NATIONAL BLOOD AUTHORITY AUSTRALIA

ANNUAL REPORT 2010–2011

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Our mission is 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.

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Images of blood and blood products contained in graphics are courtesy of NBA's suppliers.

LETTER OF TRANSMITTAL

The Hon Nicola Roxon MP
Minister for Health and Ageing
Parliament House
Canberra ACT 2600

Dear Minister,

I am pleased to present the 2010–11 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*, sub-sections 63(2) and 70(2) of the *Public Service Act 1999*, section 5 of the *Financial Management and Accountability Act 1997* and the July 2011 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,

Stephanie Gunn
Acting General Manager and Chief Executive Officer
National Blood Authority
7 October 2011

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USER GUIDE

This is the annual report of the NBA for the 2010–11 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 2010–11

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

PART 3: PERFORMANCE

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 2010–11 Portfolio Budget Statements.

PART 4: HORIZON SCANNING

Describes the external influences that could affect the way the NBA does business in the future. It provides a summary of the core developments we have monitored during 2010–11, including factors that may affect global supply, demand and pricing, donor and product safety issues and international regulatory trends.

PART 5: CORPORATE GOVERNANCE

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

PART 6: 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 the government's 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 and the NBA's senior management team, further information about fresh blood component supply by state and territory, mandatory reporting on a number of government policies, errata, acronyms and a glossary of terms, and a list of requirements.


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PART 1: OVERVIEW

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1.1 NBA ROLE AND RESPONSIBILITIES

The National Blood Authority (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 the 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 1).

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 provision
- 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 change
- provides secretariat support to the Jurisdictional Blood Committee (JBC).

1.2 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 1.1 The blood product family schematic 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.

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 free of charge to CSL Limited to produce the specific blood products needed.

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.

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.

THE BLOOD PRODUCT FAMILY

FRESH BLOOD COMPONENTS

TESTING

COLLECTION

CENTRIFUGATION, SEPARATION, POOLING

WHOLE BLOOD DONATION

APHERESIS DONATION

RED CELLS

APHERESIS PLATELETS

POOLED PLATELETS

RECOVERED PLASMA

SOURCE PLASMA

CRYO-PRECIPITATE

FRESH FROZEN PLASMA

CRYO-DEPLETED PLASMA

PLASMA FOR FRACTIONATION

PLASMA-DERIVED AND RECOMBINANT PRODUCTS

FRACTIONATION, FILTRATION, PURIFICATION

MANUFACTURED PRODUCTS

BLEEDING DISORDERS PRODUCTS
FVIII,FIX, PROTHROMBIN, THROMBOTROL, FVII CONCENTRATE

IMMUNOGLOBULINS
E.G. Ig, IVIg, HEPATITIS B, TETANUS, ANTI-RHESUS

ALBUMIN

RECOMBINANTS
rFVIIa, rFVIII, rFIX

FIGURE 1.1 *The blood product family*

1.3 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 1.2 below.

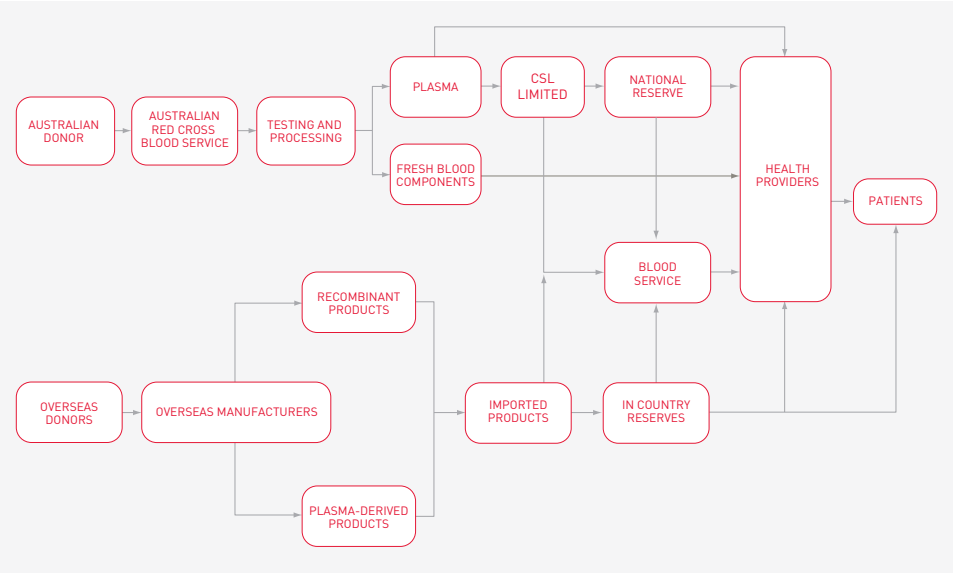

FIGURE 1.2 *The Australian blood and blood products supply chain*

The 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: the Australian Red Cross Blood Service (the Blood Service), CSL Limited, Octapharma Australia Pty Ltd, Lateral Diagnostics Pty Ltd (previously Lateral Grifols Pty Ltd), Baxter Healthcare Pty Ltd, Pfizer Australia Pty Ltd, Novo Nordisk Pharmaceuticals Pty Ltd, and OCD (Johnson & Johnson Medical Pty Ltd trading as Ortho-Clinical Diagnostics) and ALS-Abacus.

For further information about our stakeholders, see Part 3: Performance and **Appendices 4, 5** and **6.**

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.

The experience and expertise of clinicians, transfusion nurses and academics in states and territories is essential to optimise the quality use of the products purchased and to identify how current practice can be improved to maximise patient outcomes. This expertise is captured through a wide range of working groups focused on policy and management processes and on evaluating clinical evidence and preparing training material.

Clinical-based committees that assisted the NBA during 2010–11

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

Imported Plasma and Recombinant Products Tender Evaluation Committee

National IVIg Criteria Review Working Group

National Patient Blood Management Program 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

Red Cell Diagnostic Products Tender Evaluation Committee

Transfusion Medicine Services—JBC sub-committee

1.4 BLOOD SECTOR GOVERNANCE

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 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 AHMC.

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* and are shown in Figure 1.3.

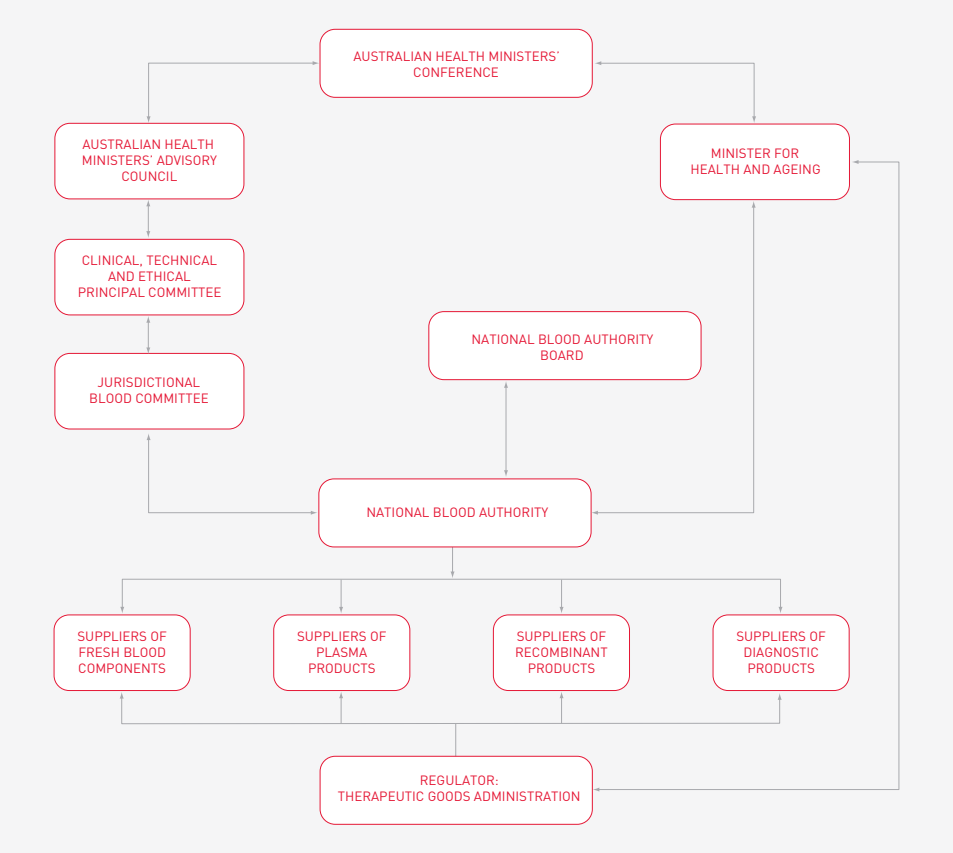

FIGURE 1.3 *Governance structure of the Australian blood sector*

For further information on the AHMC, the Australian Health Ministers' Advisory Council, the Clinical, Technical and Ethical Principal Committee and the JBC see **Appendix 2: Blood sector stakeholders and governance.**

1.5 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 spent a total of $5,558.4 million on blood and blood products. In 2010–11, the total amount provided to cover expected demand for blood and blood products was $939.2 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 2010–11*

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
TOTAL	**5,558.4**	**10.8 (average)**

TABLE 1.2 *Government funding for the operation of the NBA, 2003–04 to 2010–11*

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
TOTAL	**73.5**	**4.1 (average)**


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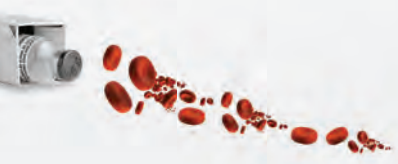
PART 2: HIGHLIGHTS OF 2010–2011



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2.1 SNAPSHOT OF THE BLOOD SECTOR IN 2010–11

VITAL STATISTICS

	2010–11	CHANGE FROM 2009–10	AMOUNT ISSUED IN 2011 (PER 1000 HEAD OF POPULATION)	INTERNATIONAL COMPARISON (PER 1000 HEAD OF POPULATION)
Number of blood supply contracts managed by NBA	14	↑ 2	NA	NA
IVIg patients treated	11,408	↑ 1,568	NA	NA
Grams of IVIg issued	2,950,370.5	↑ 295,186.4	132.2[2]	57–131 range from NPPSpa[1] (2009–10)
Number of patients with bleeding disorders registered	4,680	Not known	NA	NA
International Units of Factor VIII issued	157,350,199	↑ 15,656,730	7,050.8[2]	5,610 Average for 2009–10 NPPSpa[1]
Red cells issued (units)	800,570	↑ 4,706	35.9[2]	2008 average from CoE 41 (range 9–60)[3]
Platelets issued (units)	134,705	↑ 6,293	6.0[2]	2008 average from selected CoE countries 4.4 (range 2.8–7.0)[3]
FFP issued (litres)	47,209.5	↓ 106.1	7.2[2]	2008 average from selected CoE 9.4 (range 0.3–16.4)[3]

Notes:

1. Collaboration of National Plasma Product Supply Planners
2. Populations calculated using the ABS catalogue 3222.0 Series B
3. CoE—Council of Europe. From the *The Collection, Testing and Use of Blood and Blood Components in Europe 2008* report.

OTHER MAJOR ACHIEVEMENTS FOR THE SECTOR AND THE NBA IN 2010–11:

- finalised the tender process for imported plasma and recombinant products with significant savings to governments in the cost of treatment of haemophilia patients
- implemented BloodNet, a national online blood ordering system, in 32 sites in South Australia, Tasmania, the Northern Territory, and selected sites in Victoria (the whole of Queensland has already been implemented)
- released the first module of the Patient Blood Management Guideline—Critical Bleeding/Massive Transfusion
- implemented output based funding for the Blood Service, a model which provides improved accountability and greater transparency for government funding
- received ministerial agreement for the *Statement on national stewardship expectations for the supply of blood and blood products,* which outlines expectations for those ordering and receiving blood products
- the government-funded new purpose-built Sydney blood and blood products processing and distribution centre for NSW and the ACT was completed for the Blood Service
- published the inaugural Australian Bleeding Disorders Registry (ABDR) Annual Report
- published the IVIg Annual Report
- completed two research projects (*Blood sector research strategy preliminary gap analysis*, and *Impediments to better practice in demand management in the blood sector*) commissioned by the Department of Health and Ageing (DoHA), to inform the Australian blood sector of options to improve demand management.

