

NATIONAL BLOOD RESEARCH AND DEVELOPMENT STRATEGIC PRIORITIES

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National Blood Authority
Australia



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Introduction

Blood and blood products are a critical component of health care. Ensuring supply to meet clinical demand requires collection of over 1 million donations per annum by the Australian Red Cross Blood Service (Blood Service). Blood and blood products are provided free of charge to patients. However, the cost of blood and blood products in Australia is over \$1 billion dollars per annum, with expenditure on transfusion related health services far exceeding this figure. Research and innovation are essential to ensure the optimal use of blood and blood products.

Significant challenges face the blood sector. There are gaps in evidence to support practice improvement, including information about how, where and why blood and blood products are used. An ageing population, as well as emerging evidence supporting the use of some therapies for broader indications places the adequacy of supply into the future at risk. Welfare of donors is an important consideration when planning for potential increased demand for products. There are numerous studies suggesting high rates of inappropriate transfusions. Adverse events and poor patient outcomes, which can occur as a result of transfusion, highlight the need to ensure a strong evidence base to support practice improvement.

In addition, the health system is under increasing financial pressure. At present, blood and blood products are outside of the National Efficient Price. Enhancing price signals in the blood sector may provide new opportunities to use price levers as tools to drive changes in clinical practice. All stakeholders are responsible for ensuring that the provision of blood and blood products, and

related health services represents value for money for the Australian community.

To balance these challenges, innovations in the fields of genetics and cellular therapies provide unique opportunities to better target therapies to individual patients, which may lead to improved patient outcomes as well as reductions in demand for donated blood products. In addition, new products may provide opportunity to reduce reliance on donated blood products.

In 2010-11 the Department of Health and Ageing commissioned the NBA to undertake a project to identify information gaps in the blood sector, with the aim of driving research priorities to meet these gaps. This Blood Sector Research and Development Strategy builds on the research gaps project, and describes at a high level the areas of priority for research in the blood sector.

Building on this work, the Jurisdictional Blood Committee has developed this document to communicate governments' priorities for blood sector research. Input was sought through both a targeted consultation round, and a public consultation round.

National Blood Sector Research Priorities

The appropriate clinical use of blood and blood products is critical to optimise patient outcomes and to manage the use of a limited resource. Evidence indicates that a proportion of transfusions are inappropriate, and that the evidence base for treatment and dosing with blood and blood products is not strong. There has been a paradigm shift toward a focus on patient blood management (PBM), but uptake of PBM principles into the clinical community is variable. Understanding when and how blood and blood products are used will be critical to achieving improvement. Improvements will also require the development of strategies to educate patients about the risks and benefits of blood transfusion, as well as to educate the clinical community about blood conservation techniques. The conduct of high quality research is crucial to provide a strong evidence base to drive uptake of PBM principles.

At present the use of blood and blood products for many conditions is generic, with the product used to treat a broad range of clinical symptoms. It is important to both prepare for, and take advantage of, emerging opportunities that may reduce reliance on donated blood products. Such opportunities may include the development of blood and blood product substitutes and alternative treatments, such as synthetic oxygen carriers, and manufactured red blood cells. In addition, developments in product technologies, such as long half-life products, genetic and cellular therapies, and subcutaneous infusion products, provide opportunities for reducing the burden on the health system, and improving patient outcomes and quality of life.

Priority One

To ensure the use of blood and blood products is appropriate

What we are trying to achieve:

Improvement of clinical practice and patient outcomes by improving knowledge relating to the use of blood and blood products, as well as strategies to avoid use of blood and blood products where appropriate.



Work already underway:

- Patient blood management guidelines - NBA
- Patient blood management toolkit - NBA
- BloodSafe eLearning Australia
- Adverse event surveillance reporting for haemophilia – Australian Haemophilia Centre Directors' Organisation (AHCDO) and NBA
- Population health data analyses investigating the use of blood products in mothers and babies – University of Sydney at Royal North Shore Hospital
- Centre of Research Excellence for Patient Blood Management in Critical Illness and Trauma – Monash University and partners
- Early coagulopathy in trauma – TORC
- Audits by clinical transfusion practice improvement programs

What we want from the research community

Characterisation of the how blood and blood products are used in Australia, including analysis of the recipients (demographics, diagnosis and comorbidities, other treatments, outcomes)

Development and reporting of evidence to identify specific patient response to treatments, including identification of non-responders, to allow for better matching of condition with treatment

Identification of strategies that will reduce reliance on donated blood products, including diagnosis and treatment of iron deficiency anaemia, and identification and analysis of alternative treatment pathways

