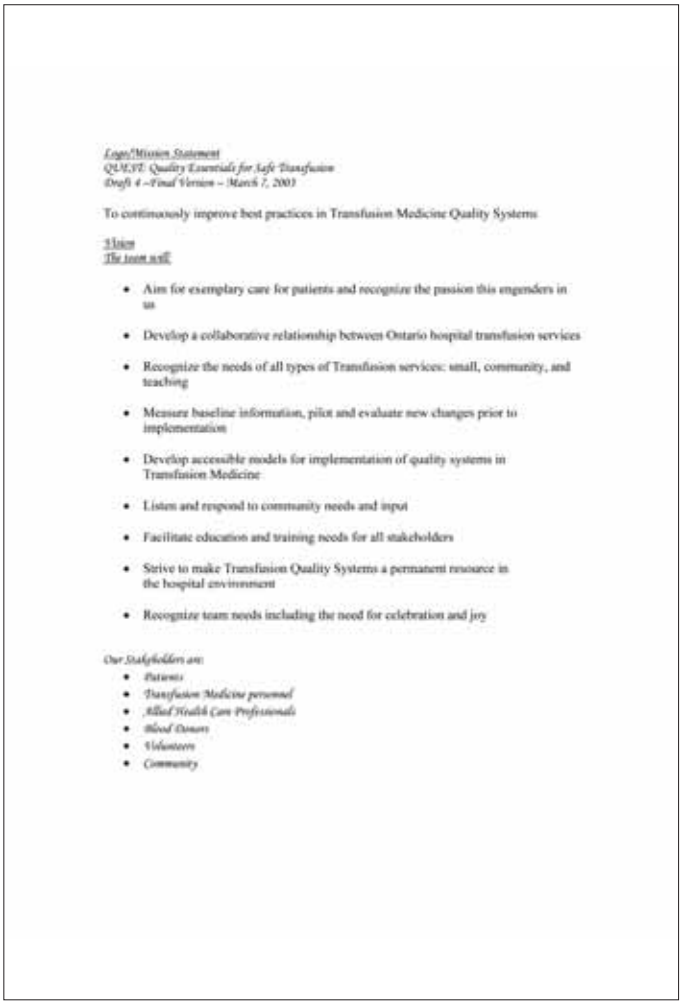
Natcher Conference Center

MILLER REPORTING CO., INC.
735 8th STREET, S.E.
WASHINGTON, D.C. 20003-2802
(202) 546-6666

5.9.2 Transfusion Ontario Programs

Linked Material\appendix 5.9.2a.pdf

Linked Material\appendix 5.9.2b.pdf



Logo/Mission Statement
QUEST: Quality Essentials for Safe Transfusion
Draft 4 – Final Version – March 7, 2003

To continuously improve best practices in Transfusion Medicine Quality Systems

Vision
The team will:

- Aim for exemplary care for patients and recognize the passion this engenders in us
- Develop a collaborative relationship between Ontario hospital transfusion services
- Recognize the needs of all types of Transfusion services: small, community, and teaching
- Measure baseline information, pilot and evaluate new changes prior to implementation
- Develop accessible models for implementation of quality systems in Transfusion Medicine
- Listen and respond to community needs and input
- Facilitate education and training needs for all stakeholders
- Strive to make Transfusion Quality Systems a permanent resource in the hospital environment
- Recognize team needs including the need for celebration and joy

Our Stakeholders are:

- *Patients*
- *Transfusion Medicine personnel*
- *Allied Health Care Professionals*
- *Blood Donors*
- *Volunteers*
- *Community*

Linked Material\appendix 5.9.2c.pdf

QUEST-Quality Essentials for Safe Transfusion

QUEST Newsletter

Volume 1 Issue 2 | Hamilton Niagara Site | November 2003

Special Points of Interest Featured Inside this Issue

IERS VS. MERS

The Hamilton hospitals have pursued the development of an error management system based on the MERS-TM System (Medical Event Reporting System-Transfusion Medicine).

MERS-TM was developed in 1995 through a grant by the Heart, Lung and Blood Institute in the United States. It is an actual event reporting system for the collecting, classifying and analyzing of events. The MERS website, www.mers-tm.net, is extensive, offering educational resources and support.

The QUEST project team was able to design a pilot with this question in mind:

Can Hamilton improve its current system of documenting, investigating and analyzing errors/events relating to the provision of a safe blood transfusion?

MERS-TM and the in-house event reporting system (IERS) ran parallel over a 6 month period in 2002 at two sites in Hamilton. Reporting frequency, code specificity, forms, data entry approaches and examples of reports were compared.

MERS offers: 96 codes to identify errors along the path of workflow, a risk assessment tool and sophisticated root cause codes. IERS consists of 23 TM specific categories that were grouped as low or high risk. MERS-TM permits benchmarking; the IERS does not. MERS-TM is on line and allows for user defined real-time report generation. IERS system is paper based with data being entered at a centrally located MS Access database.

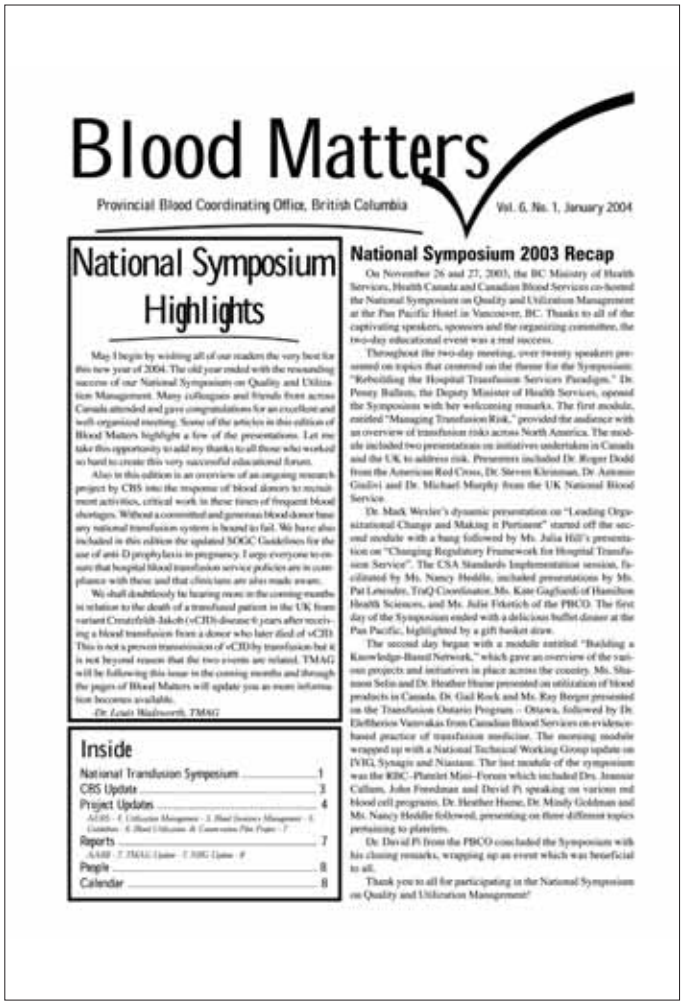
After the 6 month pilot the data was presented to a coordinating committee chaired by Dr. M. Blajchman, Head of Service, Transfusion Medicine. The decision was made to implement MERS-TM at all 4 sites. The former IERS system data collection ended January 1st, 2003. The transition to MERS has seen no decrease in error reporting. It is capturing reports in the same frequency and in a non-punitive environment.

Regional Transfusion Service Network for Sharing

On November 19th 2003, a practical, educational day will be hosted by the QUEST and McMaster Transfusion Research Program (MTRP) team members. The primary objective of this innovative day is to set up a network to enable sharing actual, tangible tools as people focus on quality improvement, building quality systems and introducing utilization initiatives. The agenda was built by the feedback received from the partners in this future network. The answers to the short survey QUEST sent out have contributed to the mapping of the day. This Regional Networking Day is the first step on the road to achieving QUEST's vision of a provincial system for Ontario hospital transfusion services. Excellent ground breaking work has been done by various groups throughout the province to date. "Let's help each other", a phrase that translates into a sharing of tools already developed. Hopefully November 19th will be the first of many such meetings as Transfusion Medicine Specialists in Ontario come together to share ideas and discuss common, workable solutions.

