‘Towards Better, Safer Blood Transfusion’

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

A/ Prof Neil Boyce
Australian Red Cross Blood Service & Department of Human Services
Melbourne, Victoria
nboyce@arcbs.redcross.org.au

Dr Chris Brook
Department of Human Services
Melbourne, Victoria
chris.brook@dhs.vic.gov.au
February 2005
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.

- Healthcare professionals involved in everyday transfusion practice must receive more adequate 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 would see organisations that currently contribute to aspects of the safety and quality of transfusion practice integrated within a single governance framework that addresses all aspects of the transfusion ‘safety chain’.

- A national better, safer transfusion (BeST) program 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 better, safer transfusion (BeST) program should operate through the normal accountability and responsibility channels of acute healthcare. 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 better, safer transfusion (BeST) program.

- Hospital Transfusion Committees and Hospital Transfusion Teams will 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.
CONTENTS.

1. SUMMARY [9]

2. BACKGROUND [14]

3. RECENT APPROACHES TO IMPROVING THE SAFETY AND QUALITY OF BLOOD PRODUCT TRANSFUSION [17]

3.1 NATIONAL
3.1.1 Australian Capital Territory [17]
3.1.2 New South Wales [17]
3.1.3 Northern Territory [20]
3.1.4 Victoria [21]
3.1.5 Queensland [22]
3.1.6 South Australia [23]
3.1.7 Tasmania [25]
3.1.8 Western Australia [25]

3.2 INTERNATIONAL
3.2.1 World Health Organization [28]
3.2.2 Council of Europe & European Union [30]
3.2.3 United Kingdom [32]
3.2.4 USA & Canada [35]
3.2.5 Haemovigilance [37]

4. OPTIONS FOR ACHIEVING BETTER, SAFER TRANSFUSION PRACTICE IN AUSTRALIA

4.1 WHAT HAVE WE LEARNT FROM RECENT EFFORTS TO IMPROVE THE SAFETY AND APPROPRIATENESS OF BLOOD TRANSFUSION? [40]

4.2 WHY AUSTRALIA SHOULD CONSIDER A NATIONAL APPROACH TO MONITORING AND IMPROVING THE SAFETY AND APPROPRIATENESS OF BLOOD TRANSFUSION. [44]
4.3 WHAT ARE SOME ALTERNATIVE MODELS FOR A NATIONAL APPROACH TO TRANSFUSION PRACTICE IMPROVEMENT IN AN AUSTRALIAN CONTEXT? [47]

4.4 WHAT MIGHT IT COST TO OVERSEE TRANSFUSION PRACTICE IN AUSTRALIA AND WHO MIGHT PAY FOR SUCH OVERSIGHT? [50]

4.5 OTHER ISSUES
4.5.1 Levers for changing transfusion practice [51]
4.5.2 Education and training [54]
4.5.3 Transfusion Nurse Role [55]

5. APPENDICES [SEE ATTACHED CD]

5.1 B T I C; NSW

5.1.1 Project report
5.1.2 Australian Centre for Effective Healthcare: Red Blood Cell Transfusion Practices in New South Wales
5.1.3 BTIC slide set

5.2 BLOODMATTERS; VICTORIA

5.2.1 Blood Matters Improvement Guide
5.2.2 Blood Matters Consumer report
5.2.3 Blood Matters slide set
5.2.4 Transfusion Nurse Course brochure

5.3 BLOODSAFE: SOUTH AUSTRALIA

5.3.1 BloodSafe final report
5.3.4 BloodSafe slide set

5.4 WESTERN AUSTRALIA

5.4.1 PathCentre poster
5.4.2 PathCentre slide set
5.4.3 WA data linkage approach
5.5 WHO

5.5.1 Rational transfusion therapy: Framework for a national blood policy and guidelines
5.5.2 Development of quality systems to improve the clinical use of blood
5.5.3 The clinical use of blood handbook
5.5.4 The clinical use of blood in medicine, obstetrics, paediatrics, anaesthesia & surgery, trauma & burns
5.5.5 Report of experts in transfusion services
5.5.6 First report of the global collaboration for blood safety
5.5.7 Second report of the global collaboration for blood safety
5.5.8 Aide memoir on national blood programs
5.5.9 Aide memoir on blood safety quality systems
5.5.10 Blood safety and technology report

5.6 EUROPEAN INITIATIVES

5.6.1 CoE recommendations on the hospitals and clinicians role in the optimal use of blood and blood products
5.6.2 European Commission directive

5.7 HAEMOVIGILANCE

5.7.1 Consultants report

5.8 UNITED KINGDOM INITIATIVES

5.8.1 Better blood transfusion 1998
5.8.2 Better blood transfusion 2002
5.8.3 Better blood transfusion 2002 resource requirements
5.8.5 CMO’s Better blood transfusion committee. Terms of Reference.
5.8.6 CMO’s annual report on better blood transfusion 2002/2003
5.8.7 CMO’s annual report on better blood transfusion 2003/2004
5.8.8 Scottish better blood transfusion 1998
5.8.9 Scottish better blood transfusion program 2004
5.8.10 National audit of blood transfusion practices
5.8.11 Blood conservation strategies for the NBTS and NBA
5.8.12 The sensible use of blood 2003
5.8.13 Better use of blood in Northern Ireland
5.8.14 Clinical audit and effectiveness strategy for the National Blood Service
5.9 NORTH AMERICAN INITIATIVES

5.9.1 Department of Health and Human Services, Food and Drug Administration & Center for Biologics Evaluation and Research: Workshop on Best Practices for reducing transfusion errors
5.9.2 Transfusion Ontario Programs
5.9.3 Provincial Blood Coordinating Office Programs; British Columbia
5.9.4 Non infectious hazards of transfusion
5.9.5 Canadian National Blood Safety Council Report
5.9.6 REDUCING TRANSFUSION ERRORS: Risk Management Strategies
5.9.7 Hospital issues in transfusion safety

5.10 SELECTED AUSTRALIAN COMMUNICATIONS REGARDING BLOOD TRANSFUSION SAFETY

5.10.1 Blood and Organ Taskforce statement
5.10.2 National Blood Authority brochure
5.10.3 New South Wales Health documents
5.10.4 Victoria Department of Human Services documents

5.11 RECOMMENDED READING
CLINICAL GOVERNANCE:
The framework for which health organizations are accountable for continuously improving the quality of their clinical services and safeguarding 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 organizations. (NHS 1998)

TRANSFUSION PRACTICE & 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
CAN J ANESTH 2001 / 48: 9 / pp 894-901

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 & Don Berwick. IHI.
WHAT ASPECTS OF TRANSFUSION PRACTICE SHOULD WE ADDRESS?

Too much of healthcare performance is primarily measured through productivity and financial indicators. This may explain why safety is not listed as a primary objective within most strategic plans and why the majority of healthcare providers are neither directed towards (nor accountable for) improving safety within 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 system wide improvements.

Sue Williams NHS 2004

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 minimize the risk of transfusion-transmitted infection. These measures have included 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 is the dominant risk of transfusion in 2004. The literal confusion of blood sample, blood product and patient identities results in the unintended transfusion of a blood product into the ‘wrong’ patient at an unacceptable frequency (variously estimated at somewhere between 1: 3,300 and 1: 20,000 transfused units). Despite the relative tolerance of the blood group antigen systems to such mishaps, these ‘wrong blood’ episodes occasionally produce major morbidity and even fatalities.

We also have well intentioned, but by all accounts ‘inappropriate’ transfusion of blood products, reflecting a failure of contemporary Australian transfusion practices to align with recommended best practice. These unnecessary transfusions are a waste of a valuable community resource. They expose patients to all of 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’ the environments where most blood often 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’, within any individual hospital it is often the case that much of the knowledge regarding optimal transfusion practice has resided within the hospital Blood Bank, rather than being grounded within the clinical units and healthcare professional groups who commonly transfuse blood products to their patients.

Within Australia Transfusion Medicine expertise has largely resided within ARCBS and ANZSBT, rather than being strong interests of those medical and nursing special interest groups who use transfusion as a common supportive therapy. Internationally it is the World Health Organization and bodies such as the EU and CoE that 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 healthcare professionals within the mainstream of healthcare 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 a failure in governance of the transfusion process. No one agency or group manages the overall transfusion ‘safety chain’. Instead different groups focus 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 terms of 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, put positively, 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% and typical compliance rates for ‘critical’ steps in the transfusion ‘safety chain’ are 10 to 70% 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’.

It is argued by some that systems for assuring quality in transfusion practice should reside entirely within the ‘mainstream’ of healthcare delivery. Currently ‘mainstreaming’ transfusion safety sees responsibility for clinical transfusion safety loosely assigned across 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 current ‘mainstream’ approach is patently inadequate. In the current mainstream, transfusion practices are often less than desirable.

There is no doubt that recent projects across Australia (and those in place internationally) have demonstrated an ability to improve a variety of aspects of transfusion practice.

Within Australia these projects have ranged from focused efforts within an individual hospital, through partnerships involving small numbers of hospitals to statewide endeavors that have engaged 20 or more health services in coordinated programs of transfusion practice improvement. The achievements of
these projects are visible in their formal reports of outcomes (such as those included in the appendices to this report). Their achievements are perhaps even more obvious when one speaks with individuals and teams engaged in the projects and see their data presented. The establishment of ongoing statewide transfusion practice improvement programs has followed two of these projects (BloodSafe in SA and Blood Matters in Vic). The available evidence indicates that transfusion practice typically reverts to historical norms within relatively short periods of time when practice improvement ‘projects’ come to closure. It is likely that enduring programs that set performance standards, monitor practice against these standards and implement improvement programs where necessary are essential for assuring sustained optimal transfusion outcomes.

As indicated above, there is a rather large ‘improvement opportunity’ target in many aspects of contemporary Australian transfusion practice. It is perhaps not surprising that each of the approaches to transfusion practice improvement used in recent Australian projects successfully achieved their stated objectives. It is worth noting that 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 may have improved from 20% to 60% within the timeframe of the project, when the ‘gold standard’ target that would see reliably safe and appropriate transfusion was actually 100% compliance.

A key lesson from these recent transfusion practice improvement projects across 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. 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 (SA, NSW and Vic) effectively raised the profile of transfusion safety within their jurisdictions during the life of their projects. They built staff capacity for clinical practice improvement. They shared ideas for improved transfusion safety and practical tools to assist organizations achieve better transfusion outcomes. The products of their endeavors deserve to be made available to the widest possible audience.

It is not possible to make definitive judgments using objective criteria in terms of whether one approach to transfusion practice improvement used in Australia
recently is *better* than another. Nor is it possible to determine if some combination of approaches might deliver better outcomes. What is clear is that project success required some degree of local re-design or modification of existing practice improvement methodologies and strategies to gain local ownership. Each of the different approaches 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.

It is recognized that as a community we have particular responsibilities and accountabilities with respect to 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 by these professionals to improve the health of those in our community who depend on transfusion support. Additionally we face the very high expectations of those requiring transfusion, with expectations regarding safety for this supportive therapy being significantly greater than our community's typical expectations regarding safety of healthcare interventions.

For a number of reasons, 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 to see changes in transfusion practice translate into enhanced patient safety. There is merit in a national model of governance of the entire transfusion ‘safety chain’. The provision of 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 healthcare. 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 onto a common platform for coordinating and prioritizing action.

Hospital Transfusion Committees and Hospital Transfusion Teams must be supported to allow meaningful monitoring and transfusion practice improvement
locally. This support will include the provision of 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.

*Haemovigilance* is essentially a French word for a program that monitors selected aspects of the safety of transfusion. It has been proposed that Australia adopt a *Haemovigilance* system. It is important that any measurement program consciously focuses on monitoring aspects of transfusion where there is known to be great potential for delivering improved patient safety. Thus *Haemovigilance* measures, in an Australian transfusion context, need to include both traditional product safety and also 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 but one component of a broader healthcare safety and quality agenda. It is not necessary to demand that any funds required for delivery of better, safer transfusion be seen as requiring entirely ‘new’ monies. Negotiations between the States and Territories and the Commonwealth could resolve an agreed mix of ‘existing’ and ‘new’ monies for this purpose. These negotiations might deliver an agreement that saw the hospital costs required for a national transfusion safety and appropriateness program as 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
2. BACKGROUND

It is the primary purpose of this report to summarize 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 learnt by those engaged in the implementation of change.

Where relevant, other national and international programs that seek to deliver better, safer transfusion practice are drawn upon 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 essentially 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.

It is hoped 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 across Australia.

Patient safety has become an increasingly important issue in healthcare. A series of national and international reports have emphasized that our efforts to enhance the quality of health service delivery should have a strong focus on patient safety. Within Australian healthcare we have witnessed the launch of various national and jurisdictional groups interested in patient safety and the design and implementation of a raft of strategies that seek to reduce levels of iatrogenic harm.

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

Translating this generic knowledge base into concrete improvements in patient safety requires that we move from the general to the particular. We must make practical changes to the way that we do business that translates into better, safer care. This must involve reviewing and improving specific systems and sub-systems in healthcare delivery. Whilst creation of a ‘culture of safety’ amongst
healthcare workers may well be 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 healthcare by virtue of work done by teams of consumers, patients, healthcare professionals and health service and health systems managers working collaboratively to enhance each and every aspect of delivered care.

Efforts to realize improved outcomes in those who require blood product transfusion by ensuring better, safer transfusion practices are but one component of this broader healthcare safety and quality agenda. In the past decade there has been a growing recognition that there are major variations in clinical transfusion practices that 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 healthcare 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 the not inconsiderable direct financial burden of 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. It is generally recognised from examining the available evidence that there is a genuine need to improve current clinical blood transfusion practices.


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 seen better, safer transfusion practice recently identified as a priority area for healthcare 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 have addressed blood and blood product safety rather than the integrity of all of 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: 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 that saw a number of different approaches to improving transfusion practice in jurisdictions introduced across Australia between 2001 and 2004.

Consistent application of best practice in transfusion across Australia would ensure that our healthcare system meets the reasonable expectations of those in our community 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 learnt in enhancing transfusion practice may well inform the design of other programs that seek to improve the safety and quality of common clinical interventions in acute healthcare.

---

**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.

3. RECENT APPROACHES TO IMPROVING THE SAFETY AND QUALITY OF BLOOD PRODUCT TRANSFUSION

3.1 NATIONAL

3.1.1 Australian Capital Territory

ACT ran an ‘Appropriate Use of Blood Products’ Project in 2001 and 2002 across public and private hospitals in the ACT. The project set out to standardize 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 familiarization 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.

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

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

It is sobering to note that a re-audit of practices in 2003 demonstrated that there was a strong trend to a reversion towards prior less adequate transfusion practices following conclusion of the formal ‘project phase’ of the initiative.