Development of evidence to address gaps or strengthen evidence such as communicated in the PBM Guidelines and the Review of the Clinical Governance and Authorisation Process for Intravenous Immunoglobulin, including clinical trials where appropriate

Development of strategies to facilitate best practice and increase the uptake of clinical guidelines, including analysis of barriers to implementation

Analysis of the pharmacokinetics of IVIg in responders and non-responders, with attention to biomarkers that predict outcome and determine appropriate dosing in the overweight or obese

Identification of minimum dosing strategies to achieve the desired clinical outcomes, based on individual patient characteristics

Systematic examination of international best practice trends in blood and blood product use for individual diagnoses

Evaluation of patient responses to education on transfusion, including the influence of the informed patient on the decision to transfuse

Characterisation of attitudes toward perioperative blood conservation, and development of strategies, including funding, safety, workforce and training, to improve implementation of blood conservation strategies

Characterisation of clinical decision making at the point of prescription, and development of strategies to support that decision making

Identification of mechanisms underlying the clinical effects of blood and blood products at a physiological and molecular level

 Initial focus

The availability of blood and blood products in the right quantities, at the right time and in the right place is dependent on a complex supply chain. The supply chain involves the collection of blood from donors, processing of the donations through manufacturing facilities and subsequent distribution across Australia. Some products are manufactured by recombinant technology, and some products are imported to meet shortfalls in domestic supply. The supply of some blood and blood products also requires careful management of inventory to ensure the correct matching of product to patient, maintenance of cold storage, management of shelf life and implementation of contingency arrangements in supply shortage situations.

Given the cost and critical nature of blood and blood products, it is essential that the supply chain is as responsive, effective and efficient as possible.

Priority Two

What we are trying to achieve

Optimisation of the blood supply chain to ensure that blood and blood products are managed in a way that ensures product is available to meet clinical demand while minimising wastage.

To ensure
**adequacy and
sustainability of
supply, realise
supply chain
efficiencies and
improve
performance**

What we want from the research community

Development of improved manufacturing strategies, such as to improve product yield, product quality during storage and product shelf-life

Modelling of different scenarios such as supply shortages or donor shortages, including during a pandemic, and identification and analysis of strategies to mitigate risk including categorisation of patients for priority supply

Identification of factors that motivate donors, and development of strategies to increase the donor population as required

Development of technological solutions, including RFID, that will support management of blood and blood products and reduce inefficiencies in the supply chain

Analysis of the changes that occur during storage of blood and blood products, and development strategies to improve the quality of blood and blood products during storage

Modelling of the impact of incentive /removal of financial barriers to donation on blood donation capacity and cost

Analysis of the costs and benefits of blood donor screening strategies, and the risk reduction achieved by donor screening

Collection of epidemiological data on the incidence and prevalence of conditions where blood use is high

Identification and analysis of changes that could lead to changes in demand for blood and/or blood products

Analysis of the current supply policy relating to self-sufficiency and voluntary non-remunerated donors

