NATIONAL BLOOD AUTHORITY AUSTRALIA

ANNUAL REPORT 2011–2012

CELLULAR

~**45%** OF BLOOD VOLUME IS RED BLOOD CELLS

~**1%** IS WHITE BLOOD CELLS AND PLATELETS

PLASMA

~55% OF BLOOD VOLUME IS PLASMA CONSISTING OF:

91–92% WATER
7–8% BLOOD PROTEINS
1–2% NUTRIENTS

NATIONAL BLOOD AUTHORITY AUSTRALIA

ANNUAL REPORT 2011–2012

7–8% OF HUMAN
BODY WEIGHT IS BLOOD

OUR MISSION

To secure a quality blood supply through world leading contractual arrangements; promote safe, high quality management and use of blood and blood products in Australia; and drive continual performance improvement across the sector.

ISSN 1832–1909

This report is available online at: www.nba.gov.au/pubs/annual-report.html

Printed by: Paragon Printers Australasia

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At the time of going to press the NBA website was being redeveloped. Hence detailed directions (URLs) to specific information on the NBA website in this year's annual report are not always available or may not be accurate.

LETTER OF TRANSMITTAL

National Blood Authority Australia

The Hon Tanya Plibersek MP
Minister for Health and Ageing
Parliament House
Canberra ACT 2600

Dear Minister

I am pleased to present the 2011–12 annual report of the National Blood Authority (NBA) and the National Blood Authority Board.

This document has been prepared in accordance with sub-sections 44(1) and 44(2) of the *National Blood Authority Act 2003*, sections 63 and 70 of the *Public Service Act 1999*, section 5 of the *Financial Management and Accountability Act 1997* and the July 2012 annual report requirements published by the Department of the Prime Minister and Cabinet. I certify that all of the requirements have been addressed.

I certify that the National Blood Authority has prepared fraud risk assessments and fraud control plans and has in place appropriate fraud prevention, detection, investigation, reporting and data collection procedures and processes that meet the specific needs of the agency and has complied with the requirements of the Commonwealth Fraud Control Guidelines.

Yours sincerely,

Leigh McJames
General Manager
National Blood Authority
10 October 2012

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USER GUIDE

This is the annual report of the NBA for the 2011–12 financial year. It also includes the NBA Board annual report for the same period.

PART 1: OVERVIEW

Presents a high level view of the sector, its stakeholders and the blood products used, and describes the NBA's objectives.

PART 2: HIGHLIGHTS OF 2011–12

Identifies key statistics and major achievements during the year, and presents reports of the NBA's General Manager and the NBA Board.

NBA'S PERFORMANCE (PARTS 3, 4 AND 5)

PART 3: SECURING THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

In the context of the NBA's outcome and program structure, summarises the NBA's performance against the key performance indicators and qualitative and quantitative deliverables established in the 2011–12 Portfolio Budget Statements, and reports on how the NBA manages the supply of blood and blood products through the development and maintenance of the National Supply Plan and Budget, the management of contracts with suppliers and on progress in developing methodologies for assessing new products.

PART 4: IMPROVING THE SECTOR AND ITS MANAGEMENT OF RISK

Summarises the NBA's outcome and program structure and reports on the NBA's performance against the key performance indicators and qualitative and quantitative deliverables established in the 2011–12 Portfolio Budget Statements, with particular reference to initiatives to improve the performance of the blood sector and manage risks associated with the supply and administration of blood products.

PART 5: SUPPORTING APPROPRIATE AND SAFE USE OF BLOOD AND BLOOD PRODUCTS

Summarises the NBA's outcome and program structure and reports on the NBA's performance against the key performance indicators and qualitative and quantitative deliverables established in the 2011–12 Portfolio Budget Statements to assist the sector to comply with standards to support the safe, high quality management and use of blood and blood products and services.

PART 6: CORPORATE MANAGEMENT

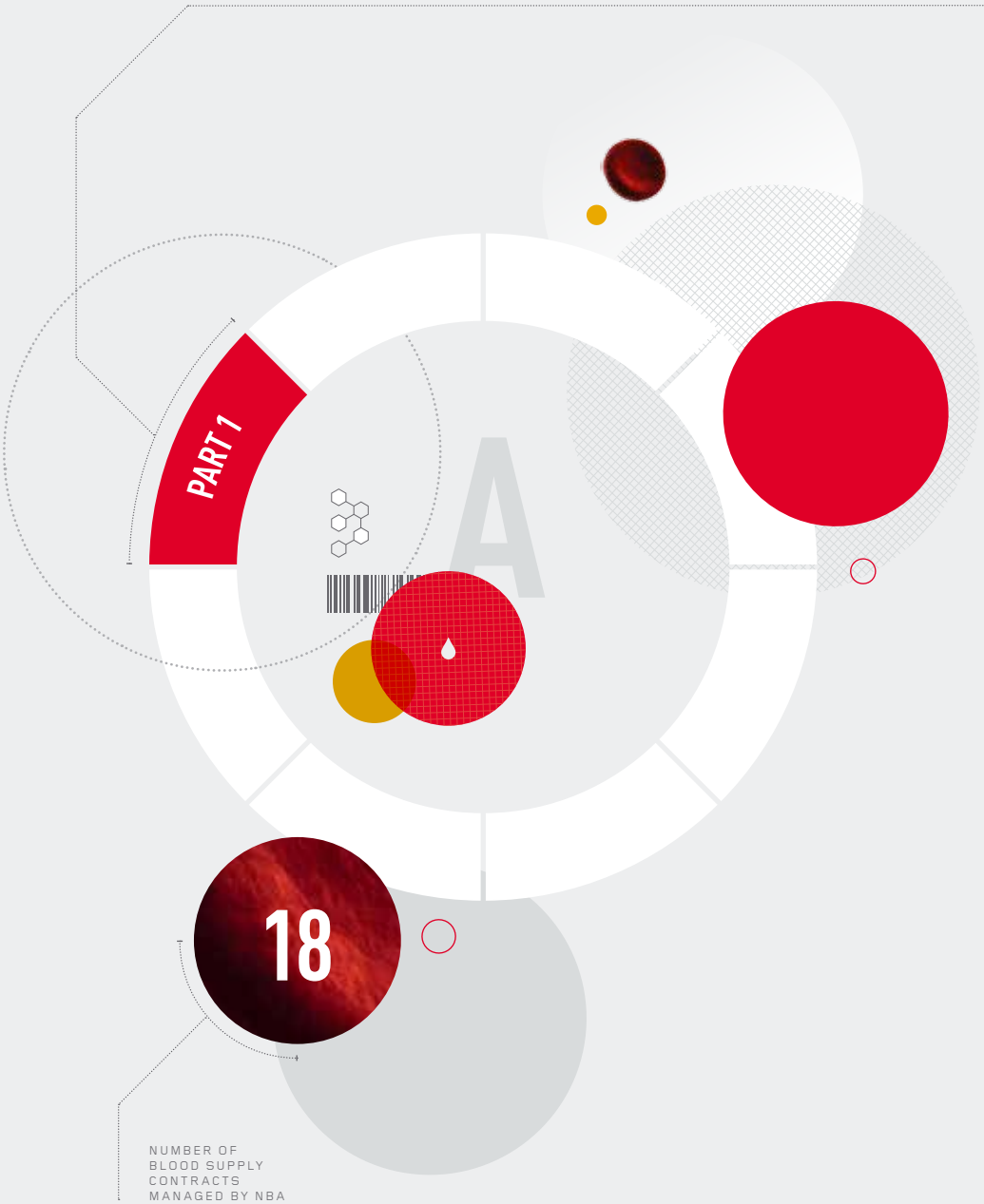
Includes information on corporate governance, planning and service delivery, people management, audit arrangements and how we manage risk and fraud.

PART 7: FINANCIAL MANAGEMENT AND ACCOUNTABILITY

Discusses the NBA's budget, financial and asset management and purchasing arrangements, and presents the audited financial statements.

APPENDICES

Contains additional information to further explain material in the body of the report such as governments' objectives under the National Blood Agreement, the NBA's agency resource statement, further information about NBA stakeholders, lists of blood and blood products supplied under contract, biographies of NBA Board members, further information about fresh blood supply by state and territory, mandatory reporting on several government policies, errata, acronyms and a glossary of terms, and a list of requirements.


PART 1
A
18
NUMBER OF
BLOOD SUPPLY
CONTRACTS
MANAGED BY NBA

1

OVERVIEW OF THE NBA AND THE BLOOD SECTOR

BLOOD SECTOR GOVERNANCE

NBA ROLE AND RESPONSIBILITIES

BLOOD PRODUCTS AND HOW THEY ARE USED

THE AUSTRALIAN BLOOD SUPPLY CHAIN

BLOOD SECTOR FUNDING

BLOOD SECTOR GOVERNANCE

The Standing Council on Health (SCoH)—formerly the Australian Health Ministers' Conference (AHMC)—is responsible for overseeing and managing the blood sector. It sets the governance, policy and financial frameworks under which the NBA operates.

Under the *National Blood Authority Act 2003* (NBA Act), the Australian Government Minister for Health and Ageing is responsible for issuing policy principles, the appointment of the NBA Board and General Manager and for determining additional functions with the endorsement of the SCoH.

The key governing bodies in the Australian blood sector and their roles and relationships with each other are set out in the National Blood Agreement and the NBA Act and are shown in Figure 1.1.

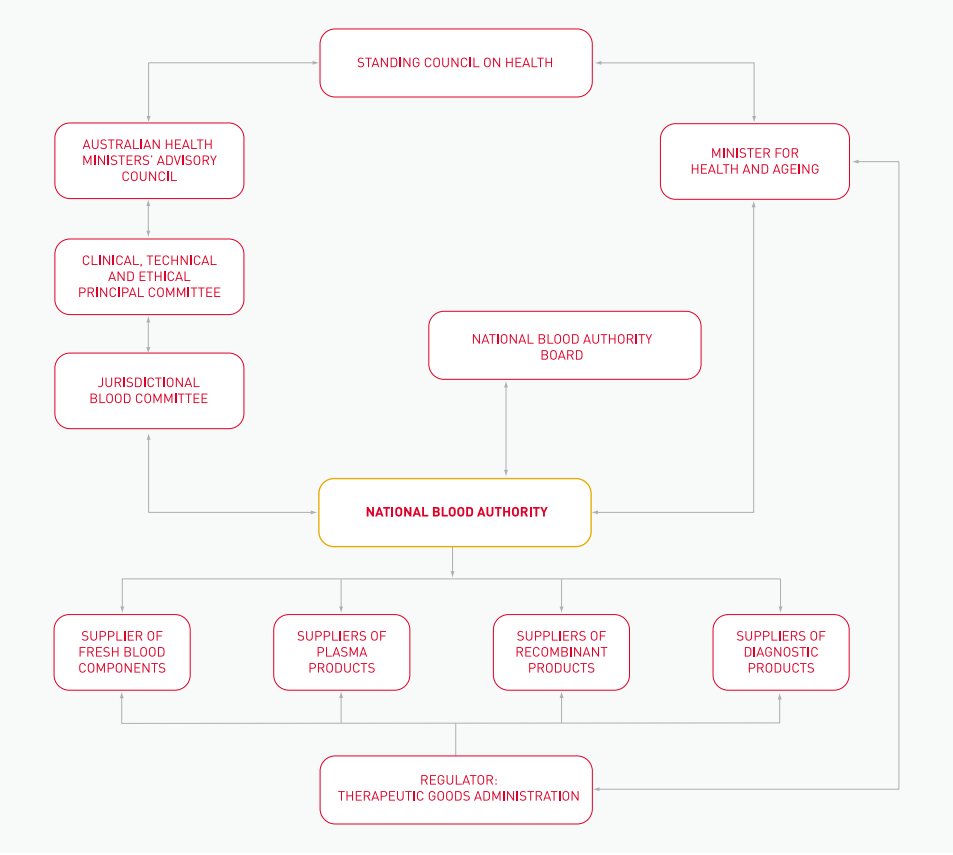


FIGURE 1.1 *Governance structure of the Australian blood sector*

For further information on the SCoH, the Australian Health Ministers' Advisory Council (AHMAC), the Clinical, Technical and Ethical Principal Committee (CTEPC) and the Jurisdictional Blood Committee (JBC) see **Appendix 1:** Blood sector stakeholders and governance.

NBA ROLE AND RESPONSIBILITIES

The NBA is a statutory agency within the Australian Government Health and Ageing portfolio that manages and coordinates arrangements for the supply of blood and blood products and services on behalf of the Australian Government and state and territory governments.

It was established by the *National Blood Authority Act 2003* following the signing of the National Blood Agreement by all state and territory health ministers in November 2002.

Our vision is saving and improving Australian lives through a world-class blood supply.

Our role is to ensure the adequate, safe, secure and affordable supply of blood and blood products in accordance with the National Blood Agreement (see **Appendix 2**).

The NBA coordinates national blood supply and demand planning; purchases blood and blood products on behalf of all Australian governments; and develops and implements national strategies to encourage better use of blood and blood products.

The NBA:

- works with jurisdictions to determine the clinical requirements for blood and blood products to meet national clinical needs and develop an annual supply plan and budget
- negotiates and manages national contracts with suppliers of blood and blood products to obtain the products needed
- assesses blood supply risk and engages in contingency planning for risks arising in the sector and impacting on the sector
- supports the work of the jurisdictions to improve the way blood products are used—including developing and facilitating strategies and programs that will improve the safety, quality and effectiveness of blood usage, particularly in the areas of national standards, guidelines and data capture and analysis
- provides expert advice to support government policy development, including identification of emerging risks, developments, trends and new opportunities
- manages the evaluation of proposals for blood sector improvements, including proposals for new products, technologies and system changes
- provides secretariat support to the JBC.

Our Values: We recognise the important role that blood and blood products play in the treatment and clinical management of Australian patients. We are committed to:

- meeting patient needs for the provision of a safe, secure, adequate and affordable supply of blood and blood products
- working collaboratively with stakeholders to develop, monitor and improve national networks and systems for improved clinical awareness and practices in the use of blood and blood products
- developing the professional and technical competence of our staff
- delivering our mission in an efficient, professional, inclusive, responsive and innovative manner.

BLOOD PRODUCTS AND HOW ARE THEY USED

Fresh blood contains red blood cells, white cells and platelets suspended in a straw coloured liquid known as plasma. A blood donor can provide a whole blood donation, or a plasma or platelet only donation through a process known as apheresis. Figure 1.2 The blood product family, illustrates how the various blood products are manufactured.

While whole blood transfusions are still used in certain circumstances, it is a more generally accepted practice to administer the separated, concentrated components of blood. Processing blood into components provides tailored treatment for patients and maximises the use of blood donations.

Fresh blood components—red cells, platelets and fresh frozen plasma (FFP)—are used in the treatment of medical conditions such as cancer, heart, stomach, bowel, liver and kidney diseases. Fresh blood components are also used during and after surgery and to treat people who suffer traumatic injury or burns.

Proteins, isolated by fractionation processes, are made into products to treat specific diseases. For example, clotting factors such as Factor VIII and Factor IX are used to treat haemophilia A and B respectively. Immunoglobulins (Ig) are used by the body to protect itself against infections. Intravenous (IV) delivery of immunoglobulin—IVIg—is used to replace and/or modulate a person's immune response in a wide range of conditions, such as primary immunodeficiency and chronic inflammatory demyelinating polyneuropathy. For some conditions, patients may be dependent on it for their well-being, needing treatment throughout their lives.

Many blood products are made from the plasma component of blood. Plasma contains a large number of proteins each of which performs a different role within the blood. Since the 1940s, it has been possible to extract different proteins from plasma on a large scale. This is commonly referred to as plasma fractionation. In Australia, CSL Limited carries out these fractionation processes on plasma collected by the Australian Red Cross Blood Service (the Blood Service). The volume of plasma to be collected is determined annually by governments and provided under NBA contract arrangements free of charge to CSL Limited to produce the specific blood products needed.

Some blood products are manufactured from non-human components using genetic engineering. These are called recombinant products and are alternatives to some fractionated plasma products. For example, recombinant clotting factors are increasingly used in place of plasma-derived clotting products to treat people with haemophilia.

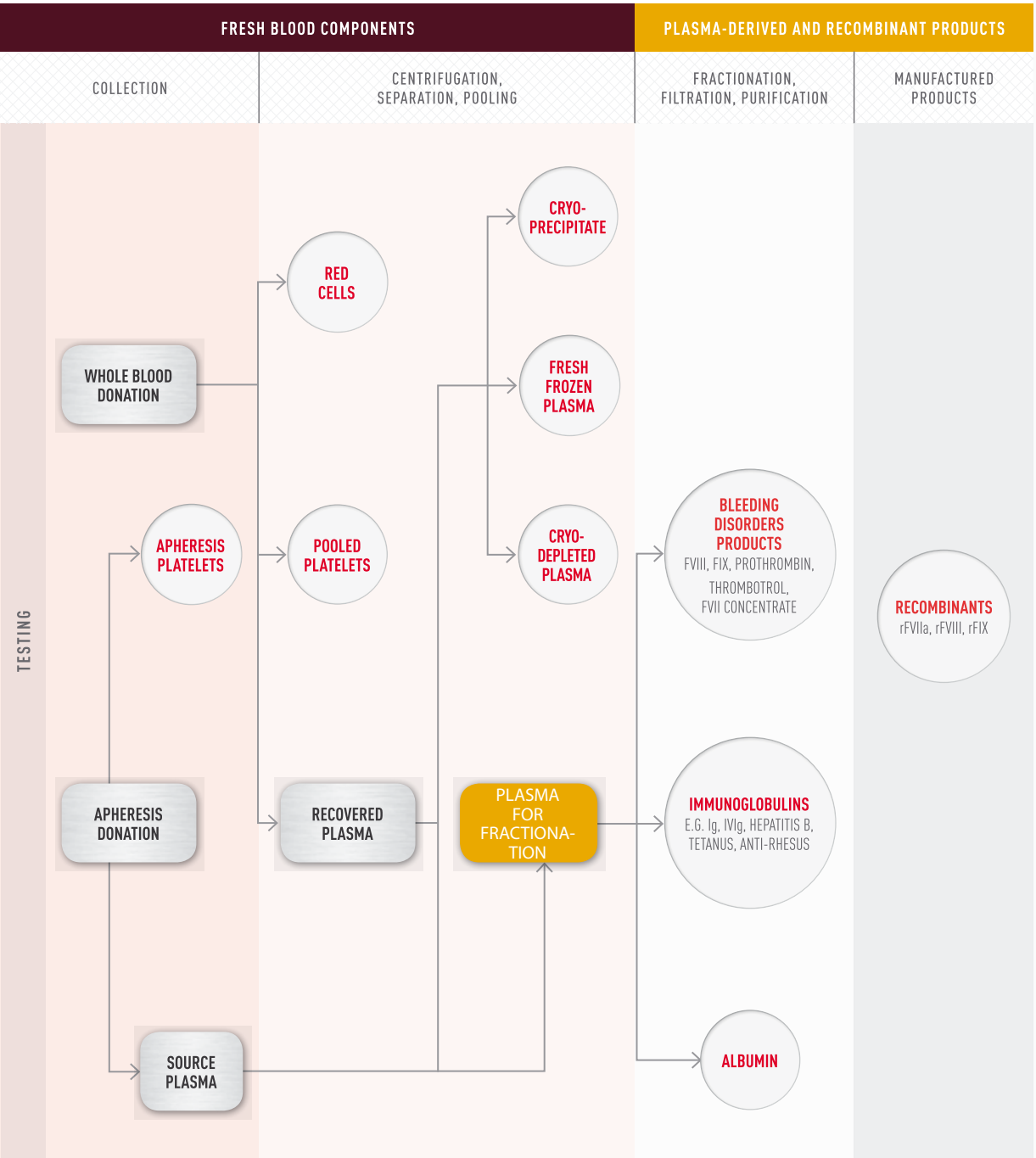


FIGURE 1.2 *The blood product family*

THE AUSTRALIAN BLOOD SUPPLY CHAIN

The NBA manages the national planning and purchasing of blood and blood products in close cooperation with a number of stakeholders. A summary of the blood supply chain is given in Figure 1.3 below.

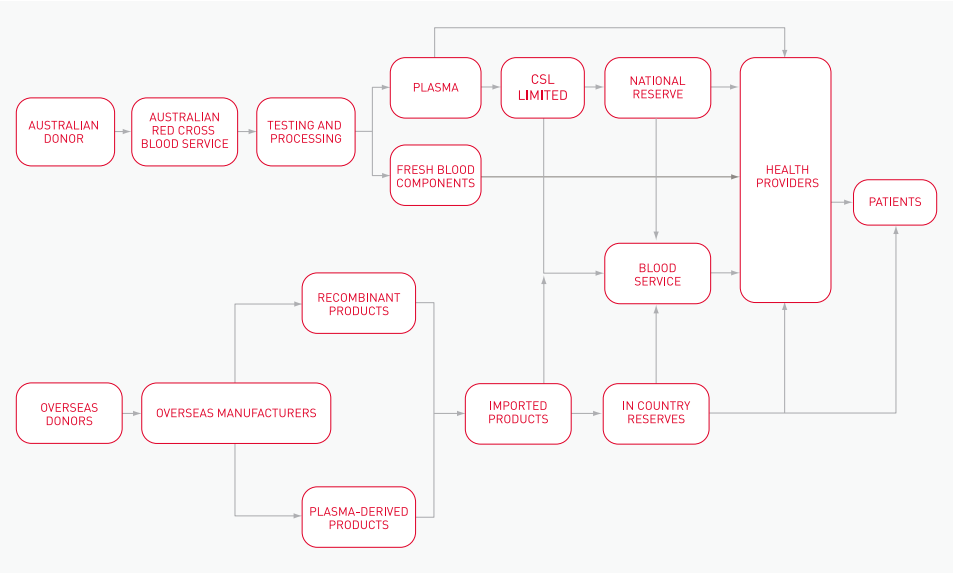


FIGURE 1.3 *The Australian blood and blood products supply chain*

OUR STAKEHOLDERS

Blood sector stakeholders include:

- the Australian Government and state and territory governments as signatories to the National Blood Agreement
- the Therapeutic Goods Administration (TGA) as the regulator for blood and blood products in Australia
- suppliers of blood and blood products and diagnostic reagents: the Blood Service, CSL Limited, Octapharma Pty Ltd, Baxter Healthcare Pty Ltd, Grifols Australia Pty Ltd, Pfizer Australia Pty Ltd, Novo Nordisk Pharmaceuticals, Bayer Australia Ltd, Johnson & Johnson Medical Pty Ltd (trading as Ortho-Clinical Diagnostics), Abacus ALS Pty Ltd and Bio-Rad Laboratories Pty Ltd
- health providers and clinicians
- the Australian public, particularly donors and patients.

For further information about our stakeholders, see Part 3: Performance: Securing the supply of blood and blood products, and **Appendices 1** and **4**.

In addition to the networks needed to maintain supply both internationally and domestically, the NBA has developed an effective network of clinical blood sector experts to facilitate the flow and exchange of information in the use of products.

Without access to the advice and expertise of our stakeholders, clinicians, suppliers and blood sector managers, we could not achieve the high quality outputs that is expected of the NBA.

Committees and working groups that assisted the NBA during 2011–12

Advisory Group for the Review of the Authorisation and Clinical Governance Framework for Intravenous Immunoglobulin

Anaemia Management Working Group

Australian Bleeding Disorders Registry Steering Committee

Australian Haemophilia Centre Directors' Organisation (external)

BloodNet User Reference Group

Complex Patient Advisory Group

Haemovigilance Advisory Committee

Imported IVIg Tender Evaluation Committee

National IVIg Criteria Review Working Group

Patient Blood Management Steering Committee

Patient Blood Management Guidelines Steering Committee

Patient Blood Management Guidelines Expert Working Group

Patient Blood Management Guidelines Clinical/Consumer Reference Group—Critical Bleeding/ Massive Transfusion Module

Patient Blood Management Guidelines Clinical/Consumer Reference Group—Critical Care Module

Patient Blood Management Guidelines Clinical/Consumer Reference Group—Medical Module

Patient Blood Management Guidelines Clinical/Consumer Reference Group

—Perioperative Module

rFVIII Transition Advisory Group

Schedule 4 and Multi-criteria Analysis/Health Technology Assessment Working Group

NBA FOCUS
COMMUNICATING WITH STAKEHOLDERS
––
HAA CONFERENCE
SYDNEY NSW

TELLING HEALTH SERVICE PROVIDERS ABOUT THE NBA

In November 2011 an NBA booth at Australia's largest blood sector conference was a huge hit, attracting up to 970 visitors out of the 1500 delegates who attended the HAA* annual scientific meeting in Sydney.

The booth was located in the exhibition hall at the Sydney Convention and Exhibition Centre in Darling Harbour to promote the role that the NBA plays in the Australian blood sector. The NBA booth was very popular—it was often the busiest booth in the exhibition hall. Visitors to the booth included clinicians, nurses and hospital laboratory scientists. Their average stay was ten minutes, indicating a strong demand for in-depth conversations with NBA staff.

Two NBA projects—Patient Blood Management Guidelines and the NBA's online blood ordering and inventory management system, BloodNet—were the focus. Most delegates were interested in the guidelines—80 per cent of visitors were keen to hear more about the development and roll out of the guidelines and to take a brochure listing all six modules under development by the NBA.

The promotion of BloodNet was supported by live demonstrations of the system to new laboratories that were otherwise unaware of the system. The NBA was able to directly engage scientists from around the country, including more than 40 pathology sites that were not yet using it—especially in Victoria and New South Wales.

Following the success of this booth, the NBA is planning to attend the next HAA conference planned for Melbourne in October 2012.

* The Annual Scientific Meeting of the HAA is a joint meeting of the Haematology Society of Australia and New Zealand (HSANZ), the Australian & New Zealand Society of Blood Transfusion (ANZSBT), and the Australasian Society of Thrombosis and Haemostasis (ASTH).

Caption: The NBA booth at the HAA 2011 annual scientific meeting

BLOOD SECTOR FUNDING

Australia's blood sector is funded by the Australian Government and state and territory governments at a ratio of 63 per cent and 37 per cent respectively.

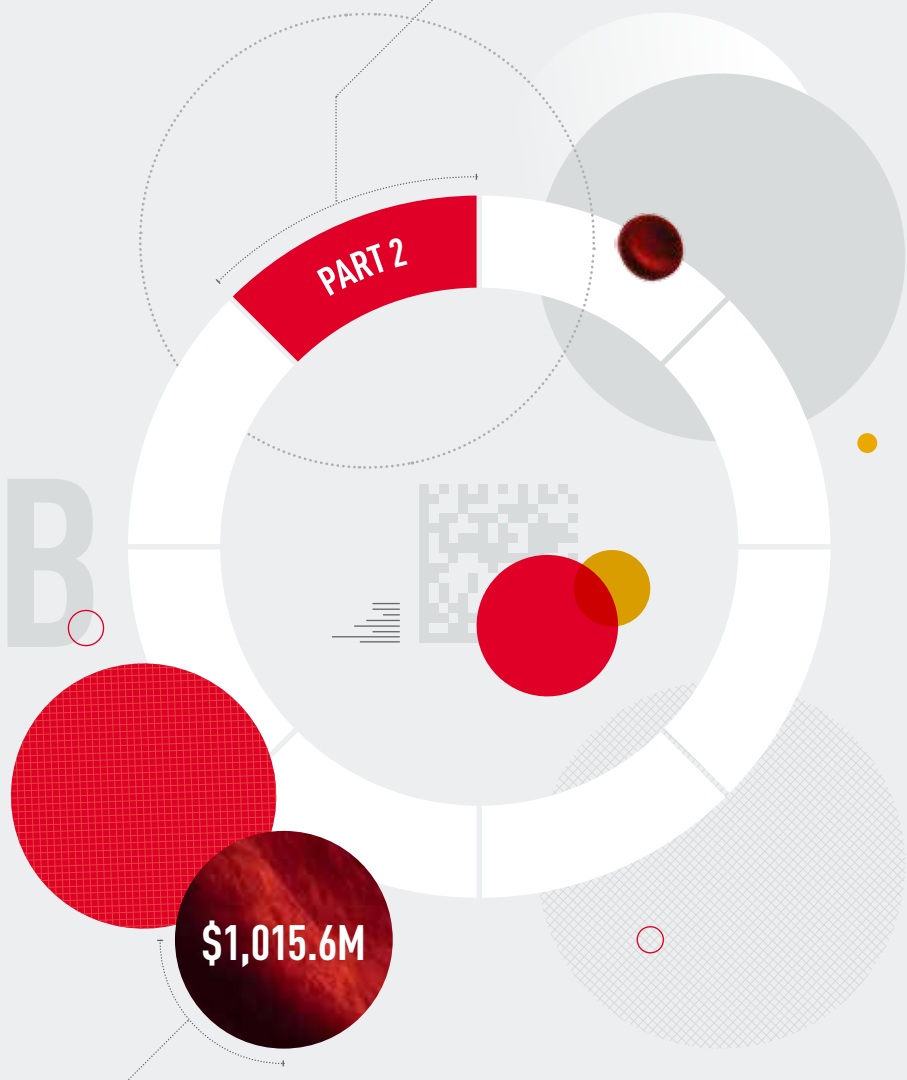
Table 1.1 shows that since the establishment of the NBA, governments have funded a total of $6,574 million on blood and blood products. In 2011–12, the total amount provided to cover expected demand for blood and blood products was $1,015.6 million. Table 1.2 shows government funding for the operation of the NBA over the same period.

TABLE 1.1 *Government funding to the NBA for the supply of blood and blood products, 2003–04 to 2011–12*

YEAR	AMOUNT ($M)	GROWTH (%)
2003–04	460.5	
2004–05	536.8	16.6
2005–06	577.4	7.6
2006–07	639.4	10.7
2007–08	719.5	12.5
2008–09	806.8	12.1
2009–10	878.8	8.9
2010–11	939.2	6.9
2011–12	1,015.6	8.1
TOTAL	**6,574.0**	**10.4 (average)**

TABLE 1.2 *Government funding for the operation of the NBA, 2003–04 to 2011–12*

YEAR	AMOUNT ($M)	CHANGE (%)
2003–04	7.4	
2004–05	8.4	13.5
2005–06	10.4	23.8
2006–07	10.1	-2.9
2007–08	9.6	-5.0
2008–09	9.2	-4.2
2009–10	8.9	-3.3
2010–11	9.5	6.7
2011–12	8.5	10.5
TOTAL	**82.0**	**2.3 (average)**



GOVERNMENT FUNDING FOR SUPPLY OF PRODUCTS

2

HIGHLIGHTS OF 2011–12

SNAPSHOT OF THE BLOOD SECTOR IN 2011–12

GENERAL MANAGER'S REVIEW

NBA BOARD AND REPORT

FIGURE 2.1 *Vein to vein: the journey of donated blood from donor to patient*

* 2010–11 DATA

SNAPSHOT OF THE BLOOD SECTOR IN 2011–12

GENERAL MANAGER'S REVIEW

Mr Leigh McJames was appointed in March 2012 as the General Manager of the NBA. He has extensive management experience in government in the defence and health sectors. In his previous health sector appointments, he was the transition manager for the formation of Albury Wodonga Health, the first cross border health service in Australia, and subsequently was a member of its senior executive. From 2006 to 2008, he was the Deputy General Manager at the NBA responsible for supply and contract management.

Before that, he held a diverse range of positions in defence, including senior roles in the management of government corporate support, acquisition and procurement, logistics and the development and implementation of strategic international defence policy. He has also filled representational advisory appointments at the Australian Embassy in Washington and in Baghdad as part of the senior civilian advisory team with the Coalition Provisional Authority.

Leigh addresses pathology staff at John Hunter Hospital, Newcastle, New South Wales

This is my first General Manager's report, since joining the NBA in April 2012. It has been another highly productive year for the agency.

A major outcome for the NBA during 2011–12 was a decision by Australian governments to increase the agency's base funding from 2012–13. The revised base funding will allow us to achieve savings in the National Supply Plan and Budget (NSP&B), including reductions in the level of inventory holdings and reductions in wastage. It will also generate potential for future savings through the establishment of information management and data analysis capabilities to capture national sector-wide blood data and establish the pre-conditions for a national patient blood management program.

ENSURING SUPPLY

The key role of the NBA is to ensure an adequate, safe, secure and affordable supply of blood and blood products. The NBA again delivered on this fundamental responsibility. Key outcomes in 2011–12 included delivery of substantial savings to governments through improved contract prices, improved inventory management, and introduction of measures to decrease demand for products from health providers through appropriate use.

The NBA continued to deliver improvements in value for money through our purchasing activities for blood and blood products. New contracts for imported plasma-derived and recombinant clotting factor products which commenced in July 2011 realised significant savings and service improvements. Over the course of 2011–12 the NBA worked closely and successfully with clinical and patient stakeholder groups and with suppliers to support the transition of a substantial number of haemophilia patients between product brands, as a result of these tender outcomes.

An imported IVIg tender process was undertaken during 2011–12. The outcomes of this tender have maintained the availability of IVIg products for Australian patients and improved supplier performance requirements and supply security. Higher concentration product versions have now been introduced which offer the potential for reduced infusion times with associated benefits for patients and health services. We estimate the price outcomes of the tender alone will save the Australian community between $13–$16 million per year.

Work continued on implementing performance and efficiency improvements to the current Deed of Agreement with the Blood Service for the supply and distribution of fresh blood products. The Blood Service delivered savings across its operations of approximately $11 million in 2011–12. The new Melbourne Processing Centre was opened at a total cost of $213 million by the Parliamentary Secretary for Health and Ageing, The Hon Catherine King, on 30 April 2012. The new centre provides the foundation for state of the art processing of blood and follows similar investments in Brisbane and Sydney over recent years. Work continued on a range of other projects to improve the efficiency and effectiveness of services provided by the Blood Service, including expanding output based funding model arrangements and improved inventory management.

SECURITY OF SUPPLY

The NBA has a range of measures in place to ensure the security of Australia's supply of blood and blood products. These measures were tested during 2012 with the emergence of risks to the supply of albumin as a result of the recall of some batches of product by CSL Ltd due to manufacturing equipment failure that caused ethylene glycol contamination. The NBA activated the National Blood Supply Contingency Plan (NBSCP) in March 2012 to manage the impact of the recall on inventory levels. The activation of the NBSCP, combined with the existence of contingency reserves, ensured that product availability was maintained and the impact on patients minimised. The NBA, in conjunction with relevant stakeholders, undertook a post implementation review of this incident to help inform future improvement to the NBSCP.

Supply security was further strengthened for the supply of plasma-derived and recombinant blood products with an increase in the range and number of international suppliers contracted to Australia. This is particularly important in relation to IVIg, where Australia relies on a substantial proportion of imported product to meet its needs. The selection of more than one supplier reduces the risk of supply shortages should a problem develop with a single supplier.

IMPLEMENTING BLOOD STEWARDSHIP

In November 2010, health ministers endorsed a *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products*. The statement outlines ministers' expectations on health providers to contribute to the sustainability of the blood supply by adopting stewardship measures. A significant proportion of the NBA activities in 2011–12 directly support the implementation of these measures, including:

- detailed input to the development of the National Safety and Quality Health Service (NSQHS) Standard 7 *Safety and quality improvement guide on blood and blood products*. Implementation of the NSQHS standard will underpin improvements at a health provider level
- development of the next three modules of the National Patient Blood Management (PBM) Guidelines, including publication of Module 2 dealing with perioperative. The guidelines provide a key reference at health provider level to improve appropriate use of blood. Notably, they are also a world first that have generated considerable international interest
- finalisation of the second edition of *the Criteria for the clinical use of intravenous immunoglobulin (IVIg) in Australia* (the Criteria). The Criteria was approved by health ministers in May 2012 and is expected to be released in early August 2012. It ensures that patient access to IVIg is consistent with the best evidence of clinical benefit
- further development and implementation of a national web-based ordering system (BloodNet) which provides the capability at health provider level to order and receipt blood and blood products. The system provides health providers with visibility of inventory levels, ordering practices and unit discards which in turn makes essential data to improve blood management practices available to governments, the NBA and health providers
- redevelopment of the Australian Bleeding Disorders Registry (ABDR) which will provide comprehensive data to a patient level, thereby improving clinicians' ability to manage patients and the availability of aggregated data for national benchmarks.

OUTLOOK FOR 2012–13

Since the establishment of the NBA in 2003, the agency has focused on improvements in the key areas of enhancing the security of supply, value for money and safety and quality of the use of products. Significant progress has been achieved and work will continue to build on success in these areas. The approved 2012–13 NSP&B contains operating funds for the NBA to undertake a range of activities aimed at improving the clinical usage of blood and blood products. 2012–13 will see a widening of the NBA activities to deliver the outcomes associated with the increased funding identified in my introductory paragraph and further support for the implementation of the ministerial *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products*. Key areas for further investment and development over the next 12 months will include:

- improving the sustainability and performance of the sector through enhanced information management, data capture and expert analysis, to capture national sector-wide blood data and establish the pre-conditions for a national patient blood management program
- raising awareness of governments' stewardship expectations of users of blood and blood products, and their management of these products, through the development and publication of evidence-based national guidelines, in close collaboration with clinicians
- promotion and support for the implementation of Standard 7 of the NSQHS and three modules of the PBM Guidelines at the health provider level
- improving supply chain management, including optimising inventory levels and strategies to minimise wastage
- investigating the feasibility and options for integrating blood into the national health reform framework
- continuing to improve strategic planning, supply and governance arrangements for IVIg, including consideration of the outcomes of the current review of clinical governance and authorisation for IVIg.

On behalf of the NBA, I take this opportunity to reiterate the comments made by the Chair of the NBA Board in her report thanking Dr Alison Turner. The NBA owes its many achievements and current excellent positioning for future outcomes to Alison's management and strategic foresight. We wish her well in retirement. I also acknowledge the enormous contribution made by Stephanie Gunn who has accepted a secondment to the Department of Families, Housing, Community Services and Indigenous Affairs after being with the NBA as a deputy general manager since soon after its establishment in 2003. Stephanie was a highly respected powerhouse in the organisation who drove outcomes in any responsibility she was given. I also thank her for the extended period she acted as the General Manager from the departure of Alison in August 2011 until my arrival in April. Our thanks also goes to Dr Chris Hogan, appointed as the NBA's first Principal Medical Officer in August 2008, who resigned in January 2012.

I close this report with a special acknowledgement of the many stakeholders across the sector who again assisted us during the year in delivering the outcomes outlined in this report. There are many clinicians, health professionals, public servants, suppliers and members of the public who gave generously of their time, professionalism and passion. We cannot do our job as well as we do without you and we look forward to working with you again in 2012–13.

Leigh McJames
General Manager
National Blood Authority

NBA BOARD AND REPORT

The NBA Board was established under the *National Blood Authority Act 2003* to:

- **participate in consultations about the performance of the NBA's functions with the Australian Government Minister for Health and Ageing**
- **provide advice to the General Manager about the performance of the NBA's functions**
- **liaise with governments, suppliers and other stakeholders about matters relating to the NBA's functions**
- **perform such other functions as specified in a written notice given by the Minister to the Chair.**

NBA BOARD MEMBERS

Ms Gayle Ginnane—chair

Mr Ken Barker—financial expert

Mr Paul Bedbrook—community representative

Adjunct Professor Chris Brook PSM—state and territory representative

Dr Stephen Christley—state and territory representative

Ms Mary Murnane—Australian Government representative

Professor George Rubin—public health expert

NBA Board members in October 2011: (from left to right) Paul Bedbrook, Mary Murnane, Ken Barker, Gayle Ginnane, Chris Brook, Stephen Christley, George Rubin

Appendix 4 contains details of the Board members.

REPORT OF THE NBA BOARD FOR 2011–12

This is my second report following my appointment as Chair of the NBA Board in May 2011.

During the year the Board met four times and also held its annual meeting with the Blood Service Board in October 2011.

During 2011–12 the NBA Board continued to provide advice to the general managers on the NBA's strategic directions, alignment with government priorities and approach to stakeholder communication and engagement. The Board has welcomed the decision of Australian governments to increase the NBA's base funding. This decision will enable the NBA to maintain current functions and build on its current investments, particularly in the areas of data collection, management and analysis.

The key areas of focus of the NBA Board over the past year were:

Fresh blood management

The annual meeting of the Blood Service and NBA boards took place in October 2011. This forum provided an opportunity to explore relevant issues. The NBA Board expressed a strong desire to ensure that, where possible, operational issues relating to the new deed were progressed while the strategic issues were considered separately.

A highlight of the year was the opening of the Blood Service's Melbourne Processing Centre on 30 April 2012. The new facility follows the opening of the Blood Service's Sydney processing centre in June 2011 and is a major enhancement to the nation's infrastructure. It will manufacture around 30 per cent of Australia's national fresh blood supply. The new centre is modular and can be scaled to meet the Blood Service's requirements for the next 20 to 30 years. This is a significant investment by the Australian taxpayer, providing infrastructure for the Blood Service to meet Australia's blood supply needs.

Assessment of proposals for changes to products and services funded under the national blood arrangements

The Board expressed concern that the development of a process to evaluate changes to the national blood supply has been protracted. The Board welcomed the JBC decision in September 2011 to establish a working group to review the process of proposals for changes to products and services funded under the national blood arrangements. The Board takes the view that the process should include an 'exceptional use' policy to address applications for small volume products and life-threatening conditions for which there is no other realistic management option.

Sector improvement

During 2011–12 the Board offered advice on the following projects designed to increase affordability and performance of the blood sector:

- a blood sector research framework to guide the development and implementation of an NBA blood sector research program. We emphasised that research to improve information systems should be a priority and suggested that the NBA approach the National Health and Medical Research Council (NHMRC) about potential research topics and possible involvement in an investigator-led research program
- the reinvigoration of the NBA Clinical Advisory Committee and replacement of the NBA Principal Medical Officer. Given the importance of improving clinical governance in the sector we supported initiatives which would guide the work of the agency on clinical matters.

Enhancing national data management

The Board has continued to provide strong oversight of the NBA's sector information management and data strategy, implementation of which was a key recommendation of the *Administrative Review of the National Blood Arrangements 2009* (the Webster Review). The aim of the strategy is to ensure the national blood arrangements are efficient, reduce waste and provide a safe supply of blood to patients. Board members were encouraged by the successful rollout of BloodNet, a key step to improving current inventory management processes. The major upgrade of the ABDR, which collects clinical information related to the treatment of bleeding disorders, is also a major step forward in improving the efficiency and provision of robust data to improve patient outcomes.

Corporate Plan for 2012–15

The Board has provided strong strategic guidance in the development of the NBA's Corporate Plan for 2012–15. The new plan will have a strong focus on addressing financial sustainability pressures on the blood sector. We suggested several innovative strategies, for example, to engage with clinicians about the development of a clinical demand management strategy, and the establishment of an information management and data analysis capability.

NBA performance

The performance of the NBA was assessed by the Australian National Audit Office's (ANAO) audit *The National Blood Authority's Management of the National Blood Supply*, tabled on 12 October 2011 (see page 103 for details of the report's findings and recommendations).

The Board acknowledged the timely release of the report and the focus of the recommendations on encouraging further blood sector efficiency, but noted there are a number of recommendations for which the NBA does not have sole responsibility and which depend on the cooperation of the states and territories and the public and private health sectors. With these issues in mind the Board provided advice on an implementation plan to comprehensively address the recommendations of the report.

A key role of the Board is to provide advice to the General Manager about the performance of the NBA against its annual operational plan. The NBA has performed to a high standard during the course of 2011–12 year, completing 87 per cent of the activities identified in the agency's 2011–12 Operational Plan. While good gains were made on the remaining activities, some key milestones were not met due to changes with sector priorities and key staff.

2012–13 priorities

The Board is mindful that the Australian blood sector faces immediate and ongoing challenges to its sustainability and effectiveness, and that these challenges must be addressed. On this basis a key priority for 2012–13 will be to commence work with key stakeholders to improve the financial sustainability of the blood sector.

Other key priorities during 2012–13 are expected to include:

- continued work on contractual arrangements with the Blood Service, including negotiating the new deed of agreement
- development of a national information data strategy
- implementation of BloodNet in all jurisdictions
- finalisation of the redevelopment of the ABDR
- continued development of the patient blood management guidelines
- input to a second national blood policy forum
- implementation of the recommendations of the ANAO report.

I would like to take the opportunity to thank my fellow Board members for their contributions over the course of 2011–12. The depth and breadth of members' experience has been invaluable. Board members also extend our very best wishes to the NBA's inaugural General Manager, Dr Alison Turner, following her retirement in August 2011. Alison was responsible for establishing the agency and provided oversight and guidance, leading to an impressive list of achievements targeted at meeting the key objectives of the National Blood Agreement. The work of the NBA was continued for an interim period by Deputy General Manager Stephanie Gunn, who was appointed Acting General Manager. The Board thanks Stephanie for her strategic leadership, hard work, attention to detail and positive influence in the sector, while in that role.

The Board welcomes the appointment of Mr Leigh McJames as the new NBA General Manager. Leigh was appointed on 27 March 2012 by the Parliamentary Secretary for Health and Ageing, the Hon Catherine King, and commenced with the NBA on 3 April 2012. He has brought strong knowledge and experience to the position, both with the NBA and the blood and hospital sectors. The Board looks forward to the future evolution of the NBA's role and contribution to the sector under his leadership.

Gayle Ginnane
Chair
National Blood Authority

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NBA'S PERFORMANCE

PARTS 3, 4 AND 5 OF THIS REPORT DESCRIBE OUR PERFORMANCE IN KEY ACTIVITIES.

SECURING THE SUPPLY OF
BLOOD AND BLOOD PRODUCTS

PART 3

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UNITS RED BLOOD
CELLS ISSUED

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3

PERFORMANCE: SECURING THE SUPPLY OF BLOOD AND BLOOD PRODUCTS

INTRODUCTION

The NBA's performance outcome is to secure Australia's blood supply.

The NBA ensures a secure supply of blood and blood products in Australia by:

- working with jurisdictions to determine and manage an annual supply plan and budget
- negotiating and managing blood supply contracts and arrangements with local and overseas suppliers
- evaluating proposals to add, remove or change blood products on the National Product Price List determined by the SCoH.

The deliverables and key performance indicators for this function, and our performance, are described below.

DELIVERABLES

Qualitative deliverables	2011–12 reference point or target	Results
New Australian Red Cross Blood Service contract arrangements are implemented	Specific elements of the contractual arrangements are implemented in accordance with the agreed timetable	The current Deed has been extended to 30 June 2013. Improvements in contractual arrangements are being negotiated in accordance with an agreed timetable. (see pages 40–45)
All new tender outcomes for imported fractionated plasma and recombinant products and diagnostic reagent products are implemented	Transition arrangements for all elements of contracts are implemented within agreed contractual timetables	All tender outcomes were implemented within agreed timeframes. (see pages 48–55)
The Australian Red Cross Blood Service Victoria and Tasmania principal site (VTPS) achieves practical completion	The VTPS achieves practical completion by April 2012	The facility, now renamed the Melbourne Processing Centre, achieved practical completion on time and within budget and was formally opened by the Hon Catherine King on 30 April 2012. (see pages 44–45)
Quantitative deliverable	**2011–12 budget**	**2011–12 actual**
Number of blood supply contracts managed	16	18[1] (see pages 39–55)

1 The two additional contracts are the funding arrangements for the Blood Service's Sydney and Melbourne Processing Centres.

KEY PERFORMANCE INDICATORS

Qualitative indicator	2011–12 reference point or target	Results
Management and coordination of Australia's blood supply in accordance with the National Blood Agreement between the Australian Government and state and territory governments	High level of satisfaction of all funding jurisdictions with planning, management and coordination of blood supply. Satisfaction is assessed through survey of Jurisdictional Blood Committee members	89% of jurisdictions expressed satisfaction with the NBA's performance, commenting that the NBA's performance has consistently improved over time. The remaining 11% were unsure. (see pages 28–38)
Quantitative indicators	**2011–12 budget**	**2011–12 actuals**
Percentage of administration costs as a proportion of the national supply plan and budget, under the National Blood Agreement	<1.4%	<1.1% (see pages 9, 114–118, 180–181)
Variance between actual and NBA estimated total demand for supply of products	<5%	6.1% variance between the estimated budget in the NSP&B and actual expenditure. However, this occurred as a result of unforecast efficiencies and savings, not additional expenditure. (see pages 28–38)

THE ANNUAL NATIONAL SUPPLY PLAN AND BUDGET (NSP&B)

A key element of the NBA's role in ensuring security of supply is to develop, coordinate and monitor the annual NSP&B, including obtaining annual approval from health ministers.

This is achieved by:

- developing a national estimate of product demand
- liaising with jurisdictions and stakeholders to refine the estimated demand for products
- collecting and distributing data on product issued and reporting variations to jurisdictions on the approved supply plan
- intensively managing products if they are in short supply.