2.2 GENERAL MANAGER'S REVIEW

As I am approaching the eve of my retirement, this will be the last review I write for the NBA's annual report. It has been my privilege to lead the NBA for eight years from its nascent beginnings to its successful professional management of our responsibilities.

SUPPLY SECURITY

During our usual hectic year, there is one event that stands out in my mind as most significant because it illustrates the value of the networks and relationships, supply planning and risk management that the NBA has implemented.

In September 2010, Octapharma, our principal supplier of imported intravenous immunoglobulin (IVIg) undertook a global recall of its product Octagam. Octapharma was expected to supply 17 per cent of our IVIg this year.

The recall was issued on 24 September and NBA staff immediately started securing alternative supplies. In the week that followed we received offers of replacement stock from major global suppliers. The NBA's risk planning meant that our contract with Lateral Diagnostics also allowed us to source and purchase alternative products from them.

The suppliers were models of cooperation and worked intensively with us over the next weeks to locate and remove all the recalled product and to introduce the new product. The Blood Service was central in assisting with the transition and design and distribution of clinical information. We also drew on CSL's inventory of IVIg, which had been built up in previous years under our contractual arrangements, to minimise the need for patients to change products mid-treatment.

This was no small task, and ensuring that this process was undertaken within weeks and without disrupting patients' lives, was vital. I am grateful for the support of industry suppliers and the Blood Service that enabled this to be achieved. All patients were successfully transitioned to an alternate product with no interruption to their treatment.

STAKEHOLDER RELATIONSHIPS

As the incident above indicates, the NBA attaches a great deal of importance to the relationships we have with our stakeholders.

Stakeholder relationships are particularly critical for our clinical development team and their program of work on the clinical use of blood. I am very humbled by the contribution of so many busy clinicians who volunteer their time and effort to work with the NBA, sifting through endless research papers and developing the exact wording of recommendations to improve clinical practice.

This year we were delighted to publish the first module of the Patient Blood Management Guidelines—Critical Bleeding/Massive Transfusion, under the auspices of the National Health and Medical Research Council (NHMRC). A second module on perioperative blood management is nearing finalisation.

DATA

Data is critical to most work in the blood sector whether it is to facilitate a recall or identify improvement opportunities. BloodNet, the new national online blood ordering and receipting system, will, when fully implemented, provide real-time information on inventory for all blood and blood products, anywhere in Australia.

BloodNet offers governments and staff in hospitals real-time access to important information such as orders, deliveries and, shortly, the fate of products. Those using BloodNet will be able to see the products within their inventory and will be able to track product trends over time.

This tool will be invaluable in supporting improvements in the blood sector and I congratulate those at the NBA and those who drove the project originally in Queensland.

To date, BloodNet has been rolled out in the Northern Territory, Queensland, South Australia, Tasmania and several sites in Victoria, with Western Australia, the Australian Capital Territory and some sites in New South Wales to be implemented early in 2011–12.

DUBLIN CONSENSUS STATEMENT

An event which will be largely opaque to the Australian public is the work that the NBA has undertaken on the Dublin Consensus Statement. This initiative arose out of discussions between the NBA and PLUS (an international coalition of plasma users) in 2009.

The goal was to negotiate a set of principles on donor management which could be accepted by like-minded global blood sector stakeholders including patients, donors, manufacturers and provider organisations. The first Statement produced in 2010 was fully endorsed by 22 patient organisations.

Further work in early 2011 resulted in a revised Statement and a significantly broader group of endorsees that now include international blood sector organisations representing blood donors, European and USA alliances of users and managers of blood, and not-for-profit plasma fractionators.

OUTLOOK FOR 2011–12

The NBA operates within the broader health sector and is very conscious of the impact on the sector of the continuing escalation of expenditure on blood and blood products. One of the major challenges for the NBA in the next 12 months will be to achieve certainty on the priorities required of the NBA by all governments and the funding associated with that, as identified in the *Administrative Review of the National Blood Arrangements 2009*.

I am very proud of our achievements and would like to acknowledge the great efforts and work of NBA staff over the years to provide a secure supply of products essential for patient health and to driving continual improvement in the efficiency of the sector.

Dr Alison Turner
General Manager and Chief Executive Officer
National Blood Authority

2.3 NBA BOARD 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.

In May 2011 a new Board was appointed and is due to meet for the first time early in July 2011.

NBA BOARD MEMBERS

Retiring members

Mr Garry Richardson—chair

Mr Rob Christie—community representative

Dr Peter Lewis-Hughes AM—state and territory representative

Continuing members

Mr Ken Barker—financial expert

Dr Stephen Christley—state and territory representative

Ms Mary Murnane—Australian Government representative

New members

Ms Gayle Ginnane—chair

Mr Paul Bedbrook—community representative

Adjunct Professor Chris Brook PSM—state and territory representative

Professor George Rubin—public health expert

For more information about members of the Board see **Appendices 2** and **4.**

This is my first report following my appointment as Chair of the NBA Board in May 2011. I am looking forward to working with my fellow Board members to provide guidance and support to the NBA to manage Australia's blood supply chain on behalf of Australian governments.

During the year the Board met four times and also held its annual meeting with the Blood Service Board in October 2010.

GOVERNANCE

Following the *Administrative Review of the National Blood Arrangements* in 2009, an implementation plan to address the recommendations was developed and endorsed by the AHMC on 12 November 2010. A key recommendation from the Review was that the NBA prepare an options paper on its priorities for the next three years, taking account of current budget projections and core responsibilities. The Board is providing oversight on the development of this important paper, which will ultimately shape the agency's future activities and resourcing.

FRESH BLOOD MANAGEMENT

The annual meeting of the NBA and Blood Service Boards in October 2010 provided an excellent opportunity for the NBA Board to offer guidance to the Blood Service about government expectations, priorities, and targets. Similarly, the meeting of the NBA Board Chair and the NBA General Manager with the Blood Service Board in March 2011 provided a forum for the Blood Service to explain its negotiating position with regard to the new Deed of Agreement with the NBA.

The opening of the Blood Service's purpose-built Sydney Processing Centre on 8 June 2011 was a highlight of the year. This Centre, funded by all Australian governments, is a modular complex that has been designed to meet the Blood Service's requirements for the next 30 years. The new Centre is responsible for processing blood and blood products from New South Wales and the Australian Capital Territory. The Board provided valuable advice to the NBA about financial negotiations with the Blood Service for this facility, as well as on the Victorian and Tasmanian Principal Site which is scheduled for completion in early 2012.

The introduction of an output based funding model for the Blood Service on 1 July 2010 was another notable event. The Board provided significant oversight and guidance to the NBA on the development and introduction of the model, which has been designed to improve accountability and provide greater transparency for government funding.

PLASMA AND RECOMBINANT SUPPLY MANAGEMENT

The Board continued to provide advice and guidance to the NBA on significant procurement processes undertaken during 2010–11. Another major achievement for the year was the announcement of the outcomes of the tender for imported plasma and recombinant products. The outcomes of the tender provide Australian patients with blood disorders continued access to quality products free of charge under the national blood arrangements, and an expected saving of between $10m–$30m per year to the Australian community, based on current demand forecasts, without compromising clinical efficacy or patient safety. These arrangements will remain in place for a minimum of three years.

SECTOR IMPROVEMENT

The *Statement on national stewardship expectations for the supply of blood and blood products* was approved by AHMC on 12 November 2010 following input from the Board. It outlines expectations for those ordering and receiving blood products such as hospitals, laboratories and prescribing doctors and supports the work of jurisdictions in improving the way in which blood is used and managed.

The NBA is assisting the Jurisdictional Blood Committee (JBC) and the Australian Commission on Safety and Quality in Healthcare (ACSQHC) on the National Safety and Quality Health Service Standard for blood and blood product to develop a national implementation framework, including key national and jurisdictional priorities for 2011–12.

The NBA received funding from DoHA to undertake two research projects: *Blood sector research strategy preliminary gap analysis* and *Impediments to better practice in demand management in the blood sector*. The Board provided advice on both the scope of the research and content of the reports. The two reports were provided to DoHA in May 2011.

RISK MITIGATION

The Board has continued to oversee measures to mitigate risks to both the blood supply and the NBA. A key focus of the Board was providing advice to the NBA on its approach to maintaining supplies of IVIg following the voluntary recall of Octagam (IVIg). The Board also advised the NBA management on the structure and content of the NBA's strategic risk management plan for 2011–12 which is a key component of the agency's overall planning processes and is linked to the corporate and operational plans.

ENHANCING NATIONAL DATA MANAGEMENT

The Board has maintained an active role in the NBA's national information management and reporting strategies through oversight of the sector information management and data strategy. This has three key elements: data capture capability; governance; and publishing and release of data. Good progress has been made in a range of national system developments. Data from these and other sources will be used to populate a national performance scorecard for the sector which will measure the sector's overall efficiency and effectiveness. A key element of the strategy is the introduction of BloodNet, a streamlined online blood ordering system that is an essential step to improving current inventory management processes. The NBA is making good progress with the national implementation of this innovative system.

CORPORATE PLAN FOR 2010–12

The NBA's new corporate plan, which is scheduled for consideration by health ministers in August 2011, was developed following considerable input from the Board. It identifies the following two core priorities for the next two years:

- further improvement of the integration and synergies between the blood sector and the wider health sector
- driving Australia's blood sector closer towards international best practice in all facets of production, management and appropriateness of use.

The Board has ensured that the two-year length of the corporate plan is aligned with a major recommendation of the *Administrative Review of the National Blood Arrangements 2009* that the NBA prepare an options paper on the agency's priorities for 2012–15 and future funding requirements. The details within the options paper that are supported by governments will then form the basis of the corporate plan for 2012–15.

NBA PERFORMANCE

A key role of the Board is to provide advice to the General Manager about the performance of the NBA's functions. The NBA has again performed to a high standard during 2010–11 completing 84 per cent of the activities identified in the agency's 2010–11 operational plan. While good gains were made, some key milestones were not met due to changes in sector priorities and key staff. The delays did not impact on external stakeholders.

BOARD PRIORITIES FOR 2011–12

In determining the 2011–12 priorities, the Board has been cognisant of broader processes including the outcomes of the inaugural Clinical, Technical and Ethical Principal Committee (CTEPC) Blood Policy Forum; the subsequent joint CTEPC/JBC meeting held on 24 March 2011; and the DoHA-funded research directed at resolving funding sustainability and better information for the sector on demand management. On this basis, key priorities that the Board will focus on during 2011–12 are:

- familiarisation with the sector including stakeholder engagement
- consideration of any actions from the Australian National Audit Office performance audit report
- development of the 2012–13 National Supply Plan and Budget (NSP&B) in accordance with agreed timeframes and processes
- the finalisation of contractual arrangements with the Blood Service, including negotiation of the new Deed of Agreement
- resolution of the NBA's priorities and associated resourcing post 2011–12
- options to drive a nationally coordinated and funded patient blood management program including identifying an appropriate clinical governance framework
- working with the ACSQHC to design a joint communication strategy for the *Statement on national stewardship expectations for the supply of blood and blood products* and the National Safety and Quality Health Service Standard for blood and blood product.

I would like to take the opportunity to thank the outgoing Chair and Board members for their significant contributions during their terms of office. The previous Board Chair, Mr Garry Richardson, stepped down in May 2011 after four years of service, as did Mr Rob Christie the community representative. Dr Peter Lewis-Hughes is also an outgoing member; he was first appointed as Public Health Expert in 2003 and as state and territory representative in 2007.

It would be remiss to finish this report without acknowledging the efforts of Dr Turner, the inaugural General Manager and CEO, in effectively establishing the NBA and building it into a credible, respected organisation that provides leadership in the blood sector with the best interests of the users of blood and blood products in mind. I thank her on behalf of past Board members for her outstanding contribution.

I look forward to working with the new and ongoing members of the NBA Board and the NBA to ensure that the blood sector continues to operate in an efficient and effective manner with enhanced flexibility to respond to the changing requirements of the health sector.

Gayle Ginnane
Chair
National Blood Authority

2.4 PRINCIPAL MEDICAL OFFICER'S REPORT

This August marks another landmark for the NBA, indeed for the blood sector in Australia. My colleague Dr Alison Turner is to retire from the helm of the NBA.

Dr Turner, in accepting the role of General Manager and CEO in 2003, took on the vast and difficult task of implementing the recommendations of the 2001 Stephen Review[1].

There was a major lack of national alignment within the sector. There were a heterogeneity of approaches to contracting, procurement, governance and oversight, both across jurisdictions and elsewhere within the sector—and at that time there was little in place nationally to measure the appropriateness of blood and blood product usage, or transfusion-related adverse events.

Under Dr Turner's stewardship, a wide range of initiatives and changes have been achieved which now form the core infrastructure for the sector.

I wish to specifically acknowledge the professional and personal support Dr Turner has given me and my role with the NBA. I wish Dr Turner well as she embarks on her next adventures and challenges.

The creation of the suite of modules comprising the Patient Blood Management Guidelines—including the release of the Critical Bleeding/Massive Transfusion module, the soon to be released Perioperative module, and the planned Medical, Critical Care, Neonatal/Paediatric and Obstetric modules—will provide a framework against which to benchmark the appropriateness of blood usage. The NBA's enhanced data capacities will materially assist this endeavour.

Work by the NBA and DoHA on two commissioned research projects, the NBA's work with the ACSQHC in the development of their new Blood Standard, along with the already live EQUiP 5 Australian Council on Healthcare Standards (ACHS) Standard, which includes a blood transfusion section, all align with, and provide hospitals with the tools required for, a drive to increased appropriateness in use and efficiency in the management of blood and blood products.

The ongoing work of the national Haemovigilance Advisory Committee, including the sponsorship of a consensus guideline for the Recognition and Management of Acute Transfusion Reactions–due for release in late 2011–and Australia's contribution to the International Haemovigilance Network, provide a risk-based counterpoint to measures to improve the appropriateness of prescribing.

1 2001 Review of the Australian Blood Banking and Plasma Product Sector, chaired by the Rt Hon Sir Ninian Stephen.

What then of the next few years ahead for the Australian blood sector? Of most significance is the range of data gathering and data linkage capacities which are being supported by the NBA. These will provide national and granular data in relation to usage, fate of product and the appropriateness of usage. The national roll out of BloodNet improves and standardises the approach to ordering products and the collection of data about product fate. The sector has largely been without data at this level which can be used to guide options for improvements.

Once again, I am indebted to my expert medical, nursing and scientific colleagues in the clinical sector for their ongoing contribution, in particular, to the mammoth work of developing the Patient Blood Management Guidelines, and to the review of the *Criteria for the clinical use of IVIg in Australia*. I am also indebted to my senior medical counterparts in the Blood Service in our work together across a wide range of issues and initiatives.

Dr Chris Hogan
Principal Medical Officer
National Blood Authority


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PART 3: PERFORMANCE

3

3.1 PERFORMANCE FRAMEWORK

The NBA has a single outcome and program and three key activities.

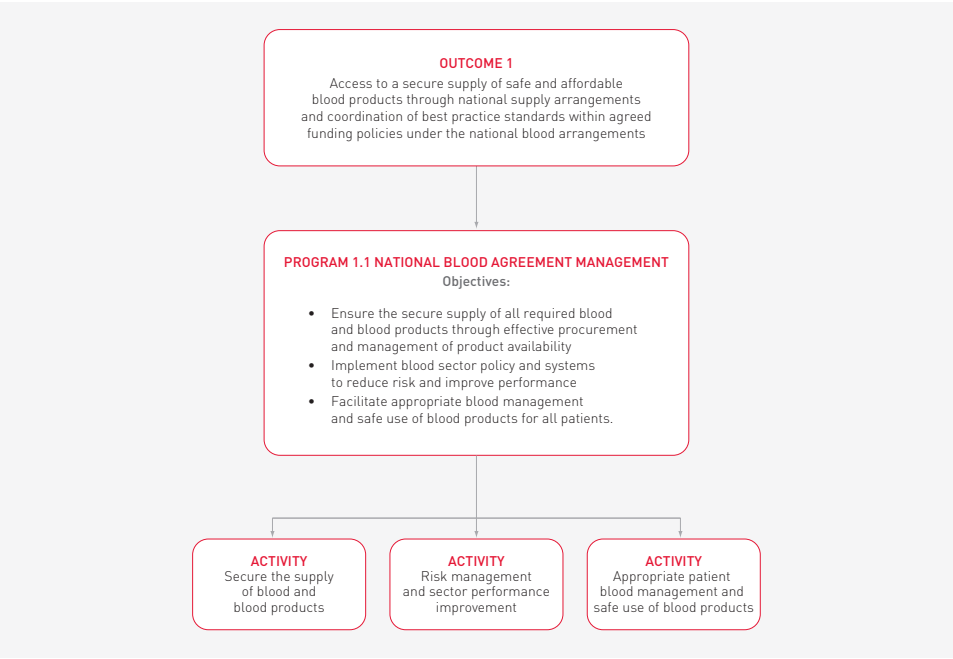


FIGURE 3.1 *NBA's outcome, program and activity structure*

Key performance indicators and deliverables have been developed for each of the activities shown above and are reported under the relevant activity.

3.2 SUPPLY OF BLOOD AND BLOOD PRODUCTS

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 AHMC.

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

Key performance indicators	Measure	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 as assessed through a survey of the JBC	89% of jurisdictions expressed satisfaction with the NBA's performance, with the remaining 11% being unsure. (Pages 26–55)
	2010–11 target	**2010–11 actual**
Percentage of administration costs as a proportion of the national supply plan budget, under the National Blood agreement	<1.4%	1.03%

Deliverables	Measure	Results
Complete contract for the importation of intravenous immunoglobulin	Contract to be effective from 1 January 2011	After assessment of value for money and procurement requirements, and with the endorsement of jurisdictions, existing contract was extended to 30 December 2011. Tender for supply from 1 January 2012 released in May 2011. (Pages 49–50)
Number of blood supply contracts managed	14	14, although considerable transition planning was undertaken on new contracts commencing 1 July 2011.

NATIONAL SUPPLY PLAN AND BUDGET (NSP&B)

The NBA's key role is to coordinate the annual NSP&B for annual approval by health ministers. This is achieved by:

- liaising with jurisdictions and stakeholders to establish the demand for products
- collecting and distributing data on product issued and reporting this issuage to jurisdictions compared to the approved supply plan
- intensively managing products if they are in short supply.

During 2010–11, the demand levels contained in the NSP&B were met. 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 2010–11 covering the supply and management of blood and blood products and services under contract was $967 million, comprising $505 million for fresh blood products and plasma collection and $440 million for plasma and recombinant products. The remaining $22 million includes items such as diagnostic products, 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 and Figure 3.2 identifies actual expenditure in each product category.

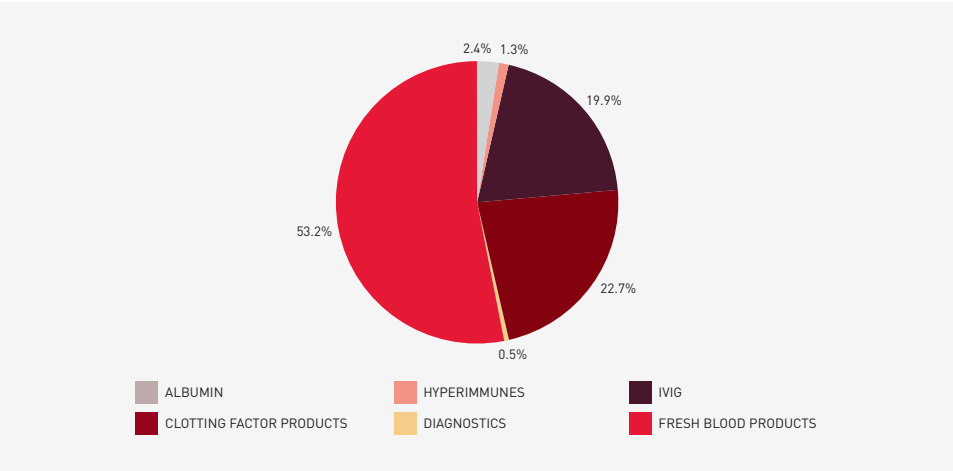


FIGURE 3.2 *Funding by product category 2010–11*

TABLE 3.1 *Blood and blood products purchased, by suppliers, 2008–09 to 2010–11*

SUPPLIER	PRODUCTS PURCHASED	2008–09 ($M)	2009–10 ($M)	2010–11 ($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 Defined Blood Products - Rh(D) immunoglobulin - Factors XI and XIII - IVIg Standing Offer Management of National Reserve	162.09	186.16	215.15
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
Baxter Healthcare	Defined Blood Products - Recombinant Factor VIII - Protein C - Factor VII concentrate - Factor Eight Inhibitor Bypass Agent (FEIBA) - WhiRho	84.09	90.62	96.93
Wyeth Australia Pty Ltd	Defined Blood Products - Recombinant Factor VIII - Recombinant Factor IX	48.65	48.94	57.03
Novo Nordisk Pharmaceuticals	Defined Blood Products - Recombinant Factor VIIa	17.40	26.42	27.37
Octapharma Pty Ltd	Defined Blood Products - IVIg Standing Offer	46.90	48.69	8.95
Lateral Diagnostics	Defined Blood Products - IVIg Standing Offer	0.00	0.00	24.50
DiaMed Australia Pty Ltd	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.92	0.81	0.60
Ortho-Clinical Diagnostics (Johnson & Johnson Company)	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.47	0.43	0.38
Abacus ALS Pty Ltd	Diagnostic Reagent Products - blood grouping sera - reagent red cell products	0.04	0.04	0.03
TOTAL PURCHASES OF BLOOD AND BLOOD PRODUCTS		**793.18**	**858.23**	**927.51**

The total cost of products issued to all jurisdictions in 2010–11 amounted to $930.7 million (including product issued from stock). This represented an increase of $59.6 million (6.8 per cent) compared with 2009–10. Figure 3.3 indicates a reduction in issues of product against the plan for some imported products. However, the plan for this year provided for slightly higher supply levels, which had been predicted on the basis of the level of deliveries in 2008–09 and the mid-year analysis of 2009–10.

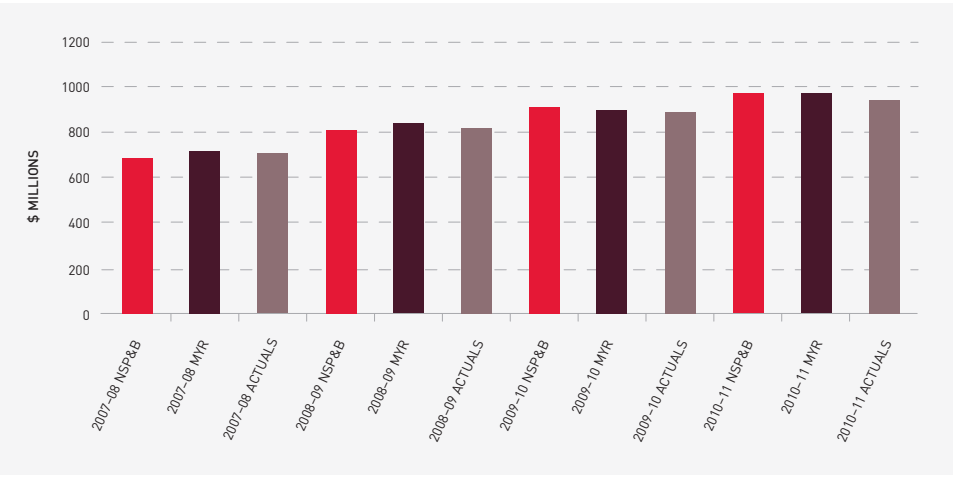


FIGURE 3.3 *Actual issues performance against the NSP&B and mid-year review, 2007–08 to 2010–11*

Fresh blood

In the eight years to 2010–11, funding for fresh blood and plasma collections has increased from $247.8 million to $496.57 million. Of this, $120.3 million is due to price increases averaging 7.1 per cent per year. These price increases include major realignment of the funding relationship with the Blood Service and the different cost structures incurred through the infrastructure invested in the new NSW and ACT processing site. Demand for fresh products—principally red cells, platelets and plasma for fractionation—has been increasing at 3.7 per cent a year, resulting in additional expenditure of $62.3 million. A further $66.2 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 4.1 per cent a year. The combined effect of these measures on expenditure can be seen in Figure 3.4.

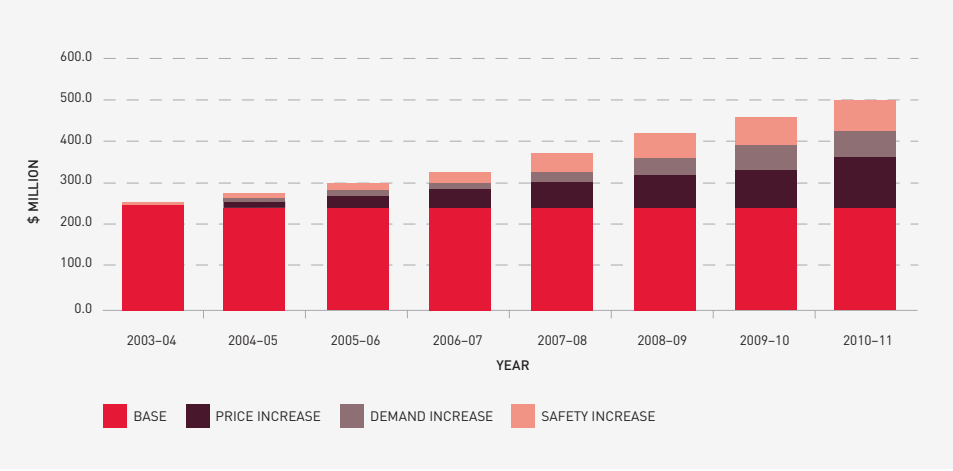


FIGURE 3.4 *Fresh blood expenditure: increases on 2003–04 base year*

The actual supply of fresh blood products for 2010–11 compared with the annual supply estimates agreed by the Australian Health Ministers' Conference is highlighted in Table 3.2.

TABLE 3.2 *Variance between actual supply of fresh blood components against the annual supply estimates*

VOLUMES	UNITS IN NSP&B	ISSUES	UNIT VARIATION ON PLAN	% VARIATION ON PLAN
Total red cells	817,247	800,570	-16,677	-2.0%
Total platelets	132,539	134,705	2,166	1.6%
Total clinical FFP	160,548	160,537	-11	0.0%
Total cryoprecipitate	64,175	70,102	5,927	9.2%
Total cryodepleted plasma	13,439	13,882	443	3.3%
Plasma for fractionation (in kgs)	495,192	472,338	-22,855	-4.6%

Issues of red cells

Red cells comprise 30.7 per cent of total blood and blood product expenditure and are the largest single item of cost in fresh products. The volume of red cells issued in 2010–11 was two per cent less than the volumes estimated in the NSP&B and demonstrated very minor growth (0.6 per cent) from 2009–10. All red cells were leucodepleted. The gradual decrease in the rate of growth in volume of product per 1000 head of population being observed appears to reflect the outcomes of policies driving appropriate use and improved inventory management.

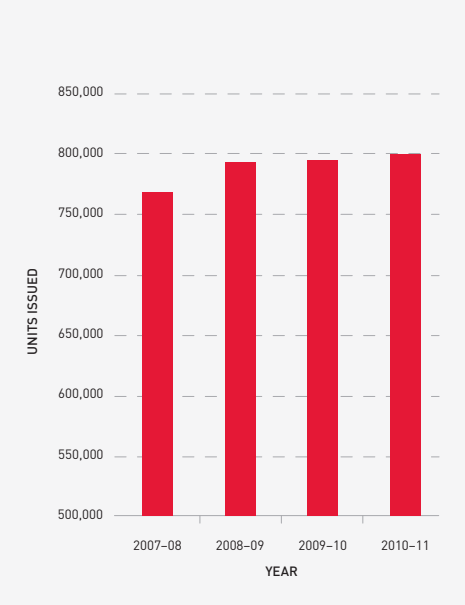


FIGURE 3.5 *Red cells issued by the Blood Service, 2007–08 to 2010–11*

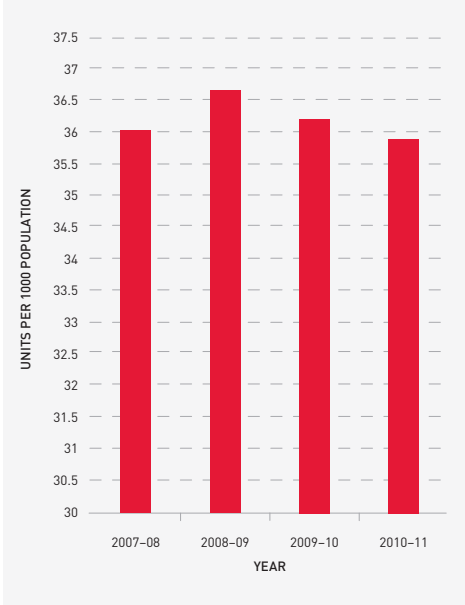


FIGURE 3.6 *Red cells issued per 1000 head of population, 2007–08 to 2010–11*[1]

Issues of platelets

In 2010–11, the rate of growth slowed from 8.7 per cent in 2009–10 to 4.9 per cent. Demand for platelets is closely linked to increases in haematology/oncology activity and is also likely to be related to the wider adoption of massive transfusion protocols. The Critical Bleeding/ Massive Transfusion module of the Patient Blood Management Guideline recommends a package of blood components that includes red cells, FFP and platelets as well as other products if indicated, rather than red cells alone as has been a common practice in the past. For more information on this protocol see pages 72–3.

All platelets issued in the year were leucodepleted and issues of platelets per 1000 population increased by only 3.4 per cent compared with a 7.0 per cent increase the previous year. The change in demand during 2010–11 has been in the mix of whole blood pooled and apheresis platelets. While the original plan allowed for a ratio of 55 per cent whole blood pooled to 45 per cent apheresis, after consultation with jurisdictions this was adjusted in August 2010 to 60 per cent whole blood pooled to 40 per cent apheresis.

The actual issues were 61.6 per cent whole blood pooled to 38.4 per cent apheresis.

1 Calculations using per 1000 head population statistics in all graphs may differ from previous years reporting, reflecting the move to a new standardised data source

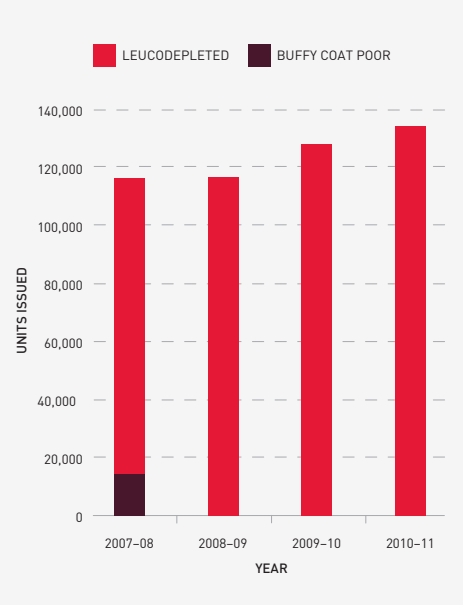


FIGURE 3.7 *Platelets issued by the Blood Service, 2007–08 to 2010–11*

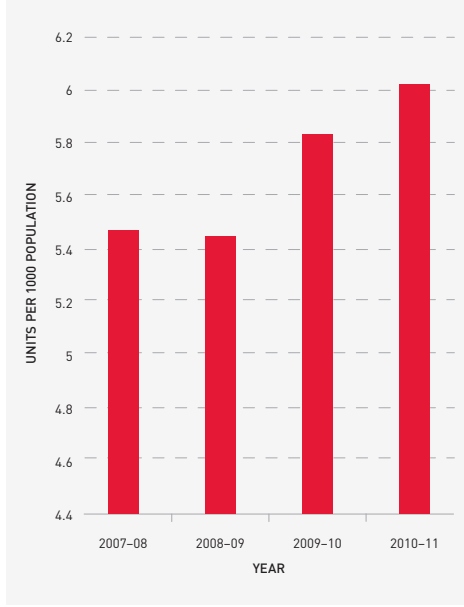


FIGURE 3.8 *Platelets issued per 1000 head of population, 2007–08 to 2010–11*

Issues of other fresh products

Demand for clinical FFP was marginally less than in the 2009–10 period and was in line with the 2010–11 supply plan. The forecast growth for future years is based on population growth.

Jurisdictions had not envisaged any growth in cryoprecipitate in 2010–11; however this product saw an increase in demand of 8.3 per cent over the previous year, 9.2 per cent above plan. 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 increased 16.9 per cent compared with 2009–10, three per cent above plan. The reason for the increase in demand of cryodepleted plasma is not well understood and jurisdictions are not aware of significant changes in clinical practice that may be driving the increased demand. 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 2010–11 are provided at pages 37–45.

Plasma and recombinant products

Total funding for plasma-derived and recombinant blood products increased to $433.8 million in 2010–11, an increase of $30 million (7.45 per cent) from 2009–10. As indicated in Figure 3.9 below, by far the largest proportion of this increase was due to increased product demand, notably for IVIg and clotting factors, as discussed further below. The effect of price increases was marginal, contributing only 1.6 per cent to the total increase. Prices for most products increased by less than 1 per cent, and the average unit price for domestically produced IVIg reduced by more than 2 per cent due to the favourable price structure under the CSL Australian Fractionation Agreement.

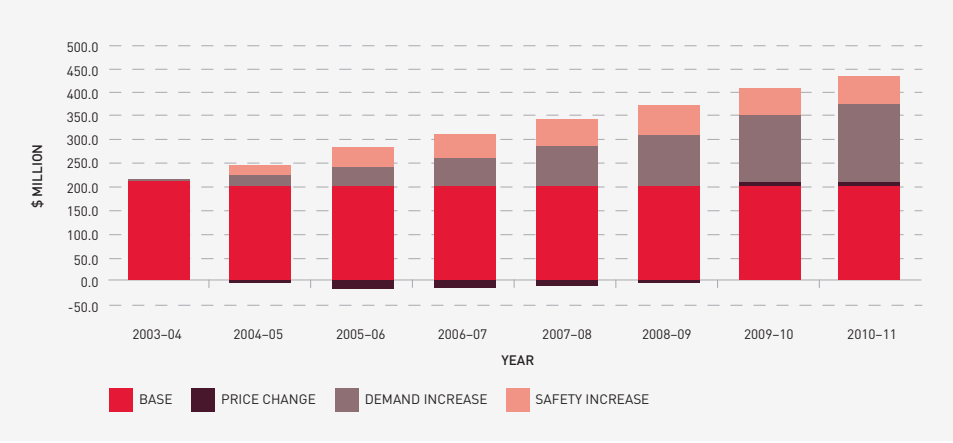


FIGURE 3.9 *Plasma-derived and overseas product expenditure: cumulative increases on 2003–04 base year*

Details of supply management for plasma-derived and recombinant products are provided in pages 46–53.

Issues of clotting factors

Growth in demand for recombinant Factor VIII (rFVIII) was just two per cent in 2009–10 but rose to 11 per cent in 2010–11, two per cent above the plan for this year. The 2011–12 plan was set at a lower growth rate than the 2010–11 plan based on the 2009–10 growth rate. However, in light of the actual 2010–11 figure, the apparent slowing in the rate of growth in 2009–10 may be an anomaly and further work will be undertaken to identify the factors behind the varying growth rates for this product.

Demand for clotting factors in Australia is heavily influenced by the number of patients on tolerisation and the management of prophylactic requirements. In addition, some clinicians are proactively trying to reduce use of FVIII in surgery. Respondents to the NBA's request for information on imported plasma and recombinant products reported a declining growth rate internationally.

In Australia, settled prophylaxis protocols may lead to a lower growth rate. However, this may be offset by the rate of diagnosis of severe Haemophilia A patients in the 0–15 age group, where demand may grow as these patients increase in size.

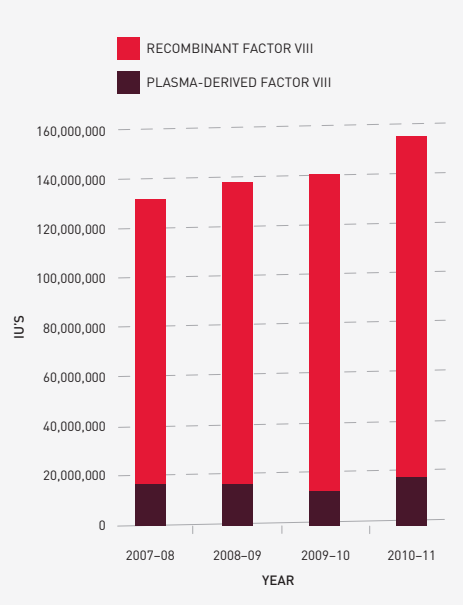


FIGURE 3.10 *Issues of Factor VIII products, 2007–08 to 2010–11*

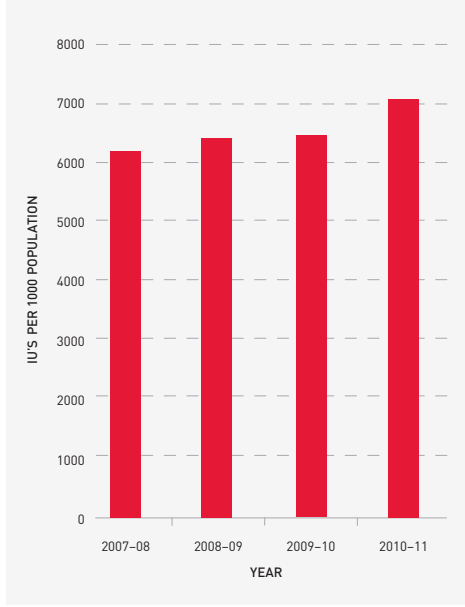


FIGURE 3.11 *Issues of total Factor VIII per 1000 head of population, 2007–08 to 2010–11*

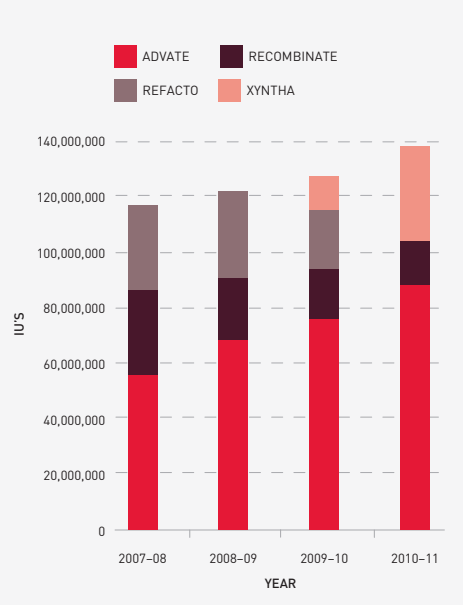


FIGURE 3.12 *Market share of recombinant Factor VIII issues, 2007–08 to 2010–11*

Demand for Factor IX (FIX) products in 2010–11 grew at a higher rate than previous years although, in planning consultations, jurisdictions had indicated a lower growth rate. Several local circumstances may mean that total demand for recombinant product may drop in 2011–12. Data from the ABDR would seem to indicate that the growth rate increase for FIX will be less than that of FVIII in the medium term.

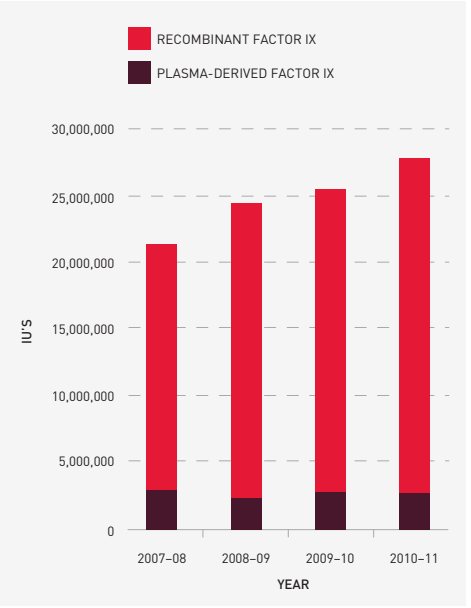


FIGURE 3.13 *Issues of Factor IX products, 2007–08 to 2010–11*

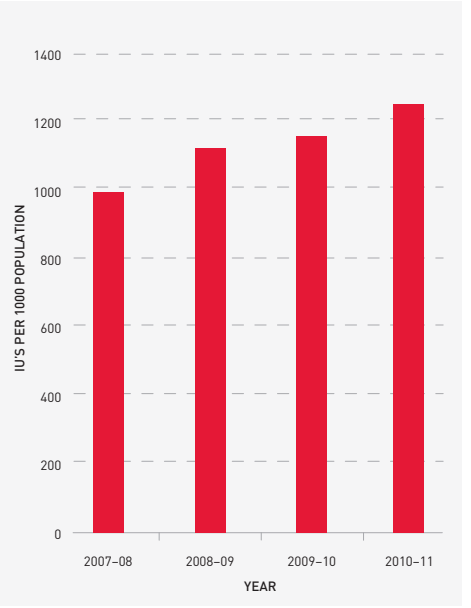


FIGURE 3.14 *Issues of Factor IX products per 1000 head of population, 2007–08 to 2010–11*

Jurisdictions acknowledge that a very small number of patients experiencing very high needs may considerably affect overall demand for recombinant Factor VIIa (rFVIIa) and FEIBA. The 2010–11 level of demand was 28 per cent above plan for rFVIIa and this trend is expected to continue, although at slightly lower rates of growth, for the foreseeable future. Accordingly the 2011–12 forecast is set at 17 per cent above the 2010–11 plan.

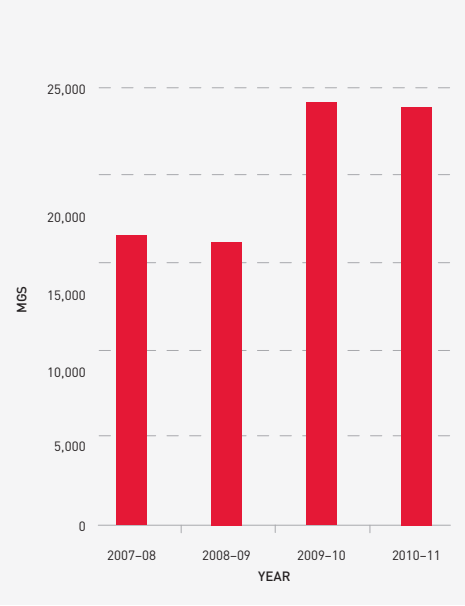


FIGURE 3.15 *Issues of recombinant Factor VIIa, 2007–08 to 2010–11*

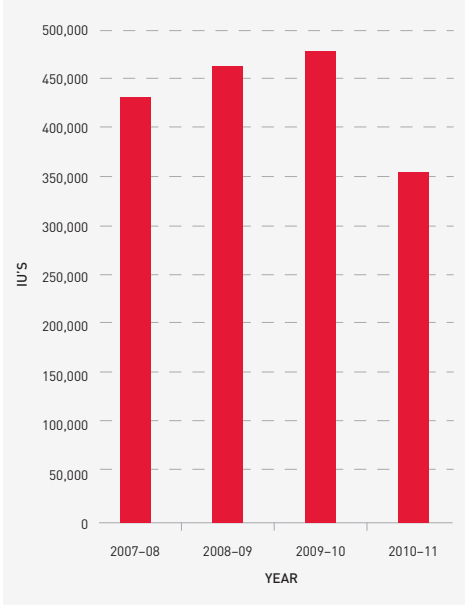


FIGURE 3.16 *Issues of FEIBA, 2007–08 to 2010–11*

Issues of intravenous immunoglobulin (IVIg)

Growth in demand for IVIg has slowed from 14 per cent in 2007–08 to 11.1 per cent in 2010–11. The average annual growth from 2003–04 to 2010–11 is 11.6 per cent per annum. A current international trend in increasing identification of patients with conditions that can be treated with IVIg is not noted in Australia. The only exception is an increase in demand for the treatment of acquired hypogammaglobulinaemia.

In 2010–11, a total of 2,950,371 grams of IVIg was issued, representing a cost of $149.4 million nationally (excluding cost of plasma collections). Of this, 86 per cent was IVIg produced in Australia and 14 per cent was imported. The reduction in the volume of imported product compared to last year was due to the voluntary recall of Octagam in September 2010 (see page 59). Excluding IVIg issued under direct orders, a total of 11,457 patients nationally were issued IVIg during 93,887 patient episodes.

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 STARS 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 top three indications for which IVIg is issued most frequently are chronic inflammatory demyelinating polyneuropathy, common variable immunodeficiency disease and chronic lymphocytic leukaemia.

The report can be found on the NBA website at www.nba.gov.au.

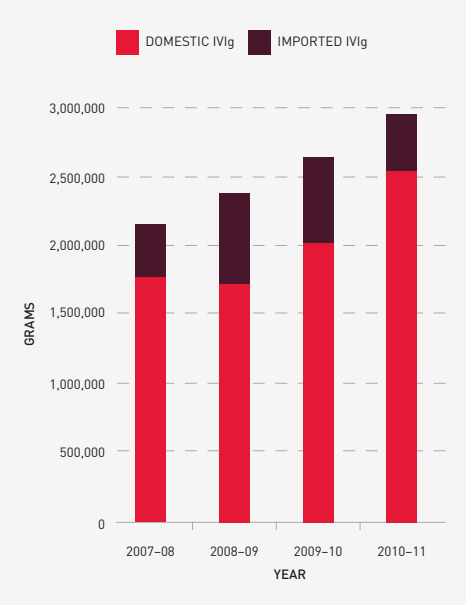


FIGURE 3.17 *Issues of IVIg products, 2007–08 to 2010–11*

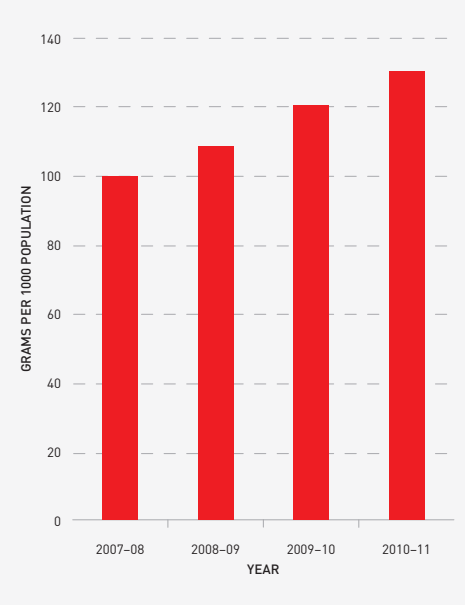


FIGURE 3.18 *Issues of IVIg (grams) per 1000 head of population, 2007–08 to 2010–11*

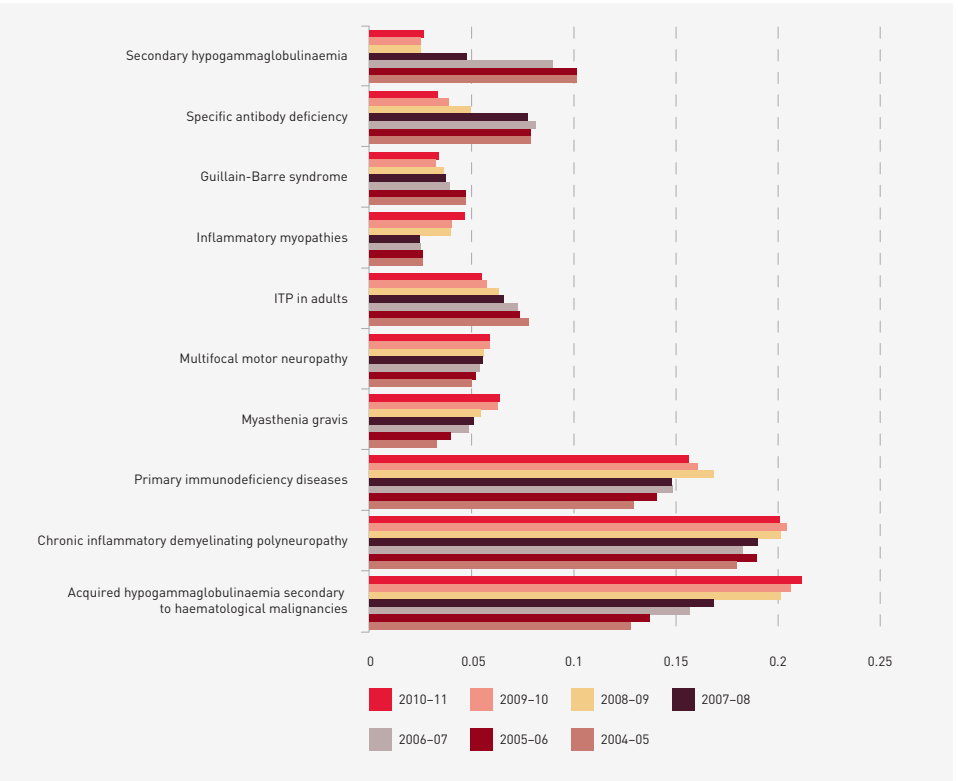


FIGURE 3.19 *Top 10 uses of IVIg, 2004–05 to 2010–11*

MANAGEMENT OF BLOOD SUPPLY CONTRACTS AND ARRANGEMENTS

In 2010–11 the NBA managed 14 blood and blood product supply contracts and arrangements. There were no changes in the suppliers contracted by the NBA during the year. Two contracts were extended and ten were subject to tender processes.

Contract management activities included:

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

Blood Service funding and product mix

Actual funding for the Blood Service increased from $456.1 million in 2009–10 to $496.6 million in 2010– 11 (see Table 3.3).

TABLE 3.3 *Blood Service: annual funding 2003–04 to 2010–11*

YEAR	AMOUNT ($M)	% GROWTH
2003–04	247.8	0
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
TOTAL	**2888.6**	**10.5 (average)**

An operating surplus of $11.2 million from efficiencies achieved within the Blood Service in 2009–10 included recurrent savings of $4.7 million. The recurrent savings will be returned to jurisdictions in 2011–12 by way of lower product prices. Under the output based funding principles for 2009–10, the Blood Service was able to retain this surplus to use as agreed by governments. To date, $2.5 million of the $11.2 million has been allocated to the establishment of a Risk Reserve Pool.

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 well against all of the key performance indicators specified in the Deed. Some indicators of particular interest this year are summarised in Table 3.4. As part of the *2010–11 to 2012–13 Statement of Expectations for the Red Cross Blood Service* provided by the Minister for Health and Ageing, the Hon Nicola Roxon, on behalf of all health ministers, a key performance target for the Blood Service is to improve *'efficiency of collection (conversion of supply) for whole blood'* by 1 per cent each year during 2010–13. For 2009–10 this indicator was 78.1 per cent and for 2010–11 the target was to achieve 79.1 per cent. The Blood Service achieved 80.2 per cent.

TABLE 3.4 *Blood Service: selected key performance indicators, 2010–11*

DOMAIN	INDICATOR	PLANNING PARAMETER	ANNUAL RESULT
Donor management	**Size of donor base:**		
	Whole blood	521,714	515,959
	Apheresis plasma	69,221	71,919
	Apheresis platelet	11,537	11,598
	Frequency of donation, by type:		
	Whole blood	2.0	1.93
	Apheresis plasma	4.78	4.34
	Apheresis platelet	3.53	3.37
Supply chain management	**Efficiency of collection (conversion to supply)**		
	Whole blood	79.1%	80.2%
	Apheresis plasma	97.2%	97.5%
Quality and level of service	Overall Approved Health Provider satisfaction with Blood Service	65%	84%
Governance and accountability	Deed reporting requirements	100%	100%

The quantity of plasma for fractionation collected (Table 3.5) did not meet the annual supply requirements. The lower than expected volume of plasma in 2010–11 was due to:

- the reduction in the rate of growth of demand for red blood cells and apheresis platelets
- a delay in implementing the provision of apheresis platelets in additive solution instead of plasma
- the slower than planned transition of donors to higher collection volumes per donor as provided for in the current Council of Europe guidelines and the need to adjust donation volumes in response to temporarily higher than expected adverse events for donors at these larger volumes.

One strategy currently being trialled is the use of a saline replacement program and this will be evaluated by the Blood Service and the JBC late in 2011.

TABLE 3.5 *Blood Service plasma volumes collected, 2003–04 to 2010–11*

	2003–04	2004–05	2005–06	2006–07	2007–08	2008–09	2009–10	2010–11
Plasma for fractionation (kg)	294,521	308,068	308,348	329,346	352,781	390,707	452,422	472,324

Deed of Agreement

Negotiations for a new deed of agreement with the ARCS commenced with the Blood Service in 2009 and the 2006–09 Deed was extended by mutual agreement of the parties until 30 June 2011. In October 2010, the ARCS wrote to the Minister to present the Society's negotiation position in relation to the new deed, including a list of issues and desired outcomes. These issues have required detailed analysis and consideration of policy by governments and accordingly the current Deed was again extended from 1 July 2011 until December 2011 (with an option to extend until 30 June 2012).

During 2010–11, negotiations between the Blood Service and the NBA continued on operational requirements for the new deed. The JBC was involved in endorsing policy parameters to inform the priorities from government that must be achieved through the new deed. Negotiations on implementing a nine-year deed of agreement, to be supported by three-year funding and services agreements and annual service delivery plans, have progressed with the Blood Service.

Figure 3.20 below sets out the relationships between each of the elements of the proposed new deed framework.

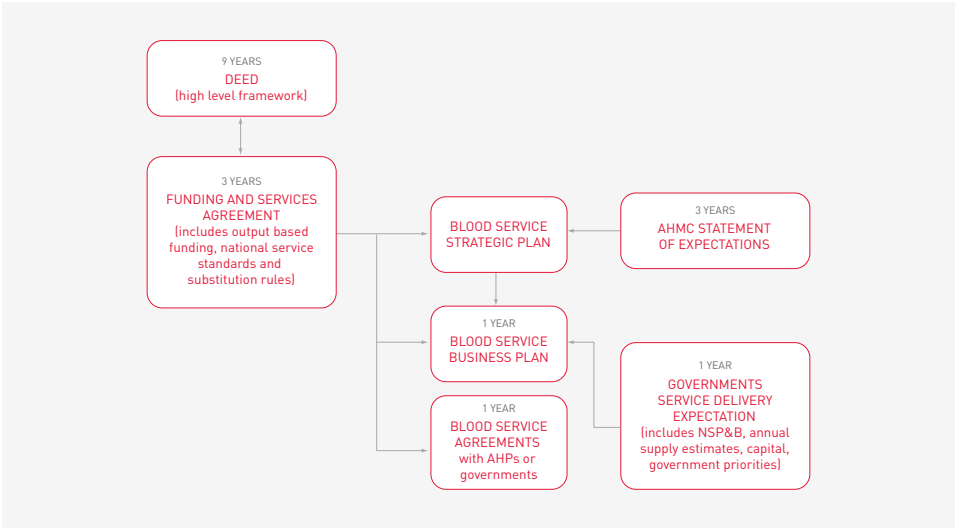


FIGURE 3.20 *Framework for the new Deed of Agreement with the ARCS for the Blood Service*

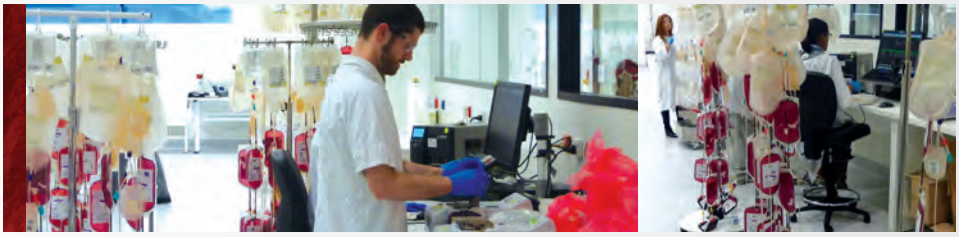
Funding and Services Agreement

The three-year Funding and Services Agreement and the associated operational arrangements will be informed by the three-year *Statement of Expectations for the Australian Red Cross Blood Service*. The current version for 2010–13 was endorsed by health ministers on 25 October 2010. 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, including:

- **National service requirements and standards** These will set out the Blood Service's relationship with approved health providers (AHPs) and the NBA. They include business rules and standards for ordering, delivery, and acceptance of products which are aligned to the requirements of the new ACSQHC National Safety and Quality Health Service Standard on blood and blood product. These will guide the Blood Service in developing consistent service level agreements with AHPs
- **Annual service delivery expectations** will set priorities for the following year including all required products and services to meet clinical need
- **Output based funding model** This provides the definitions of all of the products and services to be delivered under the contractual arrangements, product prices determined by agreed cost attribution rules, cash flows, and risk management arrangements. The implementation of this model was a key focus during 2010–11 (see page 41)
- **Substitution and payment rules** These rules will document an agreed set of arrangements under which specific products may be supplied instead of those ordered, and the payment processes relating to receipting products that are required when this occurs
- **Transfusion medicine services** The Blood Service's Transfusion Medicine Services team provides expert clinical and scientific advice, education and research, in order to improve safe and appropriate transfusion practice. Proposals for a national framework were developed and issues considered included the range of services to be provided, governance frameworks and the development of a funding structure with the key objective of ensuring an equitable allocation of services across all jurisdictions
- **National research and development framework** In 2010–11 the Blood Service received funding of approximately $7.5 million for its research and business 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.

OUTPUT BASED FUNDING—IMPROVING ACCOUNTABILITY



The new output based funding model (OBFM) for the Blood Service is helping to improve accountability, price products appropriately and deliver greater transparency of costs for jurisdictions. It enables governments to pay for the actual blood products that are delivered to approved health providers in their jurisdictions. Previously governments had made agreed budget-phased monthly payments that met the total annual costs of the Blood Service.

The OBFM was implemented from 1 July 2010 for a period of three years and will be a key component of the new Deed of Agreement with the Australian Red Cross Society for the Blood Service and the Funding and Services Agreement, that are currently being negotiated.

Two reviews of the OBFM were conducted during the first half of 2010–11 and reported to health ministers. The first review was conducted by an independent consultant who undertook a reconciliation of the cost attribution. This review was successfully completed and provided assurance to all governments that the agreed principles and cost attribution rules that underpin the methodology for determining the OBFM product prices for 2010–11 had been applied accurately and robustly.

The second was a review of the operation of the model during the initial period to identify any problems, clarify the principles of the model and provide information for the development of the 2011–12 NSP&B. This review resolved several small issues.

Each review provided opportunities for both parties to negotiate improvements during the next three-year funding cycle, under the Funding and Services Agreement.

A further review of operations will be undertaken after two and a half years to assist in the development of the next three-year funding agreement.

National inventory framework

Work commenced on developing a nationally consistent inventory framework covering blood products funded by governments and manufactured by the Blood Service. The aim is to have a comprehensive, efficient and effective inventory management strategy that will secure the supply of blood products that meet clinical demand when they are needed and also 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. Key information that will inform the inventory management framework are days of inventory at the Blood Service (see Figure 3.21), of major blood type, by month and at hospitals (data which will be available from BloodNet). Table 3.6 shows changes in red cell age at issue by quarter. Progress on the project was delayed due to reprioritisation of resources but is planned to recommence in October 2011.

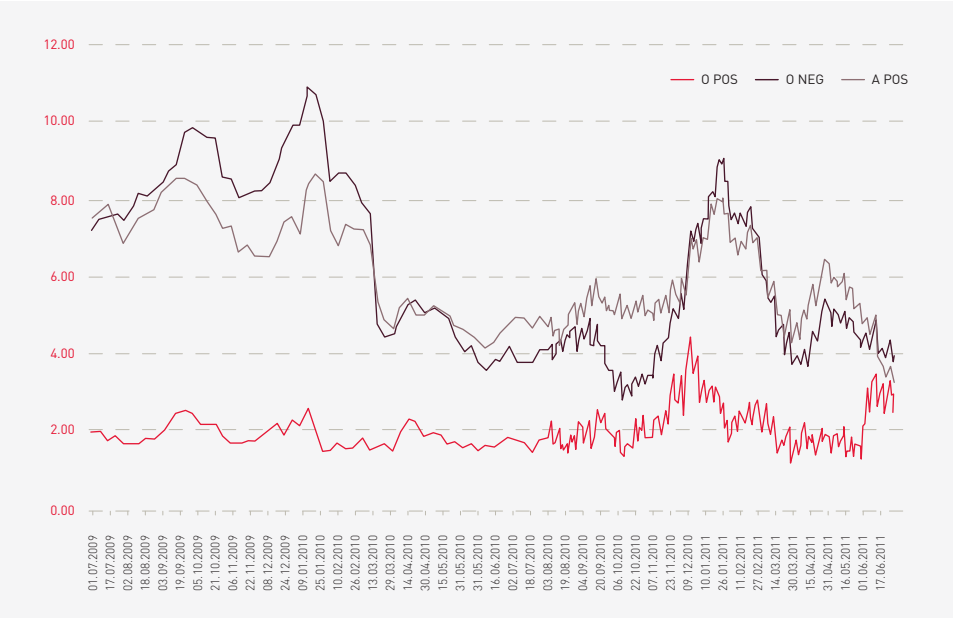


FIGURE 3.21 *Days of inventory at the Blood Service, of major blood type, by month, 2009–10 to 2010–11*

TABLE 3.6 *Red cell age at issue by quarter, 2009–10 to 2010–11*

	Q1	Q2	Q3	Q4
2009–10	10.5	10.6	9.8	7.9
2010–11	7.3	7.3	9.6	7.3

The Blood Service Strategic Capital Investment Plan

Under the Deed, the Blood Service is provided with an agreed capital budget, set at 10 per cent of total operational funds provided. For 2010–11, expenditure was approximately $44.07 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 from 2006–07 to 2010–11.

TABLE 3.7* *Blood Service annual capital plan expenditure, 2006–07 to 2010–11*

2006–07 $ MILLION	2007–08 $ MILLION	2008–09 $ MILLION	2009–10 $ MILLION	2010–11 $ MILLION
29.58	32.96	37.99	41.21	44.07

* Note that these figures represent actual expenditure. In previous years the figures reported have been the agreed budget

These funds are required to be managed through the Strategic Capital Investment Plan. The plan details the capital expenditure that is expected to be required to sustain fixed assets for three years.

In 2010–11 the Blood Service expended funds on premises (relocations and new sites), business improvement, especially their NextGen information management system, apheresis machines, replacement of computer equipment, and purchase of laboratory equipment such as analysers.

In March 2011 the JBC endorsed a Strategic Capital Investment Plan for the period 2011–14. Projected expenditure includes a detailed asset replacement program to optimise the life of equipment, and the purchase of new equipment necessary to offer improved quality and assurance processes.

The New South Wales and Australian Capital Territory principal site

In April 2008, the AHMC gave policy approval for additional funding for the Blood Service to meet building leases and fit-out for a new principal blood-manufacturing site for New South Wales and the Australian Capital Territory. Construction began in late June 2009 and practical completion was on time in January 2011 at a total cost of approximately $191 million at 2008–09 prices. The Blood Service moved into the facility over Easter 2011.

The facility was formally launched on 8 June 2011 by the Hon Catherine King MP, Parliamentary Secretary for Health and Ageing and Mr Barry O'Farrell, Premier of NSW (see page 45).

The Victoria and Tasmania principal site

In December 2008, health ministers also 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. In the 2009–10 Federal Budget, the Treasurer announced that the Australian Government would contribute $120 million of the $212 million for this project over two years through the Health and Hospitals Fund.

The principal site is being developed in a former industrial area of inner Melbourne and construction is well underway. The NBA has continued to monitor project and funding milestones. Some delays occurred during the year as a result of extensive site remediation work and an acceleration program was developed for the fit-out phase of construction. Practical completion is still expected at the end of February 2012. When completed, the facility will be responsible for the manufacture of blood for both Victoria and Tasmania comprising 26 per cent of the nation's blood supply.

A sample archiving facility is being built within the new site and this has been separately funded by governments to meet regulatory requirements. During the year work was undertaken on an ethics framework to govern the use of samples.

National Managed Fund

The National Managed Fund (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.

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

During 2010–11, the National Indemnity Reference Group commenced a review of the scope and the discretionary nature of the NMF. At a workshop held in March 2011, the NBA, the JBC and the Blood Service discussed the non-legally binding nature of the fund, current Blood Service commercial insurance coverage, and issues associated with harmonising the statutory defence legislation across all jurisdictions.

The NBA, in collaboration with members of the National Indemnity Reference Group, developed an action plan for an extensive review of the issues raised. The plan has a specific focus on strategies to effectively manage the risks inherent in the biological nature of blood and blood products. Subject to approval by health ministers, this work will commence late in 2011.

A contract for claims management and actuarial advice was tendered in 2010–11. A three-year contract, with an option to extend for a further three years, was signed with PricewaterhouseCoopers and the new arrangements took effect on 11 February 2011. The consultant will provide all core services, including incident analysis, horizon scanning, Blood Service risk management assessment and actuarial services. In addition, PricewaterhouseCoopers will undertake claims management and update the claims manual.

STATE-OF-THE-ART BLOOD PROCESSING CENTRE OPENS

The completion of Australia's largest, state-of-the-art blood processing centre in Green Square, Sydney is part of a program of government-funded capital works being undertaken by the Blood Service to ensure that Australia's blood sector has the key infrastructure it needs for the next 30 years.

The Sydney Processing Centre is a purpose-built, three-storey facility that is modular, flexible, expandable and scalable to meet changing requirements. The facility has been licensed by the TGA and was completed on-time and within budget.

All testing, processing, distribution, research and administration functions for the Blood Service in New South Wales will be based at this facility. A small distribution function will remain in the ACT while all other non-collection activity has been relocated to this site. The new centre will process all blood donated in NSW and the ACT (approximately 32 per cent of the total national inventory).

Other initiatives in the program include the completion of the Kelvin Grove Queensland centre in 2008 and the construction of a processing centre in Melbourne, which is due to be operational in 2012.

Speaking at the opening of the centre on 8 June 2011, the Hon Catherine King MP, Parliamentary Secretary for Health and Ageing said,

'The Australian Government considers building health infrastructure an essential corner stone in providing the Australian people with a health care system that will meet the needs of future generations'.

The centre has been designed to ensure both security and safety for Australia's blood supply, as well as generating manufacturing and operational efficiences to provide value for money for governments and the broader community.

Formal opening of the Sydney Processing Centre by (from left to right) the Hon Barry O'Farrell MP, Premier of NSW, the Hon Catherine King MP, Parliamentary Secretary for Health and Ageing, and Mr David Hamill, the Chair of the Blood Service Board.

From 2006–07 to 2010–11, seventeen projects costing $7 million have been funded or committed from the Blood Service Change Program Funding Pool to help the organisation transition to a national operation, deliver cost savings or otherwise increase the efficiency of the production of goods and services under the current Deed of Agreement. No new commitment of funds was made during 2010–11. However, work continued on eight projects as detailed in Table 3.8. The projects are expected to be completed in 2013–14.

TABLE 3.8 *Blood Service Change Program projects and funding, 2010–11*

PROJECT	APPROVED BUDGET ($M)
Handover Plan	0.08
National Asset Management System	0.79
Donor Services Workforce Planning	1.64
Learning Management Project	0.72
Hyperion three-year Planning	0.28
National Inventory Framework	0.36
Process Improvement in the Consumable Supply Chain	0.33
Supply Chain Blood Component Efficiency	0.12

Management of plasma and recombinant product 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 diagnostic reagents.

Locally produced plasma-derived products: CSL Australian Fractionation Agreement

In Australia, CSL fractionates plasma from donations collected by the Blood Service. 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's obligations regarding plasma stewardship, production, inventory management, product quality, pricing and payments, supply, reporting and performance and risk management.

Actual funding for CSL increased by $28.1 million in 2010–11, from $182.4 million in 2009–10 to $210.5 million in 2010–11 (see Table 3.9). This represents an increase of 15.4 per cent (the same proportional increase as in 2009–10) compared to an average annual increase of 6.1 per cent from 2003–04 to 2009–10. The increase from 2009–10 to 2010–11 comprises a volume-based increase valued at $31.5 million and a price-based saving of $3 million. The price-based saving arises from the pricing structure of the CAFA, by which the average price for IVIg reduces as IVIg supply volumes increase.

Three products contributed to most of the volume-based increase in 2010–11:

- a 19 per cent increase in IVIg issued by CSL in response to the Octagam recall, as a result of increased plasma levels, and due to better plasma stock management. This contributed to a higher level of Australian self-sufficiency for IVIg
- a 55 per cent increase in demand for plasma-derived FVIII
- a 31 per cent increase in demand for prothrombin complex concentrate.

TABLE 3.9 *CSL Limited: annual funding for plasma fractionation, 2003–04 to 2010–11*

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
TOTAL	**1260.9**	**6.1 (average)**

A number of elements of the CAFA have been subject to an agreed transition process. A Joint Transition Group was established between CSL and the NBA to implement the transition actions. New reporting arrangements have been developed and plans to maintain minimum product and national reserve inventory levels were initiated during the year.

The suite of performance indicators in the CAFA is intended to highlight those areas of CSL's performance that are of most significance to product recipients and funding 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 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 agreement
- shelf life of National CSL Reserve products—maintenance of required minimum shelf life for products held in the NBA-funded National CSL Reserve.

The process of measuring performance against the indicators provides incentive for high levels of performance by CSL 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.

In 2010–11, CSL performed well against the CAFA key performance indicators as shown in Table 3.10.

TABLE 3.10 *CSL Australian Fractionation Agreement: key performance indicators, 2010–11*

DESCRIPTION OF PERFORMANCE MEASURE		RESULTS 2010–11				
		Q1	Q2	Q3	Q4	ANNUAL
KPI 1	Plasma stewardship	100% Achieved	100% Achieved	100% Achieved	100% Achieved	100% Achieved
KPI 2	Production yield	5.25 g/kg	5.18 g/kg	5.20 g/kg	5.09 g/kg#	5.17 g/kg
KPI 3	Management of required inventory levels					
	Starting Plasma	(Not active in 2010–11)				
	Products in CSL Inventory	97 % Achieved*	98% Achieved*	94% Achieved*	97% Achieved*	96% Achieved*
	Products in National CSL Reserve	95% Achieved	100% Achieved	100% Achieved	100% Achieved	99% Achieved
KPI 4	Fulfilment of orders	100% Achieved	100% Achieved	100% Achieved	100% Achieved	100% Achieved
KPI 5	*Shelf Life of National Reserve Products	90% Achieved*	88% Achieved*	86% Achieved*	94% Achieved*	90% Achieved*

\# CSL has recently raised with the NBA the need to consider the effects of changes in plasma collection practices on CAFA contractual provisions relating to IVIg yield.

* The first full year of implementation of the CAFA has indicated a need for the NBA and CSL to review minimum inventory levels in the CSL Inventory and National CSL Reserve in order to optimise production planning against supply, shelf life and product expiry risk.

The CAFA establishes an ongoing dialogue between CSL and the NBA through an annual cycle of management and executive meetings to discuss and monitor strategic and operational matters. In 2010–11, CSL and the NBA held four contract management meetings and an annual Risk Management Workshop in August 2010. In addition, two update and planning meetings were held between the Chief Executive Officers of the NBA and CSL. Topics discussed between the CEOs included:

- CSL's global insurance and risk management, including its Australian operations
- CSL's business planning for services to support the supply of products under the CAFA
- trends and forecasts for products in Australia and globally
- CSL's research and development program
- CSL's investment in, and upgrading of, its Broadmeadows facility.

During the year, two new CSL products provided under the CAFA were approved by the JBC for supply through the NSP&B commencing in 2011–12:

- Rh(D) Immunoglobulin made with a new glycine formulation—the previous version of the product used normal immunoglobulin and the move to the new formulation will therefore allow more of the plasma available to be used for IVIg production
- Biostate in a 1000 IU presentation size, which will be welcomed by the clinical and patient communities for its dosage administration benefits.

The NBA further refined audit procedures associated with goods ordering and receipt verification, to ensure that these remain appropriate under the CAFA. NBA officers, accompanied by external auditors appointed by the Australian National Audit Office, conducted the end of financial year stock take of the National CSL Reserve in Melbourne, Sydney and Brisbane.

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.

The contracts in place for supply of imported IVIg during 2010–11 were:

- with Octapharma Australia (Octapharma) for the supply of Octagam, which had been extended in May 2010 to operate until 31 December 2011
- the Direct Order contract established with Lateral Diagnostics in 2009–10.

In September 2010, Octapharma issued a nationwide voluntary recall of Octagam due to production concerns; see page 59 for more information on the recall and pages 100–1 for further details of impact of the Octagam issue worldwide.

To enable domestic demand to be met, the NBA invoked relevant clauses which had been included in the contract with Lateral Diagnostics to allow supply of Flebogamma through the national blood arrangements (in addition to the Direct Orders supply). Lateral Diagnostics, working with the Spanish-based manufacturer of Flebogamma, Grifols S.A., responded rapidly and fully to the NBA's additional requirements and this arrangement continued for the remainder of the year. The voluntary recall of Octagam was still in place in Australia at 30 June 2011.

In 2010–11, the NBA spent $33.45 million under these contracts, comprising $8.95 million for Octagam (net of credits in relation to the voluntary product recall) and $24.5 million for Flebogamma.

Octapharma's performance against the key indicators in its contract, up to the time of the recall, is set out in Table 3.11.

TABLE 3.11 *Octapharma Australia: key performance indicators, 2010–11*

PERFORMANCE MEASURE	OCTAPHARMA QUARTER 1 2010–11
Delivery Performance	Substantially achieved
In-Country Reserve	Substantially achieved
Ordering	Fully achieved
Record Keeping	Fully achieved
Reporting	Fully achieved
Shelf-life on products delivered to Approved Recipients	Fully achieved

As it was primarily established for the purpose of Direct Order requirements, the NBA's contract with Lateral Diagnostics does not include a specific set of key performance indicators relating to supply under the national blood arrangements. However, the company met all requirements for supply.

On 6 May 2011, the NBA released a request for tender for the procurement of imported IVIg products under the national blood arrangements. The new supply arrangements are to begin on 1 January 2012; see page 52 for more information on procurement.

Prior to the release of the tender, the NBA informed all potential suppliers of its intention and followed its normal practice of consulting clinical stakeholders in order to update background information on the current arrangements for imported IVIg and on historical and forecast demand for IVIg.

The policy position taken for the imported IVIg tender involves the introduction of a second supplier for imported IVIg under the national blood arrangements. This is intended to introduce improved supply security into the supply of imported IVIg, to provide clinicians with choice of product and to maintain competitive pressure on price and performance standards.

Imported plasma-derived and recombinant blood products

The NBA has established contracts with overseas 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.

Since 2006, the NBA has maintained contracts with three overseas companies: Baxter Healthcare, Novo Nordisk Pharmaceuticals and Wyeth Australia (now Pfizer Australia Pty Ltd). Contracts with Baxter Healthcare and Wyeth Australia had been extended until June 2011 and the contract with Novo Nordisk Pharmaceuticals was extended until June 2012.

In 2010–11, the NBA spent $181.33 million under these contracts for the supply of imported blood products, as is shown in Table 3.12.

TABLE 3.12 *Annual expenditure on imported products (excluding intravenous immunoglobulin), by company, 2003–04 to 2010–11*

YEAR	BAXTER		WYETH		NOVO NORDISK	
	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
TOTAL	**$579.84**	**18.8 (avg.)**	**$263.07**	**34.98 (avg.)**	**$172.29**	**12.62 (avg.)**

Consistent with previous years, 2010–11 performance against contractual key performance indicators was high (see Table 3.13).

TABLE 3.13 *Imported recombinant blood product contracts: key performance indicators, by supplier, 2010–11*

PERFORMANCE MEASURE	BAXTER	WYETH	NOVO NORDISK
Delivery Performance	Substantially achieved	Substantially achieved	Fully achieved
In-Country Reserve	Substantially achieved*	Substantially achieved*	Substantially achieved*
Ordering	Fully achieved	Fully achieved	Fully achieved
Record Keeping	Fully achieved	Fully achieved	Fully achieved
Reporting	Fully achieved	Fully achieved	Fully achieved
Shelf-life on products delivered to Approved Recipients	Substantially achieved*	Substantially achieved*	Substantially achieved*

* In these instances, the performance of the relevant supplier departed from the contracted requirement at some periods during the year, but without a material effect on supply performance or supply security. Such instances are managed through specific prior approvals from the NBA, and increased discussion and scrutiny of supplier performance at regular contract management meetings.

During 2010–11, the NBA conducted a procurement process to establish new supply contracts for imported plasma and recombinant products from 1 July 2011.

The process began in July 2010 with the NBA seeking advice from key stakeholder groups and suppliers to inform development of the tender. The NBA also reviewed its contract management arrangements and investigated other relevant supply and market information.

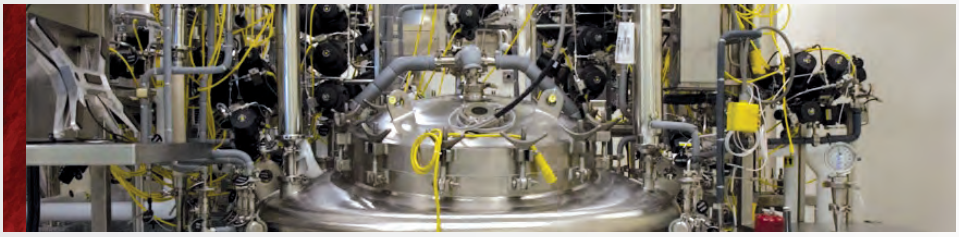
After the information gathering phase was complete, the JBC endorsed a set of policy parameters for the tender process based on advice from the NBA. These included:

- ensuring that the procurement outcomes:
  - represent sound, demonstrable value for money for Australian governments
  - provide an adequate, secure and affordable supply of imported plasma and recombinant products
  - take into account clinician and patient views
- a preference for two national suppliers of recombinant Factor VIII, provided other procurement goals are able to be met
- negotiating prices that are no less favourable, in real terms, than the current prices
- ensuring a product mix that includes the latest generation of products available in Australia at the time of the tender, providing the mix meets other policy parameters.

The request for tender for imported plasma and recombinant products was released in November 2010. The tenders were reviewed by an evaluation committee that included stakeholders with relevant expertise and the outcome was announced in early June 2011.

A particular policy issue for the procurement of imported plasma and recombinant products was the number of suppliers and products to include in the supply arrangements for rFVIII. The policy decision to retain the previous model of two rFVIII suppliers was seen as balancing the objective of providing some choice of products for clinicians and patients, while at the same time retaining competitive pressure on price and supplier performance. The decision recognises that Australia has a relatively small level of demand; and that this makes it more difficult to achieve good procurement outcomes in a market that has a small number of suppliers world-wide.

SECURING SUPPLY— IMPROVING VALUE FOR MONEY



As a result of our recent tender processes Australian governments will save between $10 million to $30 million per year for the next three years, without compromising clinical efficacy or patient safety. With six existing contracts being extended and the release of three tenders for contracts due to expire, 2010–11 was a busy year.

Important improvements have been negotiated for the new supply arrangements for the main clotting factor products, including:

- introducing a new supply security concept that requires suppliers to hold stock within their global supply chain which is dedicated to Australia, in addition to an in-country inventory reserve
- strengthening the consequences associated with suppliers not meeting key performance indicators related to in-country reserve and the shelf life of product on delivery
- encouraging suppliers to pursue initiatives to improve the environmental sustainability of supply arrangements by reducing waste through the return, reuse and/or recycling of cold chain packaging or through the use of cold chain transportation
- introducing specific obligations on the part of suppliers to provide customer feedback mechanisms and demonstrate responsiveness to feedback.

These outcomes are a result of extensive preparations and tender processes. We start preparing at least a year before releasing tenders. We:

- gather information on the global market
- obtain information and customer feedback from suppliers and stakeholders on the level of satisfaction with the current supply arrangements, the products needed and the availability of product choice, the tender period preferred by suppliers and the potential for product enhancements during that time, the extent of competition for supply of specific products, and price considerations
- review the current arrangements to identify where improvements might be gained (e.g. security of supply, safety and value for money)
- use our knowledge of normal supply chain and commercial arrangements of suppliers to design arrangements that suppliers can achieve and sustain.

The new arrangements give patients in Australia secure access to products equivalent to those available in other parts of the world at competitive prices. The new arrangements will remain in place for a minimum of three years, from 2011–12 to 2013–14.

The new contracts will see the introduction of Kogenate and the phasