

THE NATIONAL PUBLIC HEALTH PARTNERSHIP

**BACKGROUND PAPER TO THE
REVIEW OF THE AUSTRALIAN
BLOOD BANKING
AND PLASMA PRODUCT SECTOR**

23 SEPTEMBER 1999

TERMS OF REFERENCE OF THE REVIEW

1. *Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national Quality Assurance Program*
2. *Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.*
3. *Consider and recommend ways to improve system-wide decision making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time. among other things the advice should cover:*
 - *the need for and financial impact of new testing procedures and new products;*
 - *legal and ethical issues where access to products may be based on clinical priorities;*
 - *cost effectiveness of proposed safety improvements;*
 - *the role of an expert reference laboratory in setting and maintaining a national quality assurance program; and*
 - *the impact of change on public confidence in the blood supply.*
4. *Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.*
5. *Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of the safety implications, recommend, if required, strategies to improve that capacity.*

PREAMBLE

- The National Public Health Partnership (NPHP), established in October 1996, aims to improve collaboration in and coordination of public health effort across Australia. The initiative is managed by the NPHP Group, a sub-committee of the Australian Health Ministers' Advisory Council, and comprises the Directors of Public Health or Chief Health Officers of the Commonwealth, States and Territories, and includes representatives of the National Health and Medical Research Council and the Australian Institute of Health and Welfare.
- The NPHP Group agreed, at its meeting of 24 and 25 August 1999, to provide a background paper which gives a broad public health perspective on the issues of interest to the Review, especially those related to ensuring the safety of the blood transfusion system¹.
- Blood transfusion is a critical aspect of our health system, not only for those who require it, but for the community at large which holds the sufficiency, quality and safety of the blood supply very highly indeed. Public health issues related to the blood system must be viewed from this backdrop of high community expectation.
- This paper scopes public health's role and interest in the blood transfusion system and identifies public health aspects of blood services that should be improved or further examined. Public health issues span the full spectrum of the blood system from the collection, processing and production of blood products through to the transfusion act. Public health therefore has a strong interest in fostering co-ordinated, system-wide decision-making to help carry out its various roles in relation to blood services.
- This document should be read as a background paper which presents the broad, common view of jurisdictions on a range of public health issues related to blood services. Most, if not all, jurisdictions involved in preparing this paper will make their own formal submission to the Review. It is the intention that this document will complement these individual submissions.

¹ Note: In this paper, the terms "blood transfusion system", "blood system" and "blood services" are used interchangeably to refer to the whole system of blood collection, processing and transfusion and thus includes both those who supply blood products and the hospitals and clinicians who use it.

EXECUTIVE SUMMARY

The public health role in the blood service system

- The specific role of public health in relation to the blood service system is to:
 - protect recipients and the public at large from transfusion-related infection;
 - promote balanced, evidence-based decision-making for a safe blood supply;
 - encourage optimal transfusion practice and minimise blood transfusions;
 - maintain high public confidence in the voluntary blood system.
- Furthermore, public health aims to keep the prevalence of blood-borne infection in the community low to ensure a viable donor population and to minimise risks to the system.
- Public health has a role and interest across the whole chain - from blood collection to transfusion. Furthermore public health brings a population health perspective which considers the longer term benefits to society as a whole, whilst understanding the clinical responsibility to individual patients. These two broad perspectives highlight why the contribution of public health to the blood service system is so important.

The need for system-wide management

- National management and policy-making for the Australian blood system as a whole - from supply to transfusion - needs to be strengthened. This is critical to ensure a high quality, safe and cost beneficial blood system in the future. The AHMAC Blood and Blood Products Committee has, over recent years achieved a commendable level of co-ordination between jurisdictions on a number of pressing policy issues. However the breadth and complexity of issues facing the blood service system, as seen from overseas experience, raises challenges which require a more robust, system-wide approach to decision-making.
- Given the range of players which make up the blood service system - the Red Cross, CSL, overseas suppliers, the TGA, government and health services - and the fact that decisions made in isolation by any one of the players invariably impact on the others, the need for co-ordinated policy-making is paramount. This applies in particular to public health issues, which span the full spectrum of the blood transfusion system.
- Australia would do well to examine overseas experience with national mechanisms to integrate policy-making for the blood transfusion system. The examples of Canada, France and the UK may offer particularly useful insights.

Communicable disease control

- The relationship between individual health authorities and their blood services in the control of transfusion-related communicable diseases is generally informal and ad-hoc. A more structured and systematic relationship between blood services and health authorities would enable a better response to communicable disease threats to the blood transfusion system.
- Quality and safety must be addressed in a comprehensive and integrated way across the whole chain - from donor selection to the transfusion act and its effects. The artificial split between production and transfusion must be overcome as a whole of system approach is vital to promote the safety of blood services.

Risk management

- Managing risk is part and parcel of the blood service system, and a more structured approach to risk management must be achieved to ensure decision-making is fully informed and shared between all relevant parties. A risk management approach on supply, quality and safety issues (both real and perceived) needs to be developed for Australia which brings all key players together, and enables scientific information to be objectively considered. Public health has a major stake in managing risk given that the bulk of future increases in cost are likely to stem from new safety measures. Also, given its affinity with risk management, public health can make a valuable contribution in developing and implementing such an approach.

Blood system surveillance and analysis

- Australia has no surveillance capacity in relation to blood transfusion services and therefore lacks an important tool which can provide early warnings of safety problems, and also give an overall picture of the longer term outcomes of transfusion.
- The desirability of establishing an Australian haemovigilance system should therefore be investigated including its purpose, scope and management. Haemovigilance is blood system surveillance to gather, detect and analyse system errors and the adverse effects of transfusion with the aims of making transfusions safer and maintaining confidence in the blood supply.
- Furthermore, sharing of surveillance data between blood services and other public health areas eg. communicable diseases, could be mutually beneficial and should be further explored.
- Consideration should also be given to sentinel surveillance of blood donors for other disease and health markers which may have broad public health significance and may, in turn, assist future planning of blood collection services.

Promoting optimal transfusion practice

- Any review of the blood system must consider demand as well as supply issues. Significant attention has been justifiably paid over recent years to increasing the supply of certain blood products. Transfusion practice, as the driver of demand, also needs to be examined.
- There are inherent risks in all transfusions and, as a principle, transfusion should be avoided unless absolutely necessary. A recent review concluded that minimising blood loss and setting criteria under which a patient will be transfused to minimise the need for all blood products should be first priorities.
- Public health maintains a strong interest in encouraging evidence-based transfusion practice to minimise risk to patients. An issue of current debate is the extent to which alternatives to homologous blood transfusion eg. autologous and directed transfusions should be encouraged. The NPHP Group draws the Review's attention to the recent draft report (March 1999) of the AHMAC Blood and Blood Products Committee for an expert view on this issue.

1. The public health role in the blood service system

The public health perspective

- The population health perspective of public health accords with the principle of a voluntary, free blood system collectively organised for the benefit of society as a whole. Public health looks at the costs and benefits of the blood system from a societal as well as an individual perspective.
- Quality and safety failures, can occur at any point in the transfusion chain - from donor selection to the transfusion itself - so a focus only on supply side issues is narrow. A whole system approach to quality and safety is needed. Surveillance of adverse incidents and transfusion effects can provide valuable information to identify and rectify problems. Information on the clinical outcomes of transfusion - good or bad - also provides important feedback for clinical practice.