PERFORMANCE AGAINST THE 2011–12 NSP&B

Throughout 2011–12, demand was met by products supplied under the national supply plan, and supply risks were effectively managed. Lists of products supplied under contract during the year are contained in **Appendix 5:** Fresh blood components and **Appendix 6:** Plasma and recombinant products.

The approved budget for 2011–12 covering the supply and management of blood and blood products and services under contract was $1,035.5 million, comprising $548.0 million for fresh blood products and plasma collection and $473.2 million for plasma and recombinant products. The remaining $14.3 million included items such as contributions for the National Managed Fund, interest monies, support for the Australian Haemophilia Centre Directors' Organisation and administration of the ABDR.

The list of products purchased from suppliers to meet this demand is provided in Table 3.1. Figure 3.1 identifies actual expenditure in each product category.

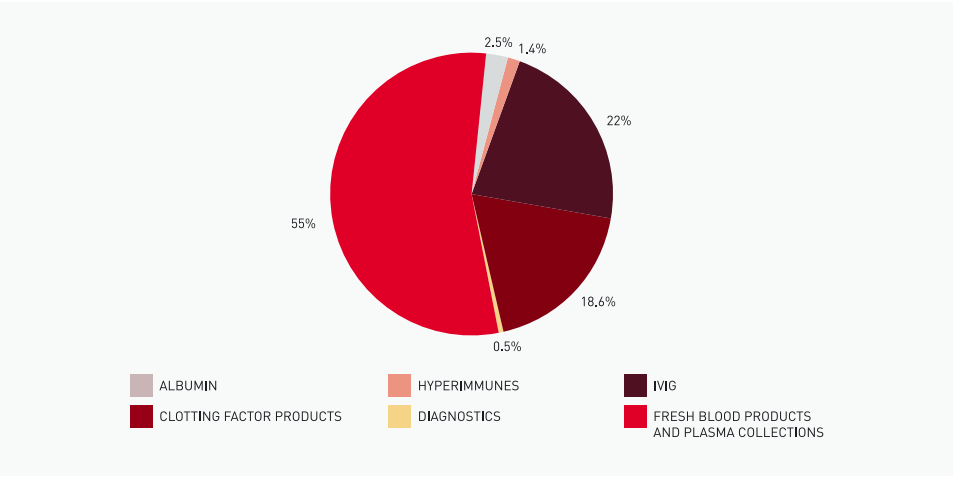

FIGURE 3.1 *Expenditure by product category 2011–12*

TABLE 3.1 *Blood and blood products purchased, by suppliers, 2008–09 to 2011–12*

SUPPLIER	PRODUCTS PURCHASED	2008–09 ($M)	2009–10 ($M)	2010–11 ($M)	2011–12 ($M)
CSL Limited	Plasma Products - albumin products - immunoglobulin products (including IVIg and hyperimmune products) - plasma-derived clotting factors Diagnostic Reagent Products - blood grouping sera - reagent red cell products Imported Plasma and Recombinant - Rh(D) immunoglobulin - Factors XI and XIII Management of National Reserve	162.09	186.16	215.15	228.22
Australian Red Cross Blood Service	Fresh Blood Products - whole blood - red blood cells - platelets - clinical fresh frozen plasma - cryoprecipitate - plasma for fractionation	432.62	456.12	496.57	526.35
Baxter Healthcare Pty Ltd	Imported Plasma and Recombinant Products - Recombinant Factor VIII - Protein C - Factor VII concentrate - Factor Eight Inhibitor Bypass Agent (FEIBA) - Imported IVIg	84.09	90.62	96.93	45.95
Bayer Australia Limited	Imported Plasma and Recombinant Products - Recombinant Factor VIII				18.67
Pfizer Australia Pty Ltd	Imported Plasma and Recombinant Products - Recombinant Factor VIII - Recombinant Factor IX	48.65	48.94	57.03	66.55
Novo Nordisk Pharmaceuticals	Imported Plasma and Recombinant Products - Recombinant Factor VIIa	17.40	26.42	27.37	24.55
Octapharma Pty Ltd	Imported Plasma and Recombinant Products - IVIg Standing Offer	46.90	48.69	8.95	23.38
Lateral Grifols	Imported Plasma and Recombinant Products - IVIg Standing Offer	0.00	0.00	24.50	22.51
Grifols Australia (DiaMed Australia Pty Ltd)	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.92	0.81	0.60	0.00
Ortho-Clinical Diagnostics (Johnson & Johnson Company)	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.47	0.43	0.38	0.45
Bio-Rad Laboratories Pty Ltd	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.00	0.00	0.00	0.13
Abacus ALS Pty Ltd	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.04	0.04	0.03	0.05
TOTAL PURCHASES OF BLOOD AND BLOOD PRODUCTS		**793.18**	**858.23**	**927.51**	**956.81**

The total cost of products issued to all jurisdictions in 2011–12 amounted to $971 million (including product issued from stock). This represented an increase of $23.6 million (2.5 per cent) compared with 2010–11 which is well below the previous year's increase of $59.6 million (6.8 per cent). Figure 3.2 indicates a reduction in issues of product against the plan for some imported, red cell and platelet products and an apparent stabilising of demand for Factor VIII (FVIII). In addition, there were significant savings against the 2011–12 approved budget as a result of the successful tender processes for the supply of recombinant Factor VIII (rFVIII) and other imported products including IVIg, delivering a $33.7 million saving for governments for 2011–12. These arrangements are in place until July 2014 and will return further savings.

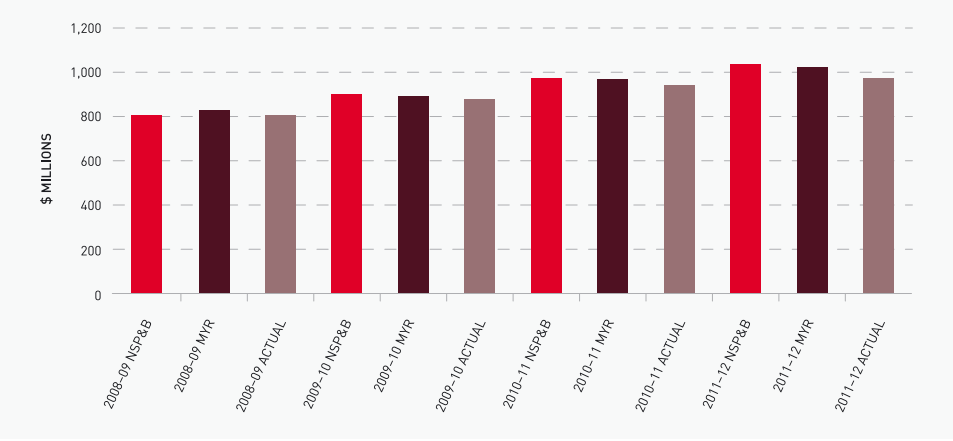

FIGURE 3.2 *Actual issues performance against the NSP&B and mid-year review, 2008–09 to 2011–12*

Fresh blood

In the nine years to 2011–12, expenditure on fresh blood and plasma collections has increased from $247.8 million to $526.3 million. Of this, $145 million is due to price increases averaging 7.5 per cent per year. These price increases include major additional operational costs and investment in principal sites such as the Sydney and Melbourne processing centres. Demand for fresh products—principally red cells, platelets and plasma for fractionation—has been increasing at 3.5 per cent a year, resulting in additional expenditure of $68.7 million. A further $69.2 million is a consequence of the introduction of government-approved quality and safety measures such as the universal leucodepletion of platelets and red cells. These safety measures have resulted in an additional increase in expenditure averaging 3.6 per cent a year. The combined effect of these measures on expenditure can be seen in Figure 3.3.

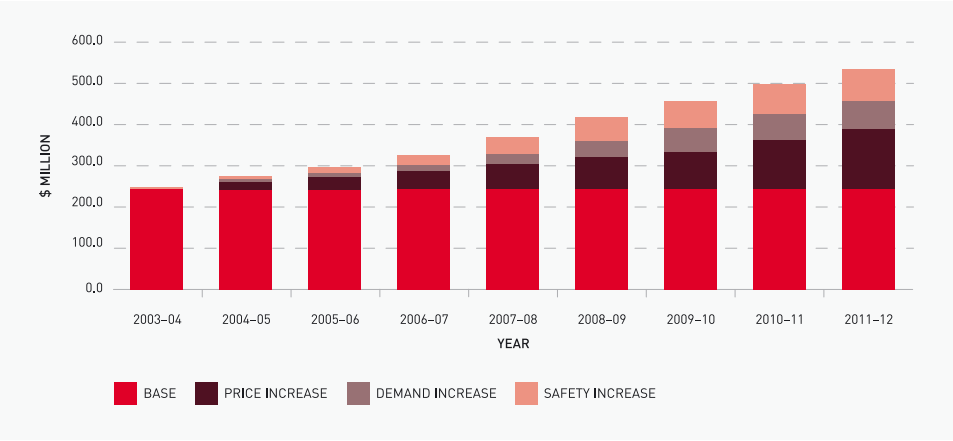

FIGURE 3.3 *Fresh blood expenditure: increases on 2003–04 base year*

The actual supply of fresh blood products for 2011–12 compared with the annual supply estimates agreed by the SCoH is set out in Table 3.2.

TABLE 3.2 *Variance between actual supply of fresh blood components against the annual supply estimates, 2011–12*

VOLUMES	UNITS IN NSP&B	ISSUES	UNIT VARIATION ON PLAN	% VARIATION ON PLAN
Total red cells	819,408	801,295	-18,113	-2.2%
Total platelets	143,422	134,149	-9,273	-6.5%
Total clinical FFP	166,747	159,024	-7,723	-4.6%
Total cryoprecipitate	76,728	78,099	1,371	1.8%
Total cryodepleted plasma	13,332	13,756	424	3.2%
Plasma for fractionation (in kgs)	510,000	502,181	-7,819	-1.5%

Issues of red cells

Red cells comprise 29 per cent of total blood and blood product expenditure and are the largest single item of cost in fresh products. Figure 3.4 indicates that the volume of red cells issued in 2011–12 was two per cent less than the volumes estimated in the NSP&B and demonstrated very little growth (0.1 per cent) from 2010-11. The gradual decrease in the rate of growth in volume of product per 1000 head of population being observed appears (see Figure 3.5) to reflect the outcomes of policies driving appropriate use and improved inventory management.

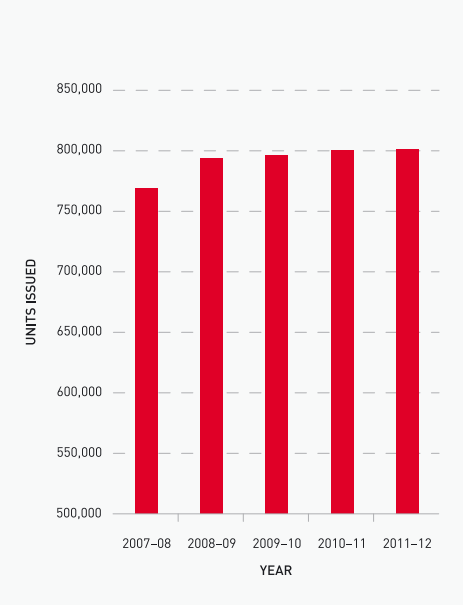

FIGURE 3.4 *Red cells issued by the Blood Service, 2007–08 to 2011–12*

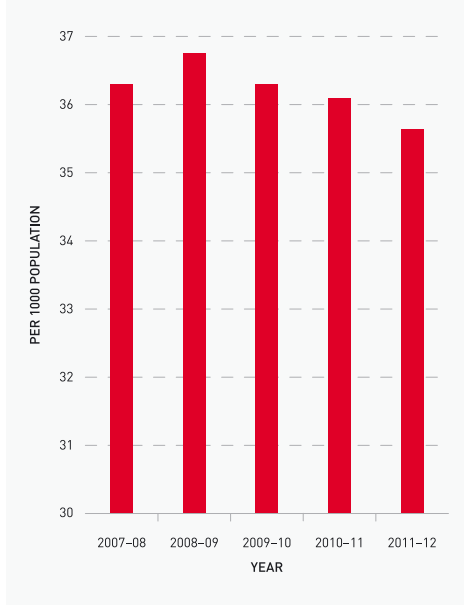

FIGURE 3.5 *Red cells issued per 1000 head of population, 2007–08 to 2011–12*

Issues of platelets

As is shown in Figure 3.6, the number of platelets issued in 2011–12 decreased slightly (-0.4 per cent) compared to 2010–11. This is the first time that a decline in the usage of platelets has been experienced. The pattern across the jurisdictions was different with declining or stable use in all states except for Queensland and Western Australia.

Issues of platelets per 1000 population decreased by 1.8 per cent in 2011–12 compared with a 3.6 per cent increase the previous year (see Figure 3.7).

While the actual issue of platelets in 2011–12 was lower than the NSP&B, the mix between whole blood pooled platelets and apheresis platelets was close to the NSP&B ratio. The 2011–12 NSP&B ratio was 61 per cent whole blood pooled and 39 per cent apheresis. The actual issue of platelets for 2011–12 was 60 per cent whole blood pooled and 40 per cent apheresis.

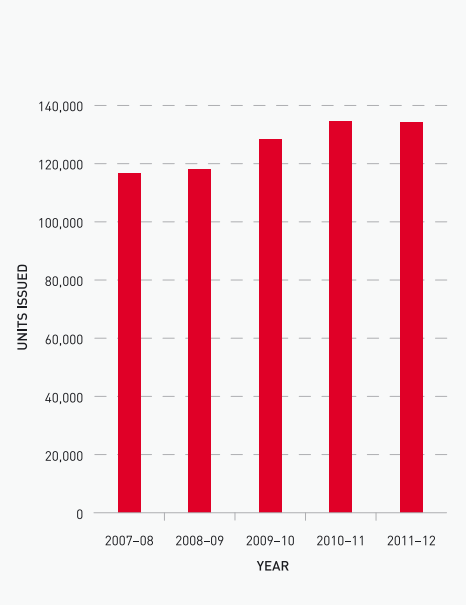

FIGURE 3.6 *Platelets issued by the Blood Service, 2007–08 to 2011–12*

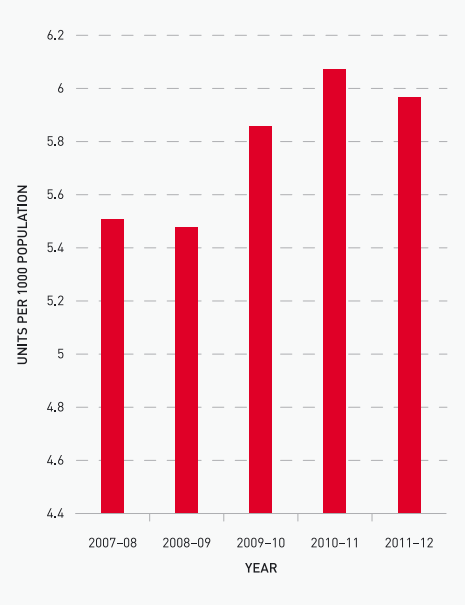

FIGURE 3.7 *Platelets issued per 1000 head of population, 2007–08 to 2011–12*

Issues of other fresh products

Demand for clinical FFP was marginally less than in the 2010–11 period and was five per cent lower than the estimate in the 2011–12 supply plan. The forecast growth for future years is based on population growth.

Cryoprecipitate in 2011–12 experienced an 11.4 per cent increase in demand over the previous year and was two per cent higher than the NSP&B. It remains difficult to predict demand for this blood component, as the number of patients treated with cryoprecipitate is small, but the volumes administered can be large.

Jurisdictions noted that cryoprecipitate is increasingly used in the treatment of massive bleeding and that this may drive an increase in demand in the coming years. Of note is that there is increasing interest in the use of fibrinogen concentrates as an alternate to cryoprecipitate, especially in emergency and remote settings.

Cryodepleted plasma demand decreased by 0.9 per cent in 2011–12 compared with 2010–11 and was 3.2 per cent above the NSP&B. It is difficult to forecast demand for cryodepleted plasma as this product is used spasmodically and episodically in very small numbers of patients.

Details of various aspects of the NBA's contractual arrangements with the Blood Service in 2011–12 are provided at pages 40–45.

Plasma and recombinant products

Products issued on plasma-derived and recombinant blood products decreased to $414.7 million in 2011–12, a decrease of $14.1 million (3.3 per cent) from 2010–11. As indicated in Figure 3.8, by far the largest proportion of this decrease was due to the reduced product prices, notably for rFVIII and imported IVIg, as discussed above. The impact of price decreases was significant, contributing 21.2 per cent to the total decrease in expenditure.

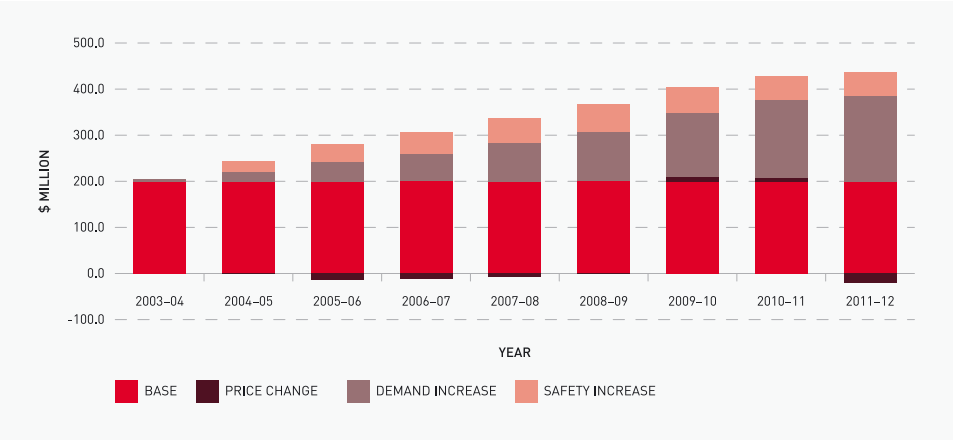

FIGURE 3.8 *Plasma-derived and overseas product expenditure: cumulative increases on 2003–04 base year*

Details of supply management for plasma-derived and recombinant products are provided in pages 48–55.

Issues of clotting factors

Figures 3.9 and 3.10 indicate that the demand for Factor VIII products in 2011–12 was one per cent less than in 2010–11. The annual growth rates for this product since 2009–10 have been 2.1 per cent, 11.3 per cent and -1 per cent respectively. The demand for plasma-derived product has decreased significantly, from 33.2 per cent growth in 2010–11 to a -6.3 per cent reduction in demand in this reporting year. Demand for rFVIII has also decreased in 2011–12 resulting in a reduction in growth from 8.6 per cent in 2010–11 to -0.3 per cent for 2011–12.

The reduction in growth for Factor VIII may be attributed to a number of factors, including a reduction in the number of patients undergoing tolerisation[2], a number of high volume patients participating in clinical trials and the continuing number of patients stabilising onto prophylaxis home treatment.

Figure 3.11 shows the market share of recombinant Factor VIII products purchased by the NBA over the past five years.

2 Tolerisation is a treatment regimen which aims to reduce or eliminate inhibitors (i.e. antibodies) to transfused clotting factors, e.g. FVIII.

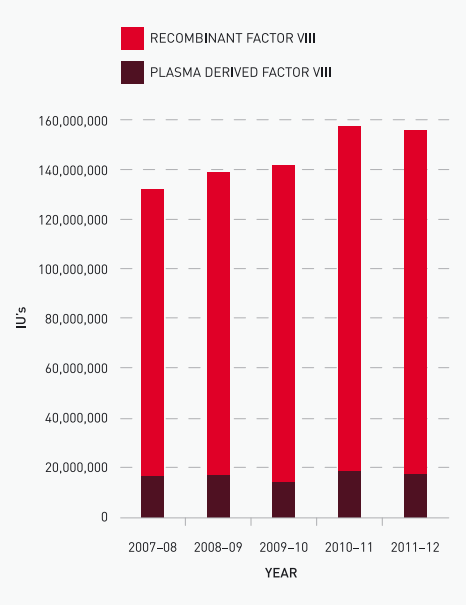

FIGURE 3.9 *Issues of Factor VIII products, 2007–08 to 2011–12*

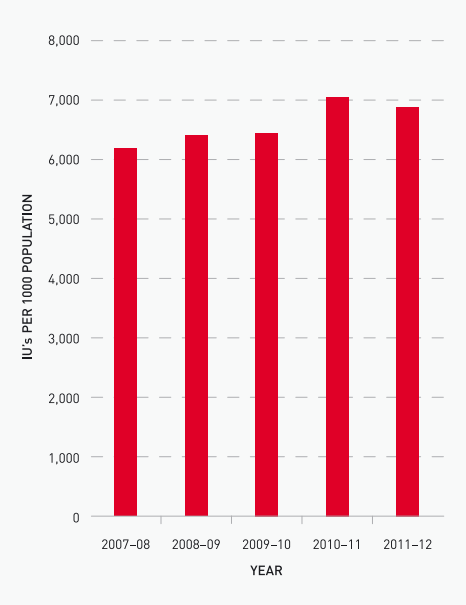

FIGURE 3.10 *Issues of total Factor VIII per 1000 head of population, 2007–08 to 2011–12*

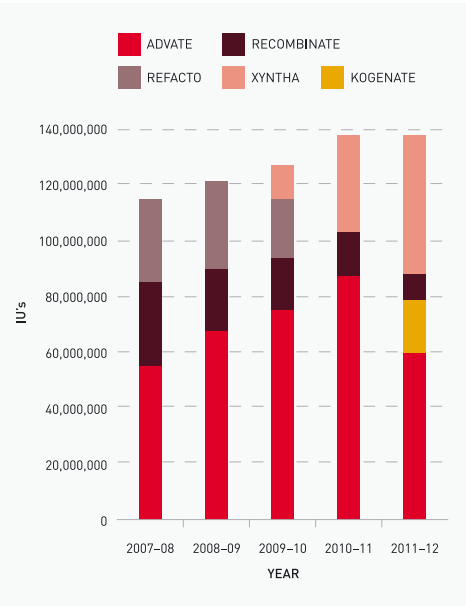

FIGURE 3.11 *Market share of recombinant Factor VIII issues, 2007–08 to 2011–12*

Demand for Factor IX (FIX) products in 2011–12 reduced by 4.4 per cent compared to 2010–11. This reduction was consistent with discussions during planning consultations with jurisdictions (see Figures 3.12 and 3.13).

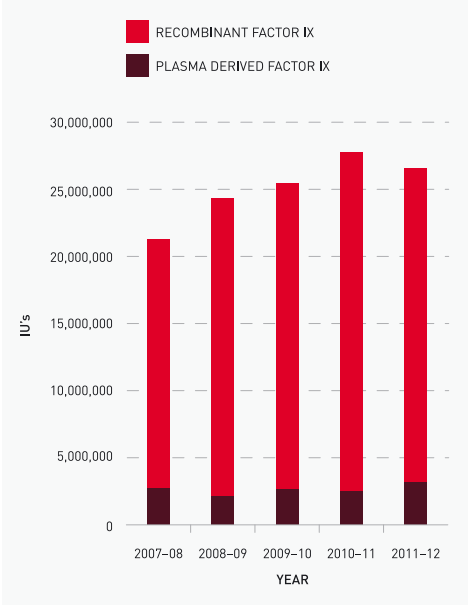

FIGURE 3.12 *Issues of Factor IX products, 2007–08 to 2011–12*

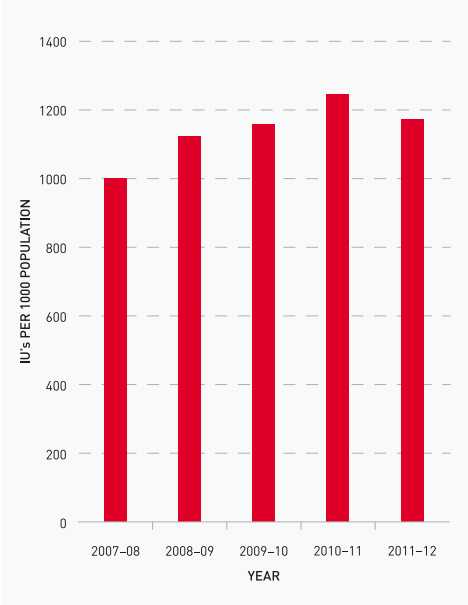

FIGURE 3.13 *Issues of Factor IX products per 1000 head of population, 2007–08 to 2011–12*

Jurisdictions acknowledge that a very small number of patients experiencing very high needs may considerably affect overall demand for recombinant Factor VIIa (rFVIIa) (see Figure 3.14) and Factor Eight Inhibitor Bypass Agent (FEIBA) (see Figure 3.15). The 2011–12 level of demand for rFVIIa was seven per cent below plan and 16 per cent below 2010–11. This trend is expected to continue, although at slightly lower rates of decrease, for the foreseeable future. FEIBA has seen a significant reduction in growth which has resulted in 2011–12 demand being 28 per cent less than in the NSP&B, and 3.2 per cent less than 2010–11. The driver behind this reduction is patient-specific with some high volume patients having now completed tolerisation.

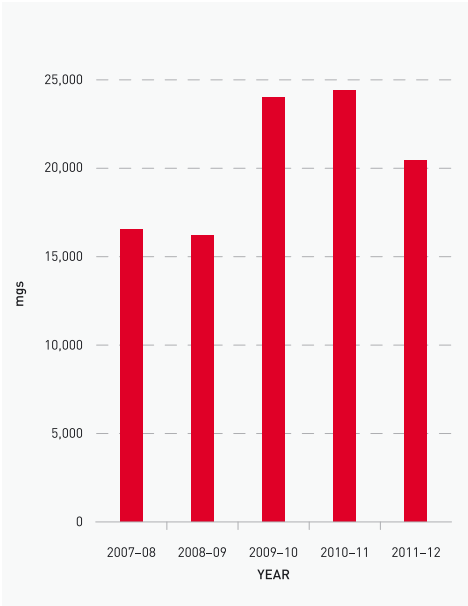

FIGURE 3.14 *Issues of recombinant Factor VIIa, 2007–08 to 2011–12*

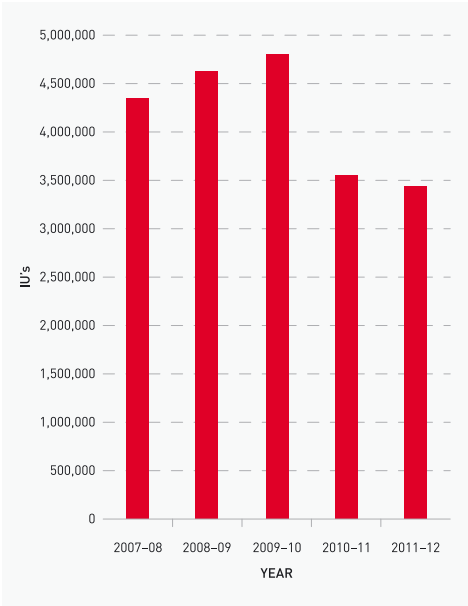

FIGURE 3.15 *Issues of FEIBA, 2007–08 to 2011–12*

Issues of immunoglobulin: IVIg and NIg

Figure 3.16 indicates that growth in demand for IVIg has continued at a relatively constant rate since 2007–08. The average annual growth from 2008–09 to 2011–12 is 11 per cent per annum.

In 2011–12, a total of 3.27 million grams of IVIg was issued, representing a cost of $204.4 million nationally (excluding the cost of plasma collections). Of this, 78 per cent was IVIg produced in Australia and 22 per cent was imported. Excluding IVIg issued under direct orders, a total of 12,130 (compared with 11,438 in 2010–11) patients nationally were issued IVIg during 101,388 treatment episodes (93,893 in 2010–11)[3]. Figure 3.17 shows comparative data on the issues of IVIg per 1000 head of population over the past five years.

Assessment of the proposed changes to the *Criteria for the clinical use of IVIg in Australia*, as detailed in the public consultation version, would indicate no new major driver for substantial growth.

The NBA produced an annual report of IVIg usage in 2010–11, in order to document the trends in the use of IVIg and provide insights into the drivers of use at the micro level. It draws on records of issues and purchases data held by the NBA, and application of IVIg to clinical indications from the Blood Service's supply tracking analysis recording system database. The report shows that there are still considerable variations in the grams issued per treatment episode across the jurisdictions for some conditions. Neurology remains the discipline using the greatest amount of IVIg and demand is still increasing. Haematology is the next largest but growth has slowed within this discipline, while growth has also declined in immunology, the third largest user of IVIg.

The report can be found on the NBA website at http://www.nba.gov.au/ivig/index.html.

The top ten indications for which IVIg is issued most frequently are shown in Figure 3.18 below. They constitute 88 per cent of total use of IVIg in 2011–12 and represent the use by disease groups of over 90,000 grams nationally. The top three uses, considerably higher than remaining indications, are acquired hypogammaglobulinaemia secondary to haematological malignancies, chronic inflammatory demyelinating polyneuropathy and primary immunodeficiency diseases.

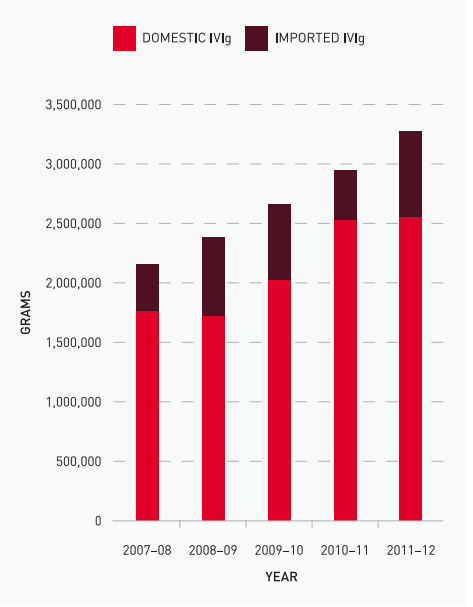

FIGURE 3.16 *Issues of IVIg products, 2007–08 to 2011–12*

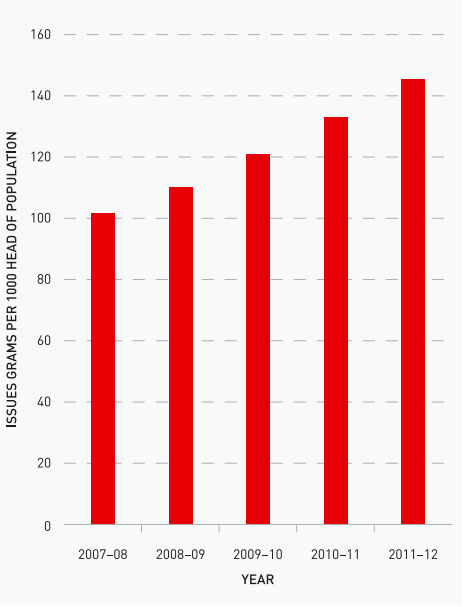

FIGURE 3.17 *Issues of IVIg (grams) per 1000 head of population, 2007–08 to 2011–12*

3 2010–11 figures differ slightly from those published in last year's annual report due to subsequent reconciliation

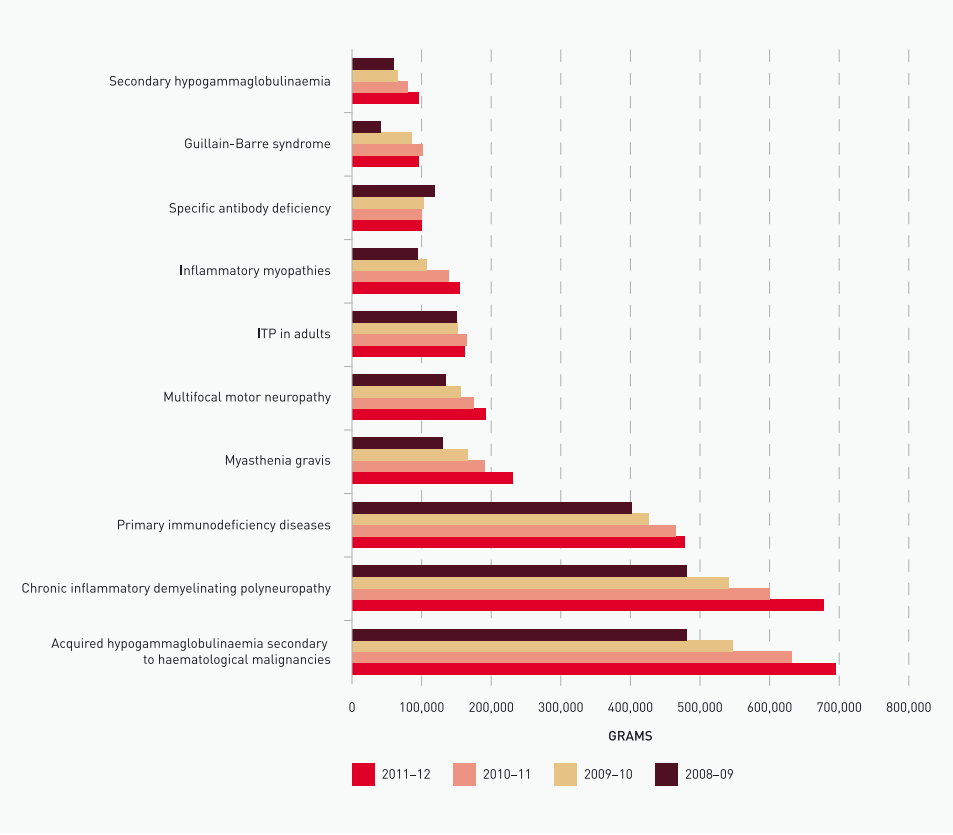

FIGURE 3.18 *Top ten uses of IVIg, 2008–09 to 2011–12*

In 2011–12 there was a substantial and unforecasted increase in demand for normal immunoglobulin (NIg). CSL Limited produces NIg from hyperimmune plasma specially collected by the Blood Service (see Figure 3.19). The volume of product is limited by the availability of this specialised plasma, and by production scheduling arrangements in CSL Limited's manufacturing facility. The TGA has approved the use of NIg for intramuscular injection in the management of hypogammaglobulinaemia and for public health purposes to treat susceptible contacts of hepatitis A, measles and poliomyelitis.

The NBA and jurisdictions investigated the reasons for the unexpected increase in demand for NIg, which varies across the states and territories. It is likely that a significant proportion of the usage is off-label (that is, outside specific TGA approval) for subcutaneous administration, particularly for primary immune deficiency patients and in part as a result of a structured home treatment program.

This raised policy issues around inappropriate use of product and potentially reduced access for urgent public health disease control. However, the JBC determined after consultation that during 2011–12 and for 2012–13 the supply of product was sufficient, and that it was the responsibility of each jurisdiction to manage demand if necessary, rather than establishing a national policy or management framework.

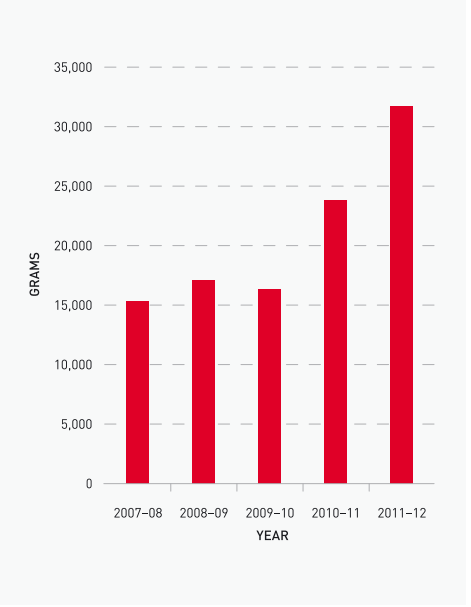

FIGURE 3.19 *Issues of NIg, 2007–08 to 2011–12*

See also page 76 which describes the current review commissioned by the CTEPC of the clinical governance and authorisation arrangements for IVIg, and potential alternatives.

PREPARATION OF THE 2012–13 NSP&B

The NBA works intensively with jurisdictions and suppliers to estimate demand and supply for products for the following year, negotiate prices, and obtain endorsement of the plan from health ministers. This process commences in September with discussions with jurisdictions and suppliers and is completed when the Federal Budget is handed down in May.

2012–13 demand for most blood and blood products is estimated to be higher than for 2011–12, although this does not translate into increased expenditure for all products. This is because the NBA has negotiated very competitive prices in its new contracts with suppliers of plasma-derived and recombinant blood products.

The approved 2012–13 NSP&B will also contain operating funds for the NBA to undertake a range of activities aimed at improving the clinical usage of blood and blood products, including:

- improving the sustainability and performance of the sector through enhanced data capture and the expert analysis of this data
- raising awareness of governments' stewardship expectations of users of blood and blood products, and their management of these products, through the development and publication of evidence-based national guidelines, in close collaboration with clinicians.

MANAGING BLOOD SUPPLY CONTRACTS AND ARRANGEMENTS

Maintaining security of supply also requires the NBA to manage contracts with suppliers of blood and blood products.

In 2011–12 the NBA managed 18 blood and blood product supply contracts and arrangements. The Deed with the Australian Red Cross Society was extended, and two new contracts were executed for the supply of imported intravenous immunoglobulin (IVIg) with Octapharma Australia Pty Ltd (Octagam) and Baxter Healthcare Pty Limited (Kiovig) and commenced on 1 January 2012.

Contract management activities included management of:

- Australia's fresh blood component requirements through the Deed of Agreement with the Australian Red Cross Society (the Red Cross)
- Australia's plasma product and recombinant product requirements through:
  - the CSL Australian Fractionation Agreement (CAFA)
  - contracts for the provision of imported IVIg, imported recombinant factors VIIa, VIII, IX, and XIII, and other imported plasma and recombinant products
- requirements for red cell diagnostic reagent products.

MANAGEMENT OF FRESH BLOOD SUPPLY ARRANGEMENTS

The NBA manages the relationship with the Blood Service—the sole supplier of fresh blood components in Australia—and is responsible for negotiating and managing the Deed of Agreement with the Red Cross. The NBA also manages a number of projects involving the Blood Service and provides secretariat and project management support for the National Indemnity Reference Group which oversees the National Managed Fund.

The CEOs and chief financial officers of the two organisations meet every quarter, each CEO and Board Chair attends one meeting of the other organisation during the year and the two boards meet annually in October. In addition, the Blood Service reports annually to the SCoH against the ministerially-approved Statement of Expectations.

Blood Service: expenditure and product mix

Actual expenditure to the Blood Service increased from $496.6 million in 2010–11 to $526.3 million in 2011–12 (see Table 3.3). A list of the fresh blood components supplied under contract by the Blood Service is given in **Appendix 5**.

TABLE 3.3 *Annual expenditure: Blood Service, 2003–04 to 2011–12*

YEAR	AMOUNT ($M)	% GROWTH
2003–04	247.8	
2004–05	277.0	11.8
2005–06	297.7	7.5
2006–07	327.1	9.9
2007–08	369.1	12.8
2008–09	417.2	13
2009–10	456.1	9.3
2010–11	496.6	8.9
2011–12	526.3	6
TOTAL	**3414.9**	**9.9 (average)**

In 2011–12 the Blood Service achieved an operating surplus of $6.2 million through continued implementation of efficiencies measures.

Blood Service: supply performance

Supply performance measures require the Blood Service to manage donations and to process the products received from these donations in an efficient and targeted manner. Governments require the Blood Service to continually improve its performance in both areas.

The Blood Service continued to perform against all of the key performance indicators specified in the Deed. Some indicators of particular interest this year are summarised in Table 3.4. In addition, the Blood Service performance was assessed against the health ministers' 2010–11 to 2012–13 *Statement of Expectations for the Australian Red Cross Blood Service*. A key performance target for the Blood Service was to improve efficiency of conversion of whole blood collections to supply by one per cent each year during 2010–13. For 2010–11 the Blood Service achieved 80.2 per cent against a target of 79.1 per cent and for 2011–12 they achieved 85 per cent against a target of 80.1 per cent.

TABLE 3.4 *Blood Service: selected key performance indicators, 2011–12*

DOMAIN	INDICATOR	ANNUAL RESULT 2010-11	PLANNING PARAMETER	ANNUAL RESULT 2011–12
Donor management	**Size of donor base:**			
	Whole blood	515,959	518,700	504,600
	Apheresis plasma	71,919	74,900	84,400
	Apheresis platelet	11,598	12,900	11,900
	Frequency of donation (per year):			
	Apheresis plasma	4.34	4.73	4.24
Supply chain management	**Efficiency of collection (conversion to supply)**			
	Whole blood	80.2%	81.2%	85%
	Order fulfillment*	85.3%	95%	89.5%
Quality and level of service	Overall approved health provider satisfaction with Blood Service	84%	48%	52%**

* As measured by the Blood Service.

** There was a change in the measurement from 2010–11 to 2011–12, and therefore comparison across the years is not possible.

The target for the quantity of plasma for fractionation collected and supplied to CSL by the Blood Service for 2011–12 was 510 tonnes. Late in 2011–12, the Blood Service advised the NBA that it would be unable to achieve the target of 510 tonnes, but suggesting that it would achieve 500 tonnes. The result at the end of 2011–12 was that the Blood Service supplied 502 tonnes of plasma to CSL, eight tonnes below target. The reasons for this variance were:

- improved efficiency of conversion of whole blood collections to supply
- reduction in the rate of growth of demand for red blood cells.

Table 3.5 sets out the plasma volumes collected by the Blood Service over the past nine years.

TABLE 3.5 *Blood Service: plasma volumes collected for fractionation (tonnes), 2003–04 to 2011–12*

2003–04	2004–05	2005–06	2006–07	2007–08	2008–09	2009–10	2010–11	2011–12
294.5	308.1	308.4	329.3	352.8	390.7	452.4	472.3	502.2

The NBA continues to work with the Blood Service to obtain a commitment to a three-year timeframe for planning the volume of plasma for fractionation to be collected. The project will seek to optimise cost-effectiveness while at the same time maintaining donor welfare and also immunoglobulin yields (see also page 46–50 on CSL performance).

Deed of Agreement

Negotiations for a new deed of agreement with the Red Cross commenced with the Blood Service in 2010. The 2006–09 Deed has been extended by mutual agreement of the parties until 30 June 2013. Finalisation of the new deed will be informed by the current review of the National Managed Fund (NMF) (see page 44), which is due to be completed in 2014. It is likely a further extension of the current Deed will be necessary to allow for finalisation of the NMF review.

During the year, the Blood Service and the NBA continued to work on operational requirements to prepare for the new deed, or for variations to the current Deed, including the following projects described further below:

- funding and services arrangement
- national service requirements and standards
- the output based funding model
- substitution and payment rules
- a research and development framework.

Funding and Services Agreement

The three-year Funding and Services Agreement and associated operational arrangements will be informed by the *Statement of Expectations for the Australian Red Cross Blood Service.* The statement sets out overarching principles and goals and contains a set of management and accountability principles addressing the core priorities of governments for improved efficiency. The Funding and Services Agreement will describe the arrangements for operational aspects of the deed framework.

National service requirements and standards

The national service requirements and standards will set out the Blood Service's relationships with health providers and the NBA. They include business rules and standards for ordering, delivery, and acceptance of products and will guide the Blood Service in developing consistent service level agreements with approved health providers.

Output based funding model

The objectives of the output based funding model are to cost products and services on the basis of actual costs of production and to pay only the costs of services actually provided. The model defines all of the products and services to be delivered under the contractual arrangements, product prices determined by agreed cost attribution rules, cash flows, product cost indexation and risk management arrangements. The model was implemented in July 2010 and the Blood Service has generated significant operational efficiencies.

The model is operating from 2010–11 to 2012–13, and negotiations for the next cycle, to start on 1 July 2013, commenced in February 2012.

Substitution and payment rules

The substitution and payment rules will document an agreed set of arrangements under which specific products may be supplied, and the payment processes relating to receipt of products that will apply. During the year the NBA held two workshops to draft the rules, with participants from the JBC, laboratory staff from three jurisdictions and the Blood Service. Work continues on a range of operational and system issues to finalise and implement the new rules.

National research and development framework

In 2011–12 the Blood Service received grant funding of approximately $7.8 million for its research and development program, primarily through the Deed of Agreement. There are four research programs:

- donor and community research
- applied and developmental research
- transfusion science research
- clinical research.

The NBA and the Blood Service are working to finalise a research and development framework, which will outline the strategy to ensure appropriate incorporation of government priorities and expectations in the development and implementation of the Blood Service research program. It also describes reporting requirements that will improve the transparency to governments of activities and expenditure of the research and development program. The agreed principles and processes of the research and development framework will be reflected in the new deed.

National inventory management framework

Work commenced on developing a nationally consistent inventory management framework covering blood products funded by governments and manufactured by the Blood Service, in particular red blood cells. The aim is to have a comprehensive, efficient and effective guideline for better practice inventory management and product safety stock levels. This will ensure that blood products are available to meet clinical demand when they are needed, improve financial performance and reduce the amount of product that is discarded. In addition, the framework will identify stakeholder responsibilities throughout the blood supply chain and the linkages between them.

During 2011–12 a project team was established that includes representatives from the NBA and the Blood Service and a project manager was recruited for the NBA (see pages 106–107).

The graph in Figure 3.20 shows the trend for total red blood cell inventory levels for 2010–11 and 2011–12, held by both approved health providers and the Blood Service. There continues to be a seasonal trend in the levels of inventory held. The levels of inventories in 2011–12 have been lower than the previous year. The changes for each quarter in red cell age at issue from the Blood Service to approved health providers, is shown in Table 3.6.

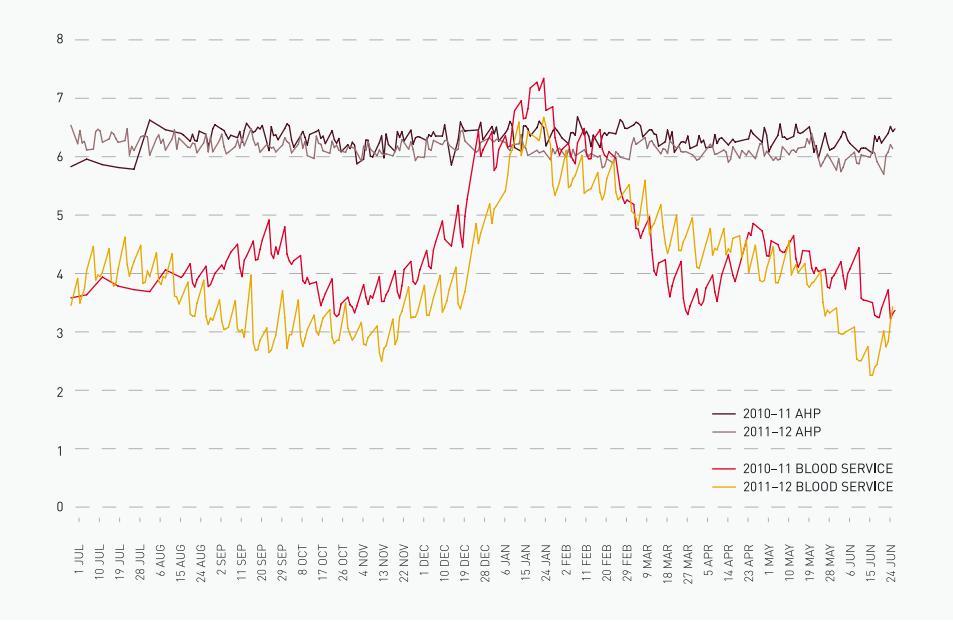

FIGURE 3.20 *Red blood cell days of inventory at the Blood Service, of major blood type, by business day, 2010–11 to 2011–12*

TABLE 3.6 *Red cell age at issue by quarter, 2010–11 to 2011–12*

	Q1	Q2	Q3	Q4
2010–11	7.3	7.4	9.7	7.3
2011–12	6.6	6.2	9.3	7.3

Blood Service: Strategic capital investment plan

Under the Deed, the Blood Service receives an agreed capital budget, set at ten per cent of total operational funds provided. For 2011–12, expenditure was approximately $46.3 million. Payment of the capital is through the output based funding model and is included in the product pricing. Table 3.7 shows the value of the approved annual capital plans over the past five years.

TABLE 3.7 *Blood Service annual capital plan: actual expenditure, 2007–08 to 2011–12*

2007–08 $ MILLION	2008–09 $ MILLION	2009–10 $ MILLION	2010–11 $ MILLION	2011–12 $ MILLION
32.96	37.99	41.21	44.07	46.3

These funds are required to be managed through the strategic capital investment plan which, with the annual capital plan, is reviewed by the NBA each year. The plan details the capital expenditure that is expected to be required to sustain assets for the next three years. The 2012–15 plan includes investment for improvement initiatives and replacement of assets such as laboratory, administration and information and communication technologies (ICT) equipment. The plan is assessed using factors such as benchmarking of like industries and international peers, manufacturer warranties, availability of parts, internal expert advice and accounting standards.

Melbourne Processing Centre *(formerly the Victoria and Tasmania principal site)*

In December 2008, health ministers gave in-principle approval for additional funding for the Blood Service over 20 years to meet the costs of building and outfitting leases for a new principal blood manufacturing site in Melbourne.

The Hon Catherine King MP, Parliamentary Secretary for Health and Ageing formally opened the centre on 30 April 2012. The centre is responsible for the manufacture of blood for Victoria and Tasmania, comprising 26 per cent of the nation's blood supply (see page 45).

National Managed Fund (NMF)

The NMF was established to cover potential future claims made against the Blood Service in relation to the supply of blood and blood products in Australia. The memorandum of understanding for the management and administration of the NMF includes an expectation that the funds will earn interest to enable the real value of the annual contributions to the fund to be maintained over time and reduce the level of contributions by governments and the Blood Service. The fund was established as a discretionary managed fund with a finite scope and there is no contractual liability to agree to claims. During the year the NBA engaged KPMG to develop an investment strategy for the NMF.

The National Indemnity Reference Group (NIRG) is a technical advisory subcommittee of the JBC, providing expertise on matters such as policy, review and monitoring of the Blood Service risk management strategy. The NBA provides secretariat support to the NIRG, which meets twice a year.

PricewaterhouseCoopers advises the NIRG on core services, including incident analysis, horizon scanning, Blood Service risk management assessment and actuarial services. In presenting its annual actuarial and liability report for 2011 and estimates of the 2012–13 contributions to the NMF from governments, the company concluded that the risk of transfusion acquired diseases for the commonly known pathogens in Australia is now very small.

During 2011–12 PricewaterhouseCoopers also commenced a review and update of the claims manual and incident reporting processes, and presented bi-annual horizon scanning reports.

In 2010–11 the JBC endorsed a review of the scope and the discretionary nature of the NMF and a review of the statutory defence legislation (blood shield legislation) for ministers to consider. In August 2011 the SCoH endorsed an action plan to review:

- NMF's policy, legislative base, scope and discretionary nature
- harmonisation of the blood shield legislation[4]
- the Blood Service's commercial insurance coverage
- roles and responsibilities of the NIRG.

Consideration of these important issues will inform, and be informed by, ongoing negotiations for the new deed of agreement with the Red Cross. The complexity of the issues to be considered will require a multidisciplinary approach and extensive consultation with a wide range of experts. A JBC subcommittee was established to oversee the review, for which the NBA is providing secretariat services, with much of the technical work to be outsourced. The subcommittee is chaired by Mr Ken Barker, a long-standing member of the NBA Board.

A tender process commenced to procure expert services to undertake some of the activities outlined in the ministerially endorsed action plan. Work is expected to commence early in 2012–13.

4 Blood shield laws protect health care providers from liability for transfusing blood products that subsequently prove to be from an individual infected with a pathogen

NBA FOCUS
FRESH BLOOD SUPPLY SECURITY
––
OPENING BLOOD SERVICE
MELBOURNE PROCESSING CENTRE
VICTORIA

WORLD-CLASS AND QUAKE-PROOF BLOOD PROCESSING CENTRE FOR MELBOURNE

A fresh injection of government funding allowed the Blood Service to open the largest blood processing facility in the southern hemisphere, converting a disused Melbourne car factory into a high-tech laboratory.

The Melbourne Processing Centre has been designed to assist Australians even in times of disaster, with its structure able to withstand a magnitude seven earthquake and to operate without water, gas, electricity or sewerage for four days.

The centre was opened on 30 April 2012 by the Parliamentary Secretary for Health and Ageing, The Hon Catherine King, who described it as 'world-class health infrastructure'. 'Australian governments have committed up to $213 million to the Blood Service to purchase, redevelop and fit-out this principal production and manufacturing site in Melbourne, and for ongoing costs over the next 20 years,' she said at the opening. This included $120 million from the Australian Government's Health and Hospitals Fund, with the remaining costs met by state and territory governments.

The Blood Service has five principal blood manufacturing facilities—located in Brisbane, Sydney, Melbourne, Adelaide and Perth—which receive blood from donor collection sites around Australia. The new Melbourne facility will process 26 per cent of the nation's blood supply, and all of Victoria's and Tasmania's blood, which amounts to about 1500 blood donations a day. All testing, processing, distribution, research and administration functions for the Blood Service in Victoria and Tasmania will be based at this facility.

An industrial area of inner Melbourne was chosen for the new site, but construction was delayed by necessary and extensive site remediation work. Despite these obstacles, construction and fit-out of the centre was completed on time and within budget. The TGA licenced the premises to operate in March 2012 and the Blood Service transitioned from their former principal processing site in Southbank to the new site in that month.

Captions: The Hon Catherine King MP, Parliamentary Secretary for Health and Ageing opening the Melbourne Processing Centre, with Gayle Ginnane (Chair, NBA Board), David Hamill (Chair, Blood Service), James Bargh (Project Manager, Blood Service), Jennifer Williams, (CEO, Blood Service) and Leigh McJames (General Manager, NBA). Photograph: Christina Birch

A laboratory in the new building before the Blood Service moved in. Photograph courtesy of the Blood Service

MANAGEMENT OF PLASMA AND RECOMBINANT SUPPLY ARRANGEMENTS

The NBA is responsible for negotiating and managing contracts and standing offers with commercial suppliers of blood and blood products. These contracts relate to the supply of locally produced plasma-derived products; imported plasma-derived and recombinant products and red cell diagnostic reagents.

In the interests of maintaining good relationships with our commercial suppliers, we have developed clear and transparent policies and reporting arrangements for our tendering processes. The NBA has also established a range of mechanisms to enhance our relationships with current and potential suppliers, including encouraging feedback. One important event is our annual Blood Product Suppliers Forum, which was held this year in April 2012 (see page 47).

Locally produced plasma-derived products: CSL Australian Fractionation Agreement

In Australia, CSL Limited fractionates plasma from donations collected by the Blood Service and supplies a range of immunoglobulin and hyperimmune products, clotting factors and albumin, for domestic use (see **Appendix 6**).

Plasma fractionation arrangements are currently governed by the CSL Australian Fractionation Agreement (CAFA) which took effect on 1 January 2010. The CAFA sets out CSL Limited's obligations regarding plasma stewardship, production, inventory management, product quality, pricing and payments, supply, reporting and performance and risk management.

The CAFA establishes an ongoing contract management dialogue between CSL Limited and the NBA through an annual cycle of management and executive meetings to discuss and monitor strategic and operational matters. In 2011–12, CSL Limited and the NBA held five contract management meetings, a regular annual risk management workshop in August 2011 and a workshop on a range of issues including minimum product inventory levels in June 2012. In addition, two update and planning meetings were held between the CEOs of the NBA and CSL Limited. Topics discussed between the CEOs included:

- trends and forecasts for products in Australia and globally
- CSL Limited's research and development program
- CSL Limited's investment in, and upgrading of, its Broadmeadows facility
- the recall of Albumex in March 2012
- management of the National CSL Reserve and the minimum product inventory
- domestic IVIg production
- potential new products.

During the year, three new versions of CSL Limited products provided under the CAFA were approved by the JBC for supply through the NSP&B commencing in 2011–12: Rh(D) immunoglobulin—625 IU and 250 IU—and Biostate 1000 IU.

NBA FOCUS
COMMUNICATING WITH SUPPLIERS
––
ANNUAL FORUM
CANBERRA ACT

TAKING THE PULSE OF BLOOD PRODUCT SUPPLIERS

Suppliers of blood products in Australia say the NBA is clear in the way it runs its contract tender process.

These findings stem from the most recent Blood Products Suppliers Forum, held at the National Portrait Gallery in April 2012, to promote face-to-face discussion with suppliers. All current and potential suppliers were invited to attend, as well as representatives of industry bodies and market consultants.

Prior to the forum, all invitees were sent an anonymous online survey asking them to rate the NBA's performance. The survey results, which were presented at the forum, revealed that 88 per cent of suppliers rated the NBA's tender process as satisfactory or better.

The Australian market for suppliers of blood products is very small. To encourage competition, the NBA stages the forum as a yearly event to hear from existing suppliers and encourage new entrants to the market. The NBA takes this approach to ensure prudent use of public funds, which supported the industry through expenditure of $426.1 million for plasma and recombinant products in 2011–12.

Changes were made to the format for the 2012 Suppliers' Forum, with many agenda items presented in a way that stimulated dialogue between the NBA and blood product suppliers. It was also an excellent opportunity for the NBA to inform suppliers of the current priorities and future plans of the NBA and encourage discussion on a number of key areas that will potentially affect suppliers. These included:

- possible future NBA directions, including the impact of health policy and reform
- new clinical practice guidelines of blood products
- development of a national data strategy for the blood sector
- priorities for contract management arising from recent tenders
- supplier developments in relation to barcoding/RFID technology
- possible linking of supplier systems to the NBA's online blood ordering and inventory management system BloodNet for future product ordering.

All presentations from the Suppliers Forum, including the results of the pre-forum and post-forum surveys, can be found on the NBA website at www.nba.gov.au/expert/suppliers.html.

Caption: Presentations by senior NBA managers at the 2012 Suppliers Forum

Expenditure

Actual expenditure on CSL Limited products increased by $14.5 million in 2011–12, from $210.5 million in 2010–11 to $225 million in 2011–12 (see Table 3.8). This represents an increase of 6.9 per cent compared to an average annual increase of 6.2 per cent from 2003–04 to 2011–12.

TABLE 3.8 *Annual expenditure on plasma fractionation: CSL Limited, 2003–04 to 2011–12*

YEAR	AMOUNT ($M)	% GROWTH
2003–04	141.2	0
2004–05	138.5	-1.9
2005–06	133	-3.9
2006–07	141.3	6.2
2007–08	155.9	10.3
2008–09	158.1	1.4
2009–10	182.4	15.4
2010–11	210.5	15.4
2011–12	225.1	6.9
TOTAL	**1486**	**6.2 (average)**

Three products contributed to most of the volume-based increase in 2011–12:

- a 34.5 per cent increase in demand for NIg 5ml
- a 12.8 per cent increase in demand for prothrombin complex concentrate
- a 27 per cent increase in demand for plasma defined Factor IX.

Performance

By the end of June 2012 specification of some reporting requirements under the CAFA remained outstanding. The establishment and maintenance of a minimum starting plasma inventory had not commenced. The latter is subject to an analysis of risk by the NBA and further policy and cost endorsement from governments.

The process of measuring performance against the indicators provides incentive for high levels of performance by CSL Limited through the application of a balanced regime of payment consequences, including a payment incentive for IVIg yield and structured rebates on other key performance indicators for performance below agreed tolerance thresholds.

The suite of performance indicators in the CAFA is intended to highlight those areas of CSL Limited's performance that are of most significance to product recipients and governments.

They cover:

- plasma stewardship—the amount of starting plasma funded by the NBA which is lost through the processes of manufacturing and distribution
- production yield—the annual average yield of IVIg production, with contractual incentives to achieve in excess of an annual average yield of 5.2 grams of IVIg per kilogram of starting plasma
- management of required inventory levels—maintenance of the required minimum inventory levels of starting plasma and finished products held either in CSL Limited inventory or the NBA-funded National CSL Reserve
- fulfilment of orders—fulfilment of orders on time, in full, to the right recipient and otherwise in accordance with the requirements of the CAFA
- shelf life of National CSL Reserve products—maintenance of required minimum shelf life for products held in the NBA-funded National CSL Reserve.

In 2011–12, CSL Limited generally performed well against the CAFA key performance indicators as shown in Table 3.9. Their performance was affected in March 2012 as a result of mandatory quarantine and recall of a number of batches of Albumex due to a manufacturing contamination (see page 80). This was assessed as a performance breach resulting in a financial penalty.

TABLE 3.9 *CSL Limited's actual performance under the CAFA, 2011–12****

DESCRIPTION OF PERFORMANCE MEASURE		RESULTS 2011–12				
		Q1	Q2	Q3	Q4	ANNUAL
KPI 1	Plasma stewardship	Substantially Achieved	Substantially Achieved	Substantially Achieved	Substantially Achieved	Substantially Achieved
KPI 2	Production yield	5.00 g/kg	5.01 g/kg	5.11 g/kg	5.22 g/kg	5.11 g/kg
KPI 3	Management of required inventory levels*					
	Minimum Starting Plasma Inventory (Not active in 2011–12)					
	Products in CSL Inventory	100% Achieved	97% Achieved	94% Achieved	92% Achieved	96% Achieved
	Products in National CSL Reserve	100% Achieved	98% Achieved	91% Achieved	89% Achieved	95% Achieved
KPI 4	Fulfilment of orders					
	Orders by Distributor (Blood Service)	100% Achieved	99% Achieved	98% Achieved	99% Achieved	99% Achieved
	Orders by Non-Distributor	100% Achieved	99% Achieved	97% Achieved	97% Achieved	98% Achieved
KPI 5	Shelf Life of National Reserve Products**	92% Achieved	98% Achieved	100% Achieved	94% Achieved	96% Achieved

* The NBA gave approval for CSL to access reserve inventories during 2011–12 in order to ensure supply.

** The NBA advised CSL that the shelf life of some hyperimmune products held in the National CSL Reserve would be reduced to avoid surplus production.

*** This table reports actual performance. There are a range of tolerances for each of the KPIs under the CAFA, and CSL's performance fell within these tolerances with few exceptions.

During the year CSL Limited requested changes to the CAFA arrangements and revisions to current agreed inventory levels:

- as a result of a significant drop in its immunoglobulin (IgG) yield due to factors related to the plasma collection program of the Blood Service. As a result of this reduction in yield, and other logistical factors, CSL Limited was unable to supply Intragam P 200ml from its working inventory against the full annual supply estimate amounts. From November 2011 the NBA worked with CSL Limited and the Blood Service to implement a revised monthly supply plan for this product. The NBA also gave approval for CSL Limited to access the Minimum Product Inventory and the National CSL Reserve to augment supply. This decision was taken on the basis that in the event of a national emergency the supply of IVIg could be maintained under the NBA's contracts for imported product; and that this course of action would be preferable to transferring patients onto alternative products. By the end of June 2012 CSL Limited had fully restocked the Minimum Product Inventory and the National CSL Reserve, although the NBA will continue to carefully manage the planned supply of Intragam P in 2012–13.
- as a result of a significant increase in demand for normal immunoglobulin (NIg). CSL Limited produces 2ml and 5ml vials of NIg from hyperimmune plasma collected by the Blood Service. The amount produced is limited by the availability of specialised plasma collected by the Blood Service and by production scheduling capacity in the CSL Limited manufacturing plant. Following a mid-year review of supply forecasts and consultations with CSL Limited and jurisdictions, the NBA determined that the Blood Service and CSL Limited had sufficient capacity to meet the increased demand.
- The NBA investigated the reasons for a sudden and unheralded increased demand in NIg, which varies between states and territories. NIg has registered indications for intramuscular injection for the management of some forms of primary hypogammaglobulinaemia, and for prophylactic treatment of susceptible contacts of hepatitis A, measles and poliomyelitis. The NBA found that NIg is increasingly being used off-label (i.e. outside TGA approval) for subcutaneous administration, particularly for primary immunodeficiency patients, in some areas as part of a structured subcutaneous immunoglobulin home treatment program. This raised a concern that NIg use may circumvent the established authorisation framework for the use of IVIg which is set down in the *Criteria for the clinical use of intravenous immunoglobulin in Australia*. As a result, jurisdictions agreed to consider specific state or territory actions to limit or manage inappropriate use of NIg, pending the outcomes of the national review of the clinical governance and authorisation framework for IVIg. During 2012–13 the NBA and jurisdictions will consider the policy implications of this new development (see also pages 76–77 describing this review, and page 56 on the evaluation of new product proposals).

A description of how the NBA and the blood sector managed a threat to CSL Limited's supply of albumin during the year is described on page 80 in the section which focuses on how the NBA manages risk.

Imported intravenous immunoglobulin

Imported intravenous immunoglobulin supplements domestic IVIg production to meet clinical demand in Australia. In addition to supply under the national blood arrangements, the NBA also supports the purchasing of small amounts of IVIg using jurisdictional direct orders.

Re-introduction of Octagam 5 per cent

The TGA approved the re-introduction of Octagam 5 per cent in October 2011 following the voluntary recall of product in September 2010, and we have observed good acceptance by clinicians. The NBA worked with the Blood Service, Octapharma Australia Pty Ltd and Grifols Australia Pty Ltd to manage the transition of patients from Flebogamma 5 per cent DIF under the national supply arrangements; this was achieved by March 2012.

New contract arrangements

In October 2011 the NBA signed contracts for the supply of imported IVIg, achieving all of the policy parameters endorsed by governments which are designed to improve security of supply, increase choice of product for clinicians and maintain competitive pressure on price and performance standards.

The contracts in place for supply of imported IVIg during 2011–12 were with:

- Octapharma Australia Pty Ltd for the supply of Octagam 5 per cent. The earlier contract had been extended in May 2010 to operate until 31 December 2011. A new contract took effect on 1 January 2012 for supply of Octagam 5 per cent. A 10 per cent formulation of this product became available in July 2012
- Baxter Healthcare Pty Ltd for the supply of Kiovig 10 per cent from 1 January 2012
- Grifols Australia Pty Ltd for a direct order contract operating until 31 December 2012 for the supply of Flebogamma 5 per cent DIF. Until March 2012 this product was also available under the national supply plan as a result of the Octagam recall. A new direct order contract for continued supply of Flebogamma 5 per cent commenced on 1 January 2012.

Under the national blood arrangements the Blood Service is responsible for the allocation of either domestic or imported IVIg in accordance with a plan. The plan is developed in consultation with IVIg user groups and jurisdictions and specifies the categories of patients to receive each type of product. In general, the plan seeks to allocate imported IVIg for shorter term conditions, and domestic IVIg for longer-term conditions, and to keep the allocation categories consistent between the states and territories.

Expenditure

The new supply arrangements generated savings to governments of $3.3 million in this financial year. In 2011–12, the NBA spent $52.7 million under these contracts, comprising $23.4 million for Octagam, $21.9 million for Flebogamma and $7.4 million for Kiovig.

Performance

The performances against key indicators of the suppliers of imported IVIg are set out in Table 3.10 overleaf.

TABLE 3.10 *Imported IVIg: key performance indicators, by supplier, 2011–12*

	PERFORMANCE MEASURE	RESULTS JULY—DECEMBER 2011 (FORMER CONTRACT WITH OCTAPHARMA)	
		Q1	Q2
KPI 1	In-Country Reserve	Quarter 1 not applicable. Octapharma did not return to the market until October 2011 following the nationwide recall of Octagam in September 2010	Fully achieved
KPI 2	Shelf Life on products delivered to Approved Recipients		Fully achieved
KPI 3	Delivery Performance		Fully achieved
KPI 4	Ordering by Approved Recipients		Fully achieved
KPI 5	Reporting		Fully achieved
KPI 6	Record-keeping		Fully achieved

	PERFORMANCE MEASURE	RESULTS JANUARY –JUNE 2012 (CONTRACT COMMENCED 1 JANUARY 2012)	
		OCTAPHARMA	BAXTER HEALTHCARE
KPI 1	In-Country Reserve	Fully achieved	Fully achieved
KPI 2	Shelf Life on products delivered to Approved Recipients	Fully achieved	Fully achieved
KPI 3	Delivery Performance	Fully achieved	Partially achieved*
KPI 4	Ordering by Approved Recipients	Fully achieved	Fully achieved
KPI 5	Reporting	Fully achieved	Fully achieved
KPI 6	Record-keeping	Fully achieved	Fully achieved

* Some delays occurred in responding to orders during the initial transition period for the new contract.

Imported plasma-derived and recombinant blood products

The NBA has contracts with suppliers for the importation of selected plasma-derived and recombinant blood products to augment domestic supply in cases where these products are not produced in Australia or domestic production cannot meet demand.

Implementation of new contract arrangements

New three-year contracts for factors VII, XIII, recombinant factors VIII and IX, Protein C, activated prothrombin complex concentrate and anti-Rh(D) immunoglobulin took effect on 1 July 2011. In 2011–12 the NBA managed contracts for the supply of imported plasma-derived and recombinant blood products with five companies: Bayer Australia Ltd, Baxter Healthcare Pty Ltd, CSL Limited, Novo Nordisk Pharmaceuticals and Pfizer Australia Pty Ltd. The NBA spent $148.81 million under these contracts; expenditure on the supply of imported blood products since the establishment of the NBA is shown in Table 3.11.

TABLE 3.11 *Annual expenditure on imported products (excluding IVIg) by company, 2003–04 to 2011–12*

YEAR	BAXTER		PFIZER		NOVO NORDISK		BAYER		CSL (IMPORTED)	
	Amount ($M)	% Growth	Amount ($M)	% Growth	Amount ($M)	% Growth	Amount ($M)	% Growth	Amount ($M)	% Growth
2003–04	$32.20	-	$5.50	-	$14.60	-	-	-	-	-
2004–05	$54.50	69.4	$10.90	96.5	$18.80	28.6	-	-	-	-
2005–06	$69.90	28.2	$15.90	45.5	$23.40	24.5	-	-	-	-
2006–07	$71.50	2.3	$33.80	45.5	$26.90	15.3	-	-	-	-
2007–08	$80.10	12.0	$42.40	25.3	$17.40	-35.3	-	-	-	-
2008–09	$84.10	5.0	$48.60	14.8	$17.40	-0.2	-	-	-	-
2009–10	$90.61	7.7	$48.94	0.7	$26.42	51.8	-	-	-	-
2010–11	$96.93	7.0	$57.03	16.5	$27.37	3.6	-	-	-	-
2011–12	$45.95	52.6	$66.55	16.7	$24.50	10.5	$11.30	-	$0.50	-
TOTAL	**$625.79**	**9.88 (avg.)**	**$329.62**	**32.69 (avg.)**	**$196.79**	**9.73 (avg.)**	**$11.30**	**-**	**$0.50**	**-**

The NBA worked with suppliers, the Australian Haemophilia Centre Directors' Organisation (AHCDO), Haemophilia Foundation of Australia (HFA), the Australian Haemophilia Nurses Group and the Blood Service to implement the new supply arrangements and encourage feedback on any side effects or other problems experienced by patients in transferring to the new products. Meetings were held with suppliers during the second half of 2011 to discuss in-country reserves, information about supply and demand, performance expectations and the management of the transitional arrangements for all of the new products. Early in 2012 consultations commenced in relation to the introduction of more comprehensive reporting arrangements aimed at producing higher quality data for monitoring inventory and delivery performance.

In particular, close monitoring throughout the year was required for rFVIII since about 75% of haemophilia A patients needed to be transferred to new products; supply of Advate and Recombinate ceased on 30 June 2012. Additional funding was provided to haemophilia treatment centres, through AHCDO, to meet the extra costs associated with the transition and to monitor any changes to adverse events arising from the change in products.

During the year the NBA also monitored the international debate on the incidence of inhibitor development in different kinds of rFVIII, following the publication of a meta-analysis of prospective clinical studies by Aledort et al[5] and associated critical responses.

5 Aledort, LM, Navickis, RJ and Wilkes, MM, 2011, 'Can B-domain deletion alter the immunogenicity of recombinant factor VIII? A meta-analysis of prospective clinical studies, Journal of Thrombosis and Haemostasis, 9:2180–2192. doi: 10.1111/j.1538–7836.2011.04472. Mannuccio P, Letter in JTH 10.1111/j.1538-7836.2011.04510. Iorio A, Marcucci M & Makris M Concentrate related inhibitor risk: Is a difference always real? JTH 10.1111/j.1538-7836.2011.04480. Aledort LM, Navickis RJ & Wilkes MM, Best evidence on B-domain deletion and the immunogenicity of recombinant factor VIII JTH 10.1111/j.1538-7836.2011.04496.

Performance

As in previous years, contracted suppliers performed well against contractual key performance indicators in 2011–12 (see Table 3.12).

TABLE 3.12 *Imported plasma and recombinant blood product contracts: key performance indicators, by supplier, 2011–12*

KPI	PERFORMANCE MEASURE	BAXTER	BAYER	CSL	PFIZER	NOVO NORDISK
1	Supply security inventory holding—maintenance of in country reserve (ICR)	Fully achieved	Fully achieved	Subject to transitional arrangements*	Fully achieved	Fully achieved
2	Shelf life of products delivered to approved health providers (AHPs)	Fully achieved	Fully achieved	Fully achieved	Fully achieved	Fully achieved
3	Delivery Performance	Subject to transitional arrangements*				
4	Reporting accuracy and timeliness					

* In these instances, the reporting requirements for the relevant KPI were subject to establishment of new contract management arrangements following the letting of new contracts to operate from 1 July 2011. Performance of the relevant suppliers was nonetheless subject to contractual requirements and was managed through regular contract management meetings.

Supply arrangements for rFVIIa

rFVIIa is used to treat haemophilia patients with inhibitors and patients with some other inherited bleeding disorders. Demand for the product is difficult to forecast as it can be highly variable. A small number of patients experiencing a high requirement can significantly increase overall demand.

Novo Nordisk is currently the sole manufacturer of rFVIIa globally and our contract with the company was extended in 2010 until 30 June 2012, with no possibility of a further extension. During the year the NBA reviewed the operation of the current contract and the performance of the company and consulted with stakeholders. In preliminary market research we also identified a number of alternative rFVIIa products which are in clinical development, but none are likely to be registered and available for supply in Australia until 2014.

At its meeting in May 2012 the JBC endorsed the policy parameters to be negotiated with Novo Nordisk during the development of a new contract. This included performance and accountability improvements similar to those in other recent commercial contracts, achieving appropriate value for money and maintenance of governments' policy of supplying rFVIIa under the national blood arrangements for treatment of bleeding disorders. At the end of June 2012 the NBA finalised a two-year contract with Novo Nordisk to commence on 1 July 2012.

Diagnostic reagent products

Diagnostic reagents are used in laboratory tests known as blood typing and cross matching. These tests ensure that a person needing a blood transfusion receives blood compatible with their own. Australian governments currently subsidise the purchase of in-vitro red cell diagnostic reagents by public laboratories and the Blood Service, through the National Blood Agreement.

On 1 July 2011 five new three-year contracts took effect for the supply of red cell diagnostic reagents to public laboratories: with CSL Limited, Grifols Australia Pty Ltd (formerly trading as Diamed), Abacus ALS Pty Ltd, Johnson and Johnson Medical Pty Ltd (trading as Ortho-Clinical Diagnostics) and Bio-Rad Laboratories Pty Ltd. The range of reagent products has been expanded from 110 to 138 under the new arrangements, and laboratories are gradually adjusting their ordering patterns to the bigger range of products. We worked closely with suppliers to implement compliance and reporting on performance indicators.

Expenditure on diagnostic reagent supply is capped at $4.8 million per year. The NBA manages the cap for all jurisdictions and our five suppliers, a complex task necessitating extensive communication with state and territory representatives on allocation of products and management of the cap between suppliers and within jurisdictions. In collaboration with Queensland, the NBA commenced a review of current policies, arrangements and the efficiency of use of diagnostic reagents.

Figure 3.21 shows that the total market share of each supplier has continued to remain relatively stable during the year.

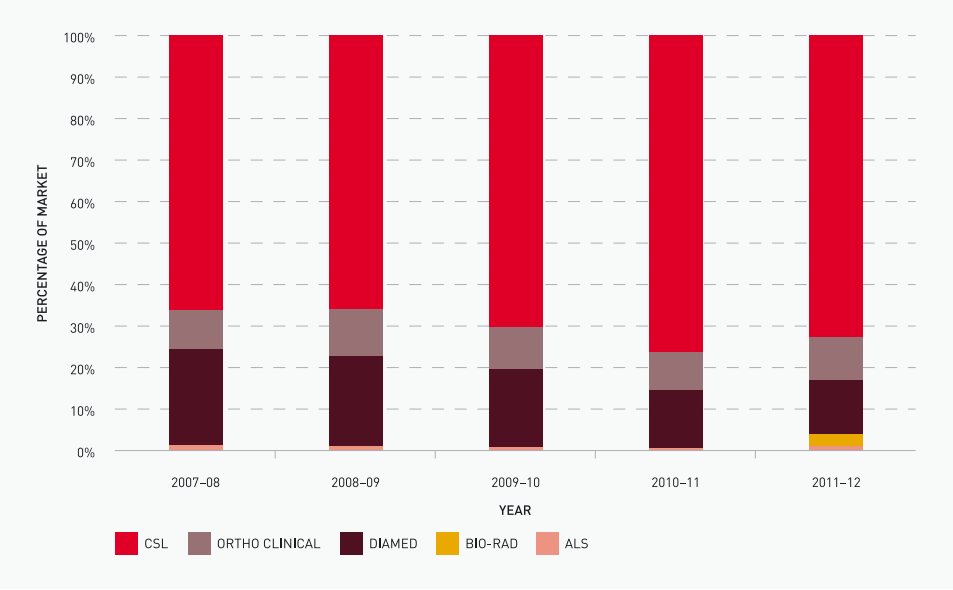

FIGURE 3.21 *Market share for suppliers of diagnostic reagent products, 2007–08 to 2011–12*

EVALUATION METHODOLOGIES FOR CHANGE PROPOSALS

Under the National Blood Agreement, interested parties can make proposals for changes to products or services on the National Product and Price List. Schedule 4 of the Agreement provides for evidence-based evaluation, information and advice to support decisions on these changes in the context of the primary and secondary objectives of the Agreement (see Appendix 2). The JBC is responsible for considering national blood supply change proposals; obtaining appropriate evaluation, information and advice; and making decisions on proposals in certain circumstances, or providing advice and recommendations on proposals to the SCoH.

The NBA developed a comprehensive framework for assessing products that addresses relevant policy considerations and the cost-effectiveness of the proposals on the blood sector and, where relevant, the wider health sector. This multi-criteria analysis framework quantifies consideration of each of the objectives of the National Blood Agreement and provides consistent rigour for the assessment process.

In 2010–11, the Department of Health and Ageing (DoHA) received funding for the development and implementation of an assessment process for blood and blood products, particularly matters of cost-effectiveness and clinical need, to help decide whether a product should be publicly funded. In March 2011, the JBC was advised that the Minister had determined that the Medical Services Advisory Committee (MSAC) had been approved to undertake the detailed cost-effectiveness analysis on behalf of the Commonwealth.

Findings from the MSAC assessment are expected to be shared with states and territories to inform the overall assessment under the NBA's multi-criteria analysis framework.

In September 2011, JBC members agreed to establish a working group to further examine the Schedule 4/multi-criteria analysis process and scenarios that may apply under the model, including the integration of the Schedule 4 processes with broader health sector reform initiatives. The working group comprises the Commonwealth and New South Wales representatives, and the NBA. As part of the group's activities, the Commonwealth engaged the Centre for Health Economics Research Evaluation (CHERE) at the University of Technology Sydney to develop a simple and feasible model to assess new product proposals for blood and blood related products. The model will consider the policy objectives of the National Blood Agreement, the Commonwealth procurement guidelines and broader government technology health technology assessment objectives and process. CHERE is finalising the report for consideration by the working group and the JBC.

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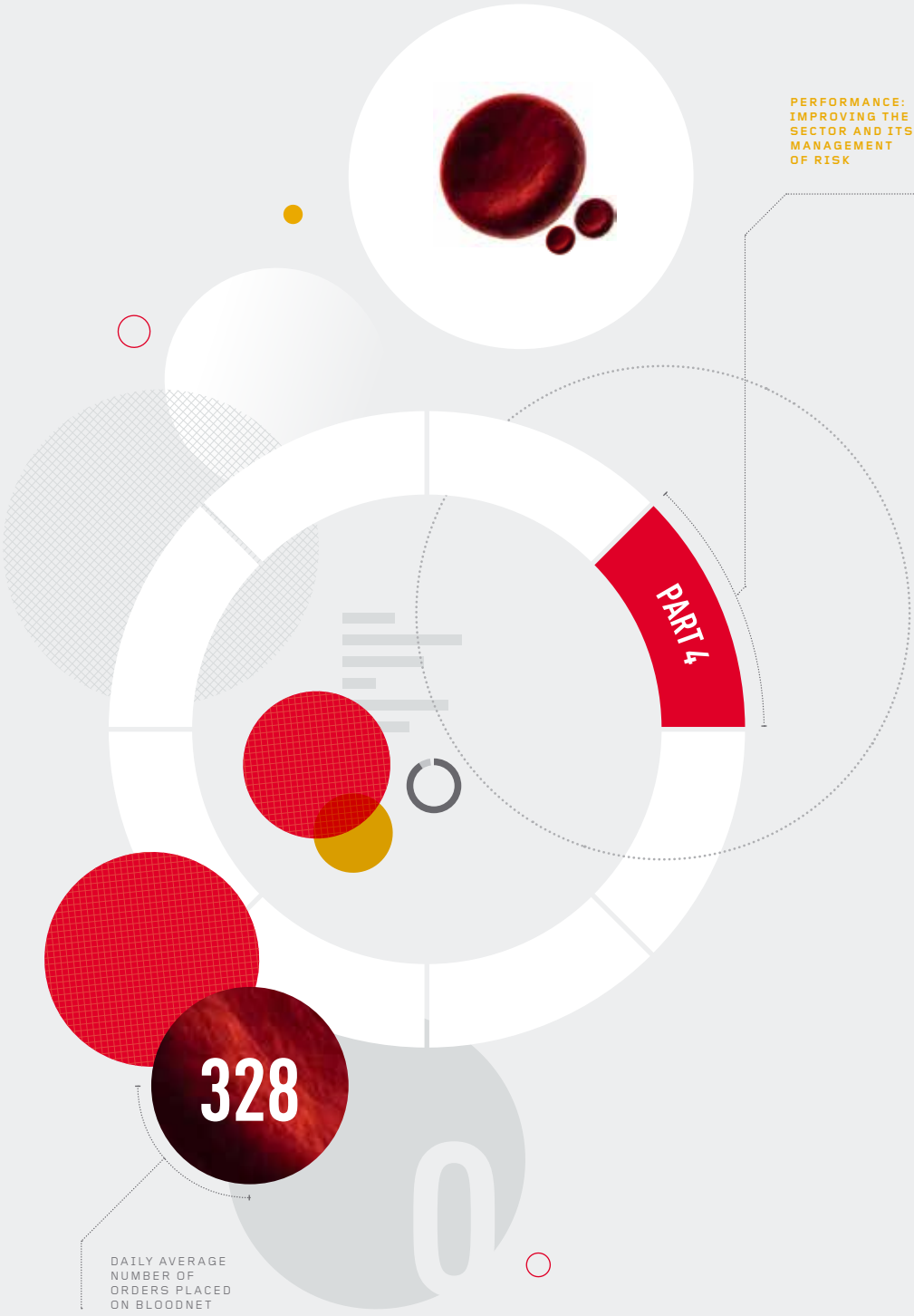


PERFORMANCE: IMPROVING THE SECTOR AND ITS MANAGEMENT OF RISK

DAILY AVERAGE NUMBER OF ORDERS PLACED ON BLOODNET

4

PERFORMANCE: IMPROVING THE SECTOR AND ITS MANAGEMENT OF RISK

INTRODUCTION

The second activity of the NBA's program is to improve the performance of the blood sector, and to manage risks associated with the supply and administration of blood products.

The deliverables and key performance indicators for this function, and our performance, are described below:

DELIVERABLES

Qualitative deliverables	2011–12 reference point or target	Results
Required reserve levels of all products are in place	Review completion of appropriate reserve levels for fractionated and recombinant products and results are implemented in accordance with agreed contractual obligations	In-country reserve and minimum product inventory levels have been established and updated for all relevant imported and domestic products under relevant contracts
Quantitative deliverables	**2011–12 budget**	**2011–12 actual**
Percentage of recommendations from the *Administrative Review of the National Blood Arrangements*, for which the NBA had responsibility, completed within timeframes	≥95%	96% Work on the outstanding recommendation is ongoing together with JBC and is expected to be completed during 2012–13.
Percentage of requesting hospitals provided with access to BloodNet within agreed timeframe	95%	100% (see pages 62–63)

KEY PERFORMANCE INDICATORS

Qualitative indicators	2011–12 reference point or target	Results
Management and support of BloodNet	High level of satisfaction of all funding jurisdictions with NBA's planning, management and coordination of blood supply. Satisfaction is assessed through survey of Jurisdictional Blood Committee members and hospitals that have implemented BloodNet	78% of jurisdictions were very satisfied with the NBA's management approach and support for users during the implementation of BloodNet. The remaining 22% were not satisfied, citing some communication issues and lack of access to data. A high level of satisfaction with BloodNet was expressed by hospitals that have implemented BloodNet, rating as good or above: • email and phone support—85%+ • user materials—80%+ • functionality—85%+ (see pages 62–63)
Management of the National Blood Supply Contingency Plan	High level of satisfaction of all funding jurisdictions with NBA's management and implementation assessed through survey of Jurisdictional Blood Committee members	78% of jurisdictions were satisfied with the NBA's management, including with the advice provided during the Albumex recall, commenting on the improvements made after each activation of the NBSCP. 22% were not satisfied, pointing to timing, coordination and communication issues, some of which were not solely the NBA's responsibility. (see page 80)
Quantitative indicators	**2011–12 budget**	**2011–12 actuals**
Percentage of hospitals using BloodNet	60%	75% (see pages 62–63)
Percentage of clotting factor usage captured in the Australian Bleeding Disorders Registry	80%	81% (see page 65)
Number of days the National Blood Supply Contingency Plan is activated for plasma and recombinant products	0	41, following notification by CSL Ltd of a potential Albumin shortage due to a product recall. (see page 80)

SECTOR IMPROVEMENT

In the 2012–13 Federal Budget the NBA received strong endorsement from governments for its drive to improve data capture and analysis across all aspects of the supply chain. This area of activity, together with our focus on knowledge acquisition and management, and other management and accountability initiatives, are key strategies to improve the overall efficiency and sustainability of the sector.

The Portfolio Budget Statements particularly promoted the appropriate and efficient use of blood and blood products through better supply management and information capability. In response to the outcomes of the Budget, the NBA started developing a new corporate plan in consultation with relevant government departments and chief medical officers.

SECTOR IMPROVEMENT THROUGH DATA COLLECTION AND ANALYSIS

The availability of comprehensive, consistent, relevant, timely and robust data, and the capacity to analyse that data, are powerful tools to identify areas where improvements can be made in supply management and clinical demand. In 2011–12 considerable progress was made in the capture and analysis of data, building on the achievements of the previous year. In addition to the projects described below, see also page 93 for a description of the red blood cell usage project.

Integrated data management system

The Integrated Data Management System (IDMS) is used by the NBA to manage the budgeting and forecasting of supply and demand for blood and blood products, inventory management and contract administration.

In 2010–11 the NBA's internal auditor had conducted a review of the system including an assessment of risks, evaluation of controls, assessment of security, interfaces with other business systems and a general review of the performance of the system. The review confirmed the system's functionality and its appropriateness as a platform for further development of NBA information and data strategies and made a number of recommendations for enhancements.

During 2011–12 the NBA addressed several issues such as developing technical specifications for the interface between BloodNet (see below) and IDMS for goods ordering and receipt verification. Build 7 of IDMS enabled the automated production of key parts of the NSP&B documentation which will reduce the potential for errors in future.

Implementation of BloodNet

Initially known as ORBS, the web-based ordering and inventory management system for blood and blood products was developed by Queensland Health. The first site went live in January 2008 and was Queensland-wide by December 2008. Last year the NBA and Queensland Health conducted a national proof of concept trial of the system. Following the successful completion of the trial, the JBC provided interest monies to implement the system throughout Australia and to undertake further development to provide additional capabilities. Reports generated from BloodNet will assist approved health providers to comply with the NSQHS standard for blood and blood products (see page 91).

During 2011–12 the roll out of the ordering and receipting modules of BloodNet throughout Australia gathered pace, and by 30 June 2012 BloodNet was processing 75 per cent of total volume issued by the Blood Service (see Table 4.1 below).

TABLE 4.1 *Implementation of BloodNet modules, by state and territory, at 30 June 2012*

JURISDICTION	ORDERING & RECEIPTING MODULES	FATE MODULE
NSW	50%	9%
VIC	77%	32%
QLD	91%	91%
SA	91%	91%
WA	89%	26%
TAS	95%	95%
NT	100%	100%
ACT	92%	92%
NATIONAL	**75%**	**45%**

Throughout the year the equivalent of two full-time trainers visited hospitals and pathology laboratories to implement BloodNet, in addition to the NBA providing training, user support groups and help desk support. The information being generated from the BloodNet system is significantly assisting the work on a national inventory management framework (see page 42).

At the same time, we started to roll out a module of BloodNet focusing on the fate of products; we expect to complete this by late 2012. This function enables users to record details of product discards, transfers of products between approved health providers and actual transfusions—essential information which has not been readily available before. Approved health providers can generate reports on demand containing reliable data to help them in managing discards and reduce wastage of blood products. They can also upload data from the Blood Service's legacy Electronic Returns Information Capture (ERIC) system.

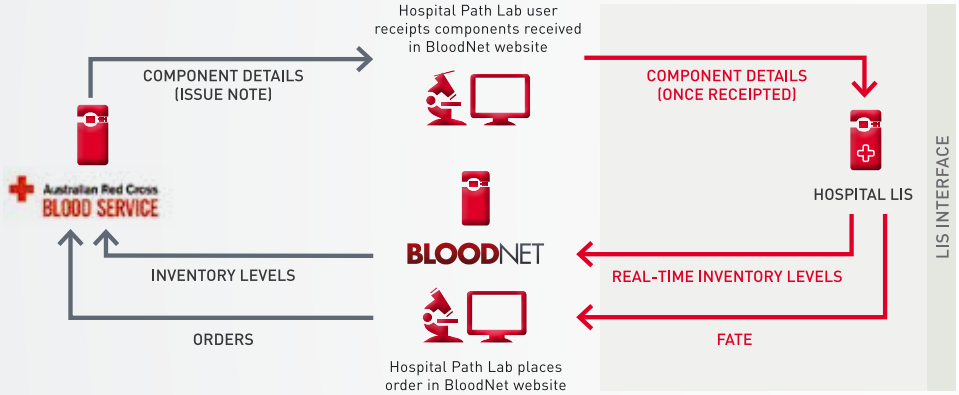
The reliability and accessibility of BloodNet were continuously improved during the year. In addition, in collaboration with those states, a proof of concept trial to interface BloodNet to approved health providers' laboratory information systems commenced in New South Wales (with eBlood) and Queensland (with AUSLAB).

The development of a central user management and authentication system for all blood sector-wide ICT systems was largely completed during 2011–12, with implementation to occur between August and December 2012. This new system, Guard, will enable users to access the relevant systems with ease, without the need for multiple usernames and passwords. When the National EHealth Transition Authority (NEHTA) completes the implementation of the National Authentication Service for Health (NASH), our intention is to integrate Guard into NASH to further enhance the user experience and provide enhanced security.

NBA FOCUS
IMPROVING SECTOR EFFICIENCY
––
LINKING BLOODNET AND LABORATORY INFORMATION SYSTEMS
––
JOHN HUNTER HOSPITAL
NEWCASTLE NSW

CONNECTING AUSTRALIA'S HOSPITALS TO BLOODNET

BloodNet, the NBA's national online blood ordering and inventory management system, took a major leap forward in 2011–12 when a trial was launched in Newcastle to connect BloodNet with the John Hunter Hospital's own computer system. This diagram illustrates how the data flows between hospitals, the NBA and the Blood Service:



The proof of concept trial is ongoing, but progress is so promising that the NBA is hopeful of connecting more hospital information systems to BloodNet during 2013.

The trial is testing the feasibility of connecting a web service between the two systems (known as an interface), so that whenever John Hunter Hospital pathology staff receipt blood orders into BloodNet, it automatically 'talks' to their hospital's own information system passing on unit data (which BloodNet receives from the Blood Service's ICT system). This eliminates the need to re-key the information. This will not only save valuable time for laboratory staff, it will also remove the possibility of any data entry errors by abolishing manual data entry processes.

The ultimate goal is to build an interface between BloodNet and the laboratory information systems used in all major Australian hospitals. Not only will this dramatically reduce the time spent on data entry for hospital staff, it will also provide a real-time view of blood inventory levels across the country for the first time.

The new features offered by the interface will benefit hospitals in several ways:

- hospital inventory levels will automatically be passed every 15 minutes from the hospital to the NBA to enable the NBA, the Blood Service and jurisdictions to more actively manage the national inventory
- the fate of the blood unit (whether it has been transferred to another hospital, discarded or transfused) is recorded in both systems
- component details (such as component type, blood group, collection and expiry dates, modifiers and phenotypes) upon being receipted into BloodNet will be passed to the hospital's laboratory information systems.

Caption: Staff of the John Hunter Hospital with the NBA General Manager, in April 2012, celebrating the 2 millionth order placed on BloodNet: (from left to right) Darren Croese, Paul Fletcher, Gregory Irwin, Dr Sandra Deveridge, Bridget Partridge, Leigh McJames, Alana Freeman, Tony Kay, Mary-Anne Hardy and Robert Bettinelli.

Early in 2012 the JBC approved expenditure on new infrastructure to host ABDR and BloodNet. Implementation of the new hardware was largely completed by the end of June 2012 in readiness for the launch of the redeveloped ABDR in mid-August 2012. We believe that there is scope to use our new infrastructure to support other sector-wide systems, thus achieving further economies for governments—as well as ensuring standardisation and consistency in quality—as part of the national health reforms.

Australian Bleeding Disorders Registry (ABDR)

The ABDR is used on a daily basis by clinicians in all Australian haemophilia treatment centres (HTCs) and clinics as a clinical tool to assist in managing the treatment of patients. The NBA also uses the registry to collect data relating to the ordering, supply and use of clotting factor products, in order to create demand models which assist in negotiations with suppliers on the provision of these products. Hence the system is designed to produce data that fulfils the needs of clinicians, patient representative groups and governments within a highly controlled governance framework. Oversight of the registry is provided by a steering committee consisting of representatives of AHCDO, the HFA, jurisdictions and the NBA. The AHCDO supports the use of the registry.

Major progress on increased data collection and quality was again achieved during the year, with a noticeable increase in the quality of data; the data capture rate exceeded eighty per cent, enabling the publishing of the second ABDR Annual Report (see www.nba.gov.au/abdr). The data in the report is useful to clinicians in a variety of settings; as at 30 June 2012 the report was downloaded 1,074 times.

The ABDR report is enabling us to compare Australian performance with other countries' data. This will assist the NBA in planning appropriate long-term supply arrangements. An example of comparative data is shown in Table 4.2 below.

TABLE 4.2 *Comparison of the proportion of patients in registers and treated, UK and Australia, major diagnoses 2011*

	FEMALE			MALE		
	NUMBER IN REGISTRY AT 30 JUN 2011	NUMBER WHO RECEIVED PRODUCT IN 2010–11	PROPORTION TREATED	NUMBER IN REGISTRY AT 30 JUN 2011	NUMBER WHO RECEIVED PRODUCT IN 2010–11	PROPORTION TREATED
AUSTRALIA						
HmA	337	25	7.4%	1772	833	47.0%
HmB	97	13	13.4%	420	172	41.0%
vWD	1135	90	7.9%	831	63	7.6%
Other conditions	337	15	4.5%	329	17	5.2%
UK*						
HmA	1119	63	5.6%	5372	2919	54.3%
HmB	347	47	13.5%	1134	611	53.9%
vWD	5770	666	11.6%	3342	386	11.6%

* The UK's reporting year is 1 April to 30 March whereas Australia's is 1 July to 30 June.

NBA FOCUS
PATIENTS WITH BLEEDING DISORDERS
––
ABDR
AT ROYAL CHILDREN'S HOSPITAL
MELBOURNE VICTORIA

HOW THE AUSTRALIAN BLEEDING DISORDERS REGISTRY HELPS CHILDREN

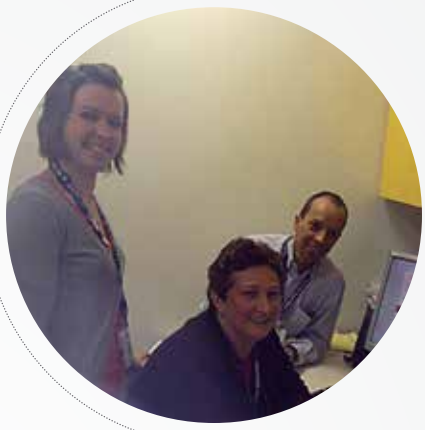
FIGURE 4.1 *ABDR haemophilia treatment centre dashboard report*.*

Children with bleeding disorders often face a life of uncertainty due to their regular 'bleeds' preventing them from activities that involve the usual bumps and scrapes of childhood.

To give them more certainty in their medical treatment, the NBA developed the ABDR which collects clinical data on patients at all haemophilia treatment centres (HTCs) across Australia, including at Melbourne's Royal Children's Hospital.