5.9.3 Provincial Blood Coordinating Office Programs; British Columbia

Linked Material\appendix 5.9.3a.pdf



Blood Matters

Provincial Blood Coordinating Office, British Columbia — Vol. 6, No. 1, January 2004

National Symposium Highlights

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National Symposium 2003 Recap

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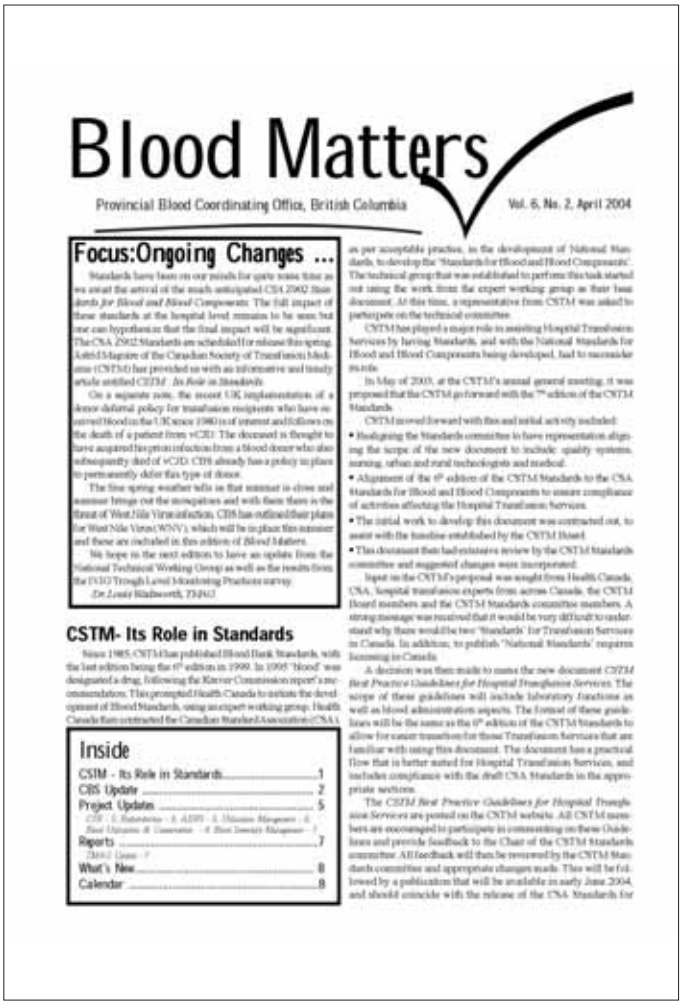

Blood Matters

Provincial Blood Coordinating Office, British Columbia — Vol. 6, No. 2, April 2004

Focus:Ongoing Changes ...

CSTM- Its Role in Standards

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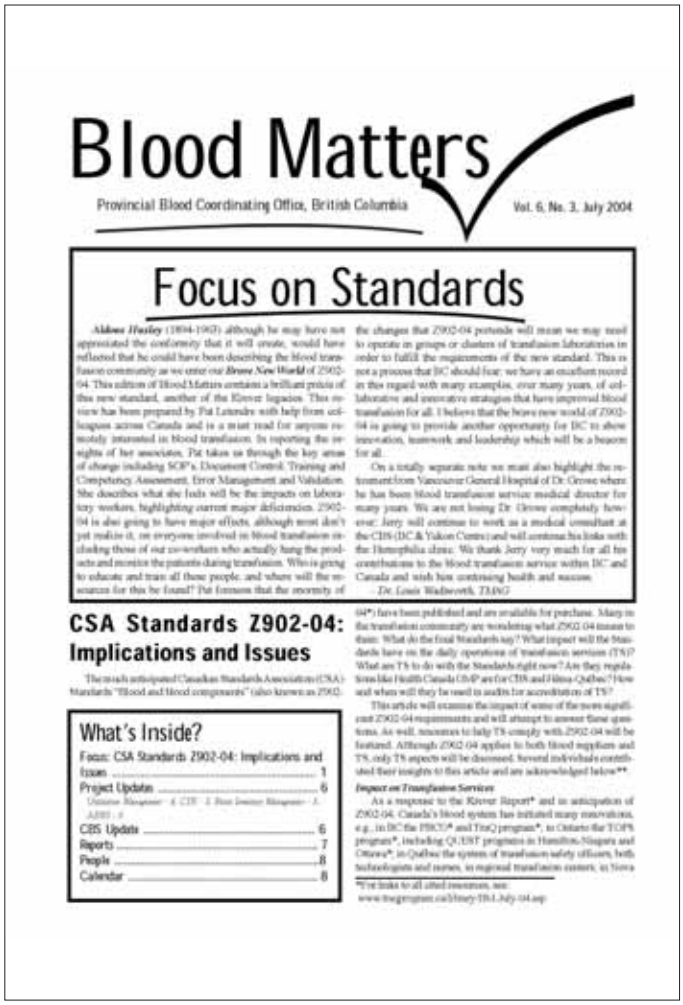


Blood Matters

Provincial Blood Coordinating Office, British Columbia — Vol. 6, No. 3, July 2004

Focus on Standards

Aldous Huxley (1894-1963), although he may have not appreciated the conformity that it will create, would have reflected that he could have been describing the blood transfusion community as we enter our *Brave New World* of Z902-04. This edition of Blood Matters contains a brilliant précis of this new standard, another of the Rivver legacies. This review has been prepared by Pat Lavender with help from colleagues across Canada and is a must read for anyone remotely interested in blood transfusion. In reporting the insights of her associates, Pat takes us through the key areas of change including SOP's, Document Control, Training and Competency Assessment, Error Management and Validation. She describes what she feels will be the impacts on laboratory workers, highlighting current major deficiencies. Z902-04 is also going to have major effects, although most don't yet realize it, on everyone involved in blood transfusion including those of our co-workers who actually hang the products and monitor the patients during transfusion. Who is going to educate and train all these people, and where will the resources for this be found? Pat foresees that the enormity of the changes that Z902-04 portends will mean we may need to operate in groups or clusters of transfusion laboratories in order to fulfill the requirements of the new standard. This is not a process that BC should fear; we have an excellent record in this regard with many examples, over many years, of collaborative and innovative strategies that have improved blood transfusion for all. I believe that the brave new world of Z902-04 is going to provide another opportunity for BC to show innovation, teamwork and leadership which will be a beacon for all.

On a totally separate note we must also highlight the retirement from Vancouver General Hospital of Dr. Growe where he has been blood transfusion service medical director for many years. We are not losing Dr. Growe completely however; Jerry will continue to work as a medical consultant at the CBS (BC & Yukon Centre) and will continue his links with the Hemophilia clinic. We thank Jerry very much for all his contributions to the blood transfusion service within BC and Canada and wish him continuing health and success.

– Dr. Louis Wadsworth, TSMG

CSA Standards Z902-04: Implications and Issues

The much anticipated Canadian Standards Association (CSA) Standards "Blood and blood components" (also known as Z902-04*) have been published and are available for purchase. Many in the transfusion community are wondering what Z902-04 means to them: What do the final Standards say? What impact will the Standards have on the daily operations of transfusion services (TS)? What are TS to do with the Standards right now? Are they regulations like Health Canada (HC)* are for CBS and Héma-Québec? How and when will they be used in audits for accreditation of TS?

This article will examine the impact of some of the more significant Z902-04 requirements and will attempt to answer these questions. As well, resources to help TS comply with Z902-04 will be featured. Although Z902-04 applies to both blood suppliers and TS, only TS aspects will be discussed. Several individuals contributed their insights to this article and are acknowledged below.**