Public health's role in relation to blood services

- Public health's fundamental role in relation to blood services is to keep the prevalence of blood-borne infection in the community low to ensure a viable donor population and to minimise risks to the system. Since testing will never be completely reliable, reducing blood-borne infection in the community is a fundamental way of reducing the risk of transmitting infection through the blood supply. Direct investments in the blood service system such as the introduction of new, expensive screening tests should therefore be weighed against making the same investment to prevent or reduce blood-borne infection in the community.
- To help maintain the viability, quality and safety of Australia's blood transfusion system, public health authorities have a range of responsibilities and interests spanning the transfusion chain as illustrated in Appendix 1, These can be summarised as :
 - protect recipients and the public at large from transfusion-related infection;
 - promote balanced, evidence-based decision-making for a safe blood supply;
 - encourage optimal transfusion practice and minimise blood transfusions;
 - maintain high public confidence in the voluntary blood system.
- Within this spectrum, public health has a primary role or capacity for a greater advisory role in a number of areas as listed in Appendix 2.
- Foremost is public health's responsibility for **communicable disease control** to prevent the spread of transfusion-related infection through: adequate safety measures for infection control; screening, reporting and surveillance of specific diseases; traceability of potentially infected recipients etc.

- Public health is also called upon to advise on the desirability of introducing new technology or other improvements when scientific advances are made or when public opinion demands it. Considered decision-making in such instances, which should be based on cost-benefit assessments, is also a task in which public health can play a lead role. Costly changes to safety practices in the blood transfusion system are often driven by media and public pressure or by changes in overseas practice without a proper assessment of the risks and benefits in the Australian context - (HTLV1 and NAT testing are cases in point, new variant CJD could be so in the future).
- Government health authorities provide the frontline response to account for real or perceived problems in the system, and to reassure public confidence. Responsibility for risk communication falls on public health.
- Public health also has an interest in the ethical issues that surround blood transfusion: autologous and directed donations, informed consent, donor selection, fair and equitable treatment eg. best use of limited blood products, which can all be informed by a population approach, and in legislation which limits the sale of blood and human tissue.
- Understanding the immediate and long term effects of transfusions is a vital body of information on which to decide future changes to the blood supply and to clinical practice. Blood transfusion surveillance and epidemiology through haemovigilance systems, whilst a new concept for Australia, is becoming an important part of the safety regime in France, the UK and US. Recently the ARCBS has sought further involvement of public health haemovigilance systems for the surveillance of post transfusion events - long term surveillance related to disease and mortality.
- Public health also has an interest in promoting optimal transfusion practice by monitoring the proper use (avoiding overuse, misuse and underuse) of blood and blood products and through the development of clinical guidelines.
- A further area is the unexplored potential for using the blood donor population as a sentinel for certain health, disease and genetic markers. Such information would have public health significance broadly but could also assist in giving a sense of the health of the donor population and be used for future planning.

Formal links between government health authorities and blood service agencies

- Generally the relationship between blood services and government health authorities, on safety issues, is not formally structured or systematic. At the same time, when there is a special cause (as occurred in recent years with HCV lookback), the involvement of public health with blood services can be quite intensive.

- Within each state/territory, administrative responsibility for blood services does not always reside with the public health unit authority. This means varying emphasis is given to public health involvement in the blood sector depending on the jurisdiction.

2. The need for system-wide management

- The preceding discussion underscores the critical relationship between public health, blood agencies, and clinicians. They share a common interest to: ensure systems which protect patients and the public from the spread of communicable disease; detect problems when they occur and take prompt and concerted corrective action; and maintain public confidence in the blood system. However since responsibility for the diverse aspects of the blood system lies with different bodies, it has been difficult for blood service providers, health services and government to act together on these issues.
- These difficulties are evidenced in the way the Australian blood system has responded to safety issues in the past (eg HTLV1) and in the present (eg NAT testing). This has been characterised by an inability: to adequately bring scientific knowledge to bear on these issues due to media and public pressure; to communicate the known facts to the public; and to co-ordinate decision-making and action between the various bodies involved.
- A striking example of fragmented arrangements is the current situation where the TGA is responsible for regulating plasma products but there is no regulation of fresh blood products. Clearly it is untenable to regulate only some products and not others particularly when these have been derived from the same donated blood. Earlier this year (at its 22/4/99 meeting) AHMAC considered this anomaly and agreed that fresh blood products should also be regulated by the TGA.
- Since 1995, the AHMAC Blood and Blood Products Committee, has to some extent provided a national co-ordinating role by driving national development on a number of issues. The Committee's work has led to significant achievements including: increased access to products to improve the treatment of haemophilia and other rare coagulation disorders; investigating questions such as uniform blood shield, public liability insurance and autologous transfusion. The importance of these achievements cannot be underestimated particularly given the limited resources at the Committee's disposal. However, the capacity of this Committee is below what is needed to effectively tackle the many issues facing the blood system. In countries such as Canada, France and the UK, where high profile bodies (ie national blood authorities) have been established as the overall policy-making instrument, the capacity for a system-wide approach has been greatly enhanced. In these cases an eminent body has been created which draws together the various components of the system under one policy-making umbrella.