Data and Product Manager at the hospital's HTC, Julia Ekert, said the ABDR was used to keep a record of each child's medical data, height, weight and dosage. From this, she can accurately order products for patients. The clinical staff also use the database on a day-to-day basis as it provides a current patient record and is used to offer treatment advice over the phone to concerned parents. In order to ensure that the ABDR is a good clinical tool, Julia works closely with the clinical team to make sure that data is accurate and up-to-date.

* This screenshot is an example of a HTC dashboard report from the redeveloped ABDR and includes a summary of HTC details for patients, interactions, bleeding disorder severity measures, products ordered and usage comparisons. This has been provided for illustrative purposes only to demonstrate one of the newly available reports in ABDR however, at the time of provision, this report was still in production and may have since undergone further refinement. The de-identified data provided relates to a HTC for a specific time period and statistical calculations and representations within this report are based on publicly available information. The data used has been migrated from the previous version of ABDR for the retrospective period of July 2012, which at the time of provision, may have included incomplete data. The NBA and ABDR Steering Committee have approved the use of this image for the NBA Annual Report only.



'If a parent says a child has had a bleed, we can deal with that because we have a record of the child's height and weight on the registry including their treatment plan and what doses they are on,' she said. 'We have an accurate history of the patient in order to give them the best advice.'

The Melbourne HTC looks after 250 children with bleeding disorders across Victoria, including about 80 who are regular visitors due to the severity of their condition. The registry is also used to monitor patients who have their products delivered at home. This provides continuity of care to patients by allowing other staff involved in ordering products access to the information required.

'If I'm not there, all the data is in one spot for the nurse who covers product ordering when I'm away,' Ms Ekert said. 'Prior to the registry, the hospital had paper records listing every haemophilia patient's name and diagnosis. If we wanted to get a medical record from the basement, it could take hours, if not the next day before you had it. The new ABDR was a significant advance in that it allowed me to use one system for many tasks, which streamlined my workload.'

The ABDR's capacity to search the data, for example by age group, has made it easier to contact patient groups when running education programs. 'We've done various education days with kids but we find the informal method works better, so we organise a Boys Day Out where patients aged eight to 14 go out for a fun day with clinicians and nurses,' she said. 'They go to arcade games and ten pin bowling where they get to talk to other kids about having haemophilia and they end up feeling like "it's not just me". At the same time, the staff can get in some education messages.'

The ABDR is the only database of its kind in Australia, collecting clinical information related to the treatment of people with bleeding disorders. With the support of the NBA, the ABDR allows accurate information regarding national clotting factor usage which can then be used in product procurement. The NBA and the ABDR are pivotal in ensuring there is an adequate supply of clotting factor concentrate which is essential to optimise the quality of life of people with bleeding disorders in Australia.

Caption for photo: Staff at the Henry Ekert Haemophilia Treatment Centre at the Royal Children's Hospital Melbourne using ABDR: Nicola Hamilton, physiotherapist, Julia Ekert, data manager and Dr Chris Barnes, Director of the Centre

In March 2011 the JBC approved expenditure on the redevelopment of the ABDR using interest monies to employ experts to undertake the project in house. This fourth generation redevelopment will improve the efficiency, performance and stability of the system, increase security of sensitive data, provide a sufficiently flexible platform to support the development of new and future enhancements, and enable the integration of the ABDR into other sector systems such as BloodNet in a cost effective way. The redevelopment is being guided by extensive consultation with key stakeholders such as nurses' groups, HTCs, data managers, jurisdictions, the HFA and representatives of haemophilia physiotherapy, social worker and counsellor groups.

As the project neared completion a workshop was held in June 2012, involving all haemophilia treatment centre staff, for final user testing, training and review of the data migrated from the earlier system. Support from the haemophilia community and users has remained high throughout the redevelopment project and the go-live date of mid-August 2012 is keenly anticipated.

In May 2012 the JBC approved additional expenditure to develop a patient interface for the ABDR. This will enable us to capture data in real time on patient infusions, problems, and home inventory management. This initiative is strongly supported by patients and the clinical community.

NBA's business intelligence system

Launched in January 2010, the NBA's business intelligence system, known as Big Red, provides a single electronic repository for the secure storage, manipulation, integration and analysis of data drawn from other NBA systems.

During the year, efforts on Big Red have focused on data cleansing and integrating data from disparate systems into a combined report. Another major effort was to complete technical work to enable secure remote access by jurisdictions to Big Red, a key feature of the system when it was originally designed. The function will enable jurisdictional users to link data on demand and supply to compare ordering practices among approved health providers. Work on the arrangements governing access to data is continuing.

National IVIg management system

The National IVIg Management System (NIMS) was to capture information on the use of IVIg in order to support and align with the *Criteria for the clinical use of IVIg in Australia*. Further development work was placed on hold following the decision of the CTEPC to undertake an independent review of the authorisation and clinical governance arrangements for IVIg (see pages 76–77).

Our annual *Report on the use of IVIg 2010–11* may be found on the NBA's website.

Barcoding

The 2007 JBC decision to mandate specific standards for barcoding of blood and blood products was subject to a further decision of the JBC in 2010 to align the implementation of the policy with the implementation of blood ordering and receipting systems.

In 2011–12 the NBA commenced work to identify the data set to be captured across the supply chain and the barcode functions needed. Extensive consultations were undertaken with NEHTA, GS1 Australia and all major laboratory information system vendors to enable the NBA to develop an implementation plan that is robust and achievable. A formal discussion paper will be issued for comment later in 2012. This project is now being undertaken in parallel with the NBA's development of the interface between BloodNet and the laboratory information systems of approved health providers (see pages 62–63).

SECTOR IMPROVEMENT THROUGH KNOWLEDGE MANAGEMENT

In depth knowledge of global trends, both in medical and pharmaceutical developments, in supply markets, and in how blood and blood products are managed elsewhere in the world, enable the NBA to provide high quality advice to governments and stakeholders, and to negotiate value for money contracts with its suppliers.

Monitoring international trends

The NBA monitors international developments that may influence the management of blood and blood products in Australia. The horizon scanning program, which forms an integral part of our knowledge network, provides up to date intelligence on emerging or potential issues, processes, techniques and technologies relevant to the sector. It enables us to provide current, proactive and informed analysis to governments and is essential in negotiating contracts for the supply of blood and blood products. We monitor advances in processes, techniques and technologies that enable the NBA to fulfil its functions under the National Blood Agreement (clause 2 refers).

Our focus is on:

- information that may have an impact on global supply, demand and pricing
- potential new product developments and applications
- trends in clinical practice, government regulation and legal decisions
- emerging risks that could put financial or other pressures on the Australian sector.

Matters of interest are posted on the NBA website www.nba.gov.au/supply/sector-monitoring and a summary of highlights from the year under review is also posted. In the highly abridged printed extract below, we describe the types of information we seek, with limited and brief examples. More details on these and other matters can be found in the summary on the website.

Products

The NBA follows product development and clinical trials that may, within a reasonable time frame, introduce new products, new uses or new treatment schedules to the market. Areas of interest in 2011–12 included:

Clotting factors

For patients with the bleeding disorder haemophilia, convenience of treatment increases with the length of half-life of clotting factors. For both Factor VIII (haemophilia A) and Factor IX (haemophilia B) there are longer-acting products in the pipeline.

Competitive pricing may develop in the markets for rFVIIa and Factor IX. There is currently only one product commercially available for each of these, but in both cases new products are in clinical trials.

Immunoglobulin

Immunoglobulin is used by patients with primary immunodeficiencies. While this has usually been given by infusion, in some countries self-administered subcutaneous injection is now possible. Intravenous immunoglobulin (IVIg) is also variously used round the world in treating certain disorders of the nerve and muscles, including Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, and multifocal motor neuropathy.

Of particular significance for the NBA is the current interest in immunoglobulin as a possible therapy or even prophylactic for Alzheimer's disease including:

- Baxter initiated a second Phase III trial evaluating the use of its Gammagard Liquid in patients with mild to moderate Alzheimer's. This complements the company's first Phase III trial, which is fully enrolled and will conclude by the end of 2012. The company also announced an extensive study for some patients who completed 18 months of treatment in the first Alzheimer's Phase III trial. This will provide additional data related to the longer-term effects.
- Grifols launched a second trial of treating Alzheimer's with plasma derivatives, combining apheresis with the administration of albumin and IVIg.

If immunoglobulin were to become a recognised therapy for Alzheimer's the increased demand would have a major impact on price, particularly in the short-term. There are a number of potential drugs in the pipeline, not based on plasma products, which are therefore of interest.

Regulatory matters

The NBA follows overseas regulatory decisions on products, processes or procedures which are or may be of relevance to its responsibilities. In the current year the frontier of stem cell research has been a focus of attention:

- The US Food and Drug Administration has collaborated with the US National Institutes of Health (NIH) on a series of workshops on moving pluripotent stem cell therapies into clinical practice.
- In Canada, Osiris Therapeutics won approval for its stem cell drug, Prochymal, for a disease that can attack patients who received bone marrow transplants. Prochymal was approved for the treatment of acute graft versus host disease in children for whom steroids have not worked.

Market structure and company news

The NBA follows company profitability, business forecasts, capital raisings or returns, mergers and takeovers, arrangements for joint research and/or development, contracts for supply of manufacturing inputs, and marketing agreements. Companies of interest include suppliers, potential suppliers and developers of products which may be of interest. In general terms, the industry is currently in growth mode. Developments of interest included:

- The US State of Georgia announced a $US78 million incentive package to Baxter to build an integrated plasma processing facility in Georgia, with greater capacity than its Los Angeles plant. Construction in Georgia will begin in 2012 and commercial production in 2018.
- In February 2012 CSL announced that first-half net profit fell 3.4 per cent as the high Australian dollar put pressure on its earnings, but that without the impact of exchange-rate movements, net profit would have grown 16 per cent. The company also upgraded its full-year profit guidance, citing vigorous demand for its products. North America was CSL's biggest market, accounting for 42 per cent of revenue, followed by Europe with 32 per cent and Australia with 10 per cent. CSL will begin reporting in US dollars in the year starting 1 July 2012, in line with industry practice and to reflect the predominance of the company's global sales.
- Grifols acquired 51 per cent of Araclon Biotech, which specialises in diagnosis and therapies for neurodegenerative diseases, especially Alzheimer's.
- Amongst recent agreements, Shire and Sangamo BioSciences will develop therapeutics for haemophilia based on Sangamo's zinc finger DNA-binding protein technology transfusions, while Axerion Therapeutics and MedImmune will develop and commercialise a biologic approach to treat Alzheimer's.

Overseas events

The NBA follows both safety concerns and instances of good practice. It monitors health issues in countries from which its visitors and immigrants come.

United Kingdom: Since 2002, in order to minimise the risk of potential variant Creutzfeldt–Jacob Disease (vCJD) transmission through blood transfusion, imported FFP has been used to treat those born on or after 1 January 1996, and therefore unlikely to have been exposed to bovine spongiform encephalopathy (BSE) through their diet. The Advisory Committee on the Safety of Blood, Tissue and Organs (SaBTO) reviewed this measure at its March 2012 meeting and concluded that it should continue, even when those recipients reach 16 years of age.

Canada: The Canadian Blood Services urged Canadians of African and Caribbean heritage to celebrate their unique culture through blood and stem cell donation. 'Individuals with African heritage possess certain minor blood groups that may make it difficult to find compatible blood when repeated transfusions are needed as in sickle cell disease treatment', said Dr Isaac Odame, Medical Director of the Global Sickle Cell Disease Network at Sick Kids Hospital in Toronto.

Israel: Pluristem Therapeutics announced in May that a seven year-old girl suffering from aplastic bone marrow, who was rapidly deteriorating, had seen a reversal of her condition following intramuscular injection of Pluristem's PLacental eXpanded (PLX) cells (in aplastic bone marrow the patient has no blood-forming haematopoietic stem cells in bone marrow).

United States: The US Department of Health and Human Services said it would re-examine the ban on blood donations from men who have sex with men, with four studies planned.

Safety issues

The impact of transfusion on outcomes in cardiac surgery remains an interest, as does the relationship between age of red cells and surgical outcome. Examples include:

- **Risk of infection:** Patients given packed red blood cells had an increased risk for major infection after cardiac surgery, according to study results presented at The Society of Thoracic Surgeons 48th Annual Meeting.[6]
- **Volume transfused:** At a professional update on paediatric and congenital cardiovascular disease in February 2012, researchers reported that in paediatric heart transplantation, increasing amounts of blood transfused appeared to be associated with worsening outcomes.[7]
- **Age of red cells:** The duration of red blood cell storage did not adversely affect outcomes in ventilated patients receiving transfusions, according to a small randomised trial reported by Daryl Kor, from the Mayo Clinic in Rochester, Minnesota[8]. The investigators noted that their results differed from earlier study results that found storage duration led to adverse clinical outcomes. One possible reason is that patients in this study received a similar red blood cell dose, while earlier researchers did not adjust for dose, they suggested. Also, pre-storage leukocyte reduction was used for all red blood cell units transfused.
- **Transfusion threshold:** The American Association of Blood Banks issued new guidelines on the level at which a patient's red blood cell count can be viewed as so low as to require a transfusion. The Association concluded most patients would do just as well if the threshold was at seven or eight grams per decilitre in hospitalised, stable patients.

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6 Horvath KA. 'Do blood transfusions affect the risk of infections after cardiac surgery? Experience of the NIH/CIHR Cardiothoracic Surgical Trials Network'. Presented at: The Society of Thoracic Surgeons 48th Annual Meeting; Jan. 28-Feb. 1, 2012; Fort Lauderdale, Fla. Howard-Quijano K, et al, 'The effect of red blood cell transfusions on pediatric heart transplant patients' PCCD 2012; Abstract 43. : *Annual Update on Pediatric and Congenital Cardiovascular Disease*, Orlando, February 2012.

7 Howard-Quijano K, et al, 'The effect of red blood cell transfusions on pediatric heart transplant patients' PCCD 2012; Abstract 43. : Annual Update on Pediatric and Congenital Cardiovascular Disease, Orlando, February 2012.

8 Kor DJ, et al 'Fresh red blood cell transfusion and short-term pulmonary, immunologic, and coagulation status: A randomized clinical trial' *Am J Respir Crit Care Med* 2012.

- **Appropriate use:** Johns Hopkins researchers said a new study confirmed there is still wide variation in the use of transfusions and frequent use of transfused blood in patients who do not need it. Some recent studies have shown that surgical patients do no better, and may do worse, if given transfusions prematurely or unnecessarily. Steven M. Frank, leader of the study described in the journal Anesthesiology said 'Blood conservation is one of the few areas in medicine where outcomes can be improved, risk reduced and costs saved all at the same time. Nothing says it is better to give a patient more blood than is needed. The exceptions', Frank says, 'are cases of trauma, haemorrhage or both, where infusing blood quickly can be lifesaving.'

Research

A wide range of scientific research has some potential to affect the use of blood and blood products, but with variable time horizons. Even research which achieves its desired scientific outcomes may not lead to scaled-up production, clinical trials, regulatory approval and market development. A selection of brief reports follows:

Stem cells

- Scientists for the first time isolated single stem cells that give rise to many different types of blood cell: white cells, platelets and red cells. It may be possible one day to use stem cells to regenerate the entire blood system, or to isolate stem cells from individual patients in order to grow their own personal supplies of blood cells or clotting factors. John Dick of the University Health Network in Toronto led the study[9], which used genetically modified mice without their own immune systems. Scientists grew human bone marrow cells within the animals to target those that are the stem cells of the blood system.

Genetics

- University of Iowa researchers are using 14 sets of twins (identical and non-identical) to determine if the rate at which red blood cells decay is inherited.
- Two recent USA studies examined two specific health issues faced by African-Americans:
  - Research[10] is shedding light on why kidney disease is far more common among African-Americans than other ethnic groups. Finding the gene believed responsible (APOL1) is the first step in developing treatments. It is a variant that wards off sleeping sickness, a disease mainly borne by tsetse flies that kills tens of thousands of people in Africa each year. The gene is carried by as many as 12 per cent of African-Americans.
  - Researchers have found five previously unknown gene mutations believed to be associated with elevated blood platelet counts in African-Americans. 'The findings', they say, 'could lead to the development of new drugs to help prevent coronary artery disease'. The study[11] is believed to be the first of its size to focus on platelet genetics in African-Americans, who have a higher risk of stroke than other racial groups. They also have relatively higher platelet counts and average platelet volume, and worse outcomes after a heart attack.
- In a small study, researchers compared plasma proteins in male and female blood. Of the 231 proteins identified, there were differences in abundance between genders. If these are confirmed in further work, male or female plasma could be selectively transfused to patients, depending on their condition[12].
- Scientists have developed a gene therapy strategy they say could feasibly treat both ß-thalassaemia and sickle cell disease. The Weill Cornell Medical College-led team that reported on the development[13] devised in parallel a simple assay to predict how well individual patients are likely to respond to the treatment.

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9 Faiyaz Notta*, Sergei Doulatov, Elisa Laurenti, Armando Poeppl,Igor Jurisica, John E. Dick, 'Isolation of Single Human Hematopoietic Stem Cells Capable of Long-Term Multilineage Engraftment' *Science* 8 July 2011: Vol. 333 no. 6039 pp. 218-221 DOI: 10.1126/science.1201219.

10 at the Beth Israel Deaconess Medical Center, led by Dr Martin Pollak.

11 Published in the online journal *PLoS Genetics* and reported 5 March, 2012.

12 'Proteomic analyses of human plasma: Venus versus Mars'. *Transfusion* 2012, 52, 417-424.

13 Stefano Rivella, and colleagues report in *PLoS One*: 'Therapeutic Hemoglobin Levels after Gene Transfer in ß-Thalassemia Mice and in Hematopoietic Cells of ß-Thalassemia and Sickle Cells Disease Patients'.

Patient blood management

- In a recent presentation[14] Dr Mark Pagnano of the Mayo Clinic said that administering fluids first rather than transfusing patients, and using an antifibrinolytic agent such as tranexamic acid (TXA), can reduce blood loss and the need for transfusion in patients undergoing hip or knee arthroplasty.
- A study[15] from the London School of Hygiene and Tropical Medicine has concluded that 'the use of TXA in the treatment of traumatic bleeding has the potential to prevent many premature deaths every year'.

Alzheimer's Disease

International research activity is broad, focusing on why the disease develops, its diagnosis, prevention and treatment options. In 2011–12, research included investigating the genetic basis of susceptibility and defining the molecular pathways responsible for neuronal degeneration. A number of drugs were in clinical trials:

- A preliminary study[16] of 46 patients found that bapineuzumab may reduce the development of tau tangles in the brain, thought by some to be a hallmark of Alzheimer's. The results of a more conclusive study are expected later in 2012.
- Science reported in April 2012 that researchers using nuclear resonance imaging and computer modeling had glimpsed proteins turning into the distinctive clumps of Alzheimer's, which may be a crucial target for preventive medicine. Researchers found compounds that disrupt formation of these amyloid clumps[17].
- A drug designed by Genentech to stop Alzheimer's before it can take hold will be tested on a family in Colombia with a genetic mutation that leads to the disease in its members, usually in their 40s.
- Intellect Neurosciences announced two new programs in its Alzheimer's pipeline. Their monoclonal antibodies target early neurotoxic forms of tau protein, and could yield therapeutic and diagnostic uses.
- Four articles in the journal *Alzheimer's and Dementia* in 2011 described new criteria for Alzheimer's, dementia and mild cognitive impairment. They emphasise that the Alzheimer's pathophysiological process starts years and perhaps decades before clinical symptoms, and that biomarkers can detect amyloid ß deposition and the effects of neurodegeneration in the brain[18].

Haemophilia

Studies have variously:

- demonstrated the potential of gene therapy to convert severe bleeding in haemophilia B into a mild form of the disease, or reverse the disease[19]
- found the overall success rate to immune tolerance induction is independent of FVIII dosing regimen although a high dose of FVIII compared to a low dose achieved tolerance more rapidly[20]

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14 Pagnano M. Minimizing blood loss: An acid trip in 2011. Paper #38. Presented at the Current Concepts in Joint Replacement 2011 Winter Meeting. Dec. 7–10. Orlando, Florida.

15 Katharine Ker, Junko Kiriya, Pablo Perel, Phil Edwards, Haleema Shakur and Ian Roberts: 'Avoidable mortality from giving tranexamic acid to bleeding trauma patients: an estimation based on WHO mortality data, a systematic literature review and data from the CRASH-2 trial', *BMC Emergency Medicine* 2012, 12:3 doi:10.1186/1471-227X-12-3 Published: 1 March 2012.

16 Published April 2, 2012 in *Archives of Neurology*.

17 The study, published April 30 in the online journal PLoS ONE, is entitled 'The influence of spin-labeled fluorene compounds on the assembly and toxicity of the Aß peptide'.

18 Andrew E Budson; Paul R Solomon. 'New Diagnostic Criteria for Alzheimer's Disease and Mild Cognitive Impairment for the Practical Neurologist', *Practical Neuology* Pract Neurol. 2012;12(2):88-96.

19 *Nathwani AC, Tuddenham EGD, Rangarajan S et al.* 'Transfer in Hemophilia B' N Engl J Med. 2011 Dec 22;365(25):2357-65. Epub 2011 Dec 10.PMID: 22149959'.

20 *Hay RM and DiMichele DM.* 'The Principal Results of the International Immune Tolerance Study: A Randomized Dose Comparison' Blood 2012;119(6):1335–1344.

- reported the in vivo therapeutic efficacy of an approach to bypass FVIII with FIX variants engineered to directly activate Factor X (FX) and propagate the intrinsic coagulation pathway in the absence of FVIII[21].

Synthetic blood substitutes

Scientists say worm blood could hold the key. The haemoglobin found in earth and sea worms carries about 50 times more oxygen than human blood, prompting University of California researchers in San Diego to examine the potential to replicate the same oxygen-carrying capacity in artificial blood[22].

Infectious diseases

Disease burden within a community (e.g. dengue in North Queensland in summer) may limit blood collection for a time. Disease in individual donors (e.g. influenza), or potential disease resulting from travel (e.g. malaria) means a donor must be deferred. Some people may not be permitted to donate at all (e.g. people who lived in the UK for a period critical in the history of vCJD). Blood donations are tested for a number of diseases (e.g. HIV and Hepatitis B), and there are others globally for which it may become necessary to test in Australia in the future (e.g. Chagas disease, the tick-borne babesiosis[23] and Lyme disease).

Vaccines: Progress was made during the year on developing universal flu vaccines, pre-pandemic avian flu vaccines protecting against a range of strains, four-strain seasonal flu vaccines, intranasal (inhaled) vaccines, and plant-expressed virus-like particle vaccines. Testing continues on tetravalent dengue vaccine.

Prion diseases

- French researchers found that prions are more easily able to jump between species than has been previously thought[24].
- In January 2012, neurologists across Britain were told by the Nationlal Health Service's National Prion Clinic, part of the University College London Hospitals Trust, and the Medical Research Council's Prion Unit that a new blood test is now available for vCJD. Until then the only way of confirming the diagnosis had been through tonsil biopsies or after the patient has died when brain samples can be taken.

Overseas intelligence gathering

The collaboration of national plasma product supply planners (NPPSpa)

The fourth meeting of the collaboration of national plasma product supply planners was held in Madrid in March 2012 and attended by the NBA's Deputy General Manager, Commercial Contracts. The group consists of a number of national agencies that have responsibility for plasma products. The aim of the group is to support participants' needs for a secure, cost effective supply of plasma for fractionation, plasma derivatives and their clinically substitutable recombinant products. It continues to be the only international forum that shares data and experiences in the management of plasma products and is especially valuable in the context of procurement mechanisms and outcomes. Meetings of the group are timed to coincide with the annual International Plasma Protein Congress. Issues discussed included:

- comparative per capita product usage trends
- product utilisation and authorisation processes

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21 *Milanov P, Ivanciu L, Abriss D et al.* 'Engineered Factor IX Variants Bypass FVIII and Correct Hemophilia A Phenotype in Mice' Blood 2012;119(2):602–611.

22 At the Australian and New Zealand College of Anaesthetists ANZCA) conference in Perth, May 2012.

23 The first reported Australian human case of the potentially lethal tick- borne infection babesiosis has been reported in the *Medical Journal of Australia*.

24 Béringue, V., Herzog, L., Jaumain, E. et al. *Facilitated Cross-Species Transmission of Prions in Extraneural Tissue*. (2012). Science. 335: pp. 472-475. Accessed 23 February 2012.

- overviews of recent and upcoming tender processes and contract terms, including product portfolios, prices and price disclosure policies, inventory holding and the role of each agency
- impacts of non-reversible anti-coagulants
- availability and implications of product home delivery/treatment
- the emergence of long-acting haemophilia products, and country strategies around licensing and contracting
- product management strategies for FVIII and immunoglobulin products
- mechanisms for feedback from clinicians and patients on products and the performance of suppliers
- relationships between registered indications, actual usage, costs and supply
- market reaction to the global recall and subsequent re-introduction of Octagam.

As in previous years, the information obtained at the meeting place the prices for plasma-derived and recombinant products achieved in recent Australian tenders at a very competitive level.

The meeting was chaired by Canada. Members agreed to continue meeting annually, and to explore the possibility of inviting other countries to join the group.

International Plasma Protein Congress

The International Plasma Protein Therapeutics Association is an industry organisation for the commercial plasma products industry. Members include all of the major global plasma fractionation companies, as well as commercial plasma collectors, suppliers of equipment and consumables, and other associated companies. The congress is attended by companies, industry suppliers, analysts, regulators, purchasing bodies and patient group representatives. It presents opportunities to gather intelligence about company strategies and 'hot topics'. For example, market analysts were very interested in the range of new recombinant clotting factors which will become available in the next few years.

Items of relevance to the Australian blood sector included: impacts of the global financial crisis, regulatory developments, including: collaboration and information sharing in the USA and Europe—including that relating to tests for prothrombotic activity in products; health technology assessment methodologies and value; plasma demand and donation; developments in tolerisation for severe haemophilia; and updates on progress on clinical trials on the use of IVIg to treat Alzheimer's disease.

Sector research framework

One of the DoHA-funded projects completed by the NBA in 2011 identified a number of significant gaps in critical information needed by the blood sector in order to make key decisions for improvement.

Under the National Blood Agreement, one of the roles of the NBA is to 'facilitate and fund appropriate research, policy development or other action in relation to new developments by relevant governments, or non-government persons or bodies'[25]. In December 2011 JBC agreed that there would be value in establishing a research framework for the blood sector which would identify priority areas for research, governance and funding arrangements and administrative processes. The national blood arrangements place the NBA in a unique position to coordinate resources for research across the blood sector.

During 2012 we commenced work to develop this framework. The NBA believes that through relevant research, evidence could be generated to improve clinical and laboratory practice, ensure product adequacy and safety into the future, and ensure patients are receiving the most appropriate products to meet their clinical needs. Work will continue through 2012–13 to refine and finalise the research strategy and develop an implementation plan for the NBA research program.

25 National Blood Agreement, Part 3, section 25 (n) refers.

Dissemination of information

The 2010 amendments to the *Freedom of Information Act 1982* require agencies to release data under an open license unless there is a cogent reason not to do so. We see this as an opportunity to publish key documents in order to increase knowledge of blood and blood products, and awareness and understanding of governments' expenditure on them.

In May 2012 the JBC members agreed to the publication on the NBA website of the annual NSP&B and monthly supply reports, reflecting their general support for the publication of data at a national and jurisdictional level in relation to product volumes and costs. In addition, the NBA's series of product monographs, initially developed in 2010, will be published on the NBA's website in future. The monographs are updated annually and contain factual information on trends on issues and costs for each supply group.

SECTOR IMPROVEMENT THROUGH MANAGEMENT AND ACCOUNTABILITY INITIATIVES

An important focus for the NBA in 2011–12 was the review and assessment of policies and procedures across aspects of the blood supply chain, in order to increase efficiency and accountability within the blood sector, and internationally. See also pages 40–41 for descriptions of selected performance measures included in contracts with suppliers. Implementation of the new National Safety and Quality Health Service (NSQHS) standard for blood and blood product safety (page 91) and our work on inventory management (page 42) will also lead to improved efficiencies and accountability within the sector.

Review of the authorisation and clinical governance framework for intravenous immunoglobulin (IVIg) and normal immunoglobulin (NIg)

In 2010–11 the NBA and key stakeholders undertook a preliminary analysis of the existing management arrangements for IVIg and alternatives that may be used. This was in response to an identified need for a higher level of cost-effectiveness to be applied to the use of IVIg. Growth has averaged approximately 11 per cent per annum since 2003, although there were reductions in the rate of growth after the release of the initial *Criteria for the clinical use of intravenous immunoglobulin in Australia* (the Criteria). The range of indications for which IVIg therapy demonstrates some clinical benefit is expanding. This factor, and the potential for a significant and ongoing growth in demand, poses challenges for both supply security and affordability.

In addition, the analysis found that current authorisation arrangements are not consistent across jurisdictions. While arrangements need to be flexible enough to accommodate the capacities of different facilities, some fundamental authorisation requirements should be in place across all jurisdictions and all facilities. The review found that current authorisation arrangements differ in their focus on the public and private sectors and the extent to which there is a dedicated review of individual patients on IVIg treatment to determine efficacy. The analysis also noted that there is no national peak body for reporting and analysing trends on how IVIg is used. In May 2011, the CTEPC commissioned an independent review of the authorisation and clinical governance framework for IVIg to identify improvements. The NBA is coordinating the review on behalf of governments. The review has the following goals to:

- ensure that funded immunoglobulin use reflects best clinical practice and is cost effective
- ensure that the outcomes of decision-making regarding access to IVIg funded under the national blood arrangements are consistent with the Criteria (see page 94)
- improve the capture of information on the need for, use and outcomes of treatment with intravenous or normal immunoglobulin (IVIg or NIg) and improve the evidence base that will inform future changes as to what is regarded as best practice in use and prescribing
- improve governments' understanding of the issues, benefits and risks of including NIg and subcutaneous immunoglobulin (SCIg)[26] in any new management framework.

26 However, SCIg is not yet funded under the national blood arrangements.

The CTEPC appointed Dr Stephen Christley to chair a review advisory group which contains representatives from health consumer and patients groups, clinicians, large and small jurisdictions, DoHA, the Blood Service and the NBA, as well as an IVIg nurse and a health economist.

In March 2012 the NBA engaged Ernst and Young to manage aspects of the review. During the initial phase the consultant reviewed and analysed current authorisation procedures and systems to access IVIg and NIg (see page 36–37). The objective of this was to determine the extent of compliance, efficiency and satisfaction of all stakeholders with the current authorisation and clinical governance arrangements for IVIg. This included identifying what is known at each step in the process to support decision-making. The consultant made a detailed study of practices in both small and large jurisdictions to determine the benefits and weaknesses in how IVIg is currently accessed and managed in different facilities.

To ensure that the NBA and the consultants had a comprehensive understanding of how IVIg is accessed, used and managed across Australia, a survey asking about prescribing and use of IVIg was developed and distributed widely in the medical community. Several follow-up focus groups with leading medical disciplines using IVIg were also undertaken. How IVIg is managed and accessed in other countries will also be investigated and research will be conducted into management frameworks for other high cost medications within Australia. Following these activities, the consultant will develop a number of models for possible future arrangements for IVIg, and subject the key models to risk and cost-benefit analysis. We anticipate that the review will be completed early in 2012–13.

Implementing the *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products*

The *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products* was approved by health ministers in November 2010. The statement is a core foundation document that defines the commitment and cooperation expected of approved health providers in how they manage these products and contribute to the objectives of the National Blood Agreement. The Agreement does not address the roles and responsibilities of health providers such as laboratories in hospitals and clinics and other institutions that receive blood and blood products for dispensing to patients.

We believe that to ensure success, it is essential to integrate our strategies to implement the statement with those of the NSQHS to implement the new blood and blood product safety Standard 7 (see page 91). During 2011–12 the NBA collaborated with the ACSQHC (Australian Commission of Safety and Quality in Health Care) on plans to implement the statement and Standard 7 nationally. We will use three approaches to ensure adoption:

- promote the statement at national, jurisdictional and local levels: with a suite of supporting publications targeted at specific groups within health providers; engaging with the private sector; and holding forums to maintain a high level of sector engagement for governments' shared objectives for, and showcase best practice of, stewardship in the management and use of blood and blood products
- integrate and prioritise the statement, for example in clinical education, quality improvement systems and processes and in national health reforms. The NBA is collaborating directly with the ACSQHC to detail the activities that are expected at hospital level to ensure compliance with Standard 7. Consideration will also be given to incorporating the principles of the statement into national agreements and relevant NBA contracts
- establish effective data linkages within and across the health sector to support accreditation, quality improvement, performance measurement and reporting. Good progress is already being made on standardising a methodology to support red blood cell data linkage (see page 93), and integrating the NBA's BloodNet system with the laboratory information systems of health providers (see pages 62–63). We have also started work on improving national inventory management (see page 42).

Some actions can be taken at a national level, while others would be more effective at a jurisdictional level. The NBA will give clear explanations on how performance will be measured and provide information on the tools available to health providers to meet these obligations.

In 2012 the NBA started work on a promotional brochure for approved health providers and consumers to outline the expectations of the statement in the context of the broader national blood arrangements and the requirements under the standard. The SA government developed a framework of key activities for implementing the statement, and in May 2012 all JBC members agreed to implement this approach at both policy and practical levels.

We also undertook research and preliminary consultations to increase our understanding of the relationships between the private health sector and the blood sector and to identify opportunities for the NBA to engage with appropriate sections of this important group. The first major step in this activity will be to invite key representatives from the private health sector to attend a forum at which we can discuss how the NBA could assist private organisations to implement reforms in the clinical governance and management of blood and blood products.

Performance scorecard for the sector

Key performance indicators are essential tools for both monitoring and improving the quality of health services. Significant advances have been made over the past decade in the development of indicators for the Australian health sector. Performance indicators originally focused mainly in the field of acute hospital care, but now extend into services such as community health, general practice and public health. The language and culture of performance measurement is now well established in the day-to-day life of acute public hospitals, and in the health care sector.

> *The vision of the National Health Performance Committee is for a health system that searches for, compares, learns from the best and improves performance through the adoption of benchmarking practices across all levels of the system. (National Health Performance Framework Report, 2001)*

This vision has underpinned the development of performance indicators for national health services and the blood sector. The emphasis has been to have a set of indicators for blood related services that serve as tools for improving service quality through collaborative benchmarking.

The stated primary policy objectives of the National Blood Agreement[27] are to:

- provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia
- promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

In order to fulfill these objectives, the Agreement requires the NBA to:

- undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply
- facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector.

The objectives have been summarised as three *perspectives*:

- *supply security*—to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia
- *clinical safety and quality*—to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia

27 National Blood Agreement paragraphs 1(a) and (b), 25 (o) and 35(f)

- *sector management*—to undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply; and facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector.

During 2011–12 the NBA has been developing and identifying a set of key performance indicators using these perspectives, aligned with the national health performance framework, for use in benchmarking and monitoring the blood sector.

The preliminary development of performance indicators for the blood sector is occurring in collaboration with key sector stakeholders. As an example, the NBA discussed the draft indicators with suppliers at the annual suppliers' forum held in April 2012.

However, while agreement on performance indicators is a necessary first step, it will not in itself lead to their introduction for blood related services. A number of issues need to be resolved for this to occur, including how the indicators are produced, how frequently they are reported, and who is responsible for reporting them. We will need to continue to collaborate with blood sector stakeholders to outline the steps required to embed performance indicators within the sector.

MANAGEMENT OF RISK

The NBA continues to give high priority to our obligation to manage blood sector risks, especially those related to supply security. We do this by ensuring that responsibility and accountability lie with those best placed to manage risk.

A key strategic direction for the NBA in 2011–12 in managing risk in the blood sector was to improve data capture, and the capacity to analyse data, across all sections of the blood supply chain (see pages 62–68). Other activities during the year included:

- continued scrutiny of compliance with, and the quality of, risk management strategies contractually required of suppliers
- development of an overall financial reserve strategy
- management of both real and potential risks to the supply plan during the year
- identification of jurisdictional preparations for managing risk.

NATIONAL BLOOD SUPPLY CONTINGENCY PLAN (NBSCP)

The NBA activated the NBSCP once during the year, on 8 March 2012. On the previous day CSL Limited had advised the TGA that a small leak of ethylene glycol from the cooling jacket of a pasteurisation vessel used in the manufacture of albumin had been detected, and that use of the affected vessel had immediately ceased and repairs conducted. In response to this threat of contamination, the TGA had then recalled 140 batches of albumin manufactured by CSL Limited.

Albumin is a plasma-derived product routinely used in the treatment of patients in intensive care and the recall created a potential shortage of albumin stocks nationally. The NBA closely monitored the situation but was able to deactivate the NBSCP on 18 April following testing and release of quarantined batches of product by the TGA.

Apart from this event, inventory levels for all products remained strong throughout the year.

MANAGEMENT OF RISK IN STATES AND TERRITORIES

In September 2011 the JBC considered information on the preparedness of states and territories for emergencies involving blood. Three categories of emergencies were identified: blood supply shortage; short-term surge in demand for blood products; and disruption to infrastructure. Several key issues were identified regarding the ability of jurisdictions to respond to emergency planning, including:

- clarification of roles of key stakeholders
- resourcing
- the importance of consistency in content and dissemination processes, and of key messages
- transport
- periodic testing of contingency arrangements.

JBC members acknowledged the value of conducting simulation exercises, provided adequate resources were available, and agreed to work towards addressing known gaps and to reporting annually on their preparedness.

FINANCIAL RISKS

The NBA has a range of assurance and controls measures in place to manage financial risks that are reviewed regularly both internally and externally. These include a rolling internal audit program, Audit Committee oversight of the governance framework, and contract risk plans.

Contracts with commercial suppliers of blood and blood products, and the implementation of the output based funding model with the Blood Service, have introduced financial risks for the NBA. The NBA's overall financial reserve strategy, developed during 2010–11, acts as a safety net to manage financial risks associated with these and future contractual arrangements.

PERFORMANCE: APPROPRIATE AND SAFE USE OF BLOOD AND BLOOD PRODUCTS

PART 5

12,443

HARD COPIES OF GUIDELINES AND CRITERIA DISTRIBUTED

5

PERFORMANCE: SUPPORTING APPROPRIATE AND SAFE USE OF BLOOD AND BLOOD PRODUCTS

INTRODUCTION

NATIONAL GUIDELINES AND CRITERIA FOR USE

STANDARDS, ACCREDITATION AND STEWARDSHIP

EDUCATION

CLINICAL GOVERNANCE AND DATA SYSTEMS

NETWORKS AND COMMUNICATIONS

QUALITY IMPROVEMENT INITIATIVES

INTRODUCTION

The third activity of the NBA's program is to contribute to promoting the safe, high quality management and use of blood and blood products and services. By working with stakeholders and other experts, clinical practices, product use guidelines and quality improvement initiatives are developed that support effective and appropriate clinical practice.

The ultimate objective of our activities is to ensure compliance with best practice in all aspects of the blood sector, achieved by working at a range of levels within an overall framework (see Figure 5.1 below). Information on some of our programs are contained in Part 4—on sector improvement—for example, our new initiative to develop a research program to inform blood sector policy (see page 75). Part 5 focuses on activities which more specifically support enhancements to clinical practice.

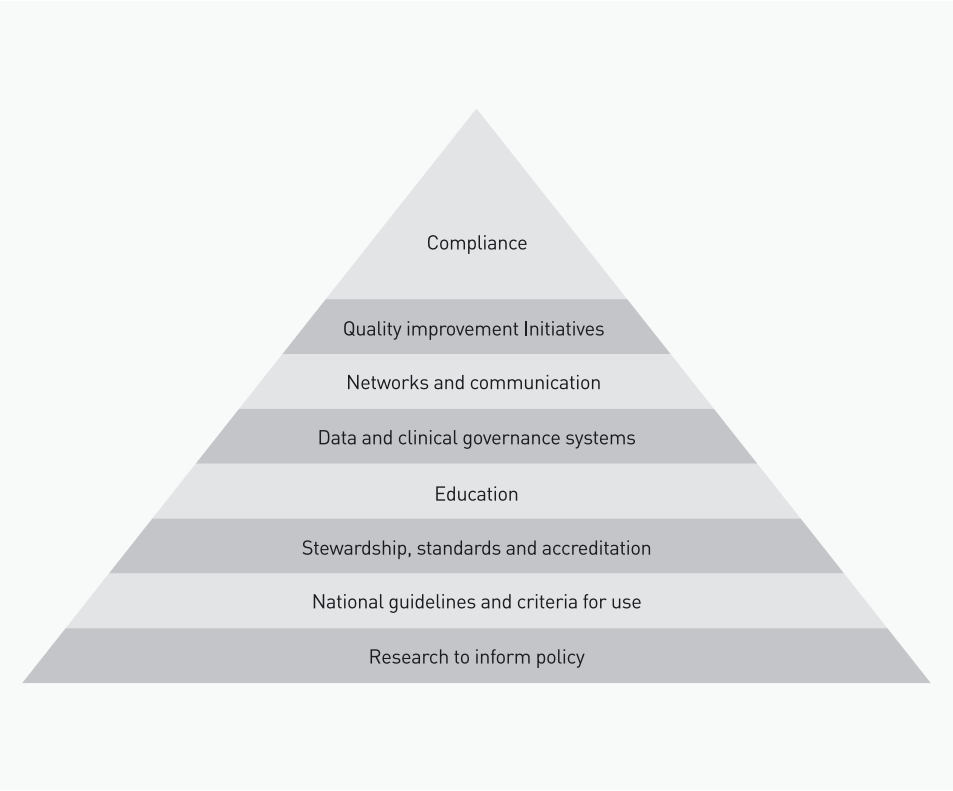

FIGURE 5.1 *Framework for supporting appropriate and safe use of blood and blood products*

The deliverables and key performance indicators for this function, and our performance, are described below:

DELIVERABLES

Qualitative deliverables	2011–12 reference point or target	Results
Second edition of the *Criteria for the use of intravenous immunoglobulin in Australia* (the Criteria) is approved by ministers and a communication plan developed to inform the clinical community of its availability	Second edition of the Criteria submitted to ministers for approval by June 2012, along with a communications plan	Met. Health ministers approved the second edition of the Criteria on 20 June 2012. (see page 90)
A report on the use of red blood cells in public hospitals is produced	A report on the use of red blood cells in public hospitals is produced by June 2012	Not met due to delays in availability of jurisdictional data. This report will now be published during 2012–13. (see page 93)
Quantitative deliverable	**2011–12 budget**	**2011–12 actual**
Number of National Health and Medical Research Council *Clinical practice guidelines for patient blood management* published	2	Perioperative module released in March 2012. Two further modules will be approved by the end of 2012. (see pages 88–89)

KEY PERFORMANCE INDICATORS

Qualitative indicator	2011–12 reference point or target	Result
Quality advice provided to guide promotion of safe, high quality patient blood management and use of blood and blood related products	High level of satisfaction of all funding jurisdictions with the NBA's advice on the promotion of patient blood management (PBM) and use of blood and blood related products as assessed through survey of Jurisdictional Blood Committee members	89% of jurisdictions were very satisfied with the NBA's work around patient blood management. The remaining 11% were unsure, pointing out that the processes to implement PBM activities need to take into account varying local health systems, and also the impact of national health reforms. (see page 87–89, 95 and 96)
Quantitative indicators	**2011–12 budget**	**2011–12 actuals**
Number of hard copies distributed and electronic downloads of guidelines and criteria made available by the NBA	200	**GUIDELINES:** **Critical bleeding** Module: Copies downloaded—5088 Hard copies—1766 Quick reference guide: Copies downloaded—3250 Hard copies—3326 **Perioperative** Module: Copies downloaded—3275 Hard copies—2366 Quick reference guide: Copies downloaded—1085 Hard copies—4305 **CRITERIA** (clinical use of IVIg): Criteria: Copies downloaded—8446 Hard copies—312 Quick reference guide: Copies downloaded—3247 Hard copies—368 (see pages 87–90)
Number of states and territories contributing haemovigilance data to the national report	7	7 (see pages 93–94)
Proportion of states and territories satisfied with the implementation of the patient blood management guidelines	100%	89%, with 11% unsure (see response for the qualitative indicator on the patient blood management guidelines).
Number of colleges and societies that agree to endorse the patient blood management modules	8	8

NATIONAL GUIDELINES AND CRITERIA FOR USE

The involvement of stakeholders and other interested individuals is a key strategy for the NBA in its role in developing and updating guidelines for the use and management of blood and blood products. In particular, our capacity to mobilise the expertise of the clinical community continues to guarantee the quality, and assist in the uptake, of the advice that our published material contains.

EVIDENCE-BASED PATIENT BLOOD MANAGEMENT GUIDELINES

Internationally, PBM is an approach which helps patients to avoid unnecessary transfusions and the associated risks, by reducing blood loss and optimising the patient's own blood.

The World Health Assembly recently resolved (63.12) to encourage the implementation of PBM in all World Health Organization member states. The NBA's wide-ranging program to implement these objectives, which includes developing PBM guidelines, developing national outcome and performance measures, and implementing effective strategies to promote our initiatives has gained considerable momentum during 2011–12.

The NBA is continuing to manage the development of evidence-based PBM guidelines. Interest monies approved by the JBC support the costs of systematic reviewers, publication and promulgation of the guidelines, and clinical meetings. The NBA procures and manages contractors, liaises with all government agencies including the NHMRC, coordinates all project related activities including clinical meetings, and conducts extensive quality assurance of technical reports and the guidelines throughout all stages of development. Clinical/consumer reference groups have been established to provide valuable oversight of the development of each module.

The guidelines will comprise a set of six separate modules each focusing on different patient populations: critical bleeding/massive transfusion; perioperative; medical; critical care; obstetrics; and paediatrics/neonates. NHMRC approval is being sought on completion of each module in order to ensure credibility within the clinical community. Together, the suite of six modules will replace the NHMRC/Australian and New Zealand Society for Blood Transfusion *Clinical practice guidelines on the use of blood components* (2001). The guidelines align with other national strategic initiatives such as the *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products* (see pages 77–78) and the NSQHS Standards (see page 91).

The cost of the systematic reviews and overall production expenses for the modules, in particular the Medical module, has been higher than estimated, because of the number and complexity of the questions and the volume of the body of evidence to be reviewed. For this reason, in 2011–12 the NBA commissioned an independent assessment of the project management processes to examine and suggest better ways of managing systematic review projects, including estimating costs. In 2012 the JBC approved additional funding from interest monies, to enable the existing contractor to complete work on the remaining two modules.

Our aim is to ensure that the modules are well known, well received, sought after and used by clinicians, other health care professionals and patients involved with transfusion. It is evident from many studies that it is not enough to just publish new guidelines. It is also essential to publicise the availability and significance of the new information and to develop a comprehensive implementation strategy. In 2012 the NBA appointed a dedicated communications and marketing officer to manage the development and implementation

of a range of communications strategies to support the promotion of the guidelines. Our PBM program includes a comprehensive implementation strategy (described in further detail in this chapter).

By June 2012 it was clear that the guidelines are well regarded, with endorsement from national colleges and societies, regular presentation at national and international conferences, strong demand for copies of the published modules, and continued requests for updates by individuals received on the NBA website.

Module 1—Critical Bleeding/Massive Transfusion

The first module of the PBM guidelines, on Critical Bleeding/Massive Transfusion, was released in March 2011. The module is intended to assist and guide healthcare professionals in making clinical decisions when managing patients who require, or are likely to require, massive transfusions. Uptake of the document has been high throughout 2011–12, with a resurgence of interest following the release of the second module. As at 30 June 2012 the module had 5088 copies downloaded from the NBA website and the quick reference guide had 3250 downloads. 1776 hard copies of the module and 3326 copies of the quick reference guide were sent out in the last twelve months. In addition, the module has frequently been presented at clinical meetings in Australia and overseas.

Module 2—Perioperative

This module is intended to inform healthcare practitioners, health educators and health service managers about the care of patients before, during and after surgery or invasive procedures, particularly those in which blood loss is anticipated.

Public consultation on this module closed on 1 April 2011. An external and independent peer review reported very favourably and the module was finalised and submitted in August 2011 for NHMRC approval; the module was approved in November 2011 and released in March 2012. As at 30 June 2012 the module had 3275 copies downloaded, the quick reference guide 1085 copies downloaded, and 2366 hard copies of the module and 4305 copies of the quick reference guide had been ordered, and this guide had also been presented many times at clinical meetings in Australia and overseas.