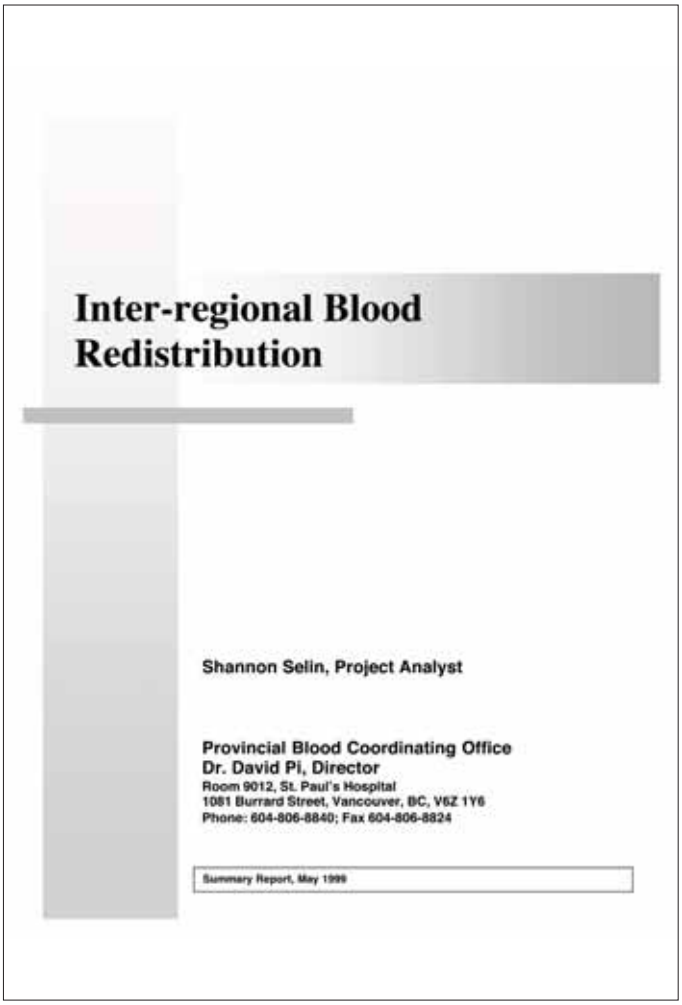
Impact on Transfusion Services

As a response to the Rivver Report* and in anticipation of Z902-04, Canada's blood system has initiated many innovations, e.g., in BC the PBCO* and TraQ program*, in Ontario the TOPS program*, including QUEST programs in Hamilton-Niagara and Ottawa*; in Québec the system of transfusion safety officers, both technologists and nurses, in regional transfusion centers; in Nova

*For links to all cited resources, see: www.bsegroup.ca/bmay-JA1-July-04.asp

What's Inside?

Linked Material\appendix 5.9.3d.pdf



Inter-regional Blood Redistribution

Shannon Selin, Project Analyst

Provincial Blood Coordinating Office
Dr. David Pi, Director
Room 9012, St. Paul's Hospital
1081 Burrard Street, Vancouver, BC, V6Z 1Y6
Phone: 604-806-8840; Fax 604-806-8824

Summary Report, May 1999

Linked Material\appendix 5.9.3e.pdf

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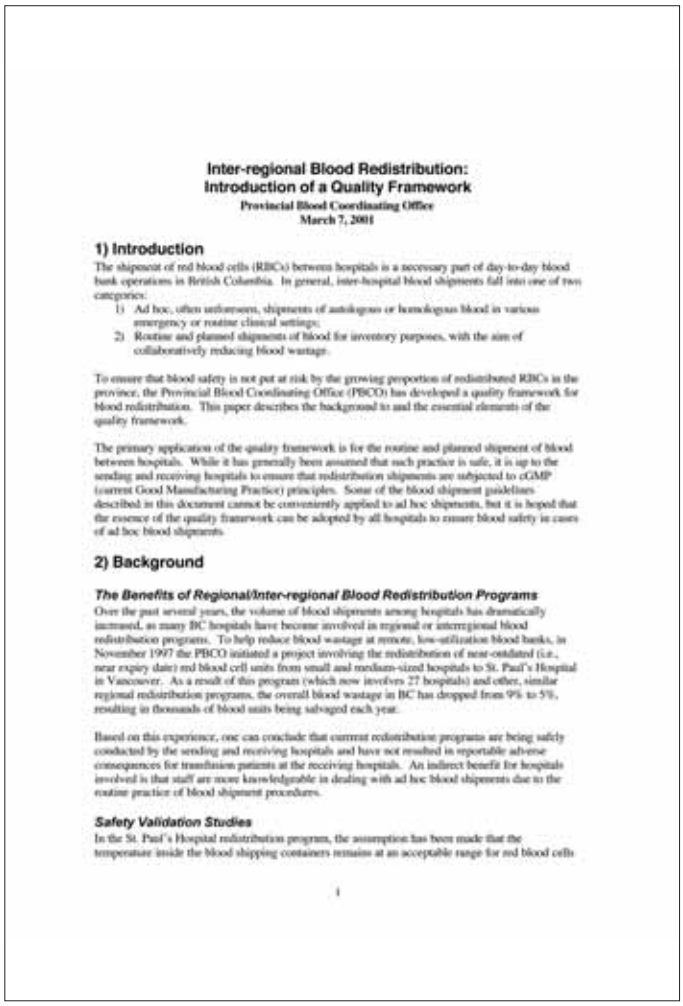


Inter-regional Blood Redistribution:
Introduction of a Quality Framework

Provincial Blood Coordinating Office
March 7, 2001

1) Introduction

The shipment of red blood cells (RBCs) between hospitals is a necessary part of day-to-day blood bank operations in British Columbia. In general, inter-hospital blood shipments fall into one of two categories:

1) Ad hoc, often unforeseen, shipments of autologous or homologous blood in various emergency or routine clinical settings;
2) Routine and planned shipments of blood for inventory purposes, with the aim of collaboratively reducing blood wastage.

To ensure that blood safety is not put at risk by the growing proportion of redistributed RBCs in the province, the Provincial Blood Coordinating Office (PBCO) has developed a quality framework for blood redistribution. This paper describes the background to and the essential elements of the quality framework.

The primary application of the quality framework is for the routine and planned shipment of blood between hospitals. While it has generally been assumed that such practice is safe, it is up to the sending and receiving hospitals to ensure that redistribution shipments are subjected to cGMP (current Good Manufacturing Practice) principles. Some of the blood shipment guidelines described in this document cannot be conveniently applied to ad hoc shipments, but it is hoped that the essence of the quality framework can be adopted by all hospitals to ensure blood safety in cases of ad hoc blood shipments.

2) Background

The Benefits of Regional/Inter-regional Blood Redistribution Programs

Over the past several years, the volume of blood shipments among hospitals has dramatically increased, as many BC hospitals have become involved in regional or interregional blood redistribution programs. To help reduce blood wastage at remote, low-utilization blood banks, in November 1997 the PBCO initiated a project involving the redistribution of near-outdated (i.e., near expiry date) red blood cell units from small and medium-sized hospitals to St. Paul's Hospital in Vancouver. As a result of this program (which now involves 27 hospitals) and other, similar regional redistribution programs, the overall blood wastage in BC has dropped from 9% to 5%, resulting in thousands of blood units being salvaged each year.

Based on this experience, one can conclude that current redistribution programs are being safely conducted by the sending and receiving hospitals and have not resulted in reportable adverse consequences for transfusion patients at the receiving hospitals. An indirect benefit for hospitals involved is that staff are more knowledgeable in dealing with ad hoc blood shipments due to the routine practice of blood shipment procedures.

Safety Validation Studies

In the St. Paul's Hospital redistribution program, the assumption has been made that the temperature inside the blood shipping containers remains at an acceptable range for red blood cells

List of Approved Medical Conditions for IVIG Use

General Prerequisites for IVIG Use:

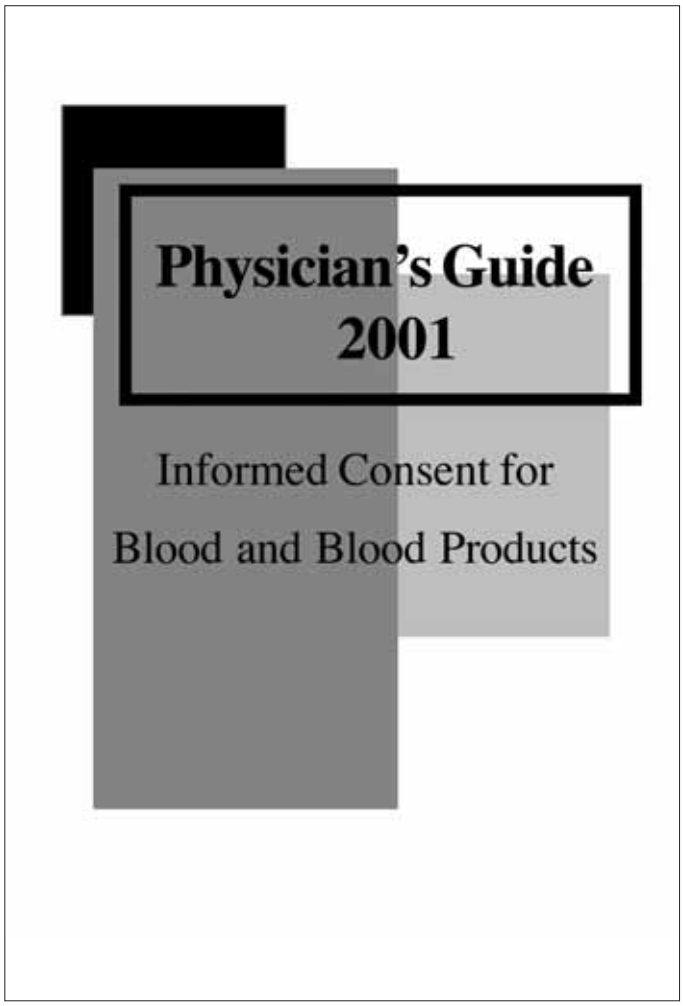
1) A definitive diagnosis must be confirmed.
2) For immune deficiency conditions, serum IgG levels must be clinically assessed to ensure optimum dosing.
3) For all other conditions, IVIG should be used only when other, less expensive, equally safe and efficacious alternative therapy has failed. The use of IVIG should be the exception, rather than the rule.
4) There must be regular clinical outcome assessment. For conditions requiring approval by the IVIG Centre, the clinical outcome must be subject to peer review for continuation of the therapy.

Specialty	Medical Condition	Prerequisite Guidelines
Immunology	Primary immune deficiency conditions	- Hypogammaglobulinemia (reduced total IgG or IgG subclasses) with recurrent bacterial infection
	Secondary immune deficiency conditions	- Monitor IgG trough level to maintain low normal range
Hematology	Idiopathic thrombocytopenic purpura (ITP) - adult	- Persistent or potentially life-threatening hemorrhage with platelet <30 x 10⁹/L - For patients with no sign of severe hemorrhage, IVIG is not considered first line treatment. IVIG is used when the patient is unresponsive to corticosteroid treatment and/or RhIG, or when these therapies are contraindicated.
	Idiopathic thrombocytopenic purpura (ITP) - pediatric	- Acute ITP: IVIG may be considered as initial therapy if platelet count <20 x 10⁹/L, especially when patient has emergency bleeding or is at risk for severe life threatening bleeding. IVIG not indicated if only mild manifestations of bleeding. - Chronic ITP: IVIG indicated in high-risk patients when platelet count low or patient symptomatic; also if failure of other therapies or when patient high risk for post-splenectomy sepsis (<5 years)
	Allogeneic stem cell or bone marrow transplantation (BMT)	- For prevention of GVHD in patients receiving matched HLA allogeneic BMT - For prevention of CMV infection: most benefit seen in low-risk patients (i.e., seronegative recipients receiving seronegative blood products and no leukocyte transfusion) - IVIG is not indicated in autologous transplantation
	Hemolytic disease of the newborn (HDN)	- IVIG may be indicated in infants with severe HDN not responding to phototherapy to decrease the need for exchange transfusion. Physician discretion important in deciding right course of treatment.
Neurology	Guillain-Barré syndrome (GBS), including Miller-Fisher syndrome (MFS), paraneoplastic polyneuropathy	- Severe GBS with significant weakness such as non-ambulatory or respiratory or bulbar weakness or cranial polyneuritis (MFS), or imminent or actual loss of ability to stand or walk - Treatment preferable in first 2 weeks of illness
	Chronic inflammatory demyelinating polyradiculo-neuropathy (CIDP), including MADSAM variant	- Symmetric or focal neurologic deficits with slowly progressive or relapsing course over 2 months or longer with neurophysiological abnormalities
	Myasthenia gravis (MG), including Lambert Eaton myasthenic syndrome (LEMS)	- Autoimmune MG: ocular or generalized or myasthenic crisis - IVIG not indicated for use in transient, neonatal or congenital MG - For LEMS, IVIG is used as an alternative to plasma exchange if weakness is severe and not responsive to anticholinesterases and 3,4 Diaminopyridine
	Multifocal motor neuropathy (with conduction block)	- IVIG treatment of choice at time of diagnosis. Patients who do not respond to initial infusion are unlikely to improve with further doses.
Rheumatology	Dermatomyositis (DM)	- Aggressive disease requiring hospitalization. At any time, life-threatening manifestations not responding to high-dose corticosteroids, i.e., life-threatening esophageal, respiratory or bulbar musculature involvement. - Lack of response or contraindication to corticosteroids, Methotrexate and/or Azathioprine therapy
	Juvenile dermatomyositis	- Lack of response or contraindication to corticosteroids, Methotrexate and/or Azathioprine therapy
	Kawasaki disease (KD)	- The validity of the diagnosis must be established - The treatment of choice at the time of diagnosis. A second dose can be given for patients who fail to respond the first time.
Dermatology	Pemphigus vulgaris	- Firm histological and immuno-diagnosis - Lack of response or contraindication to corticosteroids and immunosuppressive agents
Obstetrics & Gynecology	Fetal alloimmune thrombocytopenia (FAIT)	- Previous pregnancy affected and father homozygous for HPA-1a OR at 20 weeks corticosteroids reveals fetal platelets <100 x 10⁹/L
Infectious Diseases	Staphylococcal toxic shock syndrome	- Evidence of systemic inflammation and end organ hypoperfusion with fever, tachycardia, tachypnea, impaired mention, oliguria and hypotension - Advisable to consult with a medical microbiologist or infectious disease specialist before IVIG treatment
	Invasive Group A streptococcal fasciitis and septicemia	

Use of IVIG for conditions not listed above or in cases where the prerequisites are not met must be approved by the IVIG Centre, telephone 604-682-2344 ext. 62961, fax 604-806-8826.

The information on this card is from the IVIG Utilization Management Handbook - First Edition (1999), produced by the BC Provincial Blood Coordinating Office.

Linked Material\appendix 5.9.3g.pdf



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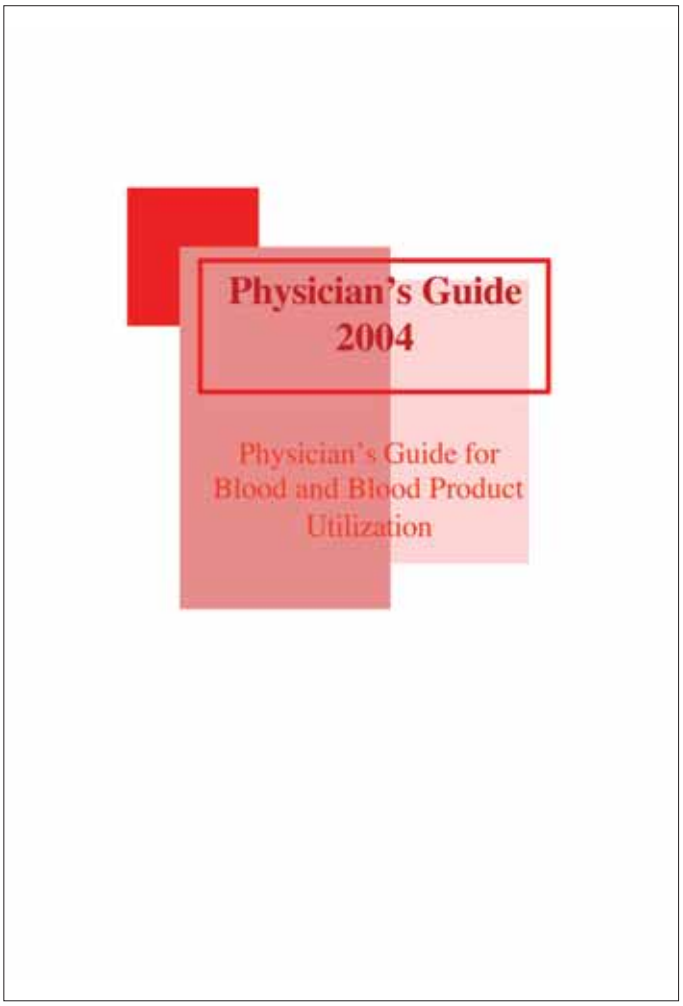

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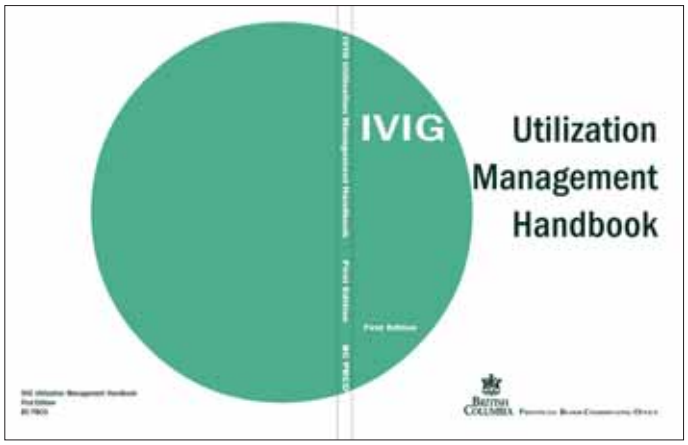