3. Communicable disease control

- A low prevalence of blood borne infections in the general population is important to maintain a safe blood supply. Safety risks to the blood supply relate directly to the prevalence of blood borne infections in the community. . The blood supply should not be looked at in isolation but in the context of overall prevention strategies such as HIV and HCV prevention. Future investment decisions to protect the blood system must be made from the broader perspective of blood-borne disease control in the community at large. For instance is it more cost-beneficial to put resources into maintaining low prevalence of blood-borne disease in the community or into new blood screening tests?
- The level of consistency between jurisdictions in relation to the different regulatory requirements to ensure safety needs to be examined. This could include donor screening, blood testing, infection control, the traceability of products, and notification of blood-borne infection detected through donor screening.
- Overall approaches to safety in blood services can feature information-driven systems (eg. clinical studies, transfusion outcomes etc), external regulation including public accountability, and internal quality systems. These are not mutually exclusive approaches and indeed combinations of these systems may in many cases be the most effective course to take.
- External monitoring and regulation of the blood services system does not diminish, but on the contrary focuses the need for internal approaches (eg quality assurance) to ensure safety. Adequate investment, not just in high technology measures but also in the education and training of staff to competently implement safety procedures is a critical, but often understated, aspect of the safety regime. Recent blood surveillance studies in the UK have shown the significant part human error plays in the overall risk to safety. Proper resourcing of infrastructure is needed to ensure the continuing safety of the blood supply.

4. Risk management

- The advent of HIV/AIDS has increased the sensitivity of users of blood services and the general public to the risk of blood transfusion resulting in an increase in autologous transfusion often illogically and at great expense. There has also been a steady increase in the number of screening tests introduced and proposed for blood transfusion.
- Decisions to introduce new tests or procedures, to recall products, trace recipients or to discard blood when the risk of contamination is only theoretical, or where there is public pressure to do so, should be made by properly weighing all the available information. A risk management approach needs to be developed for Australia's blood system to ensure decisions are made in full knowledge of the costs and benefits,

and in a way that encourages public understanding of the pros and cons of different options.

- Risk management requires that decision-making be informed by science as well as driven by public perception and political imperative. This requires both a capacity for dispassionate analyses and an ability to communicate risk to the public. The communication of infectious disease risk falls to public health as a discipline. The better the actual risks to the blood system are understood by the public, the greater the potential to base decision-making and practice on factual evidence.
- The issue of liability, which often underpins action to introduce new safety measures, is best addressed through risk management. Provisions to limit or insure against liability (eg statutory defence through blood shield legislation or financial insurance arrangements) are most effective when the overall risk is understood and if they are part of an overall management plan.
- Risk management for blood services requires both a respect for the clinical value of “duty of care” and an assessment of the costs and benefits to society as a whole. Public health is able to work from within both perspectives. Furthermore its association with health services research equips it with valuable experience to advise on cost-benefit assessments related to investment in the blood service system.

5. Blood system surveillance and analysis

- A haemovigilance system would be a valuable tool to help improve safety as well as a source of data to inform risk management decision-making. Blood surveillance can provide both an early warning system if there are adverse reactions, and a way of monitoring transfusion outcomes in the longer term. The former can help alert to immediate problems in the blood transfusion chain which must be rectified. The latter also fulfills this need but moreover can help to improve transfusion practice.
- Haemovigilance is a system to collect, interpret and use information on the short and long term outcomes of transfusion. Whilst the first focus is on acute adverse reactions, haemovigilance can also monitor the longer term outcomes of patients, and observe patterns of clinical use and misuse.
- Different haemovigilance systems are operating in France, the UK and the US, with an overall European system currently under consideration. Each country’s system differs in terms of scope (from comprehensive systems which gather data from all hospitals and transfusion patients to simpler systems which only sample from the total clinical activity) and whether its participation is voluntary or mandatory. The French system exemplifies the comprehensive, mandatory approach while the UK *Serious Hazards of Transfusion* (SHOT) scheme is voluntary and has a less ambitious scope.