Module 3—Medical

This module is intended to assist and guide clinical decisions and coordination of healthcare across the health sector, from the local general practitioner to the hospital operating theatre, for patients with acute or chronic medical conditions requiring haematological intervention. Work on this module continued, with the reference group reviewing relevant literature, and completing the evidence statements and clinical guidance sections of the guide. The systematic review process for this module was also completed during the year and a public consultation process for the draft document commenced on 23 January 2012 for an eight week period. Nine formal submissions were received, including two letters of congratulation on the high quality of the guidelines. The module was submitted for NHMRC approval in June 2012. An abstract on this module was invited for oral presentation at the 32nd Congress of the International Society of Blood Transfusion to be held in Cancun, Mexico in July 2012.

Module 4—Critical Care

This module is intended to assist and guide clinical decisions relating to blood management in patients suffering life-threatening illness or injury in an intensive care environment. During the year the systematic review of this module was completed and a public consultation process ended on 18 May 2012. Twelve submissions were received (using the submission template provided on the NBA website), of which nine were on behalf of an organisation. Three of the submissions acknowledged their endorsement of the draft guidelines but did not include any specific feedback. The clinical reference group met on 12 June 2012 to consider all responses to the public consultation process and make revisions where necessary.

The NBA anticipates submitting the module to the NHMRC in July for approval later in 2012.

NBA FOCUS
PATIENT BLOOD MANAGEMENT
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RELEASE PERIOPERATIVE MODULE
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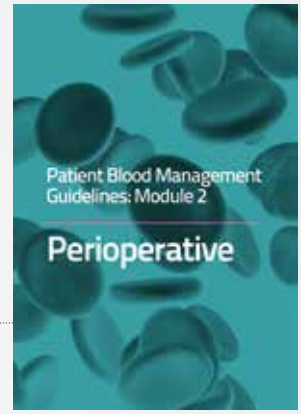
NATIONAL



NBA GUIDELINES SET TO IMPROVE PATIENT CARE AND REDUCE TRANSFUSIONS

Patient health will be improved and the number of blood transfusions will be reduced if clinicians follow new guidelines developed by clinical experts working with the National Blood Authority.

The Perioperative module is one of six modules, covering different patient populations, which make up the Patient Blood Management Guidelines. The module has been approved by the National Health and Medical Research Council and provides evidence-based recommendations that help reduce the need for transfusions, avoid infections and reduce hospital stays for patients undergoing surgery.

The Perioperative module is based on an extensive systematic review of the highest quality evidence available from trials in the perioperative setting throughout the world.

A key finding from the evidence is that diagnosis and treatment of anaemia before surgery, particularly in patients at risk of blood loss, reduces risks and improves patients' recovery and health.

Anaemia in patients is not routinely diagnosed or treated prior to admission for surgery, even though patients with anaemia have poorer outcomes when they undergo surgery and are more likely to require a transfusion.

The module includes an easy-to-use preoperative haemoglobin assessment and optimisation template which aids in the identification, diagnosis and treatment of anaemia prior to surgery.

The approach recommended has been tested in the Australian setting—Western Australia became the first jurisdiction in the world to adopt a system-wide program of patient blood management.

It did this by assessing and managing preoperative anaemia, adopting surgical techniques that minimise blood loss and introducing a policy of transfusing one unit at a time. As a result, the state's issues of red blood cells for transfusion per 1000 of the population fell from 30.5 in 2007–08 to 27.5 in 2011–12 (the national average was 35.6 per 1000 in 2011–12).

Module 5–Obstetrics and Module 6- Paediatrics/Neonates

These modules were placed on hold until all other modules to the NHMRC have been submitted and the outcomes of the independent assessment of project management processes were completed. Work will resume in July 2012.

CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN (IVIg)

IVIg is used to replace or modify a person's immune response. It is used to treat many different indications across immunology, neurology, haematology and other specialty areas, for these two purposes.

Many of the indications for which IVIg is used are extremely rare, and in these circumstances, evidence of IVIg efficacy is limited.

The *Criteria for the clinical use of intravenous immunoglobulin in Australia* (the Criteria) identifies the indications for which IVIg is funded under the national blood arrangements by all Australian governments; the book is not a medical or clinical guideline on treatment of the indications listed. Regular review of the Criteria is needed to align funded access to IVIg with the latest evidence, or in the case of limited evidence, a consensus of expert opinion. In the last twelve months, the Criteria has had 8446 copies downloaded from the NBA website and the quick reference guide 3247 copies downloaded, with 312 and 368 hard copies distributed respectively.

The NBA published the initial Criteria in December 2007, with a number of clarifications published in February 2009. A triennial review of the document commenced in 2010 and a public consultation on the recommended changes closed in August 2011. The draft second edition of the Criteria was endorsed by JBC in December 2011 and approved by health ministers in June 2012. We estimate that the overall impact of the proposed changes to the Criteria is likely to stem the rate of growth in demand for IVIg.

The NBA has also developed a communications plan to accompany the release of the second edition of the Criteria. While the new Criteria will apply from 10 August 2012 for all new patients, a transition period of six months will be allowed for existing patients affected by changes to the Criteria.

STANDARDS, ACCREDITATION AND STEWARDSHIP

Up until now none of the arrangements in place to accredit or license approved health providers have included the management and administration of blood and blood products. This has made it difficult for governments to encourage improvements, particularly as the blood and blood products are regarded by approved health providers as 'free'.

The introduction by the Australian Commission on Safety and Quality in Health Care (the Commission) of a NSQHS standard for blood and blood products is providing an excellent opportunity to encourage the adoption of best practice in clinical practice and administration. It will materially assist the NBA to implement a range of programs and initiatives we have been working on for several years, in particular the implementation of the ministerial *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products*. The NBA is assisting hospitals and doctors to comply with the new standard in several other important ways; see the sections on education and quality improvement initiatives below for a description of these.

NATIONAL SAFETY AND QUALITY HEALTH SERVICE STANDARD FOR BLOOD AND BLOOD PRODUCTS

In September 2011 health ministers endorsed the ten NSQHS Standards which will support national health reforms. Standard 7 of these relates to blood and blood products. The NBA has worked closely with the Commission throughout the development of Standard 7.

Standard 7, which will come into effect in January 2013, states that clinical leaders and senior managers of health service organisations must ensure the safe, appropriate, efficient and effective use of blood and blood products.

Our collaboration with the Commission is continuing with the NBA developing a guide to support hospitals to implement Standard 7. The guide describes the processes and strategies that hospitals can use to meet this standard. The NBA was invited to present accreditors about the expectations of this standard.

EDUCATION

The NBA considers education to be an important tool to:

- **support the implementation of the PBM guidelines**
- **improve safety and address issues identified in haemovigilance reporting**
- **improve the quality of prescribing**
- **improve the efficiency of the handling of blood and blood products.**

Over the past three years, using interest monies approved by the JBC, the NBA has supported the development and national rollout of education initiatives developed initially within jurisdictions.

BLOODSAFE ELEARNING AUSTRALIA

In 2006, the South Australian Department of Health funded the development of an online education package for clinical staff involved in the transfusion chain. Now available nationally, the BloodSafe eLearning Australia is a unique, online, free education program providing health professionals with the knowledge to prescribe and use transfusion appropriately and safely. The courses continue to be very popular throughout Australia with over 127,000 people having registered for the program up to the end of June 2012.

During the year, two new courses became available: on postpartum haemorrhage in October 2011; and on iron deficiency anaemia in January 2012. A third course on critical bleeding/ massive transfusion is under development and the original course on clinical transfusion practice has been revised. In addition, system maintenance, redesign of the website, enhancements of the reporting function, and revision of the database to allow for the new local health network reporting structures were completed. An external marketing company has been engaged to develop promotional activities to increase awareness of the modules with a range of stakeholders.

In January 2012 the JBC considered a comprehensive, independent evaluation of the program. The report found BloodSafe eLearning Australia provides value for money based on assessment of a quality product, its fitness for purpose and its impact on clinical practice. In May 2012 JBC members strongly supported the continuation of the program and approved further funding for at least three more years.

GRADUATE CERTIFICATE IN TRANSFUSION PRACTICE

The Graduate Certificate in Transfusion Practice continues to be offered by the Blood Matters program to both national and international students. The course is delivered online in conjunction with the University of Melbourne. More than 100 students have graduated since 2003, creating a wealth of highly skilled blood experts across our health system.

CLINICAL GOVERNANCE AND DATA SYSTEMS

The NBA is devoting considerable resources to the development and establishment of data and governance systems that are nationally consistent, generate robust quantitative information and provide sound decision-making functions to support and maintain sector improvements.

Many of these strategies are described in Part 4 of this report (see pages 62–79). Here we give details of several other data and governance initiatives which are more clinically-oriented.

RED BLOOD CELL USAGE PROJECT

The purpose of the red blood cell usage project is to facilitate jurisdictional-based data linkage with the aim of producing a nationally consistent data set of, and ultimately a national report on, use and the appropriateness of use of blood and blood products in Australia. To date the blood sector has largely lacked data at a national level which can be used to guide options for improvements.

The initial commitment to obtaining data on red blood cell usage began at the national level in 2009 when the NBA coordinated a workshop to determine an ideal minimum data set for recording red blood cell usage in Australia. The first data set, representing some comparative red cell, platelet and FFP utilisation data, had been published by Trevor Cobain in the mid-2000s using Western Australia hospital data. Since that time NSW, SA, WA and Queensland have advanced their data linkage capabilities and the resulting data and analyses are being used to influence clinical practice. The project was given additional impetus at the CTEPC Blood Policy Forum held in March 2011, at which participants considered examples of the types of data being generated by the WA PBM Program.

A workshop was held in August 2011 to finalise the methodology for jurisdictional data linkage specific to blood and blood products. The data elements will be a combination of selected core clinical and demographic elements which will provide information, for example, on patterns of use of red blood cells. We have continued to work on the collection, aggregation and analyses of this new national data set.

We anticipate that the same data linkage methodology could be used to capture existing data on all other blood and blood products recorded in hospital and pathology systems.

HAEMOVIGILANCE

The transfusion of blood and blood products is a core component for healthcare service delivery to patients. However, the transfusion of blood products is not without risk and can lead to complications. The monitoring of serious adverse events resulting from transfusion is critical to transfusion safety. The systems and processes for monitoring are known as haemovigilance systems.

The World Health Organization Global Database on Blood Safety Report 2004–05 indicated that 42 of 105 reporting countries had a national haemovigilance system in place and 24 were in the process of developing one. The 2008 report indicates that 57 of 106 reporting countries have implemented a national haemovigilance system.

Working within the NBA's Haemovigilance Program, the Haemovigilance Advisory Committee (HAC), established in 2009, contributes to improving patient outcomes by providing enhanced, nationally consistent reporting on transfusion-related adverse events at a national level.

During the year the HAC developed an outline of a consensus guideline on the recognition and management of acute transfusion reactions and events. The NBA anticipates developing this document in 2013 in collaboration with external experts.

The composition and functions of the HAC has changed significantly during the year:

- in addition to fresh blood products, future Australian haemovigilance reports will include information on adverse events associated with clotting factors and other blood products. This data has become available as a result of the redevelopment of the ABDR as a module of BloodNet and after reaching agreement with the AHCDO
- the committee will give more guidance on the direction, priorities and activities to reduce adverse events, including for clotting factors and other non-fresh blood products
- the membership of the committee will be adjusted to include expertise on clotting factors and issues relevant to the haemophilia community.

The next biennial Australian Haemovigilance Report will be published during 2012–13.

CLINICAL GOVERNANCE OF IVIG

The group responsible for the review of the Criteria identified the following issues during the review process:

- significant variations in prescribing practice for some clinical indications
- insufficient evidence for many indications
- insufficient quality research evidence in relation to dosing, in particular adjusted body weight dosing and dose requirements for subcutaneous administration
- a national governance strategy to manage requests for indications not currently listed in the Criteria
- emerging indications in the literature that may have a significant impact, e.g. Alzheimer's disease (see pages 70, 73 and 75)
- the management approach for managing subcutaneous and normal immunoglobulins under the Criteria.

We have recognised the value of this expert advice from the working group, and the JBC has approved the establishment of an NBA immunoglobulin clinical advisory committee. In addition to responding to clinical queries arising during the transition to the second edition of the Criteria, this committee will also provide expert clinical input to the review of the authorisation and clinical governance framework for IVIg (see pages 76–77).

NETWORKS AND COMMUNICATION

Since commencing a guidelines and clinical development program in 2006, the NBA has established a wide network of clinicians who provide expert advice to guide NBA initiatives.

These key advisors often represented colleges and societies and act as champions to communicate evidence-based recommendations arising from the guideline development process. These key experts have provided numerous presentations to clinical audiences in both Australia and overseas.

However, the NBA recognises the need to further develop and support clinical practice networks to enhance the effectiveness of initiatives to translate evidence into practice in the clinical setting. This is a key area for development into the future.

With the appointment of a new General Manager, greater emphasis is being placed on the NBA's communications function to support the implementation of clinical and other quality improvement initiatives.

QUALITY IMPROVEMENT INITIATIVES

Priorities for action identified at WHO's Global Forum for Blood Safety: Patient Blood Management was held in March 2011 and included adopting a patient-centric focus to diagnosis and treatment at the hospital level. The forum also encouraged governments to develop national guidelines and a multidisciplinary approach to PBM. The implementation of PBM in the hospital environment is an effective mechanism to implement most of the initiatives described in this report.

PATIENT BLOOD MANAGEMENT

Internationally, hospitals that have introduced PBM practices have reported significant health care savings and improved patient outcomes. In Western Australia, where initial steps have been made to introduce PBM practices, a reduced demand for red cells has been found in the pilot institution.

In 2009 a national patient blood management steering committee, now the Patient Blood Management Committee (PBMC), was established to assist governments in setting priorities and monitor the ways in which PBM initiatives could be implemented.

During 2011–12 we worked on various projects:

- at a workshop held in May 2011 the JBC had supported a nationally coordinated approach to PBM and considered ways in which this could be achieved. At the beginning of 2011–12 jurisdictions commenced a gap analysis on the extent and nature of PBM activities. Later in the year an independent consultant was engaged to synthesise the various analyses and formulate recommendations. JBC will consider these during 2012–13; ensuring sustainability will be a particular issue
- work commenced on a PBM toolkit. The first elements of the toolkit will be a 'How to guide', patient consent materials, and an exemplar transfusion ordering and consent form. The WA Health Department is developing the first of these, which will include a wide range of materials and guidance information to assist in implementing PBM at the local level. Feedback has been sought from the PBMC and the PBM Perioperative Module Clinical Reference Group to assist in developing the material
- the Anaemia Management Working Group organised a workshop on intravenous iron which was held in March 2012. Testing patients' haemoglobin levels and if necessary treating them with iron prior to surgery (particularly surgery where blood loss is anticipated) can help to reduce the need for blood transfusions during and after surgery. Treating low haemoglobin levels with iron is considered by many to be a safer option than red blood cell transfusion. The objectives of the workshop were to:
  - identify best practice use of intravenous iron and strategies to increase awareness of best practice
  - consider what intravenous iron products are available in Australia, and identify other potential intravenous iron products currently available internationally
  - identify the gaps in access to intravenous iron in Australia
  - review the limitations and barriers to using intravenous iron products in clinical practice.

The workshop was well attended by clinicians, pharmacists, nurses and government representatives with an interest in intravenous iron. We are preparing a discussion paper containing the outcomes of the workshop, for consideration by governments.

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PART 6

CORPORATE MANAGEMENT

6

CORPORATE MANAGEMENT

GOVERNANCE

PLANNING AND SERVICE DELIVERY

PEOPLE MANAGEMENT

GOVERNANCE

STRUCTURE

During 2011–12 the NBA senior executive management team comprised the following:

- General Manager and Chief Executive Officer:
  1 July—17 August 2011—Dr Alison Turner
  18 August 2011—2 April 2012—Ms Stephanie Gunn (Acting)
  27 March—30 June 2012—Mr Leigh McJames
- Deputy General Manager—3 April—23 May 2012—Ms Stephanie Gunn
- Principal Medical Officer, Dr Chris Hogan (resigned 16 January 2012)
- Deputy General Manager, Sector Coordination, Systems and Corporate
  1 July—17 August 2011—Ms Stephanie Gunn
  22 August 2011—23 May 2012—Mr Geoff Haberfield
- Acting Deputy General Manager, Fresh Blood and Clinical Development, Ms Sandra Cochrane
- General Counsel and Deputy General Manager, Commercial Contracts, Mr Michael Stone.

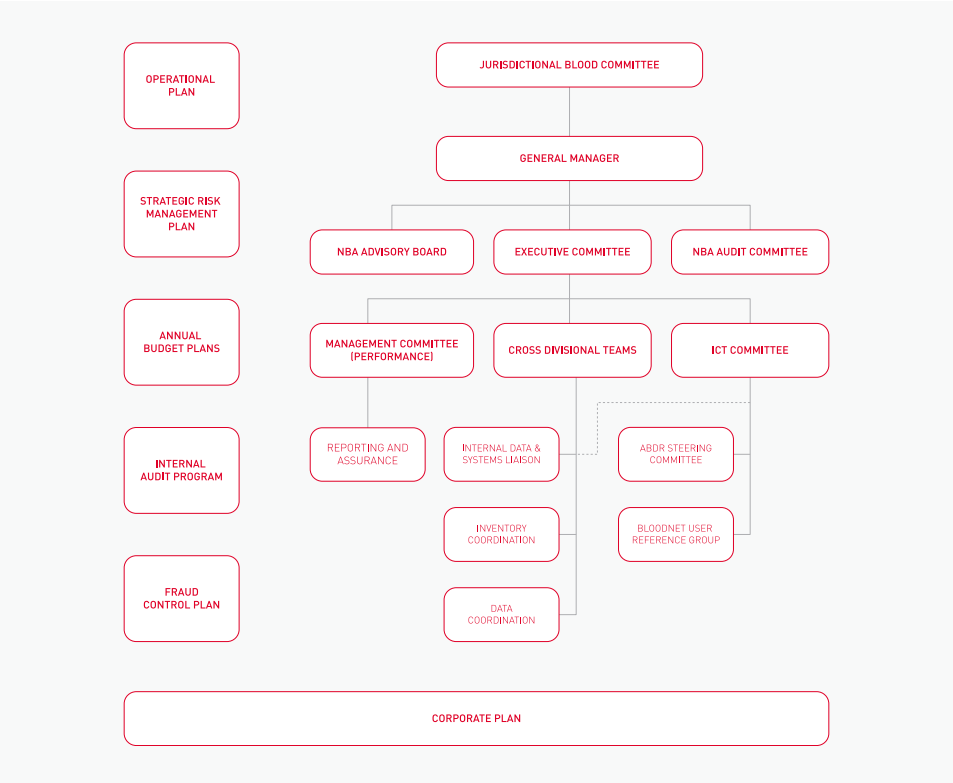


FIGURE 6.1 *NBA's governance structure at 30 June 2012*

GOVERNANCE COMMITTEES

Three formal governance committees—the Senior Executive Managers' Committee, the Executive Managers' Committee and the Audit Committee—help the NBA executive plan and manage core strategic projects and stakeholder concerns. See **Appendix 8 f**or further details.

The committees are actively involved in:

- maintaining our rigour in reporting and measuring performance against our operational plan
- improving our focus on internal and external performance indicators
- driving strategies, concepts and ideas for continual improvement.

In addition, the NBA has five formal cross-team functional committees to provide opportunities for staff to discuss strategies, issues, and processes and share experiences on issues of common relevance. These cross-team functional committees are a key element in our internal knowledge network, ensuring that work priorities and models relating to demand forecasting and coordination, inventory and supply, IVIg, and data processing and internal systems are effectively linked and prioritised to best meet internal and external priorities.

AUDIT COMMITTEE

The Audit Committee's work program progressed well during 2011–12. The committee met six times in 2011–12. Activities included:

- providing an overview of the effectiveness of the NBA control framework including consideration of testing against the business continuity plan, fraud risk management plan and risk against the risk management plans of projects
- providing advice on financial management, risk management, the Fraud Control Plan and accountability issues
- reviewing and making recommendations on the development of the internal audit work program and monitoring the progress of implementation activities to address findings
- reviewing and making minor recommendations to the General Manager on the 2010–11 annual financial statements
- reviewing and making recommendations to the General Manager on the Certificate of Compliance
- reviewing and providing advice on the Strategic Risk Management Plan
- the NBA is currently undertaking an assurance mapping exercise that will provide a framework to better target assurance activities which will ensure that risks are adequately monitored and controlled.

INTERNAL AUDIT

The NBA's internal audit program, guided by the Audit Committee, plays a key part in ensuring that risk is managed appropriately.

A review of the NBA's policies and procedures for the verification of goods ordering and receipting was completed in November 2010. The NBA continues to update its procedures to ensure a comprehensive accountability framework for contracts.

The internal auditor conducted a review of the controls, processes and general governance surrounding receipting and payments within the NBA.

The review identified that, with the addition of an extra staff member in the Finance team, that there was adequate segregation of duties in place in relation to key sign-off processes and delegations when key staff within the Finance team are not available.

The review recommended minor changes to strengthen the control environment, thus bringing the NBA in line with best practice. The NBA has adopted these processes.

RISK MANAGEMENT

The NBA's governance framework integrates risk management considerations into all of its planning activities, including:

- development of an annual strategic risk management plan—assessed against corporate plan objectives and specific annual priorities
- a six-monthly review of the strategic risk management plan by the Executive Managers' Committee
- development of detailed actions within the annual operational plan to address core risks
- monthly reporting to the Executive Managers' Committee against the operational plan and on the status of core risks
- regular reporting to the NBA Board on the operational plan and the status of core risks.

The NBA has prepared its strategic risk management plan for 2012–13. The plan identifies key risks that could impact on the ability of the NBA to deliver a safe and secure blood supply. Both the NBA Board and the Audit Committee will provide input into the draft plan which is expected to be finalised in the second half of 2012.

The NBA participated in the 2012 Comcover Risk Management Benchmarking Survey and received a benchmarking score of 6.9 out of a possible 10. This benchmarking score places the NBA at a 'Top Down' maturity level. The average score achieved by all participating agencies was 6.59 out of 10. The survey identified the areas of greatest strength for the NBA's risk management capabilities, including risk management policy and objectives, integration and accountability and responsibility. The NBA will strive for further improvement by focusing on risk assessment, risk profiling and resourcing.

Fraud Control Plan

The *Commonwealth Fraud Control Guidelines* require agencies to conduct a fraud risk assessment and develop a fraud control plan every two years.

During 2010—2012, in accordance with these guidelines, the NBA updated its fraud risk assessment and fraud control plan. No significant new risks to the NBA were identified and a strong control environment remains in operation. In addition, as part of this update, fraud awareness training was conducted with NBA staff.

Under the current fraud control plan, the NBA continually monitors accountability and control frameworks to meet the specific needs of the agency, and ensures that it complies with the *Commonwealth Fraud Control Guidelines*.

No instances of fraud were detected during the reporting year.

Relationship with external auditors

The NBA acknowledges the assistance provided by its external auditors, the ANAO, in 2011–12. This assistance enabled the NBA to ensure compliance and appropriate accountability and to identify scope for continual improvement in our activities.

ANAO Performance Audit: the NBA's Management of the National Blood Supply

The ANAO completed its performance audit of NBA activities. The objective of the 2010–11 audit was to assess whether the NBA's governance and contractual arrangements are effective in ensuring sufficient blood supply and services. The audit was presented to Parliament on 12 October 2011.

The report identified that the NBA had:

- established organisational structures and processes which allow the agency to carry out its governance arrangements
- assumed a central role in the national coordination of blood through annual supply planning activities and contracting to purchase blood products and services
- advanced a range of activities to improve the efficiency and effectiveness of the blood sector
- carried out its key role of securing the national supply of blood and blood products through effective governance and contractual arrangements.

The ANAO made five recommendations to strengthen the NBA's administration of the blood supply program. The recommendations emphasise the importance of clear priority setting, stakeholder engagement, and sound contract management in defining and measuring program effectiveness.

The NBA welcomed the timely release of the report and the focus of the recommendations on encouraging further blood sector efficiency. However, we also noted that there are a number of recommendations for which the NBA does not have sole responsibility and depend on cooperation of jurisdictions and the public and private health sectors. Work on the recommendations outlined in the report is underway.

Other external scrutiny

There were no judicial decisions or decisions of administrative tribunals that impacted on the operations of the NBA during 2011–12. There were no reports of the agency by a Parliamentary committee or the Commonwealth Ombudsman.

PLANNING AND SERVICE DELIVERY

OPERATIONAL PLANNING

In 2011–12, the NBA delivered 87 per cent of activities against the planned outcomes. Table 6.1 demonstrates the overall trend in the NBA's delivery against our operational plans over the past five years.

TABLE 6.1 *NBA's performance in achieving objectives of its operational plans, 2007–08 to 2011–12*

YEAR	2007–08	2008–09	2009–10	2010–11	2011–12
Performance (%)	81%	95%	91%	84%	87%

Good progress was made in all non-completed items, but several milestones were not met. The delays were not significant for external stakeholders as they related to objectives set for internal procedures in pursuit of continuous improvement.

The 2012–13 operational plan

The NBA commenced the development of the 2012–13 operational plan in June 2012. The plan will take into consideration the 2012–15 corporate plan which is still being finalised.

It is expected that the NBA will continue to focus on supply planning, professional contract negotiation and management, and strategies to increase the appropriateness of product use while increasing our effort on sector systems and data capture and analysis, and promoting the *Statement on National Stewardship Expectations for the Supply of Blood and Blood Products*.

CORPORATE

Secretariat

During 2011–12, the NBA provided secretariat services for five face-to-face meetings of the JBC. The secretariat implemented a number of procedural changes to address recommendations of the *Administrative Review of the National Blood Arrangements 2009*. All JBC members were satisfied with the quality and timeliness of support provided.

A total of 98.88 per cent of papers prepared by the NBA were provided to the JBC at least seven days before the meetings and 96.6 per cent of recommendations in the NBA papers were agreed by the JBC.

Secretariat services were also provided to the NBA Board, which met five times during 2011–12. All NBA Board meetings were held in Canberra.

Customer Service Charter

The NBA is committed to providing a professional, high quality and efficient service to clients, stakeholders and the general public, in accordance with the *Public Service Act 1999*. Our roles and responsibilities in dealing with external clients, and their rights in dealing with us, are described in the NBA Customer Service Charter, which was developed in early 2007.

During the year the NBA received two feedback responses through this link, both commenting positively on NBA initiatives. The Customer Service Charter is available on the NBA website at www.nba.gov.au/feedback.html.

PEOPLE MANAGEMENT

OUR VALUES

The NBA strongly endorses the Australian Public Service Code of Conduct and has a high expectation of ethical conduct from all staff. The NBA has four values that are central to our workplace. We:

- actively listen, think and encourage engagement
- criticise sparingly, praise generously
- are part of the team
- take responsibility for quality outcomes.

We implement these by explicit commitment to the behaviours that we value.
These behaviours mean that we:

- take responsibility for our outcomes by proactively analysing issues and creating solutions
- encourage ongoing personal development by taking pride in learning and sharing this learning with our teams and do things smarter and better
- seek to always understand by listening to and valuing all points of view
- are courteous by being on time, polite, accepting and giving feedback on performance and behaviour
- act on things that make a difference by striving for personal leadership in our assigned tasks and ensuring we understand the links of today's tasks to the future of the sector.

STAFFING

Staffing profile

The total number of staff employed in the NBA rose from 50 in 2010–11 to 56 at the end of June 2012, although, of these, three people were on long-term leave without pay. Table 6.2 provides a breakdown of NBA staff numbers by classification, gender and employment type.

TABLE 6.2 *Number of NBA staff at 30 June 2012*

SUBSTANTIVE ROLE CLASSIFICATION	FEMALE (FULL-TIME)	FEMALE (PART-TIME)	MALE (FULL-TIME)	MALE (PART-TIME)	TOTAL
Statutory Office Holder			1		1
Senior Executive Service	1*		2		3
Health Economist		1			1
Principal Medical Officer					0
EL 2	3	1	7*		11
EL1 Legal		2			2
EL 1	10		9		19
APS 6	7*		1		8
APS 5	6	1	1		8
APS 4	1	1			2
APS 3		1			1
TOTAL	**28**	**7**	**21**	**0**	**56**

* Three employees on long-term leave without pay

Workforce planning, staff turnover and retention

Staff turnover in 2011–12 was 22.5 per cent, with 44 per cent of separations in 2011–12 being as a result of resignation or retirement.

The average length of service for NBA staff is approximately two years and nine months. Over thirty per cent of staff have been employed by the NBA for more than four years.

During the reporting period, the NBA experienced a period of change with the retirement of Dr Alison Turner in August 2011 who was the NBA's General Manager since its inception in 2003, and the appointment of Mr Leigh McJames in April 2012.

Several staff members recruited this year, including Leigh McJames, have brought valuable experience gained in the hospital sector to the NBA. On page 107 we showcase how the expertise of one of these is being mobilised to improve the management of fresh blood components across Australia.

Staff satisfaction

A staff satisfaction survey was conducted in April 2011 and continues to be relevant in enabling the NBA to fulfill its the core objectives.

The results of the survey showed that there are many areas where the organisation is performing strongly which resulted in increased satisfaction rates. Staff feel that their work is interesting and challenging, that the NBA is a good place to work and, overall they have a sense of pride in working for the NBA. Staff have sufficient autonomy and access to the equipment they need. Furthermore, staff understand their role in the NBA within a strong, team-based environment and believe that their managers are knowledgeable, responsive to problems and sensitive to family responsibilities.

NBA FOCUS
AUGMENTING EXPERTISE
––
PROJECT ANALYST APPOINTMENT
INVENTORY MANAGEMENT
––
CANBERRA ACT

NBA RECRUITS HOSPITAL SCIENTIST TO IMPROVE HOW AUSTRALIA MANAGES BLOOD

The National Blood Authority actively recruits people who have direct experience in the hospital sector. This is done to ensure that NBA policies and projects are workable for those delivering health care across Australia.

One new appointment to the NBA in 2012 was the former Chief Scientist of the Canberra Hospital's Transfusion laboratory, Ms Joanne Cameron.

Ms Cameron spent eleven years at a private pathology service, Capital Pathology, followed by nine years at ACT Pathology at the Canberra Hospital, enabling her to gain an extensive understanding of the way blood is used in hospitals. Making the switch from a hospital setting to the NBA has allowed Ms Cameron to continue her work in determining how best to manage blood stocks.

'Working in a public hospital, you are conscious that you have to be responsible for appropriate use of blood, to make good choices, remembering that it is a precious resource,' she said. 'You are constantly trying to manage stock levels so you are not being wasteful, but at the same time not running out. That was a big personal challenge for me at the hospital—to get the inventory right.'

Ms Cameron was therefore a logical choice for the NBA to appoint as Senior Project Analyst for the National Inventory Management Framework project aimed at helping hospitals keep adequate levels of blood in stock while minimising waste.

The project is a collaboration between the NBA and the Blood Service and through this project Ms Cameron will help develop effective inventory management guidelines including appropriate stock levels, storage, handling, capacity, training, education, systems and processes that can help clinicians, nurses and scientists working in hospitals to use blood efficiently.

In 2011–12, the project team has focussed on developing a proof of concept for the framework design. The plan is to test this at a hospital in late 2012, with a view to piloting the framework across a broader selection of health care providers in 2013.

'Helping hospitals to get the inventory right is really close to my heart, because I know it's hard to do,' Ms Cameron said. 'I see a big role for the NBA in helping to give people more structure around how to do this well.'

Explaining how this project fits in with her previous career, Ms Cameron said: 'I get to do what I was doing in my hospitals, but now I get to do it for the whole country.'

Caption: Jo Cameron examines BloodNet data to investigate how blood product inventory is being managed

The staff participation forum continues to provide a good representation of the views of employees and is responsible for identifying issues, shaping policies and keeping the executive team informed of staff views and ideas. The forum has played an important role in providing input to the development of various human resources policies, raising awareness of workplace health and safety obligations, and monitoring the activities of the social club.

FEATURES OF EMPLOYMENT TOOLS

Employment tools

Table 6.3 shows numbers of NBA employees covered by the *National Blood Authority Enterprise Agreement 2011–14* (the EA), Common Law agreements, and section 24 determinations, at 30 June 2012.

TABLE 6.3 *Numbers of NBA staff on types of employment agreements*

STAFF	ENTERPRISE AGREEMENT	COMMON LAW OR SECTION 24 AGREEMENT
SES	Nil	2
Non–SES	53	Nil

NBA Enterprise Agreement

The current EA was approved on 24 June 2011. However, relevant salary increases did not take effect until 1 July 2011. Table 6.4 provides detail of the classification against salary levels.

TABLE 6.4 *Salary levels of NBA staff at 30 June 2012*

CLASSIFICATION	MINIMUM	MAXIMUM
Executive Level 2	105,266	118,600
Executive Level 1	88,580	100,605
EL1 Legal	88,197	106,784
APS Level 6	71,768	80,964
APS Level 5	65,057	68,664
APS Level 4	59,813	63,202
APS Level 3	52,793	58,519

Non–salary benefits

The EA and other employment arrangements provide a range of non-salary benefits in addition to those consistent with national employment standards and the *Fair Work Act 2009*. The benefits provided are similar to those provided by many other agencies. They are detailed in the EA, which is available on the NBA website. In summary the benefits are as follows:

For non-SES staff:

- access to the Employee Assistance Program
- maternity and adoption leave
- parental leave
- leave for compassionate purposes
- access to leave accruals at half pay
- flex-time (for APS level employees)
- flexible working arrangements with time off in lieu where appropriate, including recognition of travel time
- access to laptop computers and mobile phones (not all employees)
- support for professional and personal development
- provision of eyesight testing and reimbursement of prescribed eyewear costs specifically for use with screen-based equipment
- access to the NBA's health and fitness promotion program
- influenza vaccinations for staff and families
- annual Christmas close-down.

For SES staff and others on common law agreements or section 24 determinations:

- all the forgoing benefits except flex-time
- car parking (not all officers)
- airport lounge membership (not all officers)
- vehicle allowance.

Remuneration and performance pay

Total remuneration for senior executive officers is determined through negotiation between individual officers and the General Manager, taking into account Australian Public Service benchmarking data. Performance pay is not applicable.

PROFESSIONAL AND PERSONAL DEVELOPMENT

The NBA offers a wide range of training programs to staff so they can extend their knowledge and skills. In addition, the skill survey undertaken in 2010–11 continues to be relevant and highlighted a number of high, medium and low priorities in training for the NBA during 2011–12.

An important vehicle for professional development at the NBA is the individual personal development plan for employees. Personal development plans help the NBA to meet the objectives of our operational plan by focusing on what individual staff members must deliver in order to meet goals outlined in the plan.

The NBA attaches high priority to ensuring that staff develop their skills through sourced internal training, our Knowledge Management Forums, and/or through external training such as conferences, seminars, accredited training organisations and learning institutions. Performance against training targets is measured internally and reported to the NBA Board.

The regular NBA Knowledge Management Forums provide staff with the opportunity to increase their understanding on a wide range of subjects. There are annual Knowledge Management Forums that are mandatory in order for the NBA to meet its obligations, including sessions on APS values, conflict of interest, record-keeping, chief executive instructions and fraud and security guidelines. In addition, the NBA has been fortunate to have a number of Australian and international speakers present on blood related issues. Highlights of the year's program included presentations by:

- Dr Robert Flower, the Blood Service—current status of arbovirus concerns
- Mr Matt Riordan, Vice President—Asia Pacific, Turkey and South Africa, and Tor-Einar Svae, Corporate Medical Science Liaison Director, Octapharma—an update on Octagam
- Ms Jennifer Williams, CEO, the Blood Service—the Blood Service's year in review
- Mr Eric Buenz, Director, Global Therapy Awareness and Medical Affairs, CaridianBCT— The scientific rationale and medical literature supporting therapeutic plasma exchange as an alternative to immunoglobulin
- Ms Trudi Gallagher, State Clinical Nurse Coordinator (WA) — PBM program
- Dr Prasad Mathew, Bayer— inhibitor issues in the UK and the Aledort paper
- Dr Margaret Banks, Senior Programs Advisor, Australian Commission on Safety and Quality in Health Care — NSQHS standards
- Dr Simon Towler, Medical Advisor, Blood and Technology, Office of the Chief Medical Officer, WA Department of Health— on PBM.

The NBA would like to thank presenters for their time and effort in educating our staff.

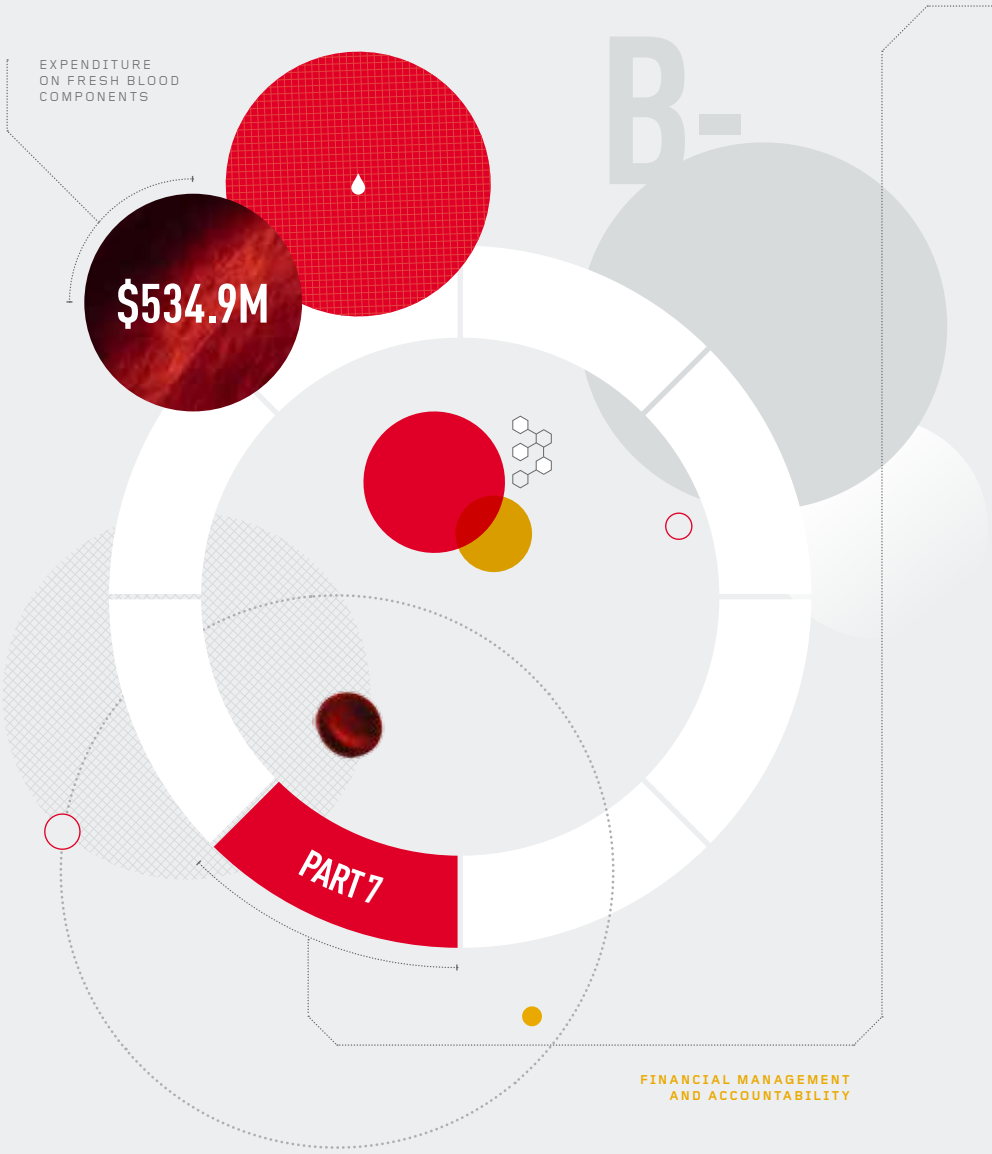
STAFF CONTRIBUTIONS AND ACTIVITIES

The NBA places great emphasis on its people and recognises the value of encouraging a work environment that supports the health and fitness of its employees.

During 2011–12, the NBA Health and Fitness Promotion Program continued. The objectives of the program are to:

- encourage all employees to improve their overall level of health and well-being, encouraging them to continue an activity relevant to their health needs or to undertake one in addition to what they do on a regular basis
- support and cultivate a philosophy of promoting good health in addition to meeting our legislative responsibilities as an employer.

Staff were also offered the opportunity to participate in a range of small, targeted activities throughout the year, including fitness and contributions to a range of community causes and donation of blood to the Blood Service.



FINANCIAL MANAGEMENT
AND ACCOUNTABILITY

7

FINANCIAL MANAGEMENT AND ACCOUNTABILITY

BUDGET AND FINANCIAL MANAGEMENT

PURCHASING

ASSET MANAGEMENT

FINANCIAL STATEMENTS

BUDGET AND FINANCIAL MANAGEMENT

This part provides an overview of the NBA's financial management and outcome in 2011–12.

FUNDING

The functions of the NBA are outlined in the *National Blood Authority Act 2003* and the National Blood Agreement. As a material statutory agency, the NBA has a range of corporate and compliance responsibilities under the *National Blood Authority Act 2003*, the *Financial Management and Accountability Act 1997*, and the *Public Service Act 1999*, along with a responsibility to meet ministerial, parliamentary and financial reporting requirements.

Under the National Blood Agreement between the Australian Government and the states and territories, 63 per cent of NBA funding is provided by the Australian Government and the remaining 37 per cent is provided by the state and territory governments. The funding covers both the national blood supply and the operations of the NBA.

SPECIAL ACCOUNTS

The NBA operates through two special accounts, the National Blood Account and the National Managed Fund (Blood and Blood Products) Special Account.

Special accounts are held in the Consolidated Revenue Fund and are used for setting aside and recording amounts to be used for specified purposes. Funding received from the Australian Government and the states and territories is held within the special accounts and expended as required.

Funding for the supply of blood and blood products and the operation of the NBA is included in the National Blood Account, established under section 40 of the *National Blood Authority Act 2003*.

The NMF (Blood and Blood Products) Special Account was established under section 20 of the *Financial Management and Accountability Act 1997* to accumulate funds required to meet potential product liability claims against the Blood Service. Contributions to the account are made by all governments and the Blood Service. In addition, interest is received on special account balances.

For budgeting and accounting purposes, the NBA's financial transactions are classified as either departmental or administered revenues or expenses:

- assets, liabilities, revenues and expenses controlled by the NBA for its operations are classified as departmental revenues and expenses
- activities and expenses controlled or incurred by the NBA on behalf of governments, mainly for the procurement of the requested products and services, are classified as administered revenues and expenses.

Transactions in the National Blood Account are separated into departmental and administered components. All balances in the NMF (Blood and Blood Products) Special Account are administered funds.

The NBA's agency resource statement and total resources for outcome tables are given in **Appendix 3**. Table 7.1 summarises the NBA's revenue and expenditure for 2011–12.

TABLE 7.1 *Overall funding and expenditure for the NBA in 2011–12: a summary*

	FUNDING INCL. APPROPRIATIONS ($M)	EXPENDITURE ($M)
Departmental—NBA Operations	9.716	10.380
Administered—national blood and blood product supply	1,034.910	955.884

OVERVIEW OF FINANCIAL PERFORMANCE IN 2011–12

This section provides a summary of the NBA's financial performance for 2011–12. Details of departmental and administered results are shown in the audited financial statements (see pages 122–173), and this summary should be read in conjunction with those statements.

Audit report

The NBA received an unqualified audit report for 2011–12.

Departmental finances

The NBA's departmental finances cover the NBA's operations.

Funding for the NBA since 2005–06 has been provided to build capacity, particularly for risk management, appropriate PBM and the safe use of blood and blood products.

Although all planned initiatives in these areas were well under way, several factors caused delays in implementation. As a result, funds provided for these initiatives were not fully spent in earlier years.

As foreshadowed in last year's annual report, in 2011–12 the unspent funds were drawn on to meet the staffing and other costs of completing these initiatives, and thus an operating deficit was incurred. The deficit was approved by the Minister for Finance and Deregulation.

Staffing and other costs will be managed to match the level of funding provided for 2012–13.

Operating result

The NBA's income statement reports a 2011–12 operating deficit of $0.664 million, compared with an operating surplus of $0.238 million in 2010–11. Table 7.2 shows the key results for the period 2008–09 to 2011–12.

TABLE 7.2 *Key results in financial performance, 2008–09 to 2011–12*

REVENUE AND EXPENSES	2011–12 ($M)	2010–11 ($M)	2009–10 ($M)	2008–09 ($M)
Contributions from the Australian Government	5.686	5.948	5.712	5.865
Contributions from States and Territories and other revenue	4.030	4.074	3.812	3.989
TOTAL REVENUE	**9.716**	**10.022**	**9.524**	**9.854**
Employee expenses	6.776	5.869	5.636	6.162
Supplier expenses	2.840	3.114	2.677	2.709
Other expenses	0.764	0.801	1.162	0.878
TOTAL EXPENSES	**10.380**	**9.784**	**9.475**	**9.749**
OPERATING RESULT	**(0.664)**	**0.238**	**0.049**	**0.105**

Income statement

Revenue

Total departmental revenue received in 2011–12 amounted to $9.716 million: $5.686 million in funding from the Australian Government; $3.936 million in contributions received from the states and territories and other revenue; and $0.094 million for resources received free of charge. This represents a decrease of $0.306 million (-3.1 per cent) on revenue received in 2010–11. Other revenue refers to contributions arising from officers transferring from other agencies and the use of funds provided in earlier years for specific projects.

Expenses

The NBA's expenses for 2011–12 amounted to $10.380 million, six per cent higher than in 2010–11.

Balance sheet

Details of the NBA's assets and liabilities are presented in the audited financial statements in this report.

Financial assets

The NBA held cash of $0.030 million at 30 June 2012. Funds received from all jurisdictions are transferred to the Official Public Account held by the Department of Finance and Deregulation until required for expenditure. In the NBA's financial statements these funds are classified as a receivable.

Non-financial assets

The reduction in the carrying amount of non-financial assets largely results from the depreciation of infrastructure and plant and equipment, particularly information technology equipment and furniture and fittings.

Payables

Payables to suppliers and other payables decreased by $1.129 million, down from $1.9 million in 2011.

Provisions

Employee provisions, which cover annual and long service leave entitlements, remained constant at $1.2 million.

Administered finances

On behalf of the Australian Government, the NBA manages and coordinates the Australian blood supply in accordance with the National Blood Agreement between the Australian Government and state and territory governments. This includes negotiating and managing national contracts with suppliers of blood and blood products on behalf of all governments.

The NBA administered finances include contributions from all states and territories and the Australian Government for the supply of blood and blood products. Each year the SCoH approves an annual NSP&B, which is formulated by the NBA from demand estimates provided by the states and territories.

A key contributor to the surplus generated on administered schedule of comprehensive income was the continued improvements in value for money through its purchasing activities for blood and blood products: new contracts for imported plasma-derived and recombinant clotting factor products commenced in July 2011, generated net savings of $35.05 million. The Blood Service also delivered savings across its operations during 2011–12.

Revenue

Total revenue for 2011–12 is presented in Table 7.3. Because funding is provided to meet the cost of supplying blood and blood products, the increase of $76.4 million in funding (eight per cent, the same as last year) for the current financial year reflects the increasing demand for products and contractually agreed increases in prices.

TABLE 7.3 *Administered revenue, 2008–09 to 2011–12*

ADMINISTERED REVENUE	2011–12 ($M)	2010–11 ($M)	2009–10 ($M)	2008–09 ($M)
Funding for supply of blood and blood products	1,015.586	939.212	871.195	827.640
TOTAL ADMINISTERED REVENUES	**1,034.910**	**941.016**	**872.549**	**829.190**

Expenses

Table 7.4 shows the NBA's administered expenses for 2008–09 to 2011–12.

TABLE 7.4 *Key results of administered expenses, 2008–09 to 2011–12*

ADMINISTERED EXPENSE	2011–12 ($M)	2010–11 ($M)	2009–10 ($M)	2008–09 ($M)
Grants to the private sector—non-profit organisation	7.773	-	456.881	433.385
Rendering of goods and services—external entities	947.820	937.954	402.143	356.568
Other	0.291	0.310	0.128	3.103
TOTAL ADMINISTERED EXPENSES	**955.884**	**938.264**	**859.152**	**793.056**

Administered expenses for 2011–12 increased by 1.9 per cent over those for 2010–11. Total payments to commercial suppliers decreased by 0.1 per cent while payments to the Blood Service increased by six per cent.

Administered assets and liabilities

Administered assets comprise the following:

- funds held in the Official Public Account
- investments made in relation to the NMF
- Goods and Services Tax (GST) receipts from the Australian Taxation Office and payment to suppliers for products
- blood and blood product inventory held for distribution, including the national reserve of blood products
- a prepayment to the Blood Service as part of the transition to the OBFM.