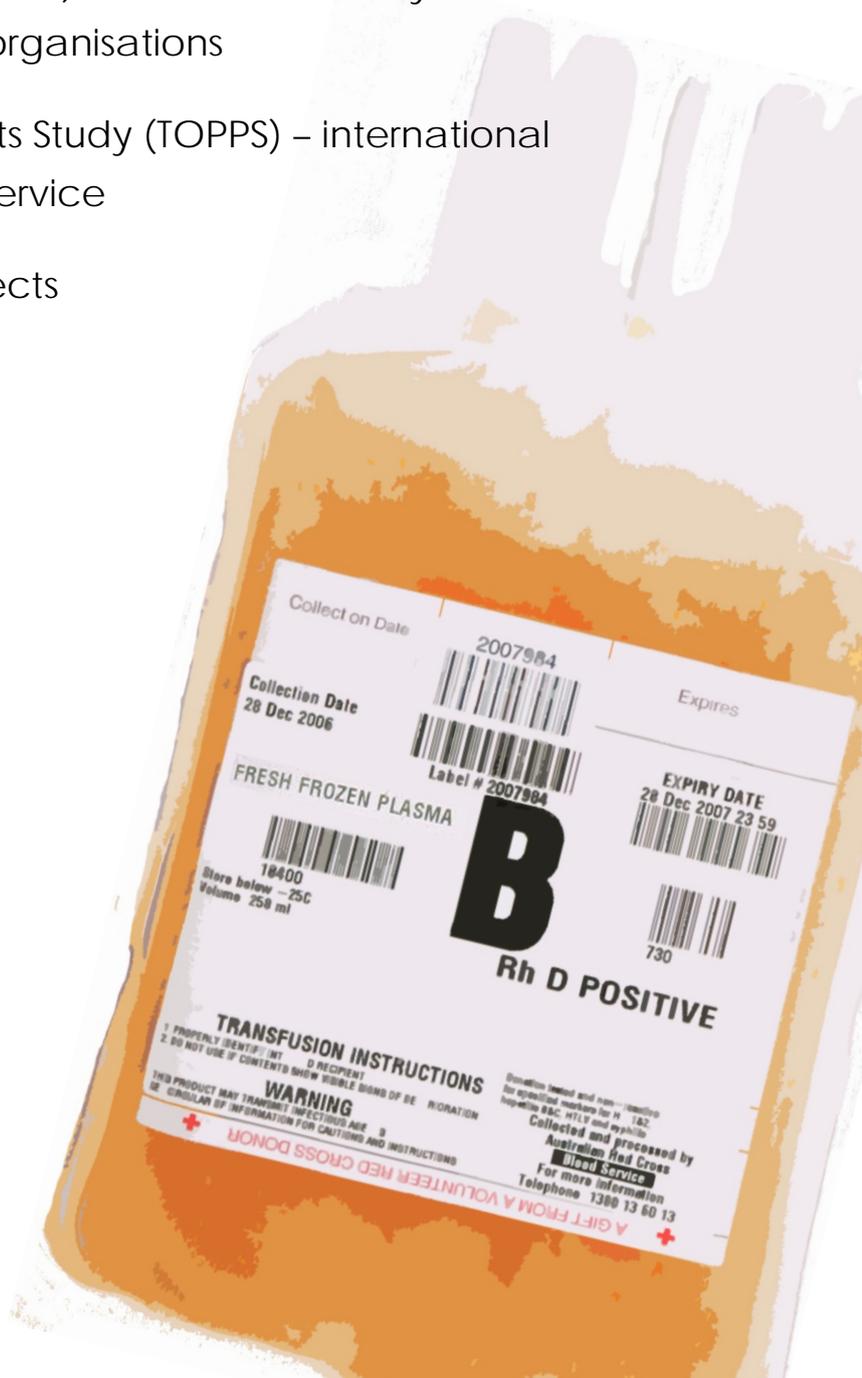
Characterisation of the most efficient and effective supply chain for blood and blood products in Australia

Development of strategies to facilitate best practice in inventory management

 Initial focus

Work already underway:

- National inventory management framework – NBA and Blood Service
- Frozen blood product development – Blood Service
- Three year plasma project– NBA and Blood Service
- National Blood Supply Contingency Plan - NBA
- IVIg governance review – NBA
- Blood system modelling project: Transfusion Outcomes Research Collaborative (TORC) - Monash University, Blood Service and other partner organisations
- Trial of Prophylactic Platelets Study (TOPPS) – international study including the Blood Service
- National data linkage projects
- BloodNet - NBA



Priority Three

To reduce donor and patient adverse events

Numerous studies describe an association between transfusion and adverse outcomes, including increased morbidity and mortality.

Some adverse events can be brought about by human factors, such as wrong blood in tube events which is a persistent problem and has the potential to lead to a potentially fatal transfusion of the incorrect blood type. Other adverse events are brought about by characteristics of the product transfused, such as febrile non-haemolytic transfusion reactions. These types of adverse events can be caused by the patient response to the donors' cells or by biological accumulations during storage of blood products. The way products are stored and handled can affect patient outcome.

Also, in spite of a strong safety profile relating to transfusion in Australia, there remains a risk of transfusion-transmitted infections. Changing climate, travel and other demographic factors are resulting in changes to pathogens, and continuous horizon scanning is required to identify changing risk profiles.

At the other end of the supply chain, the effects on the donor of multiple blood, platelet and plasma donations are not well understood. Ensuring donor welfare is important both for the health of the donors and for the future sustainability of the blood supply chain.

What we are trying to achieve

Maintenance of a safe supply of blood and blood products in Australia, and as well as implementation of collection and transfusion strategies that reduce the incidence of adverse events and maintain donor health and safety.