- The UK system, which costs about 18,000 pounds per annum to run, focuses on voluntary notification by hospitals and clinicians of the more serious transfusion events such as incorrect blood or component transfused; acute or delayed transfusion reactions; reaction to a bacterially contaminated component or post transfusion viral infection. In two years of operation, 366 cases were reported of which 52% were “wrong blood to patient” (3 resulting in death) due to multiple errors of identification. Twelve infections were also identified during this time of which two resulted in fatality.
- UK experience draws attention to risk that human error (incompatible blood transfusion) and bacterial contamination play versus diminishing risk of viral infection. Problems such as these can be largely solved through training, procedural and technological improvement and result in actual, rather than theoretical gains in safety. Also the annual publication of haemovigilance data, as has been done for the past two years in the UK, gives the public open information on the real risks of transfusion, and may help to develop a more balanced public perception and encourage confidence in the system.
- A comprehensive system would need to identify and record a wide range of information arising from:
 - * epidemiological monitoring to prevent the spread of infectious agents through blood and blood products;
 - * monitoring and classifying events related to transfusion errors to determine their distribution and causes with the aim of improving procedures in the blood transfusion chain;
 - * identifying adverse effects of transfused blood products so these can be prevented; and
 - * recording the clinical use of blood products against accepted guidelines to identify inappropriate or dangerous prescription of products
- The level of sophistication of the system would need to consider the cost, onerous data requirements, existing networks which would facilitate data collection and transfer etc.
- Haemovigilance systems can be seen as having at least three broad purposes:
 - * a formal epidemiological tool to monitor the immediate and long term transfusion effects with the aim of making improvements to the system and informing risk management decision-making (outcome monitoring);
 - * a comprehensive QA reporting system (process monitoring) for raising profile of issues leading to education and system improvement; and
 - * demonstrate to the public, patients and professionals the safety of existing transfusion systems - to present the risks and benefits of transfusion in a sensible perspective to show that where there are problems, these are

recognised, effectively tackled and not ignored or kept secret. Public confidence in the blood system ultimately depends on trust.

- In Australia, there is no body charged with responsibility for blood transfusion surveillance spanning the whole system, including the characteristics of donors, the collection, testing and handling of blood through to the transfusion characteristics of recipients and the surveillance of post-transfusion events.

6. Promoting optimal transfusion practice

- Any review of the blood system must consider demand as well as supply issues. Significant attention has been rightly paid over recent years to increasing the supply of certain blood products. Transfusion practice, as the driver of demand, also needs to be examined.
- There are inherent risks in all transfusions and, as a principle, transfusion should be avoided unless absolutely necessary. A recent review² concluded that minimising blood loss and setting criteria under which a patient will be transfused to minimise the need for all blood products should be first priorities. Also a recent study conducted in NSW (as yet not released for publication) suggests that as much as 30% of red cell transfusion is not required.
- Public health maintains a strong interest in encouraging evidence-based transfusion practice to minimise risk to patients. The development of evidence-based transfusion guidelines and the monitoring of practice against these guidelines is an area where public health input is relevant. An issue of current debate is the extent to which alternatives to homologous blood transfusion eg. autologous and directed transfusions should be encouraged. The NPHP Group draws the Review's attention to the recent report (cited above) of the AHMAC Blood and Blood Products Committee for an expert view on this issue.