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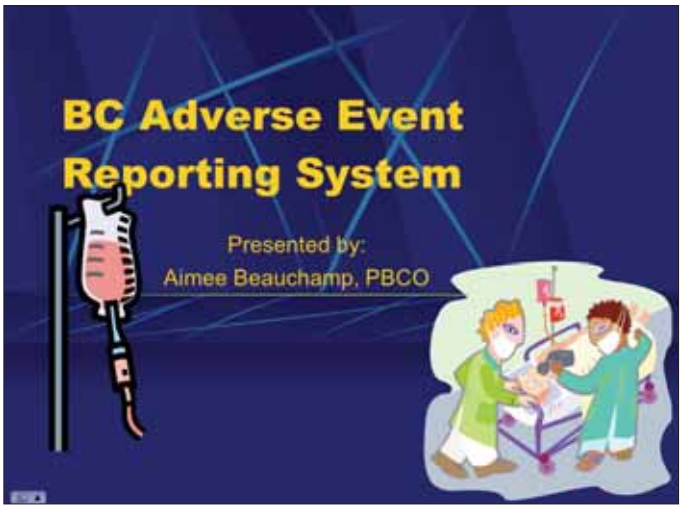

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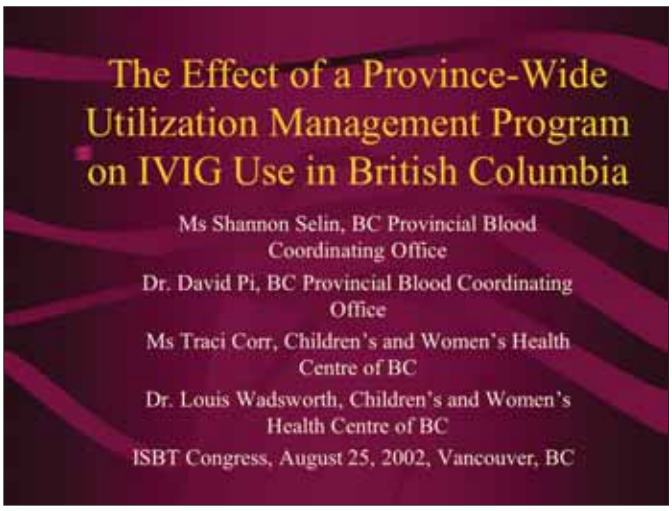


5.9.4 Non-infectious hazards of transfusion

Linked Material\appendix 5.9.4.pdf

BLOOD BULLETIN
VOL. 5 NO. 1 MAY 2002
PROVIDED BY YOUR INDEPENDENT,
NONPROFIT COMMUNITY BLOOD CENTER
in conjunction with America's Blood Centers ®

NON-INFECTIOUS SERIOUS HAZARDS OF TRANSFUSION

Sunny Dzik, M.D.

Safe transfusion therapy is a basic requirement for advanced medical care. In order to establish priorities for improving safe transfusion for patients, it is essential to distinguish transfusion safety from blood safety. Blood safety refers to the safety of the product. In contrast, transfusion safety refers to the safety of the overall process of transfusion from donor to recipient.[1]

Blood safety is not matched by increases in transfusion safety. Enormous progress has been made in blood safety during the last few decades. Donor restrictions and high performance viral screening assays have virtually eliminated viral transmission by blood transfusion in the developed world. For example, the risk of hepatitis or HIV from transfusion has declined by approximately 10,000 fold.

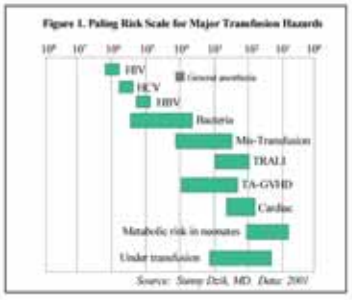
In contrast, during the same period there has been little change in the risk of non-infectious hazards. Some result from medical errors made during the collection of a patient sample or during blood administration. Data suggest that the rate of medical errors occurring in hospitals is increasing and a labor shortage in hospital laboratories also decreases patient safety. For example, a recent study from a prestigious university program documented that from 1993 to 1999 the number of errors rose from 1238 to 2052 per year.[2] It is particularly alarming that errors involving patient samples quadrupled from 112 (10% of total errors) in 1993 to 434 (20% of total) in 1999. The Institute of Medicine report, *To Err Is Human*, has called attention to the enormous morbidity and mortality associated with hospital-based errors. These errors have been largely ignored by government agencies focused on blood safety. For example, the Canadian Krever Commission selectively applied the precautionary principle only to infectious risks of transfusion, but not to the very real non-infectious hazards of transfusion.[3] Thus, while blood product safety has been a remarkable achievement, emphasis on product safety diverted attention from transfusion safety.

Hemovigilance programs and the risk of transfusion. Hemovigilance programs are national systems for reporting adverse events and provide one objective means to assess current risks of transfusion. In reports of adverse occurrences in the United Kingdom, mis-transfusion accounted for over 50% of adverse events and non-infectious hazards of transfusion accounted for over 95%.[4] Similar data generated from hemovigilance programs in France and Canada suggest that innovations to address non-infectious hazards should be given high priority.

Viewed from the perspective of risk per individual unit, non-infectious hazards overwhelm current infectious risks. Figure 1 shows current estimates of the risks of an individual unit of blood using the Paling scale. These data demonstrate two important findings. First, the confidence interval of the risk estimate is much more precise for infectious hazards compared with non-infectious hazards. The precision of infectious risk estimates has

Blood Transfusion Service J-224, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114 (Sunny Dzik, M.D.)
e-mail: sdzik@partners.org)

Figure 1. Paling Risk Scale for Major Transfusion Hazards



Source: Sunny Dzik, MD. Data: 2001

resulted from studies conducted in the last decade. Similar studies for non-infectious hazards have not been conducted. Secondly—and more importantly—the graph shows the extent to which patients are at greater risk from non-infectious serious hazards of transfusion. For example, estimates of the per-unit risk of mis-transfusion errors may exceed the risk of viral infection by as much as 10,000 fold.

Examples of non-infectious hazards of transfusion:

Mis-transfusion of blood. Mis-transfusion can be summarized as a failure to give "the right blood product to the right patient at the right time for the right reason." At its worst, mis-transfusion results in major ABO incompatible transfusions. Despite dramatic improvements in overall medical care in the past half-century, the morbidity (renal damage) and mortality associated with ABO hemolytic transfusion reactions has not improved much over that observed decades ago. For example, transfusion errors comprised 2.7 % of all sentinel events reviewed by the Joint Commission on the Accreditation of Hospitals from January 1995 through March 2002,[5] although these and other data from the US based on passive reporting may underestimate the true frequency of mis-transfusion. An active audit of transfusions at three university hospitals in Belgium observed numerous unreported mistakes. Overall, the incidence of serious error was 1 in 400 units and the rate of reported errors underestimated the true rate by 30 fold.[6]

Transfusion-related acute lung injury (TRALI). TRALI is an immune-mediated lung injury syndrome, which in its worst form is life-threatening and indistinguishable from adult respiratory distress syndrome. The actual incidence is uncertain and many cases undoubtedly are attributed to other causes. Over a two-year period in a general hospital, Clarke *et al* reported that 46 of 2,430 transfusions of platelets (2%) were associated with respiratory reactions.[7] A more recent study observed frequent oxygen desatu-

(continued on reverse)