Administered liabilities comprise payables to suppliers.

As a result of the surplus described above, net administered assets increased by $86.7 million during 2011–12.

PURCHASING

The NBA adheres to the Commonwealth Procurement Guidelines and Best Practice Guidance when undertaking procurements. The guidelines are applied to the NBA's activities through chief executive and management instructions and key business processes.

The NBA has developed business processes to ensure that the knowledge and best practices developed within the agency for our key purchasing activities are captured and made available to new staff and that relevant procedures and processes are documented and followed.

Over recent years several internal audit programs have tested these processes to ensure that they meet government policy and better practice. The audit findings have been consistently favourable in relation to complying with mandatory processes, but have also recommended opportunities to improve processes; these have been implemented.

The key business processes will be constantly reviewed and refined as part of the NBA's own requirement for continual improvement in the management of its core business functions.

The NBA used extension provisions to several current contracts, following a value for money assessment, and completed several small open source procurements, including:

- internal audit services
- systematic review services
- printing services.

The NBA has outsourced all air travel bookings. Government policy requires the NBA to obtain the 'lowest practical fare' for domestic travel and the 'best fare of the day' for international travel for NBA employees. From 1 July 2010, the NBA has been included in Australian Government whole-of-government air travel arrangements.

The NBA did not administer any discretionary grants during 2011–12.

Two funding agreements entered into with jurisdictions, using interest monies from administered funds approved by the JBC, continued in 2011–12. Information on these is available on the NBA website, www.nba.gov.au.

EXEMPT CONTRACTS

The General Manager did not issue any exemptions from the required publication if any contract or standing offer in the purchasing and disposal gazette.

COMPETITIVE TENDERING AND CONTRACTING

There were no contracts of $100,000 or more (inclusive of GST) let in 2011–12 that did not provide for the Auditor-General's access to the contractor's premises.

ADVERTISING AND MARKET RESEARCH

Section 311A of the *Commonwealth Electoral Act 1918* requires particulars of all amounts greater than $10,300 paid during a financial year to advertising agencies, market research organisations, polling organisations, direct mail organisations and media advertising organisations. The NBA made no payments of this kind in 2011–12.

CONSULTANTS

In 2011–12, fifteen new consultancy contracts were entered into, involving total actual expenditure of $630,277 (GST inclusive). In addition, five ongoing consultancy contracts were active during the year, involving actual expenditure of $1,393,674 (GST inclusive). Total expenditure on consultancies in 2011–12 was $2,023,951 (GST inclusive).

Annual reports contain information about actual expenditure on contracts for consultancies. Information on the value of contracts and consultancies is available on the AusTender website, www.tenders.gov.au.

The NBA engages consultants where it lacks specialist expertise or when independent research, review or assessment is required. Consultants are typically engaged to investigate or diagnose a defined issue or problem; carry out defined reviews or evaluations; or provide independent advice, information or creative solutions to assist in the NBA's decision-making.

Prior to engaging consultants, the NBA takes into account the skills and resources required for the task, the skills available internally, and the cost-effectiveness of engaging external expertise. The decision to engage a consultant is made in accordance with the *Financial Management and Accountability Act 1997* and related regulations including the Commonwealth Procurement Guidelines and relevant internal policies such as chief executive and management instructions and key business processes.

Standard form contracts are used. Where necessary, these documents are adapted to suit individual circumstances.

Table 7.5 shows total expenditure on all consultancy services from 2008–09 to 2011–12, covering both new contracts let in the applicable year and ongoing contracts let in previous years.

TABLE 7.5 *Expenditure on consultancy services, 2008–09 to 2011–12*

	NO. LET	TOTAL EXPENDITURE ON NEW AND EXISTING CONSULTANCIES ($)
2011–12	15	2,023,951
2010–11	9	1,399,091
2009–10	3	492,033
2008–09	14	997,076

ASSET MANAGEMENT

Physical assets are not a significant aspect of the NBA's strategic management. The NBA has developed an asset replacement strategy to ensure that it has adequate funding for the replacement of assets as these come to the end of their useful life. During 2011–12, the NBA undertook a refresh of its IT infrastructure.

FINANCIAL STATEMENTS

INDEPENDENT AUDITOR'S REPORT

To the Minister for Health and Ageing

I have audited the accompanying financial statements of the National Blood Authority for the year ended 30 June 2012, which comprise: a Statement by the Chief Executive and Chief Financial Officer; Statement of Comprehensive Income; Balance Sheet; Statement of Changes in Equity; Cash Flow Statement; Schedule of Commitments and Contingencies; Administered Schedule of Comprehensive Income; Administered Schedule of Assets and Liabilities; Administered Reconciliation Schedule; Administered Cash Flow Statement; Schedule of Administered Commitments; Schedule of Administered Contingencies; and Notes to and forming part of the Financial Statements, including a Summary of Significant Accounting Policies.

Chief Executive's Responsibility for the Financial Statements

The Chief Executive of the National Blood Authority is responsible for the preparation of financial statements that give a true and fair view in accordance with the Finance Minister's Orders made under the *Financial Management and Accountability Act 1997*, including the Australian Accounting Standards, and for such internal control as is necessary to enable the preparation of the financial statements that give a true and fair view and are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

My responsibility is to express an opinion on the financial statements based on my audit. I have conducted my audit in accordance with the Australian National Audit Office Auditing Standards, which incorporate the Australian Auditing Standards. These auditing standards require that I comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the National Blood Authority's preparation of the financial statements that give a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the National Blood Authority's internal control. An audit also includes valuating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made by the Chief Executive of the National Blood Authority, as well as evaluating the overall presentation of the financial statements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinion.

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19 National Circuit BARTON ACT
Phone (02) 6203 7300 Fax (02) 6203 7777

Independence

In conducting my audit, I have followed the independence requirements of the Australian National Audit Office, which incorporate the requirements of the Australian accounting profession.

Opinion

In my opinion, the financial statements of the National Blood Authority:

(a) have been prepared in accordance with the Finance Minister's Orders made under the *Financial Management and Accountability Act 1997,* including the Australian Accounting Standards; and

(b) give a true and fair view of the matters required by the Finance Minister's Orders including the National Blood Authority's financial position as at 30 June 2012 and of its financial performance and cash flows for the year then ended.

Australian National Audit Office

Kristian Gage
Audit Principal

Delegate of the Auditor-General

Canberra

7 August 2012

NATIONAL BLOOD AUTHORITY
FINANCIAL STATEMENTS
For the year ended 30 June 2012

Statement by the Chief Executive and Chief Financial Officer

In our opinion, the attached financial statements for the year ended 30 June 2012 are based on properly maintained financial records and give a true and fair view of the matters required by the Finance Minister's Orders made under the *Financial Management and Accountability Act 1997*, as amended.

Leigh McJames
Chief Executive Officer

7 August 2012

Ashley Jackson
Chief Financial Officer

7 August 2012

NATIONAL BLOOD AUTHORITY
STATEMENT OF COMPREHENSIVE INCOME
for the year ended 30 June 2012

	Notes	**2012** **$'000**	2011 $'000
EXPENSES			
Employee benefits	3A	**6 776**	5 869
Suppliers	3B	**2 840**	3 114
Depreciation and amortisation	3C	**751**	795
Losses from asset sales	3D	**13**	6
Total expenses		**10 380**	9 784
LESS:			
OWN-SOURCE INCOME			
Own-source revenue			
Sale of goods and rendering of services	4A	**232**	487
Other revenue	4B	**3 704**	3 493
Total own-source revenue		**3 936**	3 980
Gains			
Other gains	4C	**94**	94
Total gains		**94**	94
Total own-source income		**4 030**	4 074
Net cost of services		**6 350**	5 710
Revenue from Government	4D	**5 686**	5 948
Surplus (Deficit)		**(664)**	238
Total comprehensive income (loss)		**(664)**	238

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
BALANCE SHEET
as at 30 June 2012

	Notes	2012 $'000	2011 $'000
ASSETS			
Financial Assets			
Cash and cash equivalents	5A, 9	**30**	36
Trade and other receivables	5B	**7 993**	8 769
Total financial assets		**8 023**	8 805
Non-Financial Assets			
Leasehold improvements	6A, 6C	**-**	37
Property, plant and equipment	6B, 6C	**353**	334
Intangibles	6D, 6E	**837**	1 295
Other non-financial assets	6F	**87**	64
Total non-financial assets		**1 277**	1 730
Total assets		**9 300**	10 535
LIABILITIES			
Payables			
Suppliers	7A	**572**	427
Other payables	7B	**150**	1 424
Total payables		**722**	1 851
Provisions			
Employee provisions	8A	**1 217**	1 213
Total provisions		**1 217**	1 213
Total liabilities		**1 939**	3 064
Net assets		**7 361**	7 471
EQUITY			
Contributed equity		**1 366**	812
Reserves		**206**	206
Retained surplus		**5 789**	6 453
Total equity		**7 361**	7 471

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
STATEMENT OF CHANGES IN EQUITY
for the year ended 30 June 2012

	Retained earnings		Asset revaluation surplus		Contributed equity/capital		Total equity	
	2012 $'000	2011 $'000	**2012 $'000**	2011 $'000	**2012 $'000**	2011 $'000	**2012 $'000**	2011 $'000
Opening balance								
Balance carried forward from previous period	**6 453**	6 215	**206**	206	**812**	812	**7 471**	7 233
Adjusted opening balance	**6 453**	6 215	**206**	206	**812**	812	**7 471**	7 233
Comprehensive Income								
Surplus (Deficit) for the period	**(664)**	238	**-**	-	**-**	-	**(664)**	238
Total comprehensive income	**(664)**	238	**-**	-	**-**	-	**(664)**	238
Transactions with owners								
Contributions by owners								
Departmental capital budget	**-**	-	**-**	-	**554**	-	**554**	-
Sub-total transactions with owners	**-**	-	**-**	-	**554**	-	**554**	-
Closing balance as at 30 June	**5 789**	6 453	**206**	206	**1 366**	812	**7 361**	7 471

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
CASH FLOW STATMENT
for the year ended 30 June 2012

	Notes	2012 $'000	2011 $'000
OPERATING ACTIVITIES			
Cash received			
Appropriations		**4 940**	5 608
Sales of goods and rendering of services		**3 314**	3 933
Net GST received		**295**	366
Cash transferred from the Official Public Account		**1 314**	-
Total cash received		**9 863**	9 907
Cash used			
Employees		**6 298**	5 626
Suppliers		**3 421**	3 353
Section 31 receipts transferred to OPA		**47**	640
Total cash used		**9 766**	9 619
Net cash from operating activities	9	**97**	288
INVESTING ACTIVITIES			
Cash received			
Proceeds from sales of property, plant and equipment		**2**	-
Proceeds from sales of intangibles		**-**	24
Total cash received		**2**	24
Cash used			
Purchase of property, plant and equipment		**161**	188
Purchase of intangibles		**123**	298
Total cash used		**284**	486
Net cash (used by) investing activities		**(282)**	(462)
FINANCING ACTIVITIES			
Cash received			
Contributed equity - Departmental capital budget		**179**	-
Total cash received		**179**	-
Net cash from financing activities		**179**	-
Net increase (decrease) in cash held		**(6)**	(174)
Cash and cash equivalents at the beginning of the reporting period		**36**	210
Cash and cash equivalents at the end of the reporting period	5A	**30**	36

The above statement should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF COMMITMENTS AND CONTINGENCIES
as at 30 June 2012

	2012 $'000	2011 $'000
BY TYPE		
Commitments receivable		
Net GST recoverable on commitments	**167**	67
Total commitments receivable	**167**	67
Commitments payable		
Capital commitments		
Property, plant and equipment	**253**	-
Intangibles	**-**	1
Total capital commitments [1]	**253**	1
Other commitments		
Operating leases	**545**	164
Other	**1 043**	576
Total other commitments [2]	**1 588**	740
Net commitments by type	**1 674**	674
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**107**	67
From one to five years	**60**	-
Total other commitments receivable	**167**	67
Commitments payable		
Capital commitments		
One year or less	**253**	1
Total capital commitments [1]	**253**	1
Operating lease commitments		
One year or less	**414**	164
From one to five years	**131**	-
Total operating lease commitments	**545**	164
Other commitments		
One year or less	**514**	576
From one to five years	**529**	-
Total other commitments [2]	**1 043**	576
Net commitments by maturity	**1 674**	674

Note: Commitments are GST inclusive where relevant.

[1] The nature of capital commitments is procurement of IT hardware.

[2] Operating leases included are effectively non cancellable and comprise:

Canberra office - The current lease for office accommodation expires on 31 October 2013.
Melbourne office - The current lease for office accommodation expires on 30 November 2012.

QUANTIFIABLE CONTINGENCIES

None

Information on significant remote contingencies and contingencies that cannot be quantified is disclosed in Note 10: Contingent Assets and Liabilities.

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
ADMINISTERED SCHEDULE OF COMPREHENSIVE INCOME
for the year ended 30 June 2012

	Notes	2012 $'000	2011 $'000
EXPENSES			
Suppliers	15A	**947 820**	937 954
Grants	15B	**7 773**	-
Depreciation and amortisation	15C	**291**	310
Total expenses administered on behalf of Government		**955 884**	938 264
LESS:			
OWN-SOURCE INCOME			
Own-source revenue			
Non-taxation revenue			
Funding from governments	16A	**1 015 586**	939 212
Interest	16B	**4 801**	1 629
Other revenue	16C	**14 523**	175
Total own-source revenue administered on behalf of Government		**1 034 910**	941 016
Total own-source income administered on behalf of Government		**1 034 910**	941 016
Net (contribution by) services		**(79 026)**	(2 752)
Surplus		**79 026**	2 752
Total comprehensive income		**79 026**	2 752

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
ADMINISTERED SCHEDULE OF ASSETS AND LIABILITIES
as at 30 June 2012

	Notes	2012 $'000	2011 $'000
ASSETS			
Financial assets			
Cash and cash equivalents	17A, 20	**5 340**	41 157
Trade and other receivables	17B	**208 383**	147 848
Other investments	17C	**88 335**	40 611
Total financial assets		**302 058**	229 616
Non-financial assets			
Inventories	18A	**60 173**	55 024
Property, plant and equipment	18B	**404**	30
Intangibles	18D	**1 061**	371
Other non-financial assets	18F	**76 068**	75 401
Total non-financial assets		**137 706**	130 826
Total assets administered on behalf of Government		**439 764**	360 442
LIABILITIES			
Payables			
Suppliers	19A	**61 551**	68 934
Total payables		**61 551**	68 934
Total liabilities administered on behalf of Government		**61 551**	68 934
Net assets		**378 213**	291 508

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
ADMINISTERED RECONCILIATION SCHEDULE
as at 30 June 2012

	2012 $'000	2011 $'000
Opening administered assets less administered liabilities as at 1 July	**291 508**	283 006
Surplus (deficit) items:		
Plus: Administered income	**1 034 910**	941 016
Less: Administered expenses (non CAC)	**(955 884)**	(938 264)
Administered transfers to/from Australian Government:		
Appropriation transfers from OPA:		
Annual appropriations for administered expenses (non CAC)	**7 679**	5 750
Closing administered assets less administered liabilities as at 30 June	**378 213**	291 508

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
ADMINISTERED CASHFLOW STATEMENT
for the year ended 30 June 2012

	Notes	2012 $'000	2011 $'000
OPERATING ACTIVITIES			
Cash received			
Commonwealth contributions		**640 176**	591 889
State and territory contributions		**376 213**	347 323
Interest		**3 067**	546
Net GST received		**94 517**	96 682
Other		**15 975**	198
Total cash received		**1 129 948**	1 036 638
Cash used			
Grants		**8 551**	-
Suppliers		**1 058 418**	1 071 831
Total cash used		**1 066 969**	1 071 831
Net cash flows from (used by) operating activities	20	**62 979**	(35 193)
INVESTING ACTIVITIES			
Cash received			
Investments		**46 535**	-
Total cash received		**46 535**	-
Cash used			
Purchase of property, plant & equipment		**336**	36
Purchase of intangibles		**147**	230
Investments		**94 259**	40 611
Total cash used		**94 742**	40 877
Net cash flows (used by) investing activities		**(48 207)**	(40 877)
Net increase (decrease) in Cash Held		**14 772**	(76 070)
Cash and cash equivalents at the beginning of the reporting period		**41 157**	389
Cash from Official Public Account for:			
- Appropriations		**7 679**	5 750
- Special accounts		**1 176 715**	1 163 441
		1 184 394	1 169 191
Cash to Official Public Account for:			
- Special accounts		**1 234 983**	1 052 353
Cash and cash equivalents at the end of the reporting period	17A	**5,340**	41 157

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED COMMITMENTS
as at 30 June 2012

	2012 $'000	2011 $'000
BY TYPE		
Commitments receivable		
Net GST recoverable on commitments	**278 569**	275 254
Total commitments receivable	**278 569**	275 254
Commitments payable		
Capital commitments		
Intangibles	**-**	261
Total capital commitments [1]	**-**	261
Other commitments		
Other	**3 064 260**	3 027 529
Total other commitments [2]	**3 064 260**	3 027 529
Net commitments by type	**2 785 691**	2 752 536
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**106 635**	84 519
From one to five years	**150 500**	128 601
Over five years	**21 434**	62 134
Total other commitments receivable	**278 569**	275 254
Commitments payable		
Capital commitments		
One year or less	**-**	261
Total capital commitments [1]	**-**	261
Other commitments		
One year or less	**1 172 987**	929 449
From one to five years	**1 655 502**	1 414 610
Over five years	**235 771**	683 470
Total other commitments [2]	**3 064 260**	3 027 529
Net commitments by maturity	**2 785 691**	2 752 536

Note: All commitments are GST inclusive where relevant.

[1] Capital commitments relate to amounts payable under agreements or contracts for the development and maintenance of internally generated software in respect of which the supplier has yet to provide goods or services.

[2] Other commitments relate to amounts payable under agreements or contracts in respect of which the grantee or supplier has yet to provide goods or services for blood or blood related products required under the agreement or contract to meet demand under the National Supply Plan and Budget.

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED CONTINGENCIES
as at 30 June 2012

	2012 $'000	2011 $'000
Contingent assets		
Guarantees	-	-
Indemnities	-	-
Claims for damages or costs	-	-
Total contingent assets	-	-
Contingent liabilities		
Guarantees	-	-
Indemnities	**285 481**	-
Claims for damages or costs	-	-
Total contingent liabilities	**285 481**	-

The Deed of Indemnity between the Red Cross and the NBA indemnifies the Red Cross in relation to the Sydney Processing Centre (SPC) and the Melbourne Processing Centre (MPC) funding arrangements. If the SPC or MPC funding arrangements cease in respect of an SPC or MPC contract for any reason, the NBA indemnifies the Red Cross in respect of the liability of the Red Cross to make payments of a Funded Obligation, to the extent that the payments become due and payable under the terms of the SPC or MPC contract after the date when the Red Cross no longer has sufficient SPC or MPC funding to meet the funded obligations as a result of the cessation of the SPC or MPC funding.

Information on significant remote contingencies and contingencies that cannot be quantified is disclosed in Note 21: Administered - Contingent Assets and Liabilities.

The above schedule should be read in conjunction with the accompanying notes

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

NOTE 1 Summary of Significant Accounting Policies

1.1 Objectives of the National Blood Authority

The National Blood Authority (NBA) is an Australian Government statutory authority which was established on 1 July 2003 with the principal role of managing national blood arrangements, ensuring sufficient supply and providing a new focus on the quality and appropriateness of blood products.

The NBA is structured to meet one outcome:

> Outcome 1: Access to a secure supply of safe and affordable blood products, including through national supply arrangements and coordination of best practice standards within agreed funding policies under the national blood arrangements.

The continued existence of the NBA in its present form, and with its present programs, is dependent on Government policy, the enabling legislation *National Blood Authority Act 2003*, and on continuing funding by Parliament and contributions from States and Territories for the NBA's administration and programs.

NBA activities contributing to this outcome are classified as either departmental or administered. Departmental activities involve the use of assets, liabilities, income and expenses controlled or incurred by the NBA in its own right. Administered activities involve the management or oversight by the NBA, on behalf of the Government, of items controlled or incurred by the Government.

The NBA conducts the following administered activities on behalf of the Government:

Management and coordination of Australia's blood supply in accordance with the National Blood Agreement agreed by the Australian Government and the governments of the states and territories. Under this agreement, the Australian Government contributes 63 per cent of blood supply funding and state and territory governments provide 37 per cent.

The NBA operates under a special account – the National Blood Account. Revenues and expenses associated with the funding and supply of blood and blood products, as well as the operations of the NBA are recorded in this special account.

The NBA also operates a special account – the National Managed Fund (Blood and Blood Products) Special Account which is intended to meet potential blood and blood products liability claims against the Australian Red Cross Blood Service.

Details of planned activities for the year can be found in the Agency Portfolio Budget Statements for 2011-12 which have been tabled in Parliament.

1.2 Basis of Preparation of the Financial Statements

The financial statements are general purpose financial statements and are required by Section 49 of the *Financial Management and Accountability Act 1997*.

The financial statements have been prepared in accordance with:

- Finance Minister's Orders (FMOs) for reporting periods ending on or after 1 July 2011; and
- Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board (AASB) that apply for the reporting period.

The financial statements have been prepared on an accrual basis and in accordance with the historical cost convention, except for certain assets and liabilities at fair value. Except where stated, no allowance is made for the effect of changing prices on the results or the financial position.

The financial statements are presented in Australian dollars and values are rounded to the nearest thousand dollars unless otherwise specified.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

1.2 Basis of Preparation of the Financial Statements

Unless an alternative treatment is specifically required by an accounting standard or the FMOs, assets and liabilities are recognised in the balance sheet when and only when it is probable that future economic benefits will flow to the NBA or a future sacrifice of economic benefits will be required and the amounts of the assets or liabilities can be reliably measured. However, assets and liabilities arising under executor contracts are not recognised unless required by an accounting standard. Liabilities and assets that are unrecognised are reported in the schedule of commitments or the schedule of contingencies.

Unless alternative treatment is specifically required by an accounting standard, income and expenses are recognised in the Statement of Comprehensive Income when and only when the flow, consumption or loss of economic benefits has occurred and can be reliably measured.

1.3 Significant Accounting Judgments and Estimates

In the process of applying the accounting policies listed in this note, the NBA has made no judgements that have a significant impact on the amounts recorded in the financial statements.

No accounting assumptions or estimates have been identified that have a significant risk of causing a material adjustment to carrying amounts of assets and liabilities within the next reporting period.

1.4 New Australian Accounting Standards

Adoption of New Australian Accounting Standard Requirements
No accounting standard has been adopted earlier than the application date as stated in the standard.

All new standards, revised standards, interpretations and amending standards that were issued prior to the signing of the statement by the chief executive and chief financial officer and are applicable to the current reporting period did not have a material financial impact, and are not expected to have a future financial impact on the NBA.

Future Australian Accounting Standard Requirements
No new standards, revised standards, interpretations or amending standards were issued by the Australian Accounting Standards Board prior to the signing of the statement by the chief executive and chief financial officer, which are expected to have a financial impact on the NBA for future reporting periods.

1.5 Revenue

Revenue from the sale of goods is recognised when:

a) the risks and rewards of ownership have been transferred to the buyer;
b) the NBA retains no managerial involvement or effective control over the goods;
c) the revenue and transaction costs incurred can be reliably measured; and
d) it is probable that the economic benefits associated with the transaction will flow to the NBA.

Revenue from rendering of services is recognised by reference to the stage of completion of contracts at the reporting date. The revenue is recognised when:

a) the amount of revenue, stage of completion and transaction costs incurred can be reliably measured; and
b) the probable economic benefits associated with the transaction will flow to the NBA.

Funding from State and Territory governments is recognised by reference to the stage of completion of contracts at the reporting date. The revenue is recognised when:

a) the amount of revenue, stage of completion and transaction costs incurred can be reliably measured; and
b) the probable economic benefits with the transaction will flow to the NBA.

The stage of completion of contracts at the reporting date is determined by reference to services performed to date as a percentage of total services to be performed.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

Receivables for goods and services, which have 30 day terms, are recognised at the nominal amounts due less any impairment allowance account. Collectability of debts is reviewed at end of reporting period. Allowances are made when collectability of the debt is no longer probable.

Interest revenue is recognised using the effective interest method as set out in AASB 139 *Financial Instruments: Recognition and Measurement*.

Revenue from Government
Amounts appropriated for departmental appropriations for the year (adjusted for any formal additions and reductions) are recognised as Revenue from Government when the NBA gains control of the appropriation, except for certain amounts that relate to activities that are reciprocal in nature, in which case, revenue is recognised only when it has been earned. Appropriations receivable are recognised at their nominal amounts.

1.6 Gains

Resources Received Free of Charge
Resources received free of charge are recognised as gains when and only when a fair value can be reliably determined and the services would have been purchased if they had not been donated. Use of those resources is recognised as an expense.

Resources received free of charge are recorded as either revenue or gains depending on their nature.

Contributions of assets at no cost of acquisition or for nominal consideration are recognised as gains at their fair value when the asset qualifies for recognition, unless received from another Government entity as a consequence of a restructuring of administrative arrangements. (Refer to Note 1.7)

Sale of Assets
Gains from the disposal of assets are recognised when control of the asset has passed to the buyer.

1.7 Transactions with the Government as Owner

Equity Injections
Amounts appropriated which are designated as 'equity injections' for a year (less any formal reductions) and Departmental Capital Budgets (DCBs) are recognised directly in contributed equity.

Restructuring of Administrative Arrangements
Net assets received from or relinquished to another Australian Government entity under a restructuring of administrative arrangements are adjusted at their book value directly against contributed equity.

1.8 Employee Benefits

Liabilities for 'short term employee benefits' (as defined in AASB 119 *Employee Benefits*) and termination benefits due within twelve months of the end of reporting period are measured at their nominal amounts.

The nominal amount is calculated with regard to the rates expected to be paid on settlement of the liability.

Other long-term employee benefits are measured as net total of the present value of the defined benefit obligation at the end of the reporting period minus the fair value at the end of the reporting period of plan assets (if any) out of which the obligations are to be settled directly.

Leave

The liability for employee entitlements includes provision for annual leave and long service leave. No provision has been made for sick leave as all sick leave is non-vesting and the average sick leave taken in future years by employees of the NBA is estimated to be less than the annual entitlement for sick leave.

The leave liabilities are calculated on the basis of employees' remuneration at the estimated salary rates that will be applied at the time the leave is taken, including the NBA's employer superannuation contribution rates to the extent that the leave is likely to be taken during service rather than paid out on termination.

The liability for long service leave has been determined by reference to the work of an actuary as at 30 June 2012. The estimate of the present value of the liability takes into account attrition rates and pay increases through promotion and inflation.

Superannuation
The NBA's staff are members of the Commonwealth Superannuation Scheme (CSS), the Public Sector Superannuation Scheme (PSS), the PSS Accumulation Plan (PSSap), the Australian Government Employee Superannuation Trust (AGEST) or other non-government superannuation funds.

The CSS and PSS are defined benefit schemes for the Australian Government. The PSSap, AGEST and the non-government superannuation funds are defined contribution schemes.

The liability for defined benefits is recognised in the financial statements of the Australian Government and is settled by the Australian Government in due course. This liability is reported in the Department of Finance and Deregulation's administered schedules and notes.

The NBA makes employer contributions to the employees' superannuation scheme at rates determined by an actuary to be sufficient to meet the current cost to the Government. The NBA accounts for the contributions as if they were contributions to defined contribution plans.

The liability for superannuation recognised as at 30 June represents outstanding contributions as at 30 June 2012.

1.9 Leases

A distinction is made between finance leases and operating leases. Finance leases effectively transfer from the lessor to the lessee substantially all the risks and rewards incidental to ownership of leased assets. An operating lease is a lease that is not a finance lease. In operating leases, the lessor effectively retains substantially all such risks and benefits.

Where an asset is acquired by means of a finance lease, the asset is capitalised at either the fair value of the lease property or, if lower, the present value of minimum lease payments at the inception of the contract and a liability is recognised at the same time and for the same amount.

The discount rate used is the interest rate implicit in the lease. Leased assets are amortised over the period of the lease. Lease payments are allocated between the principal component and the interest expense.

Operating lease payments are expensed on a straight line basis which is representative of the pattern of benefits derived from the leased assets.

1.10 Cash

Cash is recognised at its nominal amount. Cash and cash equivalents includes:

a) cash on hand;
b) demand deposits in bank accounts with an original maturity of 3 months or less that are readily convertible to known amounts of cash and subject to insignificant risk of changes in value;
c) cash held by outsiders; and
d) cash in special accounts.

1.11 Financial Assets

The NBA classifies its financial assets in the following categories:

a) held-to-maturity investments; and
b) loans and receivables.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

The classification depends on the nature and purpose of the financial assets and is determined at the time of initial recognition. Financial assets are recognised and derecognised upon trade date.

Effective Interest Method
The effective interest method is a method of calculating the amortised cost of a financial asset and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset, or, where appropriate, a shorter period.

Income is recognised on an effective interest rate basis.

Held-to-Maturity Investments
Non derivative financial assets with fixed or determinable payments and fixed maturity dates that the NBA has the positive intent and ability to hold to maturity are classified as held-to-maturity investments. Held-to-maturity investments are recorded at amortised cost using the effective interest method less impairment, with revenue recognised on an effective yield basis.

Loans and Receivables
Trade receivables, loans and other receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'loans and receivables'. Loans and receivables are measured at amortised cost using the effective interest method less impairment. Interest is recognised by applying the effective interest rate.

Impairment of Financial Assets
Financial assets are assessed for impairment at each balance date.

Financial assets held at amortised cost - if there is objective evidence that an impairment loss has been incurred for loans and receivables or held-to-maturity investments held at amortised cost, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the asset's original effective interest rate. The carrying amount is reduced by way of an allowance account. The loss is recognised in the Statement of Comprehensive Income.

1.12 Financial Liabilities

Financial liabilities are classified as other financial liabilities. Financial liabilities are recognised and derecognised upon 'trade date'.

Other Financial Liabilities
Other financial liabilities, including borrowings, are initially measured at fair value, net of transaction costs. These liabilities are subsequently measured at amortised cost using the effective interest method, with interest expense recognised on an effective yield basis.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period.

Supplier and other payables are recognised at amortised cost. Liabilities are recognised to the extent that the goods or services have been received (and irrespective of having been invoiced).

1.13 Contingent Liabilities and Contingent Assets

Contingent liabilities and contingent assets are not recognised in the balance sheet but are reported in the relevant schedules and notes. They may arise from uncertainty as to the existence of a liability or asset or represent an asset or liability in respect of which the amount cannot be reliably measured. Contingent assets are disclosed when settlement is probable but not virtually certain and contingent liabilities are disclosed when settlement is greater than remote.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

1.14 Acquisition of Assets

Assets are recorded at cost on acquisition except as stated below. The cost of acquisition includes the fair value of assets transferred in exchange and liabilities undertaken. Financial assets are initially measured at their fair value plus transaction costs where appropriate.

Assets acquired at no cost, or for nominal consideration, are initially recognised as assets and income at their fair value at the date of acquisition, unless acquired as a consequence of restructuring of administrative arrangements. In the latter case, assets are initially recognised as contributions by owners at the amounts at which they were recognised in the transferor's accounts immediately prior to the restructuring.

1.15 Property, Plant and Equipment

Asset Recognition Threshold
Purchases of property, plant and equipment are recognised initially at cost in the balance sheet, except for purchases costing less than the thresholds listed below for each class of asset, which are expensed in the year of acquisition.

Asset class	*Recognition Threshold*
Infrastructure, Plant and Equipment	$2,000
Purchased Software	$5,000
Leasehold improvements	$10,000
Internally Developed Software	$50,000

The initial cost of an asset includes an estimate of the cost of dismantling and removing the item and restoring the site on which it is located. This is particularly relevant to 'make good' provisions in property leases taken up by the NBA where there exists an obligation to restore the property to its original condition. These costs are included in the value of the NBA's leasehold improvements with a corresponding provision for the 'make good' recognised.

Revaluations
Fair values for each class of asset are determined as shown below.

Asset class	*Fair value measured at*
Leasehold improvements	Depreciated replacement cost
Infrastructure, plant & equipment	Market selling price

Following initial recognition at cost, property, plant and equipment were carried at fair value less subsequent accumulated depreciation and accumulated impairment losses. Valuations were conducted with sufficient frequency to ensure that the carrying amounts of assets did not differ materially from the assets' fair values as at the reporting date. The regularity of independent valuations depended upon the volatility of movements in market values for the relevant assets.

Revaluation adjustments were made on a class basis. Any revaluation increment was credited to equity under the heading of asset revaluation reserve except to the extent that it reversed a previous revaluation decrement of the same asset class that was previously recognised in the surplus/deficit.

Revaluation decrements for a class of assets were recognised directly in the surplus/deficit except to the extent that they reversed a previous revaluation increment for that class.

Any accumulated depreciation as at the revaluation date is eliminated against the gross carrying amount of the asset and the asset restated to the revalued amount.

NATIONAL BLOOD AUTHORITY
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Depreciation
Depreciable property, plant and equipment assets are written-off to their estimated residual values over their estimated useful lives to the NBA using, in all cases, the straight-line method of depreciation.

Depreciation rates (useful lives), residual values and methods are reviewed at each reporting date and necessary adjustments are recognised in the current, or current and future reporting periods, as appropriate.

Depreciation rates applying to each class of depreciable asset are based on the following useful lives:

Asset class	2012	2011
Infrastructure, Plant and Equipment	3 to 7 years	3 to 7 years
Leasehold improvements	Lease term	Lease term

Impairment
All assets were assessed for impairment at 30 June 2012. Where indications of impairment exist, the asset's recoverable amount is estimated and an impairment adjustment made if the asset's recoverable amount is less than its carrying amount.

The recoverable amount of an asset is the higher of its fair value less costs to sell and its value in use. Value in use is the present value of the future cash flows expected to be derived from the asset. Where the future economic benefit of an asset is not primarily dependent on the asset's ability to generate future cash flows, and the asset would be replaced if the NBA were deprived of the asset, its value in use is taken to be its depreciated replacement cost.

Derecognition
An item of property, plant and equipment is derecognised upon disposal or when no further economic benefits are expected from its use or disposal.

1.16 Intangibles

The NBA's intangibles comprise internally developed software and purchased software for internal use. These assets are carried at cost less accumulated amortisation and accumulated impairment losses.

Software is amortised on a straight-line basis over its anticipated useful life. The useful lives of the NBA's software are:

Type	2012	2011
Purchased software	3 years	3 years
Internally developed software	5 years	5 years

All software assets were assessed for indications of impairment at 30 June 2012.

1.17 Taxation

The NBA is exempt from all forms of taxation except Fringe Benefits Tax (FBT) and the Goods and Services Tax (GST).

Revenues, expenses, liabilities and assets are recognised net of GST except:

a) where the amount of the GST incurred is not recoverable from the Australian Taxation Office; and
b) for receivables and payables.

NATIONAL BLOOD AUTHORITY
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for the year ended 30 June 2012

1.18 Reporting of Administered Activities

Administered revenues, expenses, assets, liabilities and cash flows are disclosed in the administered schedules and related notes.

Except where otherwise stated below, administered items are accounted for on the same basis and using the same policies as for departmental items, including the application of Australian Accounting Standards.

Administered Cash Transfers to and from the Official Public Account
Revenue collected by the NBA for use by the Government rather than the NBA is administered revenue. Collections are transferred to the Official Public Account (OPA) maintained by the Department of Finance and Deregulation. Conversely, cash is drawn from the OPA to make payments under Parliamentary appropriation on behalf of Government. These transfers to and from the OPA are adjustments to the administered cash held by the NBA on behalf of the Government and reported as such in the schedule of administered cash flows and in the administered reconciliation schedule.

Revenue
All administered revenues are revenues relating to the course of ordinary activities performed by the NBA on behalf of the Australian Government. As such, administered appropriations are not revenues of the individual agency that oversees distribution or expenditure of the funds as directed.

Loans and Receivables
Where loans and receivables are not subject to concessional treatments, they are carried at amortised cost using the effective interest method. Gains and losses due to impairment, derecognition and amortization are recognised through profit and loss.

Inventories
Inventories held for distribution are valued at cost, adjusted for any loss of service potential.

Costs incurred in bringing each item of inventory to its present location and condition are assigned as follows:

a) raw materials and stores – purchase cost on a first-in-first-out basis; and
b) finished goods and work-in-progress – cost of direct materials and labour plus attributable costs that can be allocated on a reasonable basis.

Inventories acquired at no cost or nominal consideration are initially measured at current replacement cost at the date of acquisition.

Indemnities
The maximum amounts payable under the indemnities given is disclosed in the schedule of administered items – contingencies. At the time of completion of the financial statements, there was no reason to believe that the indemnities would be called upon, and no recognition of any liability was therefore required.

Grants
The NBA administers a number of grant schemes on behalf of government.

Grant liabilities are recognised to the extent that (i) the services required to be performed by the grantee have been performed of (ii) the grant eligibility criteria have been satisfied, but payments due have not been made. A commitment is recorded when the Government enters into an agreement to make these grants but services have not been performed or criteria satisfied.

NATIONAL BLOOD AUTHORITY
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National Managed Fund

The National Managed Fund was established to manage the liability risks of the Australian Red Cross Blood Service in relation to the provision of blood and blood products. The National Managed Fund was reported in 2003-04 by the Department of Health and Ageing under "Services for Other Governments and Non-Departmental Bodies Special Account". The NBA now manages this fund on behalf of the Australian Government and States and Territories. To facilitate the transfer of the fund to the NBA a special account under Section 20 of the *Financial Management and Accountability (FMA) Act 1997* was established, and this fund was transferred to the NBA for reporting.

The Fund came into effect on 1 July 2000 and to date, no claims have been made against it. The balance of the fund as at 30 June 2012 is $93,981,870 (30 June 2011: $82,843,378) made up of a combination of cash, investments and balance of the special account.

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NOTE 2: Events after the Reporting Period

Departmental

There were no events occurring after 30 June 2012 with the potential to significantly affect the ongoing structure and financial activities of the NBA.

Administered

There were no events occurring after 30 June 2012 with the potential to significantly affect the ongoing structure and financial activities of the NBA.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 3: Expenses		
Note 3A: Employee Benefits		
Wages and salaries	**4 476**	4 189
Superannuation:		
Defined contribution plans	**391**	344
Defined benefit plans	**308**	393
Leave and other entitlements	**1 027**	720
Separation and redundancies	**104**	-
Other employee benefits	**470**	223
Total employee benefits	**6 776**	5 869
Note 3B: Suppliers		
Goods and services		
Consultants	**258**	401
Contractors	**185**	291
Travel	**297**	314
Legal	**213**	206
IT services	**706**	918
Other	**645**	478
Total goods and services	**2 304**	2 608
Goods and services are made up of:		
Provision of goods - external parties	**223**	145
Rendering of services - related entities	**215**	206
Rendering of services - external parties	**1 866**	2 257
Total goods and services	**2 304**	2 608
Other supplier expenses		
Operating lease rentals - external parties:		
Minimum lease payments	**470**	461
Workers compensation expenses	**66**	45
Total other supplier expenses	**536**	506
Total supplier expenses	**2 840**	3 114
Note 3C: Depreciation and Amortisation		
Depreciation:		
Property, plant and equipment	**133**	102
Leasehold improvements	**37**	104
Total depreciation	**170**	206
Amortisation:		
Intangibles	**581**	589
Total amortisation	**581**	589
Total depreciation and amortisation	**751**	795

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 3: Expenses		
Note 3D: Losses from Asset Sales		
Property, plant and equipment:		
Proceeds from sale	**2**	-
Carrying value of assets sold	**15**	6
Intangibles:		
Proceeds from sale	**-**	24
Carrying value of assets sold	**-**	24
Total losses from asset sales	**13**	6
NOTE 4: Income		
OWN-SOURCE REVENUE		
Note 4A: Sale of Goods and Rendering of Services		
Rendering of services - related entities	**194**	39
Rendering of services - external parties	**38**	448
Total sale of goods and rendering of services	**232**	487
Note 4B: Other Revenue		
Funding from State and Terrritory governments	**3 704**	3 493
Total other revenue	**3 704**	3 493

Funding from State and Territory governments includes $438,408 revenue (2011: $199,893) which had been previously received and recognised as unearned revenue.

GAINS		
Note 4C: Other Gains		
Resources received free of charge	**94**	94
Total other gains	**94**	94
REVENUE FROM GOVERNMENT		
Note 4D: Revenue from Government		
Appropriations:		
Departmental appropriations	**5 686**	5 948
Total revenue from Government	**5 686**	5 948

Departmental appropriations include $746,479 revenue (2011: $340,358) which had been previously received and recognised as unearned revenue.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 5: Financial Assets		
Note 5A: Cash and Cash Equivalents		
Cash on hand or on deposit	**30**	36
Total cash and cash equivalents	**30**	36
Note 5B: Trade and Other Receivables		
Goods and Services:		
Goods and services - related entities	**77**	-
Goods and services - external parties	**-**	1
Total receivables for goods and services	**77**	1
Appropriations receivable:		
For existing programs	**375**	-
Total appropriations receivable	**375**	-
Other receivables:		
GST receivable from the Australian Taxation Office	**89**	49
Special Account - cash held in the OPA	**7 452**	8 719
Total other receivables	**7 541**	8 768
Total trade and other receivables (gross)	**7 993**	8 769
Total trade and other receivables (net)	**7 993**	8 769
Receivables are expected to be recovered in:		
No more than 12 months	**7 993**	8 769
Total trade and other receivables (net)	**7 993**	8 769
Receivables are aged as follows:		
Not overdue	**7 993**	8 769
Total receivables (gross)	**7 993**	8 769

Credit terms for goods and services were within 30 days (2011: 30 days)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 6: Non-Financial Assets		
Note 6A: Leasehold improvements		
Fair value	**157**	157
Accumulated depreciation	**(157)**	(120)
Total leasehold improvements	**-**	37

No indicators of impairment were found for leasehold improvements.
No leasehold improvements are expected to be sold or disposed of within the next 12 months.

Note 6B: Property, Plant and Equipment

Other property, plant and equipment:		
Fair Value	**601**	467
Accumulated depreciation	**(248)**	(133)
Total property, plant and equipment	**353**	334

No indicators of impairment were found for property, plant and equipment.
No property, plant or equipment is expected to be sold or disposed of within the next 12 months.

Revaluations of non-financial assets
All revaluations were conducted in accordance with the revaluation policy stated at Note 1. On 30/06/10, an independent valuer, the Australian Valuation Office, conducted the revaluations.
No revaluation increments for leasehold improvements (2011: $nil) and no increments for plant and equipment (2011: $nil) were credited to the asset revaluation surplus by asset class and included in the equity section of the balance sheet. No decrements were expensed (2011: $nil).

Note 6C: Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2011-12)

	Leasehold improvements	Other property, plant and equipment	Total
	$'000	$'000	$'000
As at 1 July 2011			
Gross book value	157	467	624
Accumulated depreciation and impairment	(120)	(133)	(253)
Net book value 1 July 2011	**37**	**334**	**371**
Additions:			
By purchase	-	185	185
Depreciation expense	(37)	(133)	(170)
Other movements	-	(18)	(18)
Disposals:			
Other	-	(15)	(15)
Net book value 30 June 2012	**-**	**353**	**353**
Net book value as of 30 June 2012 represented by:			
Gross book value	157	601	758
Accumulated depreciation and impairment	(157)	(248)	(405)
	-	**353**	**353**

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

NOTE 6: Non-Financial Assets

Note 6C: Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2010-11)

	Leasehold improvements $'000	Infrastructure plant and equipment $'000	Total Property, Plant and Equipment $'000
As at 1 July 2010			
Gross book value	157	293	450
Accumulated depreciation and impairment	(16)	(39)	(55)
Net book value 1 July 2010	**141**	**254**	**395**
Additions:			
By purchase	-	188	188
Depreciation expense	(104)	(102)	(206)
Disposals:			
Other disposals	-	(6)	(6)
Net book value 30 June 2011	**37**	**334**	**371**
Net book value as of 30 June 2011 represented by:			
Gross book value	157	467	624
Accumulated depreciation and impairment	(120)	(133)	(253)
	37	**334**	**371**

	2012 $'000	2011 $'000
Note 6D: Intangibles		
Computer software:		
Internally developed - in use	**2 674**	2 566
Purchased	**542**	527
Accumulated amortisation	**(2 379)**	(1 798)
Total intangibles	**837**	1 295

No indicators of impairment were found for intangible assets.

No intangibles are expected to be sold or disposed of within the next 12 months.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

NOTE 6: Non-Financial Assets

Note 6E: Reconciliation of the Opening and Closing Balances of Intangibles (2011-12)

Item	Computer software internally developed	Computer software purchased	Total
	$'000	$'000	$'000
As at 1 July 2011			
Gross book value	2 566	527	3 093
Accumulated amortisation and impairment	(1 484)	(314)	(1 798)
Net book value 1 July 2011	**1 082**	**213**	**1 295**
Additions:			
By purchase or internally developed	108	15	123
Amortisation	(485)	(96)	(581)
Disposals:			
Other disposals	-	-	-
Net book value 30 June 2012	**705**	**132**	**837**
Net book value as of 30 June 2012 represented by:			
Gross book value	2 674	542	3 216
Accumulated amortisation and impairment	(1 969)	(410)	(2 379)
	705	**132**	**837**

Note 6E: Reconciliation of the Opening and Closing Balances of Intangibles (2010-11)

Item	Computer software internally developed	Computer software purchased	Total
	$'000	$'000	$'000
As at 1 July 2010			
Gross book value	2 453	660	3 113
Accumulated amortisation and impairment	(971)	(532)	(1 503)
Net book value 1 July 2010	**1 482**	**128**	**1 610**
Additions:			
By purchase or internally developed	142	156	298
Amortisation	(518)	(71)	(589)
Disposals:			
Other disposals	(24)	-	(24)
Net book value 30 June 2011	**1 082**	**213**	**1 295**
Net book value as of 30 June 2011 represented by:			
Gross book value	2 566	527	3 093
Accumulated amortisation and impairment	(1 484)	(314)	(1 798)
	1 082	**213**	**1 295**

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 6: Non-Financial Assets		
Note 6F: Other Non-Financial Assets		
Prepayments	**87**	64
Total other non-financial assets	**87**	64
Total other non-financial assets are expected to be recovered in :		
No more than 12 months	**87**	64
Total other non-financial assets	**87**	64
No indicators of impairment were found for other non-financial assets.		
NOTE 7: Payables		
Note 7A: Suppliers		
Trade creditors and accruals	**572**	427
Total suppliers payables	**572**	427
Supplier payables expected to be settled within 12 months:		
Related entities	**13**	38
External parties	**559**	389
Total suppliers payables	**572**	427
Settlement was usually made within 30 days.		
Note 7B: Other Payables		
Wages and salaries	**131**	112
Superannuation	**19**	18
Unearned income from Commonwealth	**-**	856
Unearned income from States and Territories	**-**	438
Total other payables	**150**	1 424
Total other payables are expected to be settled in:		
No more than 12 months	**150**	1 424
Total other payables	**150**	1 424
NOTE 8: Provisions		
Note 8A: Employee Provisions		
Leave	**1 217**	1 213
Total employee provisions	**1 217**	1 213
Employee provisions are expected to be settled in:		
No more than 12 months	**551**	498
More than 12 months	**666**	715
Total employee provisions	**1 217**	1 213

NATIONAL BLOOD AUTHORITY
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NOTE 9: Cash Flow Reconciliation

	2012 $'000	2011 $'000
Reconciliation of cash and cash equivalents as per Balance Sheet to Cash Flow Statement		
Cash and cash equivalents as per:		
Cash flow statement	**30**	36
Balance sheet	**30**	36
Difference	**-**	-
Reconciliation of net cost of services to net cash from operating activities:		
Net cost of services	**(6 350)**	(5 710)
Add revenue from Government	**5 686**	5 948
Adjustments for non-cash items:		
Depreciation / amortisation	**751**	796
Loss on disposal of assets	**13**	6
Changes in assets and liabilities:		
(Increase) in net receivables	**1 149**	(147)
(Increase) in non-financial assets	**(25)**	(5)
Increase in employee provisions	**24**	16
Increase in supplier payables	**145**	(51)
(Decrease) in other payables	**(1 296)**	(565)
Net cash from operating activities	**97**	288

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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NOTE 10: Contingent Assets and Liabilities

Quantifiable Contingencies
There were no quantifiable contingent assets or liabilities in this reporting period.

Unquantifiable Contingencies
There were no unquantifiable contingent assets or liabilities in this reporting period.

Significant Remote Contingencies
The Australian Government has indemnified the lessor of the National Blood Authority's premises for negligent acts committed by the National Blood Authority up to the value of $1,000,000.