² *Review of the Alternatives to Homologous Blood Donation* - Draft, March 1999, AHMAC Blood and Blood Products Committee

Appendix 1

Scope of public health interest in blood transfusion system

BLOOD TRANSFUSION CHAIN	PUBLIC HEALTH INTEREST OR ROLE
<p><i>COLLECTION</i></p> <p style="text-align: right;">Donor recruitment</p> <p style="text-align: right;">Donor selection</p> <p style="text-align: right;">Blood collection and handling</p>	<ul style="list-style-type: none"> - informing blood authorities on factors (eg prevalence of certain diseases, epidemics) which could affect donor recruitment - eligibility of donors / mandatory donor declaration - infection control to protect donors and staff - advising on cost benefits related to different collection technologies (apheresis)
<p><i>TESTING & PROCESSING</i></p> <p style="text-align: right;">Blood testing</p> <p style="text-align: right;">Blood safety and quality</p>	<ul style="list-style-type: none"> - notifiable disease reporting - reporting of other disease or health (eg genetic) markers which may have a public health value - provision of specialist public health laboratory services - cost/benefits of introducing new tests eg NAT and reviewing existing ones of questionable benefit eg HTLV1 - advising on the desirability of technologies eg leucodepletion to improve the quality, efficacy and safety of blood
<p><i>TRANSFUSION</i></p> <p style="text-align: right;">Product availability</p> <p style="text-align: right;">Transfusion methods</p> <p style="text-align: right;">Clinical practice</p> <p style="text-align: right;">Post-transfusion phase</p>	<ul style="list-style-type: none"> - equitable access to products in short supply (eg rationing of Anti-D and immunoglobulin) including desirability of moving to different treatment regimes and how this affects distribution (eg preventive vs emergency treatment of people with haemophilia) - cost benefit and ethical considerations of different methods eg directed, autologous, cell salvage - informing guidelines for clinical use & monitoring overall clinical practice; encouraging “bloodless” surgery and discouraging unnecessary transfusion. - monitoring of transfusion outcomes both immediate adverse effects and long term health outcomes to help inform future system decision-making and clinical practice
BLOOD TRANSFUSION CHAIN	PUBLIC HEALTH INTEREST OR ROLE

<p><i>OVERALL SYSTEM ISSUES</i></p>	<ul style="list-style-type: none"> - Input into general blood sector policy and system reform. For example: the societal and distributional benefits of voluntary donor systems compared to paid ones; the effects of price signals to optimise the clinical use of blood; cost benefits of introducing new safety measures versus the need to maintain public confidence in the blood system. - Ensuring systems and information are in place at blood banks, private labs and hospitals to enable traceability of products from donors to recipients - Various legislation eg Human Tissue Act regarding the sale of blood and other human tissue. - Advising on public health aspects of legal indemnity and financial insurance against litigation
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**BLOOD TRANSFUSION ISSUES ON WHICH
PUBLIC HEALTH HAS A LEAD ROLE OR CAPACITY FOR A
GREATER ADVISORY ROLE**

1. **Communicable disease control**
 - Maintaining low prevalence of blood-borne infection in the community
 - Notifiable disease legislation and surveillance
 - Prevention of blood-transfusion related infection involving:
 - quality assurance systems
 - product recall
 - lookbacks
 - traceability from donor to recipient
 - Process related infection control
2. **Assessing the benefits of new technology and other measures to ensure the safety of the transfusion system.**
 - Public health's contribution to a risk management approach to blood transfusion safety by bringing a societal cost-benefit perspective to decision-making.
3. **Maintaining public confidence in the blood system**
 - Public and media information related to safety issues - real and perceived.
 - Weighing costs of new safety measures against need to maintain high public confidence
4. **Input on ethical Issues**
 - Includes a range of matters such as lookbacks to advise potentially infected recipients, prohibiting the sale of blood and other human tissue, access to limited blood products and other distributional issues.
5. **Blood surveillance - "haemovigilance"**
 - Monitoring short term effects and long term outcomes - adverse reactions, long term morbidity and mortality - of transfused patients.
6. **Public health disaster management**
 - Ensuring response capacity related to potential blood needs in a crisis situation
7. **Sentinel surveillance**
 - Of other disease and health characteristics of donors which may have public health significance, and may provide opportunistic information for disease prevention and control.

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