5.9.5 National Blood Safety Council Report

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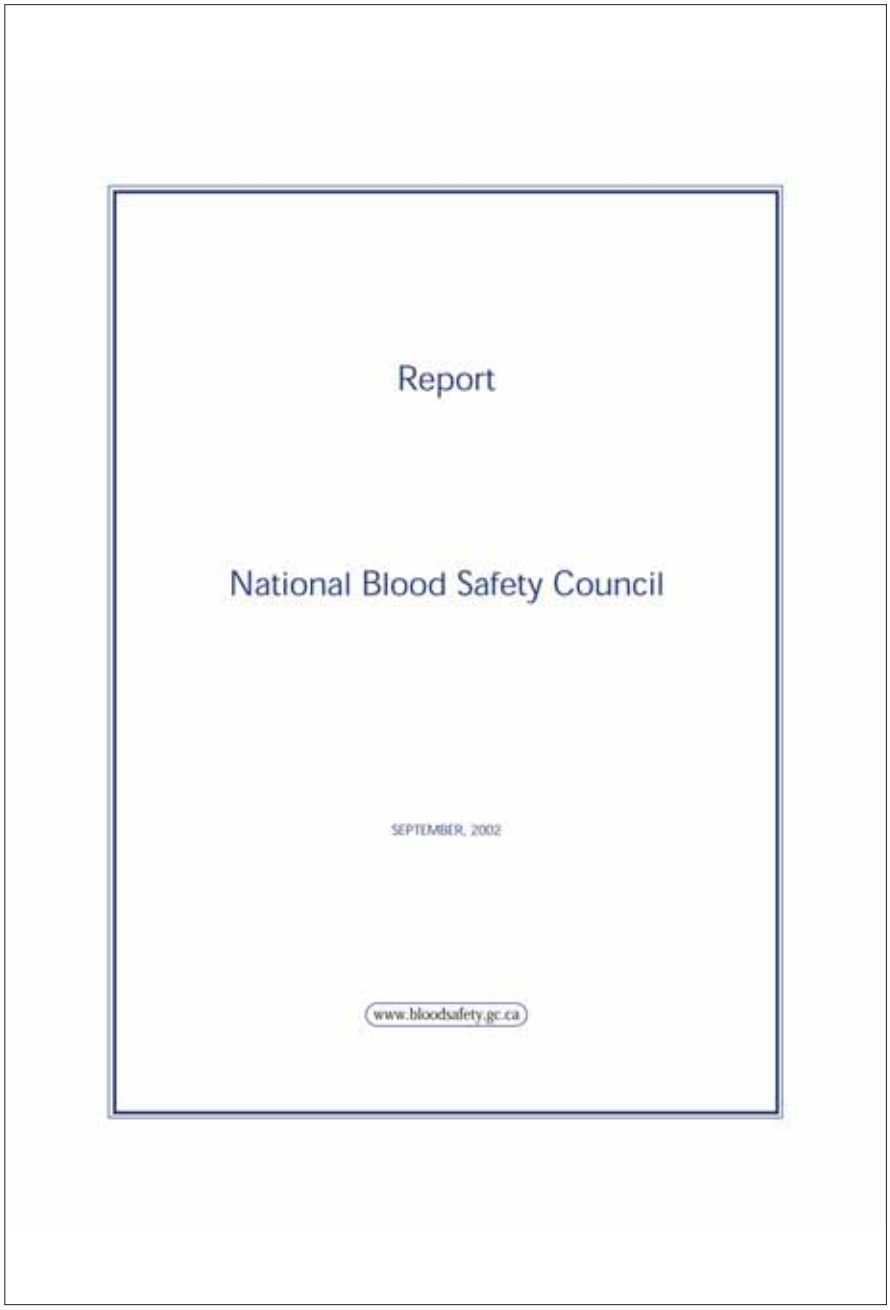

5.9.6 Reducing Transfusion Errors: Risk Management Strategies

Linked Material\appendix 5.9.6.pdf

HOSPITAL hotline

Western Professional Insurance Company

January 2003

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Eastern Washington
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Suite 1200
Spokane, Washington
99201-0503
(509) 363-4142
1-877-282-3333

Oregon Regional Office
8215 S.W. Tualatin-
Sherwood Road, #207
Tualatin, OR
97062-8441
(503) 691-3330
[illegible]

Volume VII, Number 1

REDUCING TRANSFUSION ERRORS: Risk Management Strategies

Please file in your *Hospital Risk Management Manual*

In light of information discussed at a February 2002 U.S. Food and Drug Administration (FDA) workshop, hospital administration should review all facets of blood-transfusion safety. The workshop, which explored practices for reducing transfusion errors, focused on three stages in blood transfusion: donation, testing, and administration.

The blood-transfusion process includes all of the factors recognized that increase the opportunity for errors to occur:

- Variable input—occurs when the patients have different blood types
- Complexity—includes the technical aspects of crossmatching as well as administering and monitoring the effects of blood
- Inconsistency—despite efforts to clearly define procedures within a hospital, there is no standardization across all hospitals
- Tight coupling—steps in a process may happen so closely together that if there is a failure in one step, there is little opportunity for intervention; it is difficult to interrupt the sequence of the process, especially in an emergency room, operating room, or intensive care unit
- Human intervention—occurs in processes that require a higher level of consistency than is reasonably achievable by health care workers without computer support
- Tight time constraints—occur especially in an emergency room, operating room, or intensive care unit [1]

Data presented at the FDA Workshop indicated that 56 percent of errors occurred during blood or blood-product administration. These errors are typically discovered when the patient has a hemolytic transfusion reaction, when a nurse realizes that he or she did something wrong, or when a subsequent blood request revealed the error.

Efforts to improve blood safety should focus on health care facilities, since they are mostly involved with the administration phase of blood or blood-product transfusion. To reduce the risk of a blood-transfusion error, health care facilities should consider the following risk management strategies:

- Conduct a thorough risk management review that includes what the organization is doing with respect to orientation and training procedures, identification procedures, care planning, staffing levels, communication issues, and storage issues
- Provide in-service training on transfusion-related procedures for all staff and in all

5.10 Selected Australian communications regarding blood transfusion safety

5.10.1 Blood and Organ Taskforce Statement

Linked Material\appendix5.10.1.pdf

THE BLOOD AND ORGAN DONATION TASKFORCE'S ROLE IN SAFETY AND QUALITY

The Blood and Organ Donation Taskforce plays a key role in initiatives to ensure safety and quality for Australia's blood supply, largely through its Blood Safety and Quality Working Group (BSQWG). The Working Group, chaired by the Commonwealth Chief Medical Officer, was established by the Australian Health Ministers' Advisory Council to consider and implement safety and quality recommendations in the *Review of the Australian Blood Banking and Plasma Product Sector*, including:

- donor deferral issues;
- promoting appropriate use of blood and blood products; and
- implementing a national scheme for improving safety and quality in transfusion practice.

DONOR DEFERRAL

In 2000, Australian Health Ministers collectively agreed to a temporary ban on blood transfusions from people who lived in the United Kingdom from 1980–1996 as a precaution against the theoretical risk of variant Creutzfeldt-Jakob Disease (vCJD) transmission through blood transfusion.

The Blood Safety and Quality Working Group is working in conjunction with the NHMRC Special Committee on Transmissible Spongiform Encephalopathies (SECTSE) to examine recent evidence regarding the risk of variant Creutzfeldt-Jakob Disease transmission through blood transfusion. It is also liaising with the Australian Red Cross Blood Service (ARCBS) regarding the impact on blood supplies should Australia's current donor deferral policy be further extended.

APPROPRIATE USE OF BLOOD AND BLOOD PRODUCTS

The National Health and Medical Research Council, in conjunction with the Australasian Society of Blood Transfusion, has developed evidence-based guidelines for the appropriate use of blood and blood products. The guidelines will enable hospitals and other services to optimise their use of blood components, and will also address concerns about the risk of adverse outcomes associated with blood therapy.

The Blood Safety and Quality Working Group has been liaising with States and Territories to promote the use of these guidelines nationally, and is facilitating cross-jurisdictional participation in initiatives to promote better transfusion practice in Australian hospitals.

STRENGTHENING SAFETY AND QUALITY IN TRANSFUSION PRACTICE

As a result of the Review's recommendations, the Blood Safety and Quality Working Group is investigating options for a national scheme for improving quality in transfusion practices in hospitals. This initiative fits in with the broader national strategy for improving patient safety in line with the goals of the Australian Council for Safety and Quality in Health Care.

It is intended that implementation of the scheme will help:

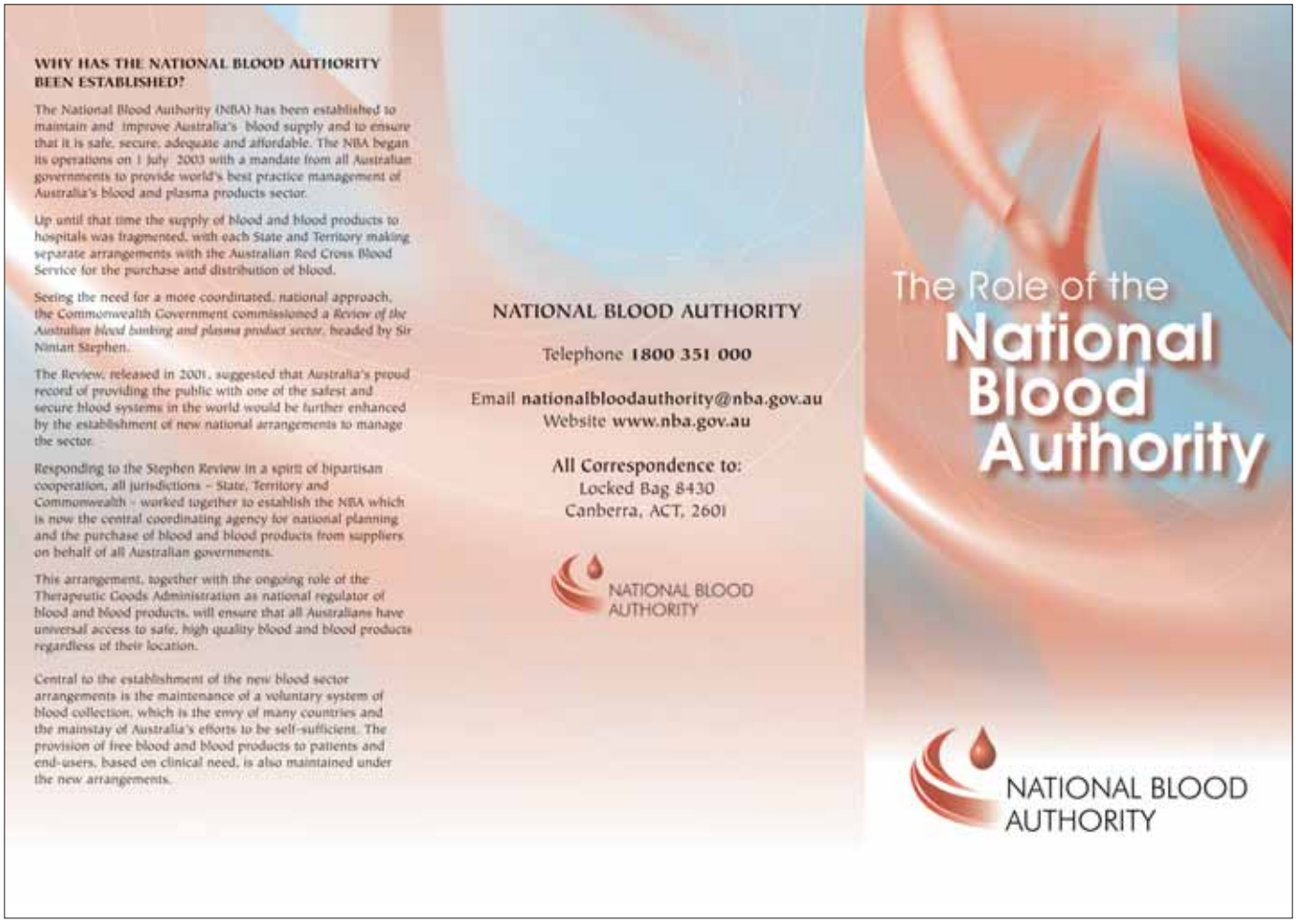
- identify opportunities for safety and quality improvements in transfusion practice;
- build awareness and understanding of safe transfusion practices;
- support those involved in blood transfusion to practise safely; and
- improve data and information collection related to transfusion events to inform clinical practice and educate the wider community about transfusion risks.

For further information PHONE 1800 351 000 or visit our Website at: http://www.health.gov.au/budd/bods/index.htm

THE BLOOD AND ORGAN DONATION TASKFORCE

5.10.2 National Blood Authority brochure

Linked Material\appendix 5.10.2.pdf



WHY HAS THE NATIONAL BLOOD AUTHORITY BEEN ESTABLISHED?

The National Blood Authority (NBA) has been established to maintain and improve Australia's blood supply and to ensure that it is safe, secure, adequate and affordable. The NBA began its operations on 1 July 2003 with a mandate from all Australian governments to provide world's best practice management of Australia's blood and plasma products sector.

Up until that time the supply of blood and blood products to hospitals was fragmented, with each State and Territory making separate arrangements with the Australian Red Cross Blood Service for the purchase and distribution of blood.

Seeing the need for a more coordinated, national approach, the Commonwealth Government commissioned a *Review of the Australian blood banking and plasma product sector*, headed by Sir Nimian Stephen.

The Review, released in 2001, suggested that Australia's proud record of providing the public with one of the safest and secure blood systems in the world would be further enhanced by the establishment of new national arrangements to manage the sector.

Responding to the Stephen Review in a spirit of bipartisan cooperation, all jurisdictions – State, Territory and Commonwealth – worked together to establish the NBA which is now the central coordinating agency for national planning and the purchase of blood and blood products from suppliers on behalf of all Australian governments.

This arrangement, together with the ongoing role of the Therapeutic Goods Administration as national regulator of blood and blood products, will ensure that all Australians have universal access to safe, high quality blood and blood products regardless of their location.

Central to the establishment of the new blood sector arrangements is the maintenance of a voluntary system of blood collection, which is the envy of many countries and the mainstay of Australia's efforts to be self-sufficient. The provision of free blood and blood products to patients and end-users, based on clinical need, is also maintained under the new arrangements.

NATIONAL BLOOD AUTHORITY

Telephone **1800 351 000**

Email **nationalbloodauthority@nba.gov.au**
Website **www.nba.gov.au**

All Correspondence to:
Locked Bag 8430
Canberra, ACT, 2601

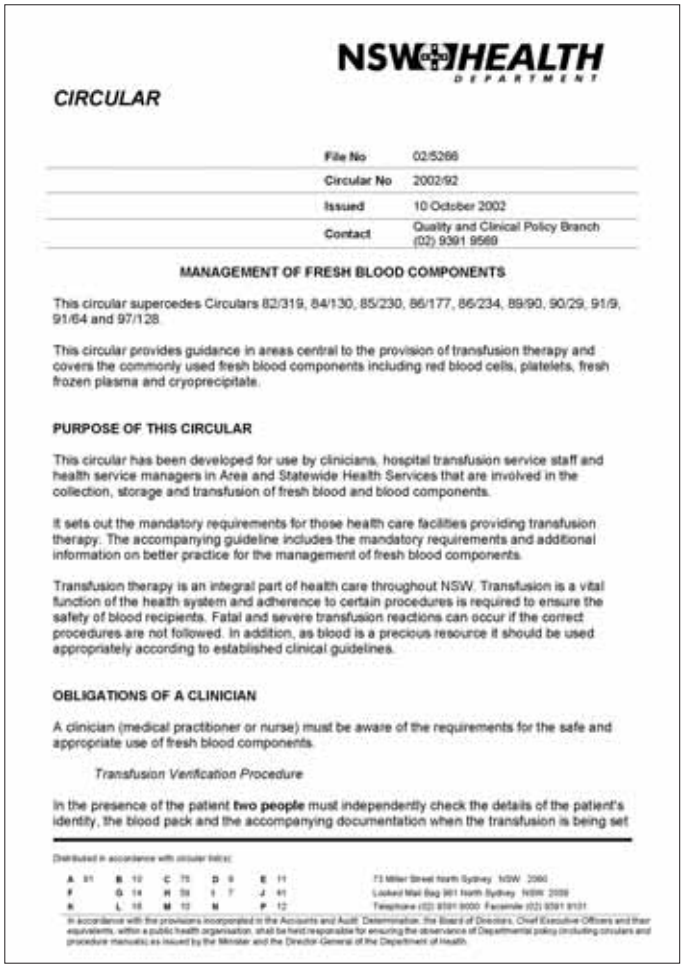
NATIONAL BLOOD AUTHORITY

The Role of the
National Blood Authority

NATIONAL BLOOD AUTHORITY

5.10.3 New South Wales Health

Linked Material\appendix 5.10.3a.pdf



NSW HEALTH DEPARTMENT

CIRCULAR

File No	02/5266
Circular No	2002/92
Issued	10 October 2002
Contact	Quality and Clinical Policy Branch (02) 9391 9569

MANAGEMENT OF FRESH BLOOD COMPONENTS

This circular supercedes Circulars 82/319, 84/130, 85/230, 86/177, 86/234, 89/90, 90/29, 91/9, 91/64 and 97/128.

This circular provides guidance in areas central to the provision of transfusion therapy and covers the commonly used fresh blood components including red blood cells, platelets, fresh frozen plasma and cryoprecipitate.

PURPOSE OF THIS CIRCULAR

This circular has been developed for use by clinicians, hospital transfusion service staff and health service managers in Area and Statewide Health Services that are involved in the collection, storage and transfusion of fresh blood and blood components.

It sets out the mandatory requirements for those health care facilities providing transfusion therapy. The accompanying guideline includes the mandatory requirements and additional information on better practice for the management of fresh blood components.