NOTE 11: Senior Executive Remuneration

Note 11A: Senior Executive Remuneration Expense for the Reporting Period

	2012 $	2011 $
Short-term employee benefits:		
Salary	**709 729**	983 219
Annual leave accrued	**15 688**	40 119
Vehicle allowances	**47 115**	64 050
Retention bonuses	**51 000**	-
Total short-term employee benefits	**823 532**	1 087 388
Post-employment benefits:		
Superannuation	**113 948**	153 984
Total post-employment benefits	**113 948**	153 984
Other long-term benefits:		
Long-service leave accrued	**15 471**	36 423
Long-service leave taken	**-**	24 902
Total other long-term benefits	**15 471**	11 521
Total employment benefits	**952 951**	1 252 893

Notes

1. Note 11A is prepared on an accrual basis (so the performance bonus expenses disclosed above differ from the cash 'Bonus paid' in Note 11B).

2. Note 11A excludes acting arrangements and part-year service where total remuneration expensed for a senior executive was less than $150,000.

3. During 2011-12, 3 substantive senior executives terminated their employment with the NBA and 3 staff became substantive senior executives for the first time.

Note 11B: Average Annual Reportable Remuneration Paid to Substantive Senior Executives During the Reporting Period

	2012					
Average annual reportable remuneration[1]	Senior Executives No.	Reportable Salary[2] $	Contributed Superannuation[3] $	Reportable Allowances[4] $	Bonus paid[5] $	Total $
Total remuneration (including part-time arrangements):						
less than $150,000	4	75 998	16 360	-	-	92 358
$180,000 to $209,999	1	180 461	17 127	-	-	197 588
$210,000 to $239,999	2	183 452	42 481	-	-	225 933
$240,000 to $269,999	1	236 259	35 858	-	-	272 117
Total	**8**					

	2011					
Average annual reportable remuneration[1]	Senior Executives No.	Reportable Salary[2] $	Contributed Superannuation[3] $	Reportable Allowances[4] $	Bonus paid[5] $	Total $
Total remuneration (including part-time arrangements):						
$180,000 to $209,999	2	170 582	27 264	-	-	197 846
$210,000 to $239,999	1	203 265	33 119	-	-	236 384
$270,000 to $299,999	1	265 533	23 807	-	-	289 340
$300,000 to $329,999	1	214 898	87 530	-	-	302 428
Total	**5**					

Notes

1. This table reports substantive senior executives who received remuneration during the reporting period. Each row is an averaged figure based on headcount for individuals in the band. During 2011-12, 3 substantive senior executives terminated their employment with the NBA and 3 staff became substantive senior executives for the first time. At 30 June 2012, the NBA had 4 continuing substantive senior executives.
2. 'Reportable salary' includes the following:
   a) gross payments (less any bonuses paid, which are separated out and disclosed in the 'bonus paid' column);
   b) reportable fringe benefits (at the net amount prior to 'grossing up' to account for tax benefits); and
   c) exempt foreign employment income.
3. The 'contributed superannuation' amount is the average actual superannuation contributions paid to senior executives in that reportable remuneration band during the reporting period, including any salary sacrificed amounts, as per the individuals' payslips.
4. 'Reportable allowances' are the average actual allowances paid as per the 'total allowances' line on individuals' payment summaries.
5. 'Bonus paid' represents average actual bonuses paid during the reporting period in that reportable remuneration band. The 'bonus paid' within a particular band may vary between financial years due to various factors such as individuals commencing with or leaving the NBA during the financial year.
6. Various salary sacrifice arrangements were available to senior executives including supererannuation, motor vehicle and expense payment fringe benefits. Salary sacrifice benefits are reported in the 'reportable salary' column, excluding salary sacrificed superannuation, which is reported in the 'contributed superannuation' column.

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Note 11C: Other Highly Paid Staff

	2012					
Average annual reportable remuneration [1]	Staff No.	Reportable Salary [2] $	Contributed Superannuation [3] $	Reportable Allowances [4] $	Bonus paid [5] $	Total $
Total remuneration (including part-time arrangements):						
$150,000 to $179,999	1	137 475	19 502	-	-	156 977
Total	**1**					

	2011					
Average annual reportable remuneration [1]	Staff No.	Reportable Salary [2] $	Contributed Superannuation [3] $	Reportable Allowances [4] $	Bonus paid [5] $	Total $
Total remuneration (including part-time arrangements):						
$150,000 to $179,999	1	137 741	20 445	-	-	158 186
Total	**1**					

Notes

1. This table reports staff:
   a) who were employed by the NBA during the reporting period;
   b) whose reportable remuneration was $150,000 or more for the financial period; and
   c) were not required to be disclosed in Tables A, B or director disclosures.
   Each row is an averaged figure based on headcount for individuals in the band.
2. 'Reportable salary' includes the following:
   a) gross payments (less any bonuses paid, which are separated out and disclosed in the 'bonus paid' column);
   b) reportable fringe benefits (at the net amount prior to 'grossing up' to account for tax benefits); and
   c) exempt foreign employment income.
3. The 'contributed superannuation' amount is the average actual superannuation contributions paid to staff in that reportable remuneration band during the reporting period, including any salary sacrificed amounts, as per the individuals' payslips.
4. 'Reportable allowances' are the average actual allowances paid as per the 'total allowances' line on individuals' payment summaries.
5. 'Bonus paid' represents average actual bonuses paid during the reporting period in that reportable remuneration band. The 'bonus paid' within a particular band may vary between financial years due to various factors such as individuals commencing with or leaving the NBA during the financial year.
6. Various salary sacrifice arrangements were available to other highly paid staff including supererannuation, motor vehicle and expense payment fringe benefits. Salary sacrifice benefits are reported in the 'reportable salary' column, excluding salary sacrificed superannuation, which is reported in the 'contributed superannuation' column.

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	2012 $'000	2011 $'000

NOTE 12: Remuneration of Auditors

Financial statement audit services were provided free of charge to the NBA by the Australian National Audit Office (ANAO).

Fair value of the services provided		
Financial statement audit services	**94**	94
Total	**94**	94

No other services were provided by the auditors of the financial statements.

NOTE 13: Financial Instruments

NOTE 13A: Categories of Financial Instruments

Financial Assets		
Loans and receivables:		
Cash and cash equivalents	**30**	36
Trade and other receivables	**77**	1
Carrying amount of financial assets	**107**	37
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**572**	427
Carrying amount of financial liabilities	**572**	427

Note 13B: Fair Value of Financial Instruments

Financial assets

The fair values of all monetary financial assets approximate their carrying amounts.

Financial liabilities

The fair values of all monetary financial liabilities approximate their carrying amounts. All financial liabilities are current, therefore a maturity analysis is not required.

Note 13C: Credit Risk

The NBA is exposed to minimal credit risk as loans and receivables are cash and trade receivables. The maximum exposure to credit risk at reporting date in relation to each class of recognised financial assets is the carrying amount of those assets as indicated in the Balance Sheet. The NBA has no significant exposures to any concentrations of credit risk.

Note 13D: Liquidity Risk

The NBA's financial liabilities are trade and other creditors. The exposure to liquidity risk is based on the notion that the NBA will encounter difficulty in meeting its obligations associated with financial liabilities. This is highly unlikely due to appropriation funding and mechanisms available to the NBA (e.g. Advance to the Finance Minister) and internal policies and procedures put in place to ensure there are appropriate resources to meet its financial obligations.

Note 13E: Market Risk

The NBA holds basic financial instruments that do not expose it to certain market risks. The NBA is not exposed to 'interest rate risk', 'currency risk' or 'other price risk'.

NOTE 14: Financial Assets Reconciliation

Financial Assets		
Total financial assets as per balance sheet	**8 023**	8 805
Less: non-financial instrument components:		
Appropriations receivable	**375**	-
GST receivable from the Australian Taxation Office	**89**	49
Special Account - cash held in the OPA	**7 452**	8 719
Total financial assets as per financial instruments note	**107**	37

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 15: Administered - Expenses		
Note 15A: Suppliers		
Purchases of blood and blood products	**944 297**	936 120
Consultants	**1 582**	1 114
Contractors	**1 159**	80
Travel	**63**	69
IT services	**468**	468
Other	**251**	103
Total goods and services	**947 820**	937 954
Goods and services are made up of:		
Provision of goods - external parties	**944 522**	936 195
Rendering of services - external parties	**3 298**	1 759
Total goods and services	**947 820**	937 954
Total suppliers expenses	**947 820**	937 954
Note 15B: Grants		
Private sector:		
Non-profit organisations	**7 773**	-
Total grants	**7 773**	-
Note 15C: Depreciation and Amortisation		
Depreciation:		
Property, plant and equipment	**33**	6
Amortisation:		
Intangibles	**258**	304
Total depreciation and amortisation	**291**	310
NOTE 16: Administered - Income		
OWN-SOURCE REVENUE		
Non-Taxation Revenue		
Note 16A: Funding from Governments		
Commonwealth contributions	**640 176**	591 889
State & Territory contributions	**375 410**	347 323
Total funding from governments	**1 015 586**	939 212
Note 16B: Interest		
Deposits	**4 801**	1 629
Total interest	**4 801**	1 629
Note 16C: Other Revenue		
Other contributions [1]	**14 523**	175
Total other revenue	**14 523**	175

[1] Other contributions relate principally to the return of the prior year Blood Service surplus under the Deed of Agreeement.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 17: Administered - Financial Assets		
Note 17A: Cash and Cash Equivalents		
Cash on hand or on deposit	**5 340**	41 157
Total cash and cash equivalents	**5 340**	41 157
Note 17B: Trade and Other Receivables		
Goods and services:		
Goods and services receivable - related entities	**-**	-
Goods and services receivable - external parties	**3 037**	3 037
Total receivables for goods and services	**3 037**	3 037
Other receivables:		
Special Account - cash held in the OPA	**191 414**	133 146
Interest	**2 818**	1 083
GST receivable from Australian Taxation Office	**14 151**	13 619
Total other receivables	**208 383**	147 848
Total trade and other receivables (gross)	**211 420**	150 885
Less impairment allowance account:		
Goods and services	**(3 037)**	(3 037)
Total trade and other receivables (net)	**208 383**	147 848
Receivables are expected to be recovered in:		
No more than 12 months	**208 383**	147 848
Total trade and other receivables (net)	**208 383**	147 848
Receivables were aged as follows:		
Not overdue	**208 383**	147 848
Overdue by:		
More than 90 days	**3 037**	3 037
Total receivables (gross)	**211 420**	150 885
The impairment allowance account is aged as follows:		
Overdue by:		
More than 90 days	**(3 037)**	(3 037)
Total impairment allowance account	**(3 037)**	(3 037)
Credit terms are within 30 days from date of invoice (2011: 30 days).		
Reconciliation of the Impairment Allowance Account		
Movements		
Other Receivables		
Opening balance	**(3 037)**	(3 037)
Increase/decrease recognised in net surplus	**-**	-
Closing balance	**(3 037)**	(3 037)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

NOTE 17: Administered - Financial Assets	2012 $'000	2011 $'000
Note 17C: Other Investments		
Deposits[1]	**88 335**	40 611
Total other investments	**88 335**	40 611
Other investments are expected to be recovered in:		
No more than 12 months	**60 215**	40 611
More than 12 months	**28 120**	-
Total other investments	**88 335**	40 611

[1] Monies invested in term deposits with various approved institutions under Section 39 of the Financial Management and Accountablility Act, 1997.

NOTE 18: Administered - Non Financial Assets

Note 18A: Inventories		
National Reserve inventory held for distribution	**39 312**	37 996
Other inventory held for distribution	**20 861**	17 028
Total inventories	**60 173**	55 024

During 2011-12, $599,548 of inventory held for distribution related to a net write-off of damaged and expired stock and was recognised as an expense (2011: $475,998). No items of inventory were recognised at fair value less cost to sell. All inventory is expected to be distributed in the next 12 months.

Note 18B: Property, plant and equipment		
Other property, plant and equipment:		
Fair value	**443**	36
Accumulated depreciation	**(39)**	(6)
Total property, plant and equipment	**404**	30

No indicators of impairment were found for property, plant and equipment.
No property, plant or equipment is expected to be sold or disposed of within the next 12 months.

Revaluations of non-financial assets
No revaluation increments for plant and equipment (2011: $nil) were credited to the asset revaluation surplus. No decrements (2011: $nil) were expensed.

Note 18C: Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2011-12)

	Other property, plant and equipment $'000	Total $'000
As at 1 July 2011		
Gross book value	36	36
Accumulated depreciation and impairment	(6)	(6)
Net book value 1 July 2011	**30**	**30**
Additions:		
By purchase	407	407
Depreciation expense	(33)	(33)
Net book value 30 June 2012	**404**	**404**
Net book value as of 30 June 2012 represented by:		
Gross book value	443	443
Accumulated depreciation and impairment	(39)	(39)
	404	**404**

NOTE 18: Administered - Non Financial Assets

Note 18C: Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2010-11)

	Other property, plant and equipment $'000	Total $'000
As at 1 July 2010		
Gross book value	-	-
Accumulated depreciation and impairment	-	-
Net book value 1 July 2010	**-**	**-**
Additions:		
By purchase	36	36
Depreciation expense	(6)	(6)
Net book value 30 June 2011	**30**	**30**
Net book value as of 30 June 2011 represented by:		
Gross book value	36	36
Accumulated depreciation and impairment	(6)	(6)
	30	**30**

Note 18D: Intangibles	2012 $'000	2011 $'000
Computer software:		
Internally developed - in progress	**801**	-
Internally developed - in use	**868**	868
Purchased	**147**	-
Accumulated amortisation	**(755)**	(497)
Total intangibles	**1 061**	371

No indicators of impairment were found for intangible assets.
No intangibles are expected to be sold or disposed of with the next 12 months.

NOTE 18E: Reconciliation of the Opening and Closing Balances of Intangibles (2011-12)

	Computer software internally developed $'000	Computer software purchased $'000	Total $'000
As at 1 July 2011			
Gross book value	868	-	868
Accumulated amortisation and impairment	(497)	-	(497)
Net book value 1 July 2011	**371**	**-**	**371**
Additions:			
By purchase or internally developed	801	147	948
Amortisation	(237)	(21)	(258)
Net book value 30 June 2012	**935**	**126**	**1 061**
Net book value as of 30 June 2012 represented by:			
Gross book value	1 669	147	1 816
Accumulated amortisation and impairment	(734)	(21)	(755)
	935	**126**	**1 061**

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

NOTE 18: Administered - Non Financial Assets

NOTE 18E: Reconciliation of the Opening and Closing Balances of Intangibles (2010-11)

	Computer software internally developed $'000	Total $'000
As at 1 July 2010		
Gross book value	638	638
Accumulated amortisation and impairment	(193)	(193)
Net book value 1 July 2010	**445**	**445**
Additions:		
By purchase or internally developed	230	230
Amortisation	(304)	(304)
Net book value 30 June 2011	**371**	**371**
Net book value as of 30 June 2011 represented by:		
Gross book value	868	868
Accumulated amortisation and impairment	(497)	(497)
	371	**371**

	2012 $'000	2011 $'000
Note 18F: Other Non-Financial Assets		
Prepayments	**76 068**	75 401
Total other non-financial assets	**76 068**	75 401
No indicators of impairment were found for other non-financial assets.		
Total other non-financial assets are expected to be recovered in:		
No more than 12 months	**76 068**	75 401
Total other non-financial assets	**76 068**	75 401

NOTE 19: Administered - Payables

Note 19A: Suppliers		
Trade creditors and accruals	**61 551**	68 934
Total suppliers	**61 551**	68 934
Supplier payables expected to be settled within 12 months:		
External parties	**61 551**	68 934
Total suppliers	**61 551**	68 934
Settlement was usually made within 30 days		

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 20: Cash Flow Reconciliation		
Reconciliation of cash and cash equivalents as per Administered Schedule of Assets and Liabilities to Administered Cash Flow Statement		
Cash and cash equivalents as per:		
Schedule of administered cash flows	**5 340**	41 157
Schedule of administered assets and liabilities	**5 340**	41 157
Difference	**-**	-
Reconciliation of net cost of services to net cash from operating activities:		
Net (contribution by) services	**79 026**	2 752
Adjustments for non-cash items		
Depreciation / amortisation	**291**	310
Changes in assets and liabilities:		
(Increase) in net receivables	**(2 267)**	(4 493)
(Increase) / decrease in inventories	**(5 149)**	12 188
(Increase) in non-financial assets	**(1 468)**	(75 389)
Increase / (decrease) in supplier payables	**(7 454)**	29 439
Net cash from (used by) operating activities	**62 979**	(35 193)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

NOTE 21: Administered - Contingent Assets and Liabilities

Unquantifiable Administered Contingencies

Under certain conditions the Australian Government and the States/Territories jointly provide indemnity for the the Australian Red Cross Blood Service (the Blood Service) through a cost sharing arrangement for claims, both current and potential, regarding personal injury and loss of damage suffered by a recipient of certain blood products. The Australian Government's share of any liability is limited to sixty three percent of any agreed net cost.

The Deed of Agreement between the Australian Red Cross Society (the Red Cross) and the NBA in relation to the operation of the Blood Service includes certain indemnities and a limit of liability in favour of the Red Cross. These cover a defined set of potential business, product and employee risks and liabilities arising from the operations of the Blood Service. The indemnities and limitation of liability only operate in the event of the expiry and non-renewal, or the earlier termination, of the Deed of Agreement, and only within a defined scope. They are also subject to appropriate limitations and conditions including in relation to mitigation, contributory fault, and the process of handling relevant claims.

NOTE 22: Administered - Investments

The principal activities of each of the NBA's administered investments were as follows:

Other Investments – The NBA has funds invested in term deposits with various approved institutions under Section 39 of the Financial Management and Accountability Act 1997 for the purposes of receiving passive investment income.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

	2012 $'000	2011 $'000
NOTE 23: Administered - Financial Instruments		
NOTE 23A: Categories of Financial Instruments		
Financial assets		
Held-to-maturity:		
Deposits	**88 335**	40 611
Total	**88 335**	40 611
Loans and receivables:		
Cash on hand or on deposit	**5 340**	41 157
Trade and other receivables	**2 818**	1 083
Total	**8 158**	42 240
Carrying amount of financial assets	**96 493**	82 851
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**61 551**	68 934
Carrying amount of financial liabilities	**61 551**	68 934

Note 23B: Fair Value of Financial Instruments

Financial assets

The fair values of all monetary financial assets approximate their carrying amounts.

Financial liabilities

The fair values of all monetary financial liabilities approximate their carrying amounts.

Note 23C: Credit Risk

The NBA is exposed to minimal credit risk as loans and receivables are cash and trade receivables. The maximum exposure to credit risk at reporting date in relation to each class of recognised financial assets is the carrying amount of those assets in the Balance Sheet.

The NBA has no significant exposures to any concentrations of credit risk.

Note 23D: Liquidity Risk

The NBA's financial liabilities are trade and other creditors. The exposure to liquidity risk is based on the notion that the NBA will encounter difficulty in meeting its obligations associated with financial liabilities. This is highly unlikely due to special account funding and internal policies and procedures put in place to ensure there are appropriate resources to meet its financial obligations.

Note 23E: Market Risk

The NBA holds basic financial instruments that do not expose it to certain market risks. The NBA is not exposed to 'interest rate risk', 'currency risk',or 'other price risk'.

NOTE 24: Administered Financial Assets Reconciliation		
Financial Assets		
Total financial assets as schedule of administered assets and liabilities	**302 058**	229 616
Less: non-financial instrument components:		
GST receivable from Australian Taxation Office	**14 151**	13 619
Special Account - cash held in the OPA	**191 414**	133 146
Total financial assets as per financial instruments note	**96 493**	82 851

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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Note 25 Appropriations

Table A: Annual Appropriations (Recoverable GST exclusive)

	2012 Appropriations							Appropriation applied in 2012 (current and prior years)	Variance
	Appropriation Act			*FMA Act*			Total appropriation		
	Annual Appropriation	Appropriations reduced [a]	AFM [b]	Section 30	Section 31	Section 32			
	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000
DEPARTMENTAL									
Ordinary annual services	4 940	-	-	-	47	-	4 987	4 987	-
Other services									
Equity	-	-	-	-	n/a	-	-	-	-
Loans	-	-	-	-	n/a	-	-	-	-
Total departmental	**4 940**	**-**	**-**	**-**	**47**	**-**	**4 987**	**4 987**	**-**
ADMINISTERED									
Ordinary annual services									
Administered items	7 679	-	-	-	n/a	-	7 679	7 679	-
Payments to CAC Act bodies	-	-	-	-	n/a	-	-	-	-
Total administered	**7 679**	**-**	**-**	**-**	**n/a**	**-**	**7 679**	**7 679**	**-**

Notes:

(a) Appropriations reduced under Appropriation Acts (Nos. 1,3&5) 2011-12: sections 10,11 and 12 and under Appropriation Acts (Nos. 2,4&6) 2011-12: sections 12,13 and 14. Departmental appropriations do not lapse at financial year end. However, the responsible Minister may decide that part or all of a departmental appropriation is not required and request the Finance Minister to reduce that appropriation. The reduction in the appropriation is effected by the Finance Minister's determination and is disallowable by Parliament.

As with departmental appropriations, the responsible Minister may decide that part or all of an administered appropriation is not required and request that the Finance Minister reduce that appropriation. For administered appropriations reduced under section 11 of Appropriation Acts (Nos 1,3&5) 2011-12 and section 12 of Appropropriation Acts (Nos 2,4,&6) 2011-12, the appropriation is taken to be reduced to the required amount specified in Table F of this note once the annual report is tabled in Parliament. All administered appropriations may be adjusted by a Finance Minister's determination, which is disallowable by Parliament.

(b) Advance to the Finance Minister (AFM) - Appropriation Acts (Nos. 1,3&5) 2011-12: section 13 and Appropriation Acts (Nos. 2,4&6) 2011-12: section 15.

Note 25 Appropriations

Table A: Annual Appropriations (Recoverable GST exclusive)

	2011 Appropriations							Appropriation applied in 2011 (current and prior years)	Variance
	Appropriation Act			*FMA Act*			Total appropriation		
	Annual Appropriation	Appropriations reduced [a]	AFM [b]	Section 30	Section 31	Section 32			
	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000
DEPARTMENTAL									
Ordinary annual services	5 608	-	-	-	640	-	6 248	6 248	-
Other services									
Equity	-	-	-	-	n/a	-	-	-	-
Loans	-	-	-	-	n/a	-	-	-	-
Total departmental	**5 608**	**-**	**-**	**-**	**640**	**-**	**6 248**	**6 248**	**-**
ADMINISTERED									
Ordinary annual services									
Administered items	5 750	-	-	-	n/a	-	5 750	5 750	-
Payments to CAC Act bodies	-	-	-	-	n/a	-	-	-	-
Total administered	**5 750**	**-**	**-**	**-**	**n/a**	**-**	**5 750**	**5 750**	**-**

Notes:

(a) Appropriations reduced under Appropriation Acts (Nos. 1 & 3) 2010-11: sections 10,11,12 and 15 and under Appropriation Acts (Nos. 2 & 4) 2010-11: sections 12,13,14 and 17. Departmental appropriations do not lapse at financial year end. However, the responsible Minister may decide that part or all of a departmental appropriation is not required and request the Finance Minister to reduce that appropriation. The reduction in the appropriation is effected by the Finance Minister's determination and is disallowable by Parliament.

As with departmental appropriations, the responsible Minister may decide that part or all of an administered appropriation is not required and request that the Finance Minister reduce that appropriation. For administered appropriations reduced under section 11 of Appropriation Acts (Nos 1,3&5) 2010-11 and section 12 of Appropropriation Acts (Nos 2,4,&6) 2010-11, the appropriation is taken to be reduced to the required amount specified in Table F of this note once the annual report is tabled in Parliament. All administered appropriations may be adjusted by a Finance Minister's determination, which is disallowable by Parliament.

(b) Advance to the Finance Minister (AFM) - Appropriation Acts (Nos. 1 & 3) 2010-11: section 13 and Appropriation Acts (Nos. 2 & 4) 2010-11: section 15.

NATIONAL BLOOD AUTHORITY
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Note 25 Appropriations

Table B: Departmental and Administered Capital Budgets (Recoverable GST exclusive)

	2012 Capital Budget Appropriations				Capital Budget Appropriations applied in 2012			
	Appropriation Act		*FMA Act*		*(current and prior years)*			
	Annual Capital Budget	Appropriations reduced [b]	Section 32	*Total Capital Budget Appropriations*	Payments for non-financial assets [c]	Payments for other purposes	Total payments	Variance
	$'000	$'000	$'000	$'000	$'000	$'000	$'000	$'000
DEPARTMENTAL								
Ordinary annual services - Departmental Capital Budget [a]	554			554	179	-	179	375
ADMINISTERED								
Ordinary annual services - Administered Capital Budget [a]	-	-	-	-	-	-	-	-

Notes:

(a) Departmental and Administered Capital Budgets are appropriated through Appropriation Acts (No. 1,3,5). They form part of ordinary annual services, and are not separately identified in the Appropriation Acts. For more information on ordinary annual services appropriations, please see Table A: Annual appropriations.

(b) Appropriations reduced under Appropriation Acts (No. 1,3,5) 2011-12: sections 10,11,12 and 15 or via a determination by the Finance Minister.

(c) Payments made on non-financial assets include purchases of assets, expenditure on assets which has been capitalised, costs incurred to make good an asset to its original condition and the and the capital repayment component of finance leases.

(d) The NBA commenced operating under the Net Cash Funding arrangements for Departmental Capital Expenditure on 1 July 2011.

Note 25 Appropriations

Table C: Unspent Annual Appropriations (Recoverable GST exclusive)

Authority	2012 $'000	2011 $'000
DEPARTMENTAL		
Appropriation Act (No.1) 2011-12	**375**	-
Total	**375**	-

Table D: Special Appropriations (Recoverable GST exclusive)

Table D is blank for financial years 2011 and 2012.

Table E: Disclosure by Agent in Relation to Annual and Special Appropriations (Recoverable GST exclusive)

Table E is blank for financial years 2011 and 2012.

Table F: Reduction in Administered Items (Recoverable GST exclusive)

2012	Amount required[3] - by Appropriation Act				Total amount required[3]	Total amount appropriated[4]	Total reduction[5]
Ordinary Annual Services	**Act (No.1)**	**Act (No.3)**	**Act (No.5)**	**Act (No. n)**			
Outcome 1	$ 7,679,000.00	-	-	-	$ 7,679,000.00	$ 7,679,000.00	-

Notes:

1. Numbers in this section are disclosed to the cent.
2. Administered items for 2012 were reduced to these amounts when these financial statements were tabled in Parliament as part of the NBA's 2012 annual report. This reduction is effective in 2013 , but the amounts are reflected in Table A in the 2012 financial statements in the column 'Appropriations reduced' as they are adjustments to 2012 appropriations.
3. Amount required as per Appropriation Act (Act 1 s. 11; Act 2 s. 12).
4. Total amount appropriated in 2012.
5. Total reduction effective in 2013.

2011	Amount required[2] - by Appropriation Act				Total amount required[2]	Total amount appropriated[3]	Total reduction[4]
Ordinary Annual Services	**Act (No.1)**	**Act (No.3)**	**Act (No.5)**	**Act (No. n)**			
Outcome 1	$ 5,750,000.00	-	-	-	$ 5,750,000.00	$ 5,750,000.00	-

Notes:

1. Numbers in this section are disclosed to the cent.
2. Administered items for 2011 were reduced to these amounts when these financial statements were tabled in Parliament as part of the NBA's 2011 annual report. This reduction is effective in 2012 , but the amounts are reflected in Table A in the 2011 financial statements in the column 'Appropriations reduced' as they are adjustments to 2011 appropriations.
3. Amount required as per Appropriation Act (Act 1 s. 11; Act 2 s. 12).
4. Total amount appropriated in 2011.
5. Total reduction effective in 2012.

NATIONAL BLOOD AUTHORITY
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NOTE 26: Special Accounts and FMA Act Section 39

Note 26A: Special Accounts (Recoverable GST exclusive)

	The National Blood Account [1]		National Managed Fund (Blood and Blood Products) [2]	
	2012 $'000	2011 $'000	**2012 $'000**	2011 $'000
Balance brought forward from previous period	**148 183**	185 154	**1 076**	74 449
Increases:				
Appropriation credited to special account	**12 798**	11 358	**-**	-
Costs recovered	**-**	-	**-**	-
Realised investments	**-**	-	**182 408**	41 157
Other receipts - Commonwealth contributions	**635 070**	586 953	**5 106**	4 936
Other receipts - State and territory contributions	**376 479**	347 716	**2 999**	2 899
Other receipts - External parties	**14 404**	679	**3 231**	706
Total increases	**1 038 751**	946 706	**193 744**	49 698
Available for payments				
Decreases:				
Departmental				
Payments made to employees	**6 298**	5 627	**-**	-
Payments made to suppliers	**3 396**	3 898	**-**	-
Total departmental decreases	**9 694**	9 525	**-**	-
Administered				
Payments made to suppliers	**970 082**	974 152	**198**	146
Investments made from the special account (FMA Act section 39)	**-**	-	**194 315**	122 925
Total administered decreases	**970 082**	974 152	**194 513**	123 071
Total decreases	**979 776**	983 677	**194 513**	123 071
Total balance carried forward to the next period	**207 158**	148 183	**307**	1 076

1 *Appropriation:* Financial Management and Accountability Act 1997 section 21

Establishing Instrument: National Blood Authority Act 2003

Purpose: The National Blood Authority was established on 1 July 2003 with the principal role of managing the national blood arrangements, ensuring sufficient supply and to provide a new focus on the safety and quality of blood and blood products. The funding for blood and blood products is funded from a special account established under the National Blood Authority Act 2003, section 40. The NBA's activities contributing to its outcome are classified as either departmental or administered. Departmental activities involve the use of assets, liabilities, revenues and expenses controlled by the agency in its own right. Administered activities involve the management or oversight by the NBA on behalf of the Government of items controlled or incurred by the Government.

2 *Appropriation:* Financial Management and Accountability Act 1997 section 20

Establishing Instrument: Financial Management and Accountability Act 1997 section 20

Purpose: For the receipt of monies and payment of all expenditure related to the management of blood and blood products liability claims against the Australian Red Cross Society (ARCS) in relation to the activities undertaken by the operating division of the ARCS known as the Australian Red Cross Blood Service.

NOTE 26: Special Accounts and FMA Act Section 39

Note 26B: Investments made under section 39 of the FMA Act (Recoverable GST exclusive)

2012	Balance brought forward from previous period $'000	Investments made $'000	Investment income $'000	Transactional charges $'000	Investments realised $'000	Total balance carried to the next period $'000
Financial Management and Accountability (Finance Minister to Chief Executives) Delegation 2009 - Amendment No. 2 2010	81,768	191,248	3,067	-	182,408	93,675
Total	**81,768**	**191,248**	**3,067**	**-**	**182,408**	**93,675**

On 28 June 2010, the Finance Minister delegated to NBA investment powers under Section 39 of the FMA Act.
An analysis of the risk profile, desired investment returns and length of investment was independently performed by expert consultants in developing an approved investment strategy. During the year all investments were made in accordance with the approved investment strategy.

2011	Balance brought forward from previous period $'000	Investments made $'000	Investment income $'000	Transactional charges $'000	Investments realised $'000	Total balance carried to the next period $'000
Financial Management and Accountability (Finance Minister to Chief Executives) Delegation 2009 - Amendment No. 2 2010	-	122,379	546	-	41,157	81,768
Total	**-**	**122,379**	**546**	**-**	**41,157**	**81,768**

On 28 June 2010, the Finance Minister delegated to NBA investment powers under Section 39 of the FMA Act.
An analysis of the risk profile, desired investment returns and length of investment was independently performed by expert consultants in developing an approved investment strategy. During the year all investments were made in accordance with the approved investment strategy.

NATIONAL BLOOD AUTHORITY
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for the year ended 30 June 2012

NOTE 27: Compliance with Statutory Conditions for Payments from the Consolidated Revenue Fund

Section 83 of the Constitution provides that no amount may be paid out of the Consolidated Revenue Fund except under an appropriation made by law. The Department of Finance and Deregulation provided information to all agencies in 2011 regarding the need for risk assessments in relation to compliance with statutory conditions on payments from special appropriations, including special accounts.

During 2011-12, the NBA developed a plan to review exposure to risks of not complying with statutory conditions on payments from appropriations. The plan involved:

- identifying each special account;
  determining the risk of non-compliance by assessing the difficulty of administering the statutory conditions and
- assessing the extent to which existing payment systems and processes satisfy those conditions;
  determining procedures to confirm risk assessments in medium risk cases and to quantify the extent of non-
- compliance, if any, in higher risk situations;
- obtaining legal advice as appropriate to resolve questions of potential non-compliance; and
  considering legislative or procedural changes to reduce the risk of non-compliance in the future to an
- acceptably low level.

The NBA identified 2 appropriations involving statutory conditions for payment, comprising:

- 2 special accounts

As at 30 June 2012, this work had been completed in respect of all appropriations with statutory conditions for payment.
The work conducted to date has identified no issues of compliance with Section 83.

NOTE 28: Compensation and Debt Relief

Departmental

No 'Act of Grace' payments were expensed during the reporting period (2011: no expenses).

No waivers of amounts owing to the Australian Government were made pursuant to subsection 34(1) of the *Financial Management and Accountability Act 1997* (2011: no waivers).

No payments were provided under the Compensation for Detriment caused by Defective Administration (CDDA) during the reporting period (2011: no payments).

No ex gratia payments were provided for during the reporting period (2011: no payments).

No payments were provided in special circumstances relating to APS employment pursuant to section 73 of the *Public Service Act 1999* (PS Act) during the reporting period (2011: no payments).

Administered

No 'Act of Grace' expenses were incurred during the reporting period (2011: no expenses).

No waivers of amounts owing to the Australian Government were made pursuant to subsection 34 (1) of the *Financial Management and Accountability Act 1997* (2011: no waivers).

No payments were provided under the Compensation for Detriment caused by Defective Administration (CDDA) during the reporting period (2011: no payments).

No ex gratia payments were provided during the reporting period (2011: no payments).

No payments were provided in special circumstances relating to APS employment pursuant to section 73 of the *Public Service Act 1999* (PS Act) during the reporting period (2011: no payments).

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2012

Note 29: Reporting of Outcomes

Note 29A: Net Cost of Outcome Delivery

	Outcome 1	
	2012	2011
	$'000	$'000
Departmental		
Expenses	**10 380**	9 784
Own-source income	**4 030**	4 074
Administered		
Expenses	**955 884**	938 264
Own-source income	**394 734**	349 127
Net cost of outcome delivery	**567 500**	594 847

Note 29B: Major Classes of Departmental Expense, Income, Assets and Liabilities by Outcomes

The NBA has only one Outcome. Refer to the Statement of Comprehensive Income and the Balance Sheet.
Outcome 1 is described in Note 1.1. Net costs shown include intra-government costs that were eliminated in calculating the actual Budget Outcome.
Refer to Outcome 1 Resourcing Table in this Annual Report.

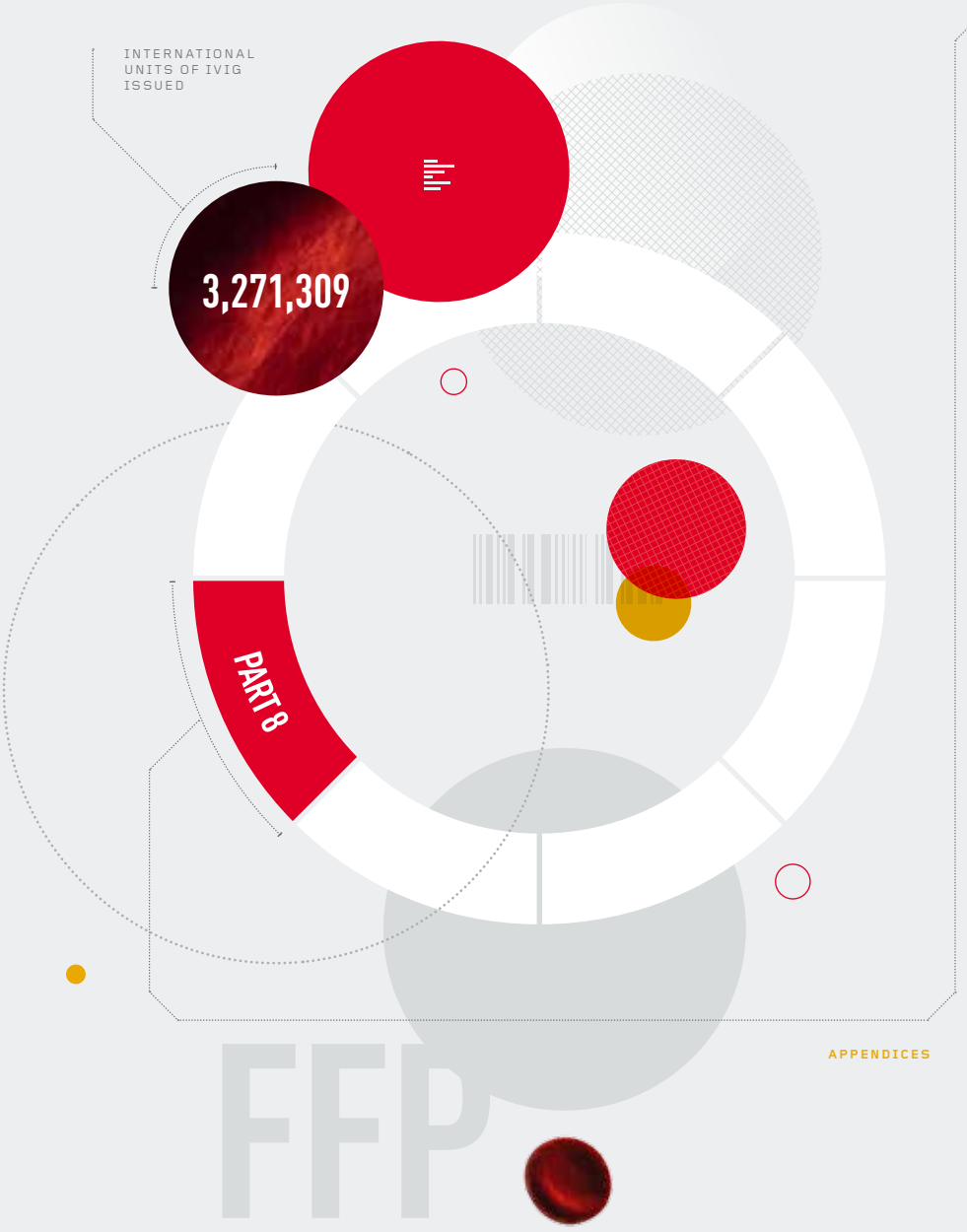
Note 29C: Major Classes of Administered Expenses, Income, Assets and Liabilities by Outcomes

The NBA has only one Outcome. Refer to the Administered Schedule of Comprehensive Income and the Administered Schedule of Assets and Liabilities.
Outcome 1 is described in Note 1.1. Net costs shown included intra-goveernment costs that were eliminated in calculating the actual Budget Outcome.

NOTE 30: Net Cash Appropriation Arrangements

	2012	2011
	$'000	$'000
Total comprehensive (loss) less depreciation/amortisation expenses previously funded through revenue appropriations [1]	**(1 415)**	(557)
Plus: depreciation/amortisation expenses previously funded through revenue appropriation	**751**	795
Total comprehensive income (loss) - as per the Statement of Comprehensive Income	**(664)**	238

[1] From 2010-11, the Government introduced net cash appropriation arrangements, where revenue appropriations for depreciation/amortisation expenses ceased. However, the NBA was granted an exemption until the 2011-12 year. The NBA now receives a separate capital budget provided through equity appropriations. Capital budgets are to be appropriated in the period when cash payment for capital expenditure is required.


INTERNATIONAL
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8

APPENDICES

APPENDIX 1. BLOOD SECTOR STAKEHOLDERS AND GOVERNANCE

STAKEHOLDERS

Australian, state and territory governments

As signatories to the National Blood Agreement, the Australian, state and territory governments are responsible for:

- establishing the policy framework and specific policies relating to the national blood supply
- overseeing the NBA's management of the blood supply arrangements
- fostering the development and implementation of best practice systems to promote efficient use and minimal wastage of blood and blood products
- providing information on demand for blood and blood products
- managing local issues.

Therapeutic Goods Administration (TGA)

The TGA is the regulator for blood and blood products in Australia. It is responsible for:

- regulating the efficacy and safety of blood and blood products under the *Therapeutic Goods Act 1989*
- auditing supplies against good manufacturing practice
- issuing product recalls
- issuing modifications to safety standards
- issuing directives such as those relating to donor deferral.

Suppliers of blood and blood products in Australia

The NBA contracts with a number of suppliers for the provision of blood and blood components and products including:

- the Australian Red Cross Blood Service (the Blood Service), which collects fresh blood from voluntary donors
- CSL Limited, which fractionates plasma from blood collected by the Blood Service and supplies a range of plasma products purchased through the NBA contract with CSL Limited.

During the year, the NBA has held contracts with suppliers for the provision of blood and blood products under standing offer arrangements with:

- Baxter Healthcare Pty Ltd, Grifols Australia Pty Ltd and Octapharma Australia Pty Ltd, for the provision of overseas-sourced intravenous immunoglobulin (IVIg)
- Baxter Healthcare Pty Ltd, Bayer Australia Ltd, CSL Limited, Novo Nordisk Pharmaceuticals Pty Ltd and Pfizer Australia Pty Ltd for the provision of a range of imported plasma-derived and recombinant blood products
- Abacus ALS Pty Ltd, Bio-Rad Laboratories Pty Ltd, CSL Limited, Grifols Australia Pty Ltd and Johnson and Johnson Medical Pty Ltd (trading as Ortho-Clinical Diagnostics), for the supply of diagnostic reagents.

Governance

The key governing bodies in the Australian blood sector and their roles and relationships with each other are set out in the National Blood Agreement and the *National Blood Authority Act 2003*.

Standing Committee on Health (formerly the Australian Health Ministers' Conference)

The SCoH is responsible for overseeing and managing the blood sector. It sets the governance, policy and financial frameworks under which the NBA operates. In 2011–12 health ministers:

- endorsed a proposed action plan for the development of a new deed of agreement with the Red Cross
- noted funding proposals for rebasing the NBA office and for data and performance improvement activities, over four years
- noted the Blood Service's Statement of Expectations performance report for 2010–11 and approved in-principle publication of the report on the NBA website each year
- endorsed the revised *Criteria for the Clinical use of intravenous immunoglobulin in Australia (second edition)*
- endorsed the *NBA Corporate Plan 2010–2012*
- noted the report on progress with implementing the recommendations of the *Administrative Review of the National Blood Arrangements 2009*
- approved the NSP&B 2011–12.

The Hon Catherine King MP, Parliamentary Secretary to the former Minister for Health and Ageing, the Hon Nicola Roxon MP, and to the current Minister for Health and Ageing, the Hon Tanya Plibersek MP, has had executive responsibility for the NBA within the Australian Government health portfolio since 14 September 2010.

Australian Health Ministers' Advisory Council (AHMAC)

AHMAC provides support to the SCoH. It advises the health ministers on strategic matters relating to the coordination of health services across the nation and, as necessary, with New Zealand. The Council considers blood sector matters referred to it by the JBC through the CTEPC, and reports as necessary, to the SCoH. The Council has no statutory power and decisions are reached by consensus.

Clinical, Technical and Ethical Principal Committee (CTEPC)

The CTEPC was established in 2006 to provide advice to the AHMAC on a range of issues, such as:

- clinical, technical and medico-ethical developments that are likely to affect more than one jurisdiction
- options for ongoing coordination of the clinical and technical services that are managed on a national basis
- the appropriateness, effectiveness and safety of clinical and technical developments and any policy implications arising from such issues
- the impact of clinical and technical developments on the delivery and management of health care and other services
- the impact of these developments outside the health care sector.

The CTEPC held its last meeting in February 2012. Following a review of AHMAC Principal Committees, jurisdictions have agreed that a new AHMAC Principal Committee structure will commence in July 2012. Under the new arrangements the JBC will report to the Hospitals Principal Committee which will meet for the first time in early July 2012.

Jurisdictional Blood Committee (JBC)

Australian, state and territory governments are represented on the JBC, which was established by the National Blood Agreement in 2003. The committee is the conduit between governments and the NBA. It represents the Australian, state and territory governments' positions on blood policy, demand, supply planning and product distribution, funding and evidence-based approaches to emerging products, services and technologies. It oversees the NBA's role in blood supply contracting. It is also the primary body responsible for providing advice and support on these matters to the SCoH through the CTEPC, of which it has been a subcommittee since September 2006, and the AHMAC.

Following a recommendation of the *Administrative Review of the National Blood Arrangements 2009*. The CTEPC strengthened communication links between it and the JBC by appointing a representative of the CTEPC to attend the JBC meetings. During 2011–12, Dr Stephen Christley attended the JBC meetings.

Members of the JBC serve on various NBA committees and working groups and are a highly respected and valuable source of advice and expertise. During the year, several members stepped down, including Mr Geoff Simon (QLD), Ms Kelly Burns (NT), Ms Donna Burton (Commonwealth), and Dr Priya Dubey (TAS).

The members of the committee at 30 June 2012 were:

MEMBER	JURISDICTION
Ms Mary McDonald (Chair)	Commonwealth
Ms Peter Woodley	Commonwealth
Ms Carolyn Duck	Australian Capital Territory
Ms Kim Stewart	New South Wales
Ms Michelle Casey	Northern Territory
Dr Julie Stokes	Queensland
Ms Susan Ireland	South Australia
Ms Julie Tate	Tasmania
Ms Karen Botting	Victoria
Dr Audrey Koay	Western Australia

APPENDIX 2. THE NATIONAL BLOOD AGREEMENT: OBJECTIVES OF GOVERNMENTS

1. The primary policy objectives for the Australian blood sector are:
   a. to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia
   b. to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.
2. In pursuing the primary policy objectives, the Parties will have regard to the following secondary policy aims:
   a. to meet international obligations and standards
   b. to maintain reliance on voluntary, non-remunerated donations of whole blood and plasma
   c. to promote national self-sufficiency
   d. to provide products to patients, free of charge and based on clinical need and appropriate clinical practice
   e. to promote optimal safety and quality in the supply, management and use of products, including through uniform national standards
   f. to make best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sectors
   g. to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sector
   h. to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs
   i. to ensure public support and confidence in the Australian blood sector
   j. to work towards optimal access to blood and blood products across the nation, ensuring that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude states and territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction.

APPENDIX 3. NBA AGENCY RESOURCE STATEMENT

The agency resource statement provides details of the funding sources that the NBA drew upon in 2011–12. In addition it provides information about special accounts balances to be carried over to 2012–13.

	Actual Available Appropriations for 2011–12 ($'000)	Payments Made 2011–12 ($'000)	Balance Remaining 2011–12 ($'000)
Ordinary annual services			
Departmental appropriation			
Departmental appropriation	5 119	5 119	-
Total	**5 119**	**5 119**	**-**
Administered expenses			
Outcome 1:	7 679	7 679	
Total	**7 679**	**7 679**	
Total ordinary annual services	**12 798**	**12 798**	
Special accounts			
Opening balance	149 259		
Appropriation receipts	12 798		
Non-appropriation receipts	1 219 697		
Payments made		1 174 289	
Closing balance			207 465
Total resourcing and payments	1 381 754	1 174 289	

RESOURCES FOR OUTCOMES

This table is intended to provide details of the total funding for each outcome. In 2011–12 the NBA operated under a single outcome.

Outcome 1— Australia's blood supply is secure and well managed

	Budget 2011–12 ($'000)	Actual Expenses 2011–12 ($'000)	Variation 2011–12 ($'000)
Output Group 1			
Special Accounts			
Administered Items	1 034 535	955 884	78 651
Departmental Outputs	10 941	10 380	561
Total for Outcome 1	**1 045 476**	**966 264**	**79 212**
Average Staffing level (number)		**46.5**	

APPENDIX 4. NBA BOARD MEMBERS

Board members are selected by the SCoH. They are appointed by the Australian Government Minister for Health and Ageing to serve a term not exceeding four years and are eligible for reappointment. The Board is required, under section 44(2) of the *National Blood Authority Act 2003,* to report on its activities on an annual basis.

In accordance with these arrangements, the current Board members took up their appointments on 14 May 2011.

Ms Gayle Ginnane—chair

Ms Gayle Ginnane was the CEO of the Private Health Insurance Administration Council, a government agency reporting to the Minister for Health and Ageing, with financial and regulatory responsibility for the private health insurance industry until May 2008. She has broad experience as a senior manager in an insurance and regulatory environment, and an in depth understanding of governance, risk management and finance.