3.1.2 New South Wales

In November 1998, the Australian Centre for Effective Healthcare signed an agreement with the NSW Health Department to conduct a project on the appropriateness of red blood cell transfusion in NSW hospitals. The final report on the project was presented to the Chief Health Officer and Deputy Director General, Public Health, NSW Health Department, and the Chairman of the NSW Ministerial Advisory Committee on Quality in Healthcare 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 (i.e. ‘elective’ red cell transfusion).

Subsequently NSW Health established an additional ‘User Group’ to assist in the
development of improved blood product usage. The ‘NSW 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 Hemophilia Council and the Intravenous
Immunoglobulin User Group who provided advice to the Department on best use
of coagulation factor therapeutics and intravenous immunoglobulin. NSW Health
also received input from an Australian Red Cross Blood Service / NSW Health
Liaison Committee that provided a forum for decision-making on management of
blood and blood products within NSW.

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 NSW Blood Transfusion Improvement
Collaborative (BTIC) during 2002-2003 that used the Breakthrough Collaborative
methodology to focus on improving the appropriateness of red cell transfusion in
haemodynamically stable patients. At the time of commissioning the
Collaborative the NH&MRC/ASBT guidelines for Red Cell use was the sole
available national guideline. BTIC was seen as a first step in a structured NSW
implementation of the NH&MRC/ASBT guidelines into clinical practice.

In 2004 NSW Health revised its governance structure for blood and blood
products in NSW, 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 within the state. This governance structure is
shown below.
The BTIC Project reported in September 2003 on their work in the 17 participant hospital teams, including 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 seen in the project and improving other aspects of blood transfusion practice.

BTIC demonstrated that it was feasible to deliver improved red cell transfusion practice by use of 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 100G/L or greater in participating centers, with an overall significant reduction in pre-transfusion ‘threshold’ haemoglobin across participant clinical sites (see Statistical Process Control chart below).
The final report from BTIC emphasized 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 NSW.

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 NSW Health.

The BTIC report includes a wealth of invaluable resource materials and change strategies (see appendix 5.1.1).

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

The Fresh Product User Group that reports to the NSW 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 within NSW Health.

3.1.3 Northern Territory

Given the population of the NT and the concentration of transfusion practice to a relatively small number of hospitals they have addressed the issue of improving transfusion practice and guideline implementation within their 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. NT Health also has regular “End User” liaison meetings with ARCBS to canvass relevant blood product issues. Hospital medical scientific staffs are felt 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 available financial and human resources it is felt that transfusion safety and quality matters are well in hand. There is the view that should additional resource be available there would be merit in having a Transfusion Medicine Specialist available for local CME sessions for medical staff and laboratory scientists

3.1.4 Victoria

Studies in Victorian hospitals in the late 1990’s had 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, through poor documentation and adherence to administration and monitoring guidelines, to poor inventory management, with consequent unnecessary product losses.

In 2001 the Department of Human Services funded a “Blood Matters” pilot project 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 Department of Human Service 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 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 healthcare professionals’ knowledge regarding fresh blood product transfusion and hospital protocols and procedures for ordering, provision, and administration and monitoring of transfusions. The pilot and collaborative demonstrated an ability to improve all targeted aspects of transfusion practice. The 16 participant Health Services in the collaborative (15 Victorian and the Royal Hobart Hospitals) 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 Clinical Innovations Agency.

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 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 most critical success factor for their program of transfusion practice improvement endeavors. This view is repeated wherever else in Australia that transfusion nurses have been embraced.

A summary of some of the more significant achievements of the ‘Blood Matters’ project is provided (appendix 5.2.1) and the Blood Matters resource material CD-ROM is included with this report.

In 2004-2005 the Department of Human Services established a ‘Better, Safer Transfusion Program’ for Victoria to follow the Blood Matters project. This 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.

### 3.1.5 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 upon the Blood Products User Group and the Hospital Transfusion Committees that feed into the ARCBS-Qld User Group to implement the NH&MRCA/SBT guidelines.

Queensland Health has overseen a number of statewide initiatives addressing Pathology and Scientific Services Quality Management, audit and staff training programs. They have not as yet approached clinical transfusion practice improvement within their exemplary statewide Healthcare Improvement program. Currently Queensland Health Pathology and Scientific Services are looking at options for introducing appropriate practice improvement strategies for blood product transfusion in Queensland and are looking at using the experiences of other jurisdictions to inform their planning processes.
3.1.6 South Australia

The Department of Human Services in South Australia 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 Sub-Committees of the South Australian Hospital Safety and Quality Council and teaching hospitals and their transfusion service providers. 5 major hospitals participated in the project (the Royal Adelaide Hospital, Flinders Medical Centre, Repatriation General Hospital, Queen Elizabeth Hospital and the Woman's & 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 throughout the BloodSafe project demonstrated major deficiencies in healthcare 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 report of their project the BloodSafe team found that they had delivered a significant reduction in inappropriate red cell transfusion. Initial audit revealed that red cell transfusion was inappropriate in 18% (RANGE 9 to 36%) in target hospitals and following interventions this inappropriate red cell transfusion rate fell to 4% (RANGE 0 to 5%) [P< 0.001]. They also reported on 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 had proven themselves to be effective change agents in hospitals. This role significantly improved the safety and appropriateness of blood transfusion practices within their hospitals. The demonstrated success of the approach of the BloodSafe project and the transfusion nurse consultants saw an initial 12 month extension of project funding by the Department of Human Services in South Australia (including a state transfusion nurse educator for country and private sectors). More recently the Department has provided of triennial funding support for BloodSafe. This funding allows for transfusion nurses in major hospitals.
The inventory management sub-project developed a number of practical tools to assist small hospitals in their management of blood products. These tools help support good inventory management and minimize product expiry and assist in product to patient traceability.

### Red Cell Audit Results

<table>
<thead>
<tr>
<th>Number audited</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>units of red cells</td>
<td>664</td>
<td>519</td>
</tr>
<tr>
<td>transfusion episodes</td>
<td>357</td>
<td>284</td>
</tr>
<tr>
<td>patients</td>
<td>191</td>
<td>170</td>
</tr>
<tr>
<td>% episodes involving:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>planned surgery</td>
<td>50%</td>
<td>41%</td>
</tr>
<tr>
<td>autologous blood</td>
<td>9%</td>
<td>10%</td>
</tr>
<tr>
<td>patients with a comorbidity*</td>
<td>55%</td>
<td>54%</td>
</tr>
<tr>
<td>% episodes started in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>general wards</td>
<td>32%</td>
<td>47%</td>
</tr>
<tr>
<td>theatre &amp; recovery</td>
<td>36%</td>
<td>33%</td>
</tr>
<tr>
<td>intensive care</td>
<td>24%</td>
<td>17%</td>
</tr>
</tbody>
</table>

* Cardiac, respiratory or cerebrovascular insufficiency

The current governance structure in South Australia sees several expert groups providing advice to the Department in addition to the enduring practice improvement activities of BloodSafe (see below).
The major achievements and lessons from BloodSafe are included in their reports and presentations in Appendix 5.3.1 and 5.3.2.

3.1.7 Tasmania

Tasmania established a TASMANIAN BLOOD & BLOOD PRODUCTS MANAGEMENT GROUP in 2003 as a high-level policy and decision-making group to ensure efficient, effective arrangements for the provision of blood and blood products in Tasmania. The Group reports to the Director, 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 within Tasmania, including the promotion of efficiency in use and minimization of wastage.

Each of the three major Tasmanian public hospitals has embarked on transfusion practice improvement projects in the past 3 years (Royal Hobart initially through participation in the Blood Matters Collaborative in Victoria). These have 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 have been led by their local Transfusion Committees and have been 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.

3.1.8 Western Australia

Western Australia has a long-standing Blood User Group (BUG) under the auspice of the Australian Red Cross Blood Service. This BUG includes representation from ARCBS, public and private hospital hematologists, hospital blood bank and Pathology Service scientists and the Western Australian Department of Health. This 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 WA has supported 2 projects that have used a ‘data-linkage’ approach to measure aspects of blood product transfusion practice. The first of these was in collaboration with ARCBS in WA. This used the return of ‘bag-tags’ attached to blood products issued by ARCBS that contained the name of the transfused recipient, their unit record number and the date of transfusion as identifiers. These identifiers allowed linkage of that transfusion episode with data contained in other health event registries via the WA Data Linkage Project. The Data Linkage Unit of the School of Population Health at the University of Western Australia manages this project. The unit represents collaboration between the Health Information Centre in the Department of Health and the Centre for Health Services Research at the University of
WA, the Centre for Health Informatics at Curtin University of Technology and 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 WA population. Privacy sensitive protocols, probabilistic matching and extensive clerical review are used to create and manage links within and between the state's 7 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 WA and the Department of Health in WA 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, the Cancer Registry and the Midwives Notification System. Clearly this IT resource has the potential to provide comparative transfusion practice data that could underpin future such projects. For examples of the data derived from this linked dataset see Appendix 5.4.

The Western Australian Centre for Pathology and Medical Research performed a second ‘data linkage’ project, funded by the WA 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 healthcare 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 reanalysis 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 and re-audit several months after the initial interventions shows 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. For additional information on this data linkage project see Appendix 5.4.

Data-linkage approaches such as those applied in WA have the potential to deliver outstanding transfusion epidemiology data. While some of this may inform transfusion practice improvement, it would be of even greater utility 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 would indicate that the costs of developing systems to collect these data are modest.

The Transfusion Medicine Unit at 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 regularly audit various aspects of clinical transfusion practice 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 across the hospital is in large part attributable to the availability of the transfusion nurse resource, acting as both educator and auditor. Hospitals in WA without this resource expressed concerns that they are limited in the scope of their transfusion practice monitoring and improvement efforts by the lack of a similar human resource.

---

**Patient Safety and Blood Transfusion: New Solutions**

Walter H. Dzik, Howard Corwin, Lawrence Tim Goodnough, Martha Higgins, Harold Kaplan, Michael Murphy, Paul Ness, Ira A. Shulman, and Roslyn Yomtovian

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.

*Transfusion Medicine Reviews, Vol 17, No 3 (July), 2003: p 169-180*
3.2 INTERNATIONAL

3.2.1 World Health Organization

The Paris AIDS Summit (1994) declaration recognized 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).

**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)
- 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 GCBS operates through consensus proposals and recommendations addressed to its participants. Any proposal and recommendation does not commit the participating organizations or participating governmental agencies and institutions, but constitute 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.

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 for dissemination at global level.

The GCBS recognized that a continuum of processes determine the ultimate safety and quality of transfusion.

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 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 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 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 Pharmaceutical’s (HTP) have led the WHO program to enhance transfusion safety. An international workshop held in 1997 in Edinburgh was followed by publication of ‘Recommendations on developing a National policy and Guidelines on the Clinical Use of Blood’ which was published by WHO/ BTS in 1998.
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 use by the users of blood products. A report of the 1999 deliberations is included in Appendix 5.5. 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 a myriad of excellent recommendation 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 healthcare professionals
♦ Make alternatives to blood products available and 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 the year 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.

3.2.2 Council of Europe & 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 co-operation between member states to improve the quality of life for all Europeans. The Council of Europe selected blood transfusion as one area to encourage co-operation among member states. From the outset in the 1950's, 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 co-operation 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 it on the exchange of blood grouping reagents (European Treaty Series, No. 39) and of 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 a number of Recommendations covering ethical, social, scientific and training aspects of blood transfusion. Whereas 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 that 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 up-dates. These updates of these 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.


These set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. These directives will have major consequences for blood product suppliers. They do 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, although relatively little impact on clinical transfusion practices.
Several factors have aligned within 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: 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.

There had been a long history in the UK of national and zonal ‘Blood User Groups’ under the leadership of blood suppliers (in recent years the National Blood service). These groups had 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 a ‘Better Transfusion Program’ with the publication of 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 2 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 prior ‘Blood user groups’ to focus on promoting safe and effective transfusion practice within hospitals. The NBS were involved in establishing these committees and provide administrative support to them. Clinical users of blood always chair them. Whilst 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 a ‘Clinical Audit and Effectiveness Strategy’ in May 2002 (appendix 5.8.14). This program sees the NBS partnered 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 a number of 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 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 (appendix 5.8.4) indicates that progress is mixed. While some has made good progress, other Trusts 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 in its own way unique and separate from the larger UK program.

The Scottish ‘Better Blood Transfusion’ program is of particularly interest, given both its organisation and the fact that it has grown out many years of systematic endeavours within Scotland with a focus on improving hospital transfusion practice.
With leadership from healthcare professionals supported by the Scottish Blood Transfusion Service a number of 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 has 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% reduction in red cell utilisation in the coming year.

The central project management of the Scottish program contrasts with the approach taken in ‘Better Blood Transfusion’ 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 across 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 within Western Australia.

IMPROVEMENT OPPORTUNITIES.
Better Blood Transfusion.
Scotland. 2004
3.2.4 USA & 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 utilization 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 Vol. 17, No 3 (July), 2003: p 169-180].

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

In Canada, a National Blood Safety Council was established following 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 (appendix). 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. The full report of these meetings (which run to several hundred pages of transcript) is available at http://www.bloodsafety.gc.ca/docs/index-e.html

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 clearly 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.


Various provincial transfusion practice improvement programs were established across Canada in the late 1990’s and early 2000 (see below). 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 (appendix 5.9.3 and 5.9.4).

Bloodlink BC

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 Provincial Blood Coordinating Office is funded by and reports to the British Columbia Ministry of Health Services. The PBCO 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,
utilization management and quality management activities. They operate under the guidance of two advisory groups (on blood product and transfusion medicine issues) supported by a central secretariat. PBCO centrally develops materials and ‘push’ communication on relevant transfusion issues to the field through regular newsletters and forums across the Province.

The PBCO has successfully implemented improvements in informed consent processes, introduced red blood cell redistribution plans that have reduced product expiry, rationalized and reduced utilization of IVIG and rationalized 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/ QEST); clinician education programs and the development of an Ontario Transfusion Nurse Coordinators (ONTrac) program. There are also specific projects on the optimum use of autologous blood, the utilization 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 across the Province, with the program acting as a ‘clearing house’ for the outputs of each project.

3.2.5 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-miss and error; 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 of 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 intrinsically correct answer to the ‘What is Haemovigilance?’ question. Anyone embarking on any level of haemovigilance activity must make some arbitrary decisions up front that will inform the scope and nature of their program.

Typically we use measurement systems to help manage some aspect of our endeavors. It is important that decisions informing the collection of transfusion-related performance data 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 would enhance the quality of transfusion practice and patient safety.

Given that principle, haemovigilance programs should include measures of those aspects of transfusion practice that, on the basis of current knowledge, are known to be most significantly compromising patient safety. These include appropriateness of the decision to transfuse, the choice and quantity of transfused product and procedural safety (in particular matters that impact on accurate patient, sample and product reconciliation).

If the rationale for measurement is use of data for performance improvement, it follows that there is no point in embarking on programs of transfusion measures in Australia, howsoever styled, if there is to be 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 up front.

There is a detailed recent consultants report on Haemovigilance options (appendix 5.7.1). It is not our intention to engage in major additional commentary on the details of any proposed haemovigilance program for Australia. Recent international measurement programs have 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 have provided a basis for systematic efforts to improve the quality and safety of blood and blood product transfusion.

It would be unwise to await either evidence of a perfect haemovigilance model or unanimous support for a model before embarking on a national haemovigilance program. The international evidence is that those who embark on measuring transfusion practice and outcomes using some credible measures learn about 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 has confirmed that there is no existing Australian incident monitoring or reporting system in acute healthcare that adequately captures a reasonable proportion of current transfusion error and/or adverse events. Both paper-based and on-line incident-reporting systems see significant underreporting of transfusion events, whenever these have been compared with alternate local transfusion safety data capture. These inadequacies likely 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 clearly 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 SA and NSW 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 these data 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.

Suffice it to say that once there is clarity on the drivers for any national (or jurisdictional) haemovigilance program, there are a number of 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 healthcare 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.

In addition there would be the added advantage of having available international comparisons that would 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.1, 2 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.


4. OPTIONS FOR ACHIEVING BETTER, SAFER TRANSFUSION PRACTICE IN AUSTRALIA

4.1 WHAT HAVE WE LEARNT 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 that seek to enhance product safety.

The safety and appropriateness of clinical transfusion practice is, however, very different. Each of the projects in Australia that looked at contemporary transfusion practices in their jurisdictions found that clinical transfusion procedures and practice varied significantly from recommended best practice. Overuse of blood products is common and under use is rare. With very rare exceptions, there was more 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 optimize transfusion safety were also frequently absent, errant or ignored.

Contemporary transfusion practice in Australia does not differ from those described in recent times in other developed countries. The overwhelming majority of blood product transfusion risk is now known to be associated with those 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 in training of undergraduate and postgraduate healthcare 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 there being no sense of any negative consequences for healthcare 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 currently is determined by a chain of individuals and organizations, ranging from those responsible for recruiting blood donors, through to those who care for patients after they have received a transfusion. This dependency on multiple agencies and multiple healthcare professionals makes it extremely unlikely that high levels of overall safety could be achieved via ‘spontaneous combustion’ or via efforts of only some of those embedded within 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’, with an area of clinical practice that has had a relatively low profile for many decades suddenly put into the spotlight. It may also be that 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. As one program catch phrase retorted “We will have been successful if we get healthcare 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 back to clinicians and managers on the progress in adherence to desired practice in their target areas.

In the larger jurisdictions (NSW & Victoria), more formal approaches to healthcare Quality Improvement (more particularly a version of the Institute for Health Care Improvement’s ‘Breakthrough Collaborative’ methodology) were applied. The NSW approach allowed for flexibility in the make-up of participant teams, resulting in differences in team size and professional mix. They specifically focused on red cell transfusion in haemodynamically stable patients in their collaborative.

The Victorian approach had a more structured team composition, with team membership set in the requirements for participation in the collaborative. The lever of the provision of 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 a number of 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 in fact explicitly designed for such large-scale change exercises in healthcare. Experience in the Australian context, both in transfusion and elsewhere would support 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 healthcare delivery.

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

In WA, 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. Their experience is that when this feedback occurred in an environment with an active transfusion committee, the availability of performance data and provision of education was associated with changes in clinician behavior.
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 utilization at relatively modest costs. The level of information derived will assist clinical governance by providing data for utilization review and would also inform blood product production planning and purchasing decisions.

The projects in NSW, SA and Victoria have shown the benefits that accrue when healthcare 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 healthcare.

It must be emphasized that these Australian transfusion practice improvement exercises have all been essentially ‘demonstration projects’. They have provided ‘proof of principle’ that it is feasible to significantly improve on commonly accepted levels of safety and appropriateness of transfusion using a number of 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 within 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 reflects on any ‘failure’ of these projects.

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 within hospitals) of an enduring program of work designed to spread the demonstrated improvements across their entire hospital and sustained 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 see 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 across the nation to ensure that patient needs are met. We will not reiterate within this report the rationale that led to this consolidation.

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 within this framework a nationally consistent approach to clinical governance for transfusion, 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. Clearly 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 endeavors. There have been announcements from peak agencies involved in governance in the blood sector that have helped establish an expectation within the field that national leadership and direction for quality of transfusion practice will be forthcoming. (Appendix 5.10.1 and 5.10.2).

Indeed there is a degree of concern that there has been apparently slow progress on these critical areas of activity following the creation of the NBA, which has to date 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 are all too aware 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 healthcare 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 confidently assure their constituencies 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 those in our community requiring transfusion support.

It would appear difficult, if not impossible, to fulfill 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. A national program would 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 healthcare interventions in our hospitals have at their focal point 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 embraces key stakeholders 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 healthcare professionals and managers in acute healthcare. History would suggest 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.

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 ‘conductor’ 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, Vol 17, No 3 (July), 2003: p 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 WHAT ARE 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:

**LEADERSHIP AND DIRECTION.**

A national transfusion safety and quality program could identify opportunities for monitoring and improvement of transfusion practice and prioritize these within an Australian context.

It could decide upon a parsimonious set of core objectives and require that jurisdictions deliver the requisite measures and implement targeted improvement programs within explicit time frames to achieve these agreed national objectives.

Such a national program should be integrated into existing authority and governance structures to maximize 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 most probably 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 HTC's to engage in additional relevant local activities targeting enhanced transfusion safety.

In our opinion, adequate resourcing of HTC's 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, how-so-ever titled (Transfusion Nurse / Transfusion Safety Officer / Specialist Practitioner of Transfusion), the utility and potential effectiveness of any transfusion monitoring and improvement program is uncertain.

**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, 1 to 2% of the current direct costs of blood and blood product supply. These direct product costs represent approximately one third of the overall healthcare costs of transfusion support.

It is not for the authors of this report to perform formal cost-benefit analyses on any such proposed investment. However, given the evidence of current fresh blood product clinical transfusion practice in comparison with recommended best practice, it is clear that there are major potential returns from even modest investment in transfusion practice improvement.

**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.

The provision of 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 across 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 standardize particular processes.

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

Requests to standardize care processes should be minimized. 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.
4.4 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 clearly a 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 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 1-2% of the current cost of blood product supply. These funds would represent less than 1% of the overall cost of blood and blood product transfusion a very small fraction of the overall national cost of acute healthcare.

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 within 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% ‘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 healthcare, albeit a subset with certain special characteristics. Rather than requiring entirely new monies to support the implementation of better, safer transfusion practices across Australia, it would be 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. It could be suggested that a component of these funds 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 within these communications.

4.5 OTHER ISSUES

4.5.1 Levers for changing transfusion practice.

Financial levers are often used within healthcare 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. Indeed 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 (i.e. the volume of products purchased). It may be that ‘allocative efficiency’ is the more important dimension for determinations of blood sector efficiency (i.e. to what extent the funds directed have purchased the blood and blood products required to meet the transfusion needs of our 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 to be found within the potential avoidance of product purchase.

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

Although blood product costs are rising, they currently equate to approximately 3% of the overall budget for acute hospitals in Australia and less than 1% of recurrent national expenditure on healthcare. Put simply, for most hospitals the need to plot strategies to save some fraction of 1% of their overall organizational budget that could be reasonably achieved by attacking their ‘blood budget’ may not keep many hospital Finance Managers awake at night.

It should be remembered that our entire national blood supply budget equates to the budget allocated to two or three of our major teaching hospitals.

The ability of price signals to influence hospital transfusion practice may 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 (e.g. Albumin versus saline). Where no alternative exists, pricing alone may have little impact on clinical demand and utilization patterns.

Price signals should be used with great caution for high cost blood products that are essential for patient well being (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 organizational 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 side-by-side with 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 see 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). Whilst 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 preemptive
planning or actions by hospitals in NSW in anticipation of operating in this new funding
paradigm. We believe that it would be useful to regard the current NSW 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
NSW 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 NSW 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.

By and large, the available evidence from international programs would 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 would indicate 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 healthcare management agenda by making the safety and appropriateness of
hospital transfusion an explicit responsibility of health service CEO’s.

At the end of the day, 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  
NBS Medical Director, England.  
2003

4.5.2 Education and training.

A constant theme in the literature and from our experience of hospitals’ transfusion practitioners’ experience is the need to establish education and training programs for healthcare 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 healthcare professionals no longer acquire even the basic knowledge and skills required to deliver safe and appropriate blood product transfusion.

By and large, consumers are not 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 healthcare system.

There needs to be a nationally consistent education and training framework that ensures exposure to relevant education on transfusion practice in medical, nursing and medical science undergraduate curricula. Even more importantly there needs to be postgraduate workplace training 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 adequately address the needs of healthcare professionals involved in everyday transfusion practice.

The provision of vision and practical guidance on such education and training issues would be one important activity for a national transfusion safety and appropriateness program.
4.5.3 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 Programme: 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 roll-out 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). We have encountered nothing but strong support for the value of this role in our discussions with jurisdictions and hospitals that have utilized 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.

The ‘experiment of history’ would indicate that, with rare exception, hospitals in Australia fail to self organize and effectively deliver safe and appropriate transfusion practice in the absence of such a focused resource.

While there has been enthusiasm (and often a degree of frustration) within 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 a number of 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 HTC’s 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 (howsoever 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 provision of 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 HTC’s when they have been installed into hospitals either through local enthusiasm or by projects such as the BloodSafe and Blood Matters projects within Australia, the Better Blood Transfusion programs across 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 Dept 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, Vol 17, No 3 (July), 2003: p 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, Vol 17, No 3 (July), 2003: p 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.