Transfusion therapy is an integral part of health care throughout NSW. Transfusion is a vital function of the health system and adherence to certain procedures is required to ensure the safety of blood recipients. Fatal and severe transfusion reactions can occur if the correct procedures are not followed. In addition, as blood is a precious resource it should be used appropriately according to established clinical guidelines.

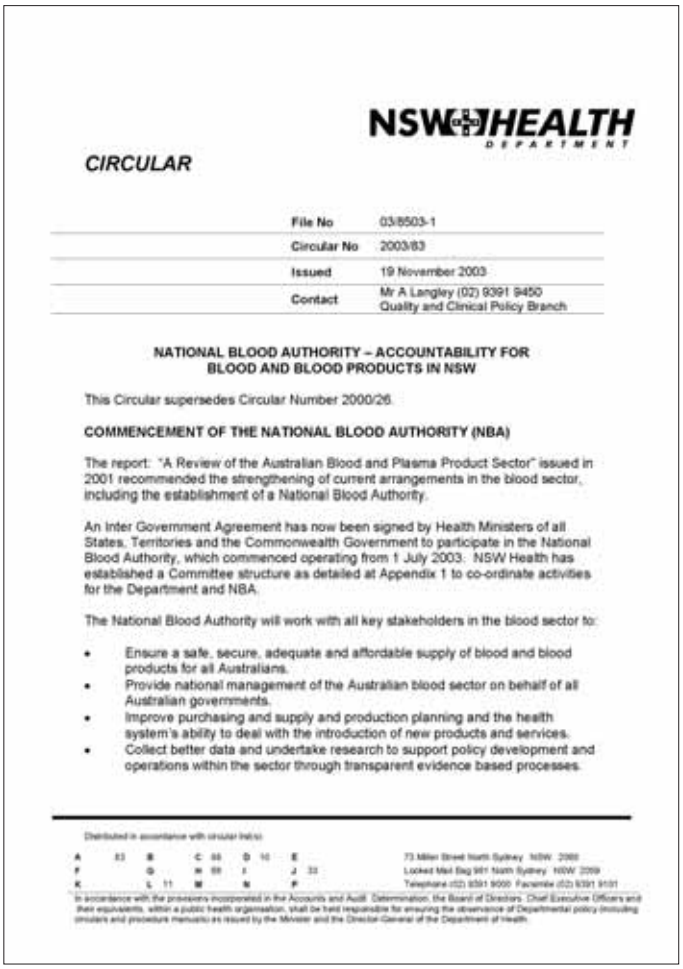
OBLIGATIONS OF A CLINICIAN

A clinician (medical practitioner or nurse) must be aware of the requirements for the safe and appropriate use of fresh blood components.

Transfusion Verification Procedure

In the presence of the patient **two people** must independently check the details of the patient's identity, the blood pack and the accompanying documentation when the transfusion is being set

Linked Material\appendix 5.10.3b.pdf



NSW HEALTH DEPARTMENT

CIRCULAR

File No	03/8503-1
Circular No	2003/83
Issued	19 November 2003
Contact	Mr A Langley (02) 9391 9450 Quality and Clinical Policy Branch

NATIONAL BLOOD AUTHORITY – ACCOUNTABILITY FOR BLOOD AND BLOOD PRODUCTS IN NSW

This Circular supersedes Circular Number 2000/26.

COMMENCEMENT OF THE NATIONAL BLOOD AUTHORITY (NBA)

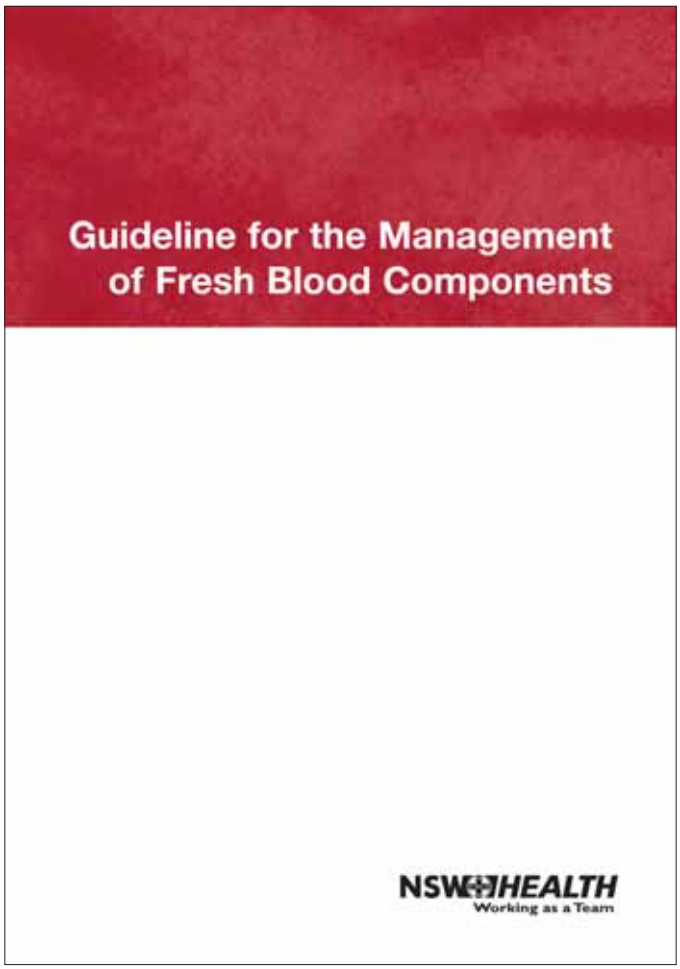
The report: "A Review of the Australian Blood and Plasma Product Sector" issued in 2001 recommended the strengthening of current arrangements in the blood sector, including the establishment of a National Blood Authority.

An Inter Government Agreement has now been signed by Health Ministers of all States, Territories and the Commonwealth Government to participate in the National Blood Authority, which commenced operating from 1 July 2003. NSW Health has established a Committee structure as detailed at Appendix 1 to co-ordinate activities for the Department and NBA.

The National Blood Authority will work with all key stakeholders in the blood sector to:

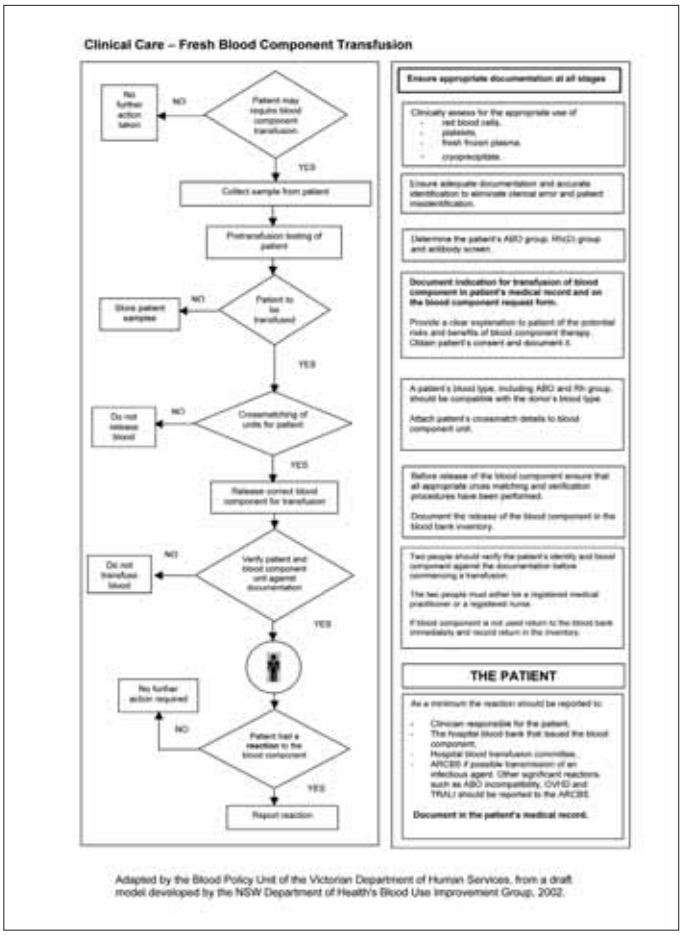
- Ensure a safe, secure, adequate and affordable supply of blood and blood products for all Australians.
- Provide national management of the Australian blood sector on behalf of all Australian governments.
- Improve purchasing and supply and production planning and the health system's ability to deal with the introduction of new products and services.
- Collect better data and undertake research to support policy development and operations within the sector through transparent evidence based processes.

Linked Material\appendix 5.10.3c.pdf



5.10.4 Victorian Department of Human Services

Linked Material\appendix 5.10.4.pdf



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