Work already underway:

- Blood and blood product standard - ACSQHC
- National Haemovigilance report – NBA (with cooperation from the jurisdictions)
- Age of blood studies including Quantification of the relationship between adverse outcomes and age of red blood cells at transfusion (The Sax Institute and the Blood Service), and TRANSFUSE (STandarRd issue trANSfusion versuS Fresher red blood cell Use in intenSive care, Monash University)
- Pathogen inactivation studies – Blood Service, HealthPact
- Human factors research – Transfusion Outcomes Research Collaborative (TORC), Monash University, Blood Service, Department of Health Victoria
- Haemophilia adverse event monitoring - ACHDO and NBA
- State haemovigilance programs

What we want from the research community

Improved understanding of the physiological and product characteristics (including storage time) associated with adverse reactions such as TRALI and febrile non-haemolytic transfusion reactions, and development of strategies to reduce the incidence

Analysis of changes in blood characteristics following multiple blood donations, including improved understanding of the development of iron deficiency in donors and strategies to reduce its occurrence

Development of strategies or systems to support the clinical community to reduce, recognise and respond to adverse events relating to transfusion

Development of processes to assess the cost and benefits ratio of new technologies and/or strategies in reducing risks associated with transfusion

Analysis of human factors which contribute to adverse events, and identification of process improvement opportunities

Identification of blood manufacturing strategies that reduce patient adverse events

Identification of collection modalities, including frequency of donation that reduce donor adverse effects and ensure donor health and welfare

Identification of strategies to prevent alloimmunisation

Development of treatment protocols for bleeding disorders that most effectively reduce the risk of, and manage the development of, inhibitory antibody responses

Development and identification of cost-effective tests and/or pathogen reduction strategies to reduce risk of transfusion transmitted infection

Development of data systems to enable more systematic monitoring of adverse events following transfusion, and that support implementation and monitoring of the effectiveness of actions to reduce adverse events

 Initial focus

National Health Reforms will result in changes to the way health services are delivered in Australia. For example, shifting focus to more community based care may require changes to the blood supply chain such as broader implementation of home delivery of products. Supply arrangements for blood and blood products need to be sufficiently flexible to respond to changes in the delivery of health services.

In addition, National Health Reforms have resulted in the development of a national efficient price for health service activities. At this time, funding for blood and blood products has not been included in the national efficient price. Differences between current funding arrangements for blood and blood products and alternative treatments may lead to inflation in demand for blood and blood products.

Another significant change in the nature of health service delivery is the evolving methodologies available to support diagnosis and treatment decisions, such as genotyping and whole genome sequencing. These advances are likely to lead to an expansion of personalised medicine, which uses genetic knowledge to predict disease development and to tailor medical treatment to an individual. Successful implementation of these technologies is critical to the development of targeted therapies that may reduce reliance on blood and blood products. This will require building capacity in the health system to improve access to these tests, and to train the workforce in the interpretation of such tests.

Priority Four

**To optimise
health
service
delivery to
best meet
patients'
needs**

What we are trying to achieve

Development of evidence to facilitate strategic improvements to the way health services are delivered, including through access to world-class diagnostic services and therapeutic products to enable diagnosis of diseases and tailoring of treatments.

Work already underway

- Home delivery of plasma and recombinant products
- Early coagulopathy in trauma – TORC
- Molecular typing and genotyping for complex blood group typing – Blood Service
- Jurisdictional Clinical Practice Improvement Programs

What we want from the research community

Development and implementation of capacity building strategies relating to testing and diagnosis to support treatment decisions relating to blood and blood products and alternatives

Analysis of transfusion practice and development of evidence to support decisions relating to pricing policies in the future

Identification and analysis of different ways of providing blood and blood products to patients, such as home administration of treatments, and the impacts on the effectiveness and efficiency of the health system and on patient outcomes and quality of life

Analysis and modelling of the impact of incentives (including financial incentives) to support best practice relating to the use and management of blood and blood products

Identification of inequities in practice across Australia, and development of strategies to reduce inequities

Analysis of funding arrangements, including differences between funding of blood and blood products compared with related treatments such as anaemia management, erythropoiesis-stimulating agents (ESA), and other transfusion alternatives

Education tools to support roll out of new tests, products and technologies

Development of strategies to ensure minimal duplication of effort through a national approach to the delivery of new tests, products and technologies

 Initial focus

Priority Five

To improve data collection, availability, accuracy and sharing across the sector

In order to realise improvements in the management and use of blood and blood products individuals, organisations and governments must work together in a coordinated and effective manner. The capacity to work together is underpinned by the accessibility and availability of accurate and relevant data and information, and its dissemination in a timely and secure manner. Australia is in a unique position to collect and analyse data on blood and blood products due to a single, centralised agency responsible for the procurement of all blood and blood products.

The NBA has commenced introduction of supporting infrastructure through the development of innovative information systems including BloodNet and the Australian Bleeding Disorder Registry (ABDR). These systems have already led to improvements in the collection and availability of data. In addition there has been much work in Australia undertaken by the Transfusion Outcomes Research Collaborative (TORC) and other groups developing data registries. High quality data registries based on standard datasets and definitions provide a valuable resource, and can facilitate information capture through data collection and linkage.

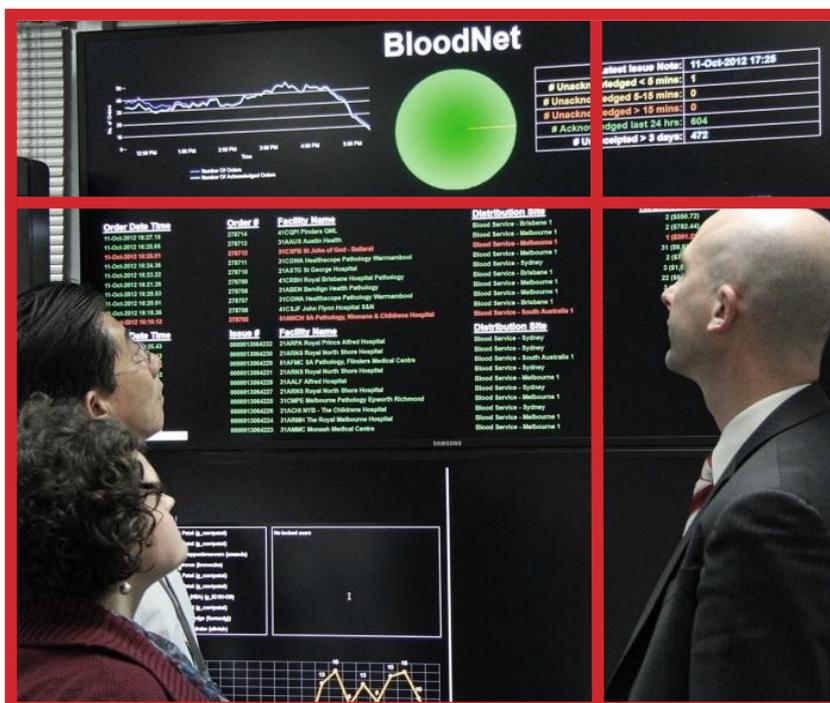
Data can be used to support benchmarking to both facilitate and enable measurement of practice improvement.

What we are trying to achieve

A coordinated, national system for the collection of information relating to blood and blood products, including to support tracking of product from donor to recipient, as well as the dissemination of this information to support clinical and laboratory practice, decision-making, performance monitoring, and research and development.

Work already underway

- BloodNet - NBA
- Australian Bleeding Disorder Registry - ACHDO, Haemophilia Foundation of Australia (HFA) and NBA
- National red cell data linkage – states and territories
- Barcoding standard – NBA
- RFID trials
- Data registries, including in trauma, cardiac surgery, neonatal alloimmune thrombocytopenic purpura, thrombotic thrombocytopenic purpura and aplastic anaemia – Transfusion Outcomes Research Collaborative
- State and territory admission episode datasets



What we want from the research community

Development of new and enhanced data systems to support access to relevant and accurate data and information

Development of improved strategies for data acquisition from hospital IT systems

Feasibility and cost-effectiveness studies relating to use of more sophisticated electronic tracking and monitoring, such as RFID

Enhanced technical capability to share information, providing access to interoperable, timely, mobile and fit-for-purpose information across organisations

Development of new concepts and technologies to improve the management and use of blood and blood products

Benchmarking studies relating to use of blood and blood products

Validation work surrounding the use of electronically captured and stored health information related to blood use

 Initial focus

Acronyms and glossary of terms

ACRONYMS

ABDR	Australian Bleeding Disorders Registry
ACSQHC	Australian Commission for Safety and Quality in Healthcare
AHCDO	Australian Haemophilia Centre Directors' Organisation
Blood Service	Australian Red Cross Blood Service
HFA	Haemophilia Foundation of Australia
IVIg	Intravenous immunoglobulin
NBA	National Blood Authority
NHMRC	National Health and Medical Research Council
PBM	Patient blood management
TORC	Transfusion Outcomes Research Collaborative

GLOSSARY OF TERMS

blood products	Products manufactured from donated blood
patient blood management	Activities to improve clinical outcomes by avoiding unnecessary exposure to blood components



National Blood Authority
Australia