Ms Ginnane has considerable experience as an independent director on a number of boards, both commercial and not for profit, in the voluntary, government and private sectors. As well as Chair of the NBA Board, Ms Ginnane is a councillor on the Australian Pharmacy Council, a director of the ACT Medicare Local, the Australian Children's Education and Care Quality Authority and Police Health. She has also contributed to a number of voluntary organisations at senior and Board levels including Scouts ACT, the Arthur Shakespeare Foundation for Scouting and the Community Living Project.

Ms Ginnane is a member of the Institute of Public Administration and the Australian Institute of Management, a fellow of the Australian Institute of Company Directors and an affiliate member of the Institute of Actuaries of Australia.

Ms Ginnane was appointed Chair of the NBA Board in May 2011.

Mr Ken Barker—financial expert

Until 2009 Mr Ken Barker had some 42 years of experience in the New South Wales Government. He worked for New South Wales Health for 24 years where his last appointment was as Chief Financial Officer. He is now director of his own company, which specialises in financial management and provision of strategic advice, mainly to government agencies. He is also a member of a number of state government governance boards and of several New South Wales agency audit and risk committees.

Mr Barker was involved in the former New South Wales Blood Transfusion Service, and has made important contributions to many of the key decisions and events that have shaped the current Australian blood sector: the establishment of the Australian Red Cross Blood Service, the NBA; provision of national indemnity arrangements for blood and blood products; the Stephen *Review of the Australian Blood Banking and Plasma Product Sector*; and the 2008 KPMG business study of the Blood Service.

Mr Barker was appointed to the NBA Interim Board and has served as a full Board member since the inception of the NBA. He was reappointed in May 2011. He served as Chair of the NBA Audit Committee between 2003 and 2007 and continues to serve as an Audit Committee member.

Mr Paul Bedbrook—community representative

Mr Paul Bedbrook has had a connection with blood issues via his personal involvement with haemophilia for over two decades. He is the father of two adult sons with haemophilia. For much of those two decades Mr Bedbrook has been involved with the Haemophilia Foundation NSW (HFNSW) and the Haemophilia Foundation Australia (HFA). He is a past President of HFNSW and past Treasurer of HFA. He brings his personal experiences with blood issues to the Board as well as feedback from a community of individuals who rely on the blood and plasma products distributed to Australia's health services under the auspices of the NBA.

Professionally, Mr Bedbrook has over thirty years of experience in financial services. He was a senior executive for over 20 years with the Dutch global banking, insurance and investment group, ING. His early career was as an investment analyst and investment portfolio manager and he was the General Manager Investments and Chief Investment Officer for the Mercantile Mutual (ING) Group in Sydney from 1987 to 1995. In the decade to 2010, he was President and CEO, INGDIRECT, Canada; CEO and director of ING Australia and Regional CEO, ING Asia Pacific based in Hong Kong. His current roles include independent non-executive director of Zurich Australia Ltd and Credit Union Australia Ltd, and Deputy Chairman, Australian Athletes with a Disability.

Mr Bedbrook was appointed community representative on the NBA Board in May 2011.

Professor Chris Brook PSM—state and territory representative (large jurisdiction)

Professor Chris Brook is the Executive Director, Well-being, Integrated Care and Ageing for the Victorian Department of Health. This role focuses on prevention and population health, aboriginal health, integrated care, aged care, workforce policy and planning in the health sector and internal departmental human resource functions. He is also the State Health and Medical Commander for Emergency Management, a portfolio involving hospitals, residential aged care facilities, community health centres, non-government organisations and local government.

Professor Brook's original postgraduate training was as a specialist physician but he has subsequently gained specialist qualifications in public health medicine and in medical administration.

Professor Brook is a regular attendee at SCoH meetings and during the year was a member of CTEPC. He has extensive policy and management experience in blood and blood products. He is a former president and an honorary life member of the International Society for Quality in Healthcare and a Fellow of the Victorian Division of the Institute of Public Administration, Australia.

He chairs the Advisory Committee of Deakin University Medical School and is a member of the boards of the HealthSmart program and the Centre for Evidence in Intervention and Prevention Science. In 2011, he was awarded a Public Service Medal.

Professor Brook was appointed to the NBA Board in May 2011.

Dr Stephen Christley—state and territory representative (small jurisdiction)

Dr Stephen Christley is Chief Public Health Officer and Executive Director of Public Health and Clinical Systems in the South Australian Department of Health. He has previously served as a CEO of three separate area health services in New South Wales. He is a medical practitioner and has worked in rural, public health and community settings.

Dr Christley's interests are public health, health system improvement and safety and quality. He has been a member of a number of research/fundraising foundation boards and is a member of the Australian Health Protection Principal Committee of AHMAC.

Dr Christley was appointed state and territory representative on the NBA Board in March 2009.

Ms Mary Murnane—Australian Government representative

Ms Mary Murnane is a former Deputy Secretary of the Department of Health and Ageing. She retired recently but is continuing to work part-time providing strategic and policy support to the Department of Health and Ageing. Ms Murnane was recently appointed to the Human Genetics Advisory Committee of the NHMRC.

She was reappointed as Commonwealth representative to the NBA Board in May 2011.

Professor George Rubin MB BS (Hons) FRACP FAFPHM FAChAM—public health expert

Professor George Rubin is Director of Clinical Governance with the South Eastern Sydney Local Health District and is Professor of Public Health at both the University of Sydney and the University of New South Wales. He is a past President of the Australasian Faculty of Public Health Medicine and Board member of the Royal Australasian College of Physicians. He currently works part-time as an addiction medicine specialist at the Langton Centre in Sydney. He has worked internationally in the Americas and Asia and has published more than 150 scientific papers in the peer reviewed literature including reports on the appropriateness of use of blood products.

He served formerly as Director of the Centre for Health Service and Workforce Research, in Sydney's West. Before that he was Director of Epidemiology and Health Services Evaluation and Chief Health Officer with NSW Health where he was instrumental in developing public health infrastructure and education in NSW. He was chair of the Australian Technical Advisory Group on Immunisation from 1997 to 2005 and served two consecutive terms on the NHMRC Health Advisory Committee. For 10 years he was a medical epidemiologist working in reproductive health with the USA Centers for Disease Control and Prevention and with the Ford Foundation in Bangladesh.

Professor Rubin was appointed to the NBA Board in May 2011.

APPENDIX 5. FRESH BLOOD COMPONENTS SUPPLIED UNDER CONTRACT BY THE BLOOD SERVICE 2011–12

PRODUCT NUMBER	PRODUCT NAME
2b	Whole blood red cell—leucodepleted
2d	Whole blood paediatric red cell—leucodepleted (set of 4)
2f	Whole blood washed red cell—leucodepleted
2g	Apheresis red cell—leucodepleted
3b	Whole blood platelet pool—leucodepleted
3d	Apheresis platelet—leucodepleted
3e	Paediatric apheresis platelet—leucodepleted (set of 4)
4b	Whole blood clinical FFP—buffy coat poor
4c	Paediatric clinical FFP (set of 4)
4d	Apheresis clinical FFP
5a	Whole blood cryoprecipitate
5b	Apheresis cryoprecipitate
6a	Whole blood cryo-depleted plasma
6b	Apheresis cryo-depleted plasma
7a	Autologous donation
7b	Directed donations complying with AHMAC guidelines
7c	Therapeutic venesections for whole blood for discard
7d	Serum eye drops—single collection unit
7e	Granulocytes

APPENDIX 6. PLASMA AND RECOMBINANT PRODUCTS SUPPLIED UNDER CONTRACT IN 2011–12

Products supplied under the CSL Australian Fractionation Agreement

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS
CSL Limited	**Albumin:**	
	Albumex 4	Used to treat hypovolaemia arising from shock, surgery or multiple organ failure
	Albumex 20	Used to treat patients suffering extensive burns or shock due to blood loss, or kidney or liver disease
	Immunoglobulins:	
	Hyperimmune globulins	Used to prevent a specific infection such as tetanus, hepatitis B, Zoster or cytomegalovirus
	Intragam P	Used to reduce susceptibility to infections and manage many immune system disorders
	Rh (D) Immunoglobulin	Used in the prevention of haemolytic disease of the newborn (HDNB), a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers
	Clotting factors:	
	Biostate	Used in the treatment of bleeding episodes in patients with FVIII deficiency due to haemophilia A. Biostate is also used in the treatment of bleeding episodes in patients with von Willebrand disease
	MonoFIX-VF	Used in the treatment of bleeding episodes in patients with Factor IX deficiency, known as haemophilia B or Christmas disease
	Prothrombinex-VF	Used to manage patients who need warfarin reversal for urgent surgery and treatment of some bleeding episodes in patients who have factor deficiency II, IX and X when a more purified factor concentrate is not available
	Thrombotrol-VF	Used to manage an inherited condition wherein a patient's blood clots too quickly

Imported IVIg products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS OR JURISDICTIONAL BLOOD ORDERS
Octapharma Australia Pty Ltd	Octagam	Used to reduce susceptibility to infections and manage many immune system disorders
Grifols Australia Pty Ltd	Flebogamma 5% DIF	Used to reduce susceptibility to infections and manage many immune system disorders (available for Jurisdictional Direct Orders) and under the national blood arrangements in defined circumstances

Imported rare bleeding and blood disorder plasma products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS OR JURISDICTIONAL BLOOD ORDERS
Baxter Healthcare Pty Ltd	Anti-inhibitor coagulant complex concentrates/ FEIBA	Used in the treatment of bleeding episodes including surgical interventions in haemophilia A and B patients with inhibitors
	FVII concentrate	Used in the treatment of bleeding episodes in people with Factor VII deficiency
	Protein C/Ceprotin	Used in the treatment of haemorrhagic conditions associated with congenital Protein C deficiency
CSL Limited	FXI/BPL Factor XI	Used in the treatment of bleeding episodes in people with Factor XI deficiency (sometimes called haemophilia C)
	FXIII/Fibrogammin P	Used in the treatment of bleeding episodes in people with Factor XIII deficiency
	Rh (D) Immunoglobulin	Used in the prevention of HDNB, a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers

Imported rare bleeding and blood disorder recombinant products[28]

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS OR JURISDICTIONAL BLOOD ORDERS
Novo Nordisk Pharmaceuticals Pty Ltd	rFVIIa/NovoSeven	Used in the treatment of bleeding episodes including surgical intervention in haemophilia A or B patients with inhibitors to Factor VIII or Factor IX
Baxter Healthcare Pty Ltd	rFVIII/Recombinate[29]	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients
	rFVIII/Advate	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients
Pfizer Australia Pty Ltd	rFVIII/Xyntha	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients
	rFIX/BeneFIX	Used in the prevention and control of haemorrhagic episodes in haemophilia B or Christmas disease (Factor IX deficiency) patients
Bayer Australia Ltd	rFVIII/Kogenate	Used in the prevention and control of haemorrhagic episodes in haemophilia A (Factor VIII deficiency) patients

28 Supply of Advate and Recombinate under NBA contracts ceased from1 July 2012.

APPENDIX 7. UNITS OF RED CELLS, PLATELETS AND IVIG ISSUED PER 1000 HEAD OF POPULATION BY STATE AND TERRITORY 2007–08 TO 2011–12

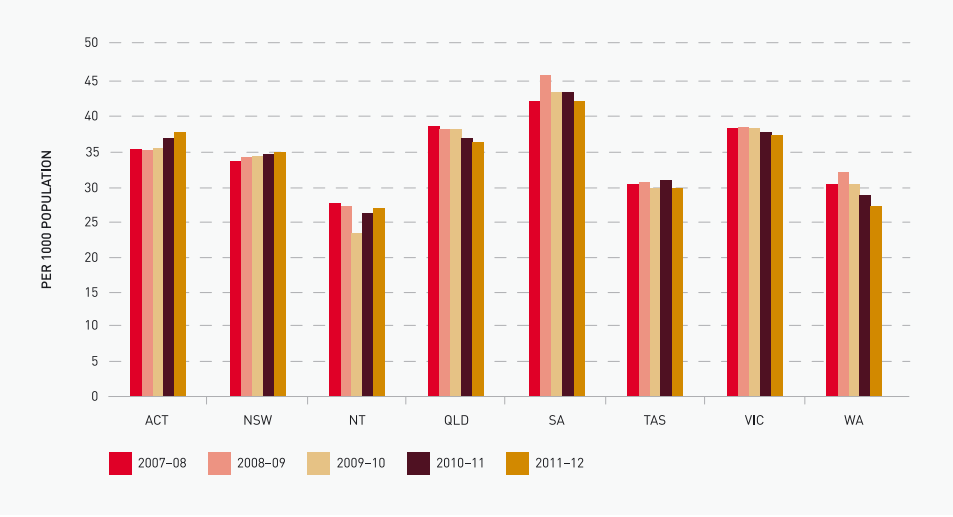

FIGURE A7.1 *Units of red cells issued per 1000 head of population by state and territory, 2007–08 to 2011–12*

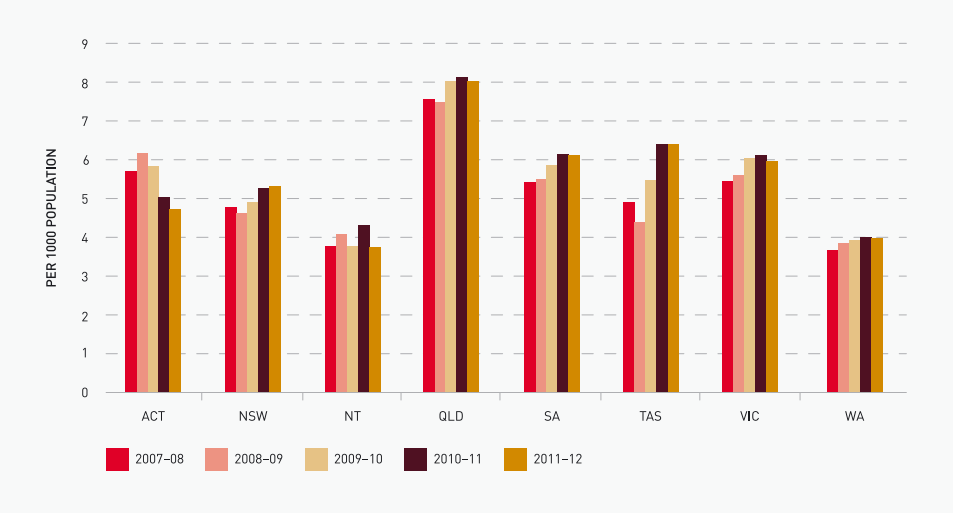

FIGURE A7.2 *Units of platelets issued per 1000 head of population by state and territory, 2007–08 to 2011–12*

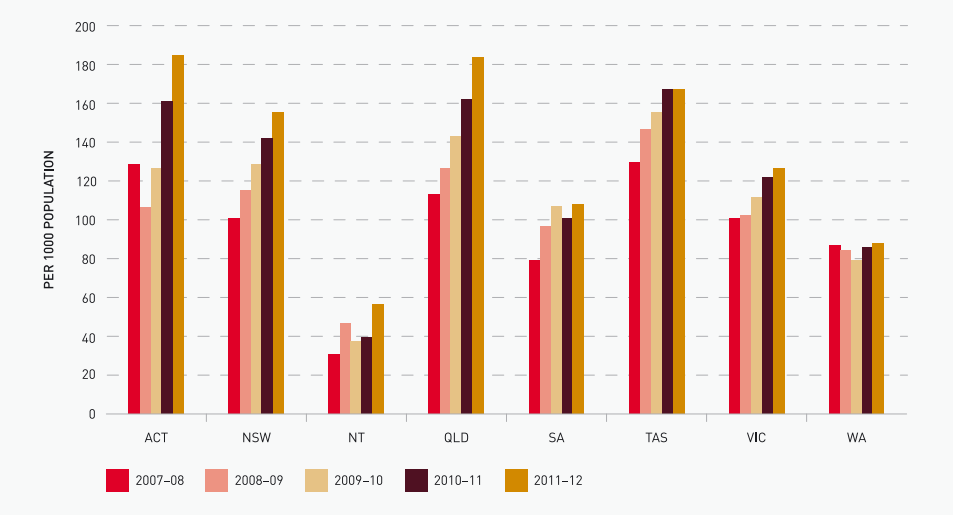

FIGURE A7.3 *Units of IVIg issued per 1000 head of population by state and territory, 2007–08 to 2011–12*

APPENDIX 8. RESPONSIBILITY AND COMPOSITION OF GOVERNANCE COMMITTEES

SENIOR EXECUTIVE MANAGERS' COMMITTEE

The Senior Executive Managers' Committee is the NBA's primary policy and process decision-making body and it supports the General Manager in matters relating to risk, compliance, stakeholder management, ethics and governance of the NBA. Members of the committee are the General Manager and Chief Executive Officer, deputy general managers, General Counsel and (until Dr Hogan's resignation in January 2012) the NBA's Principal Medical Officer.

The committee is responsible for:

- identifying, considering and agreeing on strategic directions for key emerging policy issues to ensure that the understanding, approach and communication on these issues are consistent
- maintaining an overview of the progress and development of the NBA and the environment in which it operates and translating this into NBA programs, projects and policies
- applying their collective experience and skills to the development of policies where more complex elements are involved—for example, where policies affect more than one program element—thus enhancing quality and commitment
- regularly considering key strategic planning, documentation and relationships.

The committee meets three times a month.

EXECUTIVE MANAGERS' COMMITTEE

The Executive Managers' Committee consists of all NBA officers at director level and above. It focuses on monitoring and improving performance and identifying and managing operational risks. It is also a forum in which major projects can be discussed and synergies and dependencies identified.

The committee is responsible for:

- identifying NBA performance issues that arise as a result of changes to processes, resourcing or other areas
- monitoring the effectiveness of performance measures and identifying improvements.

The committee meets once a month.

AUDIT COMMITTEE

The Audit Committee advises the General Manager on strategies to enhance the organisation's control framework, improve the objectivity and reliability of externally published financial information and comply with legislative requirements and obligations. Its membership is as follows:

- Ms Jennifer Morison (Chair)
- Mr Ken Barker
- Mr Mick Roche
- NBA Executive Member—currently vacant

Representatives from the ANAO and the NBA internal auditors also attend meetings as observers for most matters.

The Senior Executive Managers' Committee considers the Audit Committee minutes and any findings from internal and other audits to confirm priorities and resourcing for any recommended changes or improvements.

Ms Jennifer Morison FCA, FCPA, FAIM—Chair, Audit Committee

Ms Jennifer Morison, the Chair of the Audit Committee, is a chartered accountant with 31 years of broad experience in the profession and in commerce. Her career has included audit, taxation, management consulting, corporate advisory work, and consulting to government. She is a leading consultant in the area of public sector financial management reform in Australia and is an independent member and chair of a number of Commonwealth and ACT government audit and risk committees. She was awarded the Centenary medal for services to the accounting profession in 2000.

Ms Morison was appointed Chair of the NBA's Audit Committee in 2007, having been a member of the committee since 2004.

APPENDIX 9. MANDATORY REPORTING

CHANGES TO DISABILITY REPORTING IN ANNUAL REPORTS

Since 1994, Commonwealth departments and agencies have reported on their performance as policy advisor, purchaser, employer, regulator and provider under the Commonwealth Disability Strategy. In 2007–08, reporting on the employer role was transferred to the Australian Public Service Commission's *State of the Service Report* and the *APS Statistical Bulletin*. These reports are available at www.apsc.gov.au. From 2010–11, departments and agencies were no longer required to report on these functions.

The Commonwealth Disability Strategy has been overtaken by a new National Disability Strategy which sets out a ten year national policy framework for improving life for Australians with disability, their families and carers. A high level report to track progress for people with disability at a national level will be produced by the Standing Council on Community, Housing and Disability Services to the Council of Australian Governments and will be available at www.fahcsia.gov.au . The Social Inclusion Measurement and Reporting Strategy agreed by the Government in December 2009 will also include some reporting on disability matters in its regular *How Australia is faring* report and, if appropriate, in strategic change indicators in agency annual reports. More detail on social inclusion matters can be found at www.socialinclusion.gov.au.

ECOLOGICALLY SUSTAINABLE DEVELOPMENT AND ENVIRONMENTAL REPORTING

The ability of the NBA to promote ecologically sustainable principles outlined in Section 3A of the *Environment Protection and Biodiversity Conservation Act 1999* are limited but we remain mindful of the potential to ensure that:

- our decision-making processes effectively integrate both long-term and short-term economic, environmental, social and equitable considerations (the 'integration principle')
- the principle of inter-generational equity—that the present generation should ensure that the health, diversity and productivity of the environment is maintained or enhanced for the benefit of future generations (the 'inter-generational principle')
- improved valuation, pricing and incentive mechanisms should be promoted (the 'valuation principle').

These principles are most relevant to our purchasing activities. In 2011–12, further improvements were made within our blood product supply contracts with suppliers' commitments including:

- maintaining a corporate commitment to environmental health and sustainability, including water, waste, energy and materials
- utilising wind energy as a major sustainable CO2-free energy source in product manufacturing
- using returnable cold chain cartons for product
- using cardboard packaging made with 35% recycled paper
- recycling and landfill reduction strategies
- providing plastics for recycling into rubber mats and garden hoses.

During 2011–12, the NBA continued to focus on activities aimed at maintaining and improving our environmental performance outcomes, as reflected in the following examples:

- using 100% recycled A3 and A4 paper for all printing
- recycling into three streams of waste—co-mingled material, paper and printer cartridges
- purchasing 100% GreenPower for electricity use
- offsetting air travel through the GreenFleet program
- encouraging staff to recycle and re-use existing stationery before ordering new supplies
- replacing printers and photocopiers with fewer, new, energy-efficient multi-function devices and introducing swipe-to-print technologies resulting in a reduction of paper use and waste from uncollected print jobs
- commenced a project to replace our ICT infrastructure with more efficient equipment
- maintaining paper use reduction initiatives such as defaulting printer settings to print double sided and in black and white
- running the air conditioning system on a timer for operation only during business hours
- reducing energy consumption: by shutting down tenancy lighting after hours and utilising motion sensors in offices during working hours to turn off lighting when offices and conference rooms are unoccupied
- participating in Earth Hour—the office was fully compliant and all staff were encouraged to participate.

While the initiative to move key NBA committees from paper to electronic agenda papers was not implemented in 2011–12, it is anticipated to occur in 2012–13 and is expected to lead to increased efficiencies in meeting and secretariat functions, a substantial decrease in paper usage and an increase in the security of the agenda papers.

We continue to look at further opportunities in our internal operations and in our premises to further minimise our impact on the environment.

In summary, Table A9.1 provides information on the impact our activities have on the natural environment and measures taken and planned to further reduce these impacts.

TABLE A9.1 *NBA Environmental performance indicators*[29]

THEME	PERFORMANCE MEASURE	INDICATOR(S)	2009–10	2010–11	2011–12[31]
Energy efficiency	Total consumption of energy—this includes all energy consumed when undertaking the functions of the agency, such as energy consumed for office buildings and transportation	Amount of electricity purchased/consumed ($/kWh)	139,701 kWh	140,900 kWh	154,160 kWh
		Amount of gas purchased/consumed ($/MJ)	0 MJ	0 MJ	0 MJ
		Amount of other fuels purchased/consumed ($/kWh/MJ/L)	2,356 L	0[32]	0
		Air travel distances (km)	543,492 km	825,716 km[33]	743,949 km
	Total consumption of green energy—this includes the purchase of energy from sustainable resources	Amount of green energy purchased/consumed ($/kWh) during the reporting period	139,701 kWh	140,900 kWh	154,160 kWh
	Greenhouse gas emissions	Amount of greenhouse gases produced (tonnes)	169.3 tonnes	20.22 tonnes[34]	0 tonnes[35]
	Relative energy uses—this includes the green energy use relative to non-renewable energy use and energy use per employee	Amount of green energy purchased/consumed divided by the amount of electricity/gas/other fuels purchased/consumed	100%	100%	100%
		Amount of total energy purchased/consumed ($/kWh) per employee	2,910 kWh	2,818 kWh	2,964 kWh
Waste	Total waste production—this includes the green energy waste (i.e.unwanted byproducts) produced undertaking the functions of the agency	Amount of waste produced (tonnes)	Monitoring will be introduced for all waste	7.64 tonnes	7.09 tonnes
	Un-recyclable waste production—this includes all wastes that are not re-used or recycled	Amount of waste going to landfills (tonnes)		3.69 tonnes	3.69 tonnes

29 Note that all measures are best estimates only, and are likely to change substantially as measurement capacities improve.

30 Increases mainly due to the number of contractors engaged throughout the year to develop national ICT systems who are not included in employee calculations. Calculations for per employee figures have been based on 52 FTE.

31 There was no amount associated with other fuels purchased/consumed in 2010-11 due to the NBA no longer having a leased car.

32 Increase was due to deployment of national ICT systems throughout Australia requiring travel for trainers, and the intensive consultation phase for clinical guideline development.

33 Electricity fully off-set through 100% green energy purchased and during the year, the NBA off-set 767,757 kms in air travel through the GreenFleet program.

34 Electricity fully off-set through 100% green energy purchased and the NBA off-set 743,949 kms in air travel through the GreenFleet program.

THEME	PERFORMANCE MEASURE	INDICATOR(S)	2009–10	2010–11	2011–12[31]
	Recyclable waste production (excluding office paper)	Amount of waste going to recycling facilities (tonnes)		1.335 tonnes	0.486 tonnes
	Paper waste production	Amount of waste paper going to recycling facilities (tonnes)		2.615 tonnes	2.918 tonnes
		Amount of paper sourced from recyclable sources (tonnes)		1.99 tonnes	2.075 tonnes
		Percentage of paper sourced from recyclable sources (per cent)		76%	96%
	Use of renewable/ recyclable products	Amount of products sourced from renewable/recyclable sources (tonnes)		1.99 tonnes	2.075 tonnes
	Relative waste production	Amount of total waste (tonnes) per employee		0.15 tonnes	0.136 tonnes
Water	Total consumption of water—this includes all water consumed when undertaking the functions of the agency	Amount of water purchased/consumed ($/L)	680,000 L	493,000 L[36]	369,999 L
	Grey water capture and use—this includes all waste water capture and re-use/recycling	Amount of grey water captured (L)	0 L	0 L	0 L
		Amount of grey water recycled (L)	0 L	0 L	0 L
		Amount of grey water re-used(L)	0 L	0 L	0 L
	Rainwater capture and use—this includes all rain water captured and used onsite	Amount of rainwater captured (L)	0 L	0 L	0 L
		Amount of captured rainwater used (L)	0 L	0 L	0 L
	Relative consumption/ use of water—this includes the use of water per employee	Amount of total water use (L) per employee	14,000 L	9,680 L	7,115 L

35 The decrease in reported water consumption reflects more accurate measurement of allocation of water of our joint tenancy.

FREEDOM OF INFORMATION

Agencies subject to the *Freedom of Information Act 1982* (FOI Act) are required to publish information to the public as part of the Information Publication Scheme (IPS). This requirement is in Part II of the FOI Act and has replaced the former requirement to publish a section 8 statement in an annual report. Each agency must display on its website a plan showing what information it publishes in accordance with the IPS requirements.

The NBA's IPS is available at: http://www.nba.gov.au/foi-ips/nba-ips.pdf.

The NBA's IPS includes: information about the NBA (including the NBA's organisational structure and statutory appointments); information on what the NBA does (including the NBA's functions and powers and operational information); details of the NBA's reports and responses to Parliament; and a disclosure log listing information that can be published resulting from freedom of information requests and any routinely released information arising from such requests. Together with this suite of information, the NBA's IPS also includes details about the NBA's consultation arrangements and who to contact in relation to an FOI request or in relation to a query regarding the IPS.

In 2011–2012 the NBA received one request for access to documents and no requests for internal review, under the FOI Act. The NBA was not involved in any Administrative Appeals Tribunal matters in respect of the FOI Act.

WORK HEALTH AND SAFETY

The NBA commissioned a work health and safety review in December 2011 in preparation for compliance with the *Work Health and Safety Act 2011* ((the Act) effective January 2012). The positive outcome of this review made recommendations on reporting compliance to meet the obligations under the new Act, which were duly implemented. Following a desktop audit, the NBA's Health and Safety Management Arrangements (HSMA) were determined to be compliant with section 16(2) of the *Occupational Health and Safety Act 1991*. Comcare undertook this audit as part of its national proactive campaign on HSMA for Commonwealth agencies.

The NBA's elected health and safety representative fulfilled the requirements of the Health and Safety Representative Refresher Training course during the year.

The NBA executive reviewed regular monthly work health and safety reports. One reportable incident was logged with Comcare during the year.

Other initiatives that the NBA undertook during the year to maintain our ongoing commitment to a safe and secure workplace included:

- regular reporting on workplace health and safety issues and wider HSMA issues to our Staff Participation Forum
- holding a workplace health and safety knowledge management session for all staff that included showing an occupational health and safety video
- conducting another knowledge management session to brief staff on the new Act
- the NBA conducted a staff participation survey which included workplace health and safety questions.

The NBA continued its health program to assist staff in maintaining and improving their health (see page 111). The NBA also continued to offer employees allowances for screen-based spectacles, software for assistance in managing keyboard requirements, the provision of hand sanitiser equipment upon entry to our premises, as well as influenza vaccinations to employees and their immediate families.

APPENDIX 10. ERRATA

p.35 ***FIGURE 3.16*** *Issues of FEIBA, 2007–08 to 2010–11*

The incorrect volumes are recorded. The vertical axis should read (from top to bottom): 5,000,000 / 4,500,000 / 4,000,000 / 3,500,000 / 3,000,000 / 2,500,000 / 2,000,000 / 1,500,000 / 1,000,000 / 500,000

p.214 ***TABLE A9.1*** *Environmental performance indicators*

The indicator under the second performance measure of 'Waste' is incorrect and should read 'Amount of waste going to landfills (tonnes)'

APPENDIX 11. GLOSSARY OF TERMS AND ACRONYMS

ACRONYMS

ABDR	Australian Bleeding Disorders Registry
ACSQHC	Australian Commission of Safety and Quality in Health Care
ACT	Australian Capital Territory
AHCDO	Australia Haemophilia Centre Directors' Organisation
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AHP	approved health providers
ANAO	Australian National Audit Office
ANZSBT	Australia and New Zealand Society of Blood Transfusion
APS	Australian Public Service
ARCBS	Australian Red Cross Blood Service (the Blood Service)
AWA	Australian Workplace Agreement
BSE	Bovine spongiform encephalopathy
CAFA	CSL Australian Fractionation Agreeement
CEO	Chief executive officer
CHERE	Centre for Health Economics Research Evaluation
CSL Limited	Now the name of a private company; the name derives from its earlier existence as the Commonwealth Serum Laboratories
CTEPC	Clinical, Technical and Ethical Principal Committee
DIF	dual inactivation and nanofiltration
DoHA	Department of Health and Ageing
ERIC	Electronic Returns Information Capture (Blood Service)
FEIBA	Factor Eight Inhibitor Bypass Agent
FFP/FP	fresh frozen plasma/frozen plasma
FVIII	Factor eight
FX	Factor ten
GST	goods and services tax
HAA	annual scientific meeting of the HAA—Haematology Society of Australia and New Zealand—**H**SANZ, the Australian & New Zealand Society of Blood Transfusion—**A**NZSBT, and the Australasian Society of Thrombosis and Haemostasis—**A**STH

HAC	Haemovigilance Advisory Committee
HFA	Haemophilia Foundation of Australia
HFNSW	Haemophilia Foundation of New South Wales
HIV	human immunodeficiency virus
HSMA	Health and Safety Management Arrangements
HTC	haemophilia treatment centres
IDMS	Integrated Data Management System
IgG	immunoglobulin
IPS	Information Publication Scheme
ITP	Idiopathic thrombocytopenic purpura
IVIg	intravenous immunoglobulin
IU	International unit
JBC	Jurisdictional Blood Committee
KPI	key performance indicator
kWh	kilowatt hour
MSAC	Medical Services Advisory Committee
NASH	National Authentication Service for Health
NAT	nucleic acid test
NBA	National Blood Authority
NBSCP	National Blood Supply Contingency Plan
NEHTA	National E Health Transition Authority
NF	nanofiltration
NHMRC	National Health and Medical Research Council
NIg	Normal immunoglobulin
NIH	National Institutes of Health (USA)
NIMS	National IVIg Management System
NIRG	National Indemnity Reference Group
NMF	National Managed Fund
NSQHS	National Safety and Quality Health Service
NSP&B	National Supply Plan and Budget
NT	Northern Territory
ORBS	Ordering and Receipting Blood System
PBM	Patient blood management
PBMC	Patient Blood Management Committee
Red Cross	The Australian Red Cross Society
rFVIIa	recombinant Factor seven (A)
QLD	Queensland
rFVIII	recombinant Factor eight (clotting factor)

rFIX	recombinant Factor nine (clotting factor)
SA	South Australia
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs (UK)
SCIg	Subcutaneous Immunoglobulin
SCoH	Standing Council on Health (formerly the Australian Ministers' Health Conference)
SES	Senior Executive Service
TAS	Tasmania
TGA	Therapeutic Goods Administration
TXA	tranexamic acid
vCJD	variant Creutzfeldt-Jacob Disease
vWD	von Willebrand disease
WA	Western Australia
WHO	World Health Organization

GLOSSARY OF TERMS

TERM	DEFINITION
Acquired hypogammaglobulinaemia	See http://www.nba.gov.au/ivig/pdf/criteria.pdf.
Acquired immunodeficiency syndrome	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
albumin	The main protein in human blood and the key to the regulation of the osmotic pressure of plasma. It is extracted from blood and manufactured into an intravenously administered product
Alzheimer's disease	The most common form of dementia, a neurological disease resulting in impaired memory thinking and behaviour
amino acids	One of the 21 building blocks of protein
anaemia	A medical condition in which the haemoglobin is less than normal. For men, anaemia is typically defined as haemoglobin level of less than 13.5 gram/100ml and in women less than 12.0 gram/100ml
anti-Rh(D) immunoglobulin therapy	The provision of product containing Anti-Rh(D) immunoglobulin, to prevent Rhesus sensitisation in Rh(D) negative females at or below child-bearing age
apheresis	A procedure in which blood is cycled out into a machine, one or more components are selectively removed, and the remainder of the blood is reinfused back into the donor
assay	An analysis undertaken to determine the presence of a substance and the amount of that substance
bleeding disorders	Diseases that cause abnormal or exaggerated bleeding and poor blood clotting
blood products	Products manufactured from donated blood
Blood Service	The Australian Red Cross Blood Service
bovine spongiform encephalopathy	Commonly known as mad cow disease, is a fatal neurodegenerative disease in cattle that causes spongy degeneration in the brain and spinal column
Chagas disease	An infection caused by a protozoan parasite (Trypanosoma cruzi) that can result in acute inflammatory skin changes
Chronic inflammatory demyelinating polyneuropathy	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
critical bleeding	Major haemorrhage that is life-threatening and is likely to result in the need for massive transfusion and/or haemorrhage of a smaller volume in a critical area or organ (e.g. intracranial, intraspinal or intraocular), resulting in patient morbidity or mortality
Cytomegalovirus	A member of the herpesvirus group
deferral	Postponement of blood donation due to current or potential prior exposure to infection. In some cases the deferral may be permanent (e.g. people resident in the UK for more than 6 months between 1980 and 1996)
Dengue	A disease caused by a family of viruses that are transmitted by mosquitoes. It is an acute illness of sudden onset that usually follows a benign course with symptoms such as headache, fever, exhaustion, severe muscle and joint pain
diagnostic reagent products	Products used in blood typing and cross matching

TERM	DEFINITION
Direct Orders	(previously known as Jurisdictional Direct Orders) Arrangements implemented by the NBA with suppliers to facilitate the purchase of IVIg for the treatment of conditions not satisfying the *Criteria for the clinical use of IVIg in Australia*
fractionation	Blood plasma fractionation refers to the general processes of separating the various components of blood plasma
fresh whole blood	Fresh blood contains red blood cells, white cells and platelets suspended in a straw-coloured liquid known as plasma
genome	The entire genetic complement, all of the hereditary material possessed by an organism
Guillian-Barré syndrome	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
haemoglobin	A molecule in red blood cells that transports molecular oxygen
haemoglobin-based oxygen carriers	A type of blood substitute
Haemophilia A	Classic haemophilia: an inherited blood coagulation disorder that results from a quantitative deficiency of Factor VIII, a blood clotting protein necessary for normal coagulation
Haemophilia B	An inherited blood coagulation disorder similar to haemophilia A but caused by a quantitative deficiency of Factor IX
haemostasis	The cessation of bleeding through clot formation, platelet plug formation and vasoconstriction
haemovigilance	A set of surveillance procedures covering the transfusion chain, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.
Hereditary angiodema	A rare genetic disorder caused by a deficiency in a blood protein, that can cause rapid swelling of the face and other parts of the body
human leucocyte antigen	The human leucocyte antigen system is the name of the major histocompatibility complex (MHC) in humans
Hyperimmunes	Products used to provide rapid passive immunity in the post exposure period
Hypoproliferative thrombocytopenia	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
Idiopathic thrombocytopenic purpura	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
IgG2 levels	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
immune replacement therapy	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
immune tolerance induction	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
immunodeficiency diseases	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
in-country reserve	A contractual requirement for blood product suppliers to the NBA for maintenance of a specified volume of product in Australia
infectious window period	The time between first infection and when a test can reliably detect that infection. In antibody-based testing, the window period is dependent on the time taken for sero-conversion

TERM	DEFINITION
intravenous immunoglobulin	Immunoglobulin administered intravenously (as opposed to intramuscular or sub-cutaneous injection), provided under the national blood arrangements to reduce susceptibility to infections and manage many immune system disorders
iron deficiency	A common disorder, sometimes nutritional, which results in anaemia as iron is necessary to make haemoglobin
issues/issuage	The volume of a particular product provided to Approved Health Providers in a jurisdiction under the national blood arrangements
jurisdiction	A signatory to the National Blood Agreement. This includes the Australian Government and all state and territory governments
leucodepletion	The removal of white cells from a blood product
leucocytes/leukocytes	White cells in the blood
Malaria	An infectious disease transmitted by the bite of an infected Anopheles mosquito
massive transfusion	In adults, 'massive transfusion' may be defined as a transfusion of half of one blood volume in 4 hours, or more than one blood volume in 24 hours (adult blood volume is approximately 70 mL/kg). In children, 'massive transfusion' may be defined as a transfusion of more than 40 mL blood/kg.
mg	Milligram
monoclonal antibody	Monospecific antibodies that are all identical, arising from a single lymphocyte cell clone
National Blood Agreement	The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the blood sector
National Blood Supply Contingency Plan	A plan approved by ministers to coordinate an appropriate response to a shortage of blood or blood products
National Product Price List	The price of all products supplied under the national blood arrangements approved by ministers
national reserve products	Products held in the national reserve managed by CSL to mitigate against an interruption to supply
National Supply Plan and Budget	The agreed volume of products to be supplied under the national blood arrangements approved by ministers
nonsense mutation	A nonsense mutation is a change in the DNA sequence resulting in either the production of mRNA (the 'instructions' from the gene) that does not then produce (code for) a peptide, or causes the premature signal to stop mRNA production
normal immunoglobulin	Immunoglobulin administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection). The product is approved in Australia for use in the management of hypogammaglobulinaemia and for public health purposes to treat susceptible contacts of hepatitis A, measles and poliomyelitis
nucleic acid testing	A biochemical technique used to detect a virus or a bacterium
off-label use	The practice of prescribing pharmaceuticals for an unapproved indication, in an unapproved age group, unapproved dose, or unapproved form of administration

TERM	DEFINITION
orphan drug designation	A pharmaceutical agent that has been developed specifically to treat a rare medical condition (referred to as an 'orphan disease')
output based funding model	A funding arrangement whereby the supplier is paid for product receipted, rather than on a grant basis
pathogen inactivation technology	Pathogen inactivation is a method for treating blood products that inactivates existing or unknown pathogens that may be present in blood components
patient blood management	The process of improving the status of the patient's own blood using non-transfusion methods with the consequence that transfusions and the associated risks of transfusion are avoided
Peptides	A molecule consisting of two or more amino acids
peri-operative settings	The period of time extending from when the patient goes into hospital, clinic, or doctor's office for surgery or a procedure, until the time the patient is discharged
plasma	The liquid part of the blood and lymphatic fluid, which makes up approximately half of its volume. Blood plasma contains antibodies and other proteins. It is taken from donors and made into products for a variety of blood-related conditions
platelets	An irregular, disc-shaped element in the blood that assists in blood clotting. During normal blood clotting, the platelets clump together (aggregate)
pluripotent stem cell	A stem cell with the capacity to differentiate into cells of all germ layers (endoderm, ectoderm and mesoderm) and usually derived from early embryos or embryonic germ cells
prion	An infectious agent composed primarily of protein
prion filtration	The removal of prions from blood
prophylaxis	A treatment designed and used to prevent an episode or worsening of disease from occurring
r	The prefix 'r' means recombinant
recombinant products	Synthetic or manufactured blood products (as opposed to products derived from plasma)
red blood cells	The blood cell that carries oxygen. Red cells contain haemoglobin and it is the haemoglobin which permits them to transport oxygen (and carbon dioxide)
Rh(D) haemolytic anaemia	Anaemia due to haemolysis, the abnormal breakdown of red blood cells either in the blood vessels or elsewhere in the body
Rh(D) haemolytic disease	An alloimmune condition that develops in a foetus, when the IgG molecules (one of the five main types of antibodies) produced by the mother pass through the placenta
Sickle cell disease	A type of anaemia associated with the presence of haemoglobin S
Specific Antibody Deficiency	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
sub-cutaneous immunoglobulin	Immunoglobulin administered by injection into the layer of skin directly below the dermis and epidermis (as opposed to intravenous or intramuscular injection). Not currently approved under the national blood arrangements

TERM	DEFINITION
Thalassaemia	A blood disorder passed down through families in which the body makes an abnormal form of haemoglobin, the protein in red blood cells that carries oxygen. The disorder results in excessive destruction of red blood cells, which leads to anaemia
Thrombosis	The formation or presence of a thrombus (a clot of coagulated blood) in a blood vessel or cardiac chamber
tolerisation	Some patients with haemophilia have antibodies (inhibitors) to transfused clotting factors (e.g. Factor VIII). Tolerisation is a treatment regimen aiming to reduce or eliminate those inhibitors
transfusion-transmitted infection	An infection that can be transmitted via transfusion
variant Creutzfeldt-Jakob disease	A rare, degenerative, fatal brain disorder in humans
vasoconstriction	Narrowing of the blood vessels resulting from contracting of the muscular wall of the vessels
von Willebrand disease	An inherited bleeding disorder in which a clotting protein called von Willebrand factor is deficient or defective

APPENDIX 12. LIST OF REQUIREMENTS

REF*	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
8(3) & A.4	Letter of transmittal	Letter of transmittal	Mandatory	iii
A.5	Contents	Table of contents	Mandatory	iv–vii
A.5	Index	Index	Mandatory	211
A.5	Appendix 11	Glossary	Mandatory	201
A.5	Inside cover	Contact officer(s)	Mandatory	ii
A.5	Inside cover	Internet home page address and Internet address for report	Mandatory	ii
9	REVIEW BY SECRETARY			
9(1)	2	Review by departmental secretary	Mandatory	14
9(2)	2	Summary of significant issues and developments	Suggested	15–16
9(2)	2	Overview of department's performance and financial results	Suggested	15–16
9(2)	2	Outlook for following year	Suggested	17
9(3)	-	Significant issues and developments—portfolio	Portfolio departments—suggested	Not applicable
10	DEPARTMENTAL OVERVIEW			
10(1)	1 & Appendix 2	Role and functions	Mandatory	3, 179
10(1)	6	Organisational structure	Mandatory	100
10(1)	NBA's Performance	Outcome and program structure	Mandatory	23
10(2)		Where outcome and program structures differ from PBS Statements/ PAES or other portfolio statements accompanying any other additional appropriation bills (other portfolio statements), details of variation and reasons for change	Mandatory	Not applicable
10(3)	1	Portfolio structure: part of the Health and Ageing portfolio	Portfolio departments—mandatory	2

REF*	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
11	REPORT ON PERFORMANCE			
11(1)	2, 3, 4, 5	Review of performance during the year in relation to programs and contribution to outcomes	Mandatory	12–13, 23–96
11(2)	3, 4, 5	Actual performance in relation to deliverables and KPIs set out in PB Statements/PAES or other portfolio statements	Mandatory	26–27, 60–61, 85–86
11(2)	-	Where performance targets differ from the PBS/ PAES, details of both former and new targets, and reasons for the change	Mandatory	Not applicable
11(2)	3, 4, 5	Narrative discussion and analysis of performance	Mandatory	23–96
11(2)	1, 3, 4, Appendix 7	Trend information	Mandatory	9, 28–38, 40–43, 48, 55, 189–190
11(3)	4	Significant changes in nature of principal functions/ services	Suggested	62–81
11(3)	3, Appendices 5, 6	Performance of purchaser/provider arrangements	If applicable, suggested	39–56, 186–188
11(3)	2, 3, 4	Factors, events or trends influencing departmental performance	Suggested	14–16, 28–38, 69–76
11(3)	2, 3, 4, 6	Contribution of risk management in achieving objectives	Suggested	16, 44, 46, 80–81, 101–103
11(4)	-	Social inclusion outcomes	If applicable, mandatory	Not applicable
11(5)	6	Performance against service charter customer service standards, complaints data, and the department's response to complaints	If applicable, mandatory	104
11(6)	7	Discussion and analysis of the department's financial performance	Mandatory	114–118
11(7)	7	Discussion of any significant changes from the prior year, from budget or anticipated to have a significant impact on future operations.	Mandatory	117
11(8)	Appendix 3	Agency resource statement and summary resource tables by outcomes	Mandatory	180–181

REF*	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
12	MANAGEMENT AND ACCOUNTABILITY			
	Corporate Governance			
12(1)	Letter of transmittal	Agency heads are required to certify that their agency comply with the Commonwealth Fraud Control Guidelines	Mandatory	iii
12(2)	6, Appendix 1	Statement of the main corporate governance practices in place	Mandatory	100–103, 176–178
12(3)	6	Names of the senior executive and their responsibilities	Suggested	100
12(3)	6, Appendix 8	Senior management committees and their roles	Suggested	101, 191–192
12(3)	6	Corporate and operational planning and associated performance reporting and review	Suggested	104
12(3)	6	Approach adopted to identifying areas of significant financial or operational risk	Suggested	102–103
12(3)	6	Policy and practices on the establishment and maintenance of appropriate ethical standards	Suggested	105
12(3)	6	How nature and amount of remuneration for SES officers is determined	Suggested	109
	External Scrutiny			
12(4)	6	Significant developments in external scrutiny	Mandatory	103
12(4)	6	Judicial decisions and decisions of administrative tribunals	Mandatory	103
12(4)	6	Reports by the Auditor-General, a Parliamentary Committee or the Commonwealth Ombudsman	Mandatory	103
	Management of Human Resources			
12(5)	6	Assessment of effectiveness in managing and developing human resources to achieve departmental objectives	Mandatory	106
12(6)	6	Workforce planning, staff turnover and retention	Suggested	106
12(6)	6	Impact and features of enterprise or collective agreements, individual flexibility arrangements (IFAs), determinations, common law contracts and AWAs	Suggested	108

REF*	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
12(6)	6	Training and development undertaken and its impact	Suggested	110
12(6)	Appendix 9	Work health and safety performance	Suggested	197
12(6)	-	Productivity gains	Suggested	Not applicable
12(7)	6	Statistics on staffing	Mandatory	105–106
12(8)	6	Enterprise or collective agreements, IFAs, determinations, common law contracts and AWAs	Mandatory	108
12(9) & B	6	Performance pay	Mandatory	109
	Assets management			
12(10)-(11)	7	Assessment of effectiveness of assets management	If applicable, mandatory	121
	Purchasing			
12(12)	7	Assessment of purchasing against core policies and principles	Mandatory	119
	Consultants			
12(13)-(24)	7	The annual report must include a summary statement detailing the number of new consultancy services contracts let during the year; the total actual expenditure on all new consultancy contracts let during the year (inclusive of GST); the number of ongoing consultancy contracts that were active in the reporting year; and the total actual expenditure in the reporting year on the ongoing consultancy contracts (inclusive of GST). The annual report must include a statement noting that information on contracts and consultancies is available through the AusTender website.	Mandatory	120
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12(25)	7	Absence of provisions in contracts allowing access by the Auditor-General	Mandatory	119
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14(1) & C.2	7	Advertising and Market Research (section 311A of the *Commonwealth Electoral Act 1918*) and statement on advertising campaigns	Mandatory	120
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* The reference is to the location of the item in the PM&C Requirements for Annual Reports, 28 June 2012—e.g., 'A.4" refers to the fourth item in Attachment A in that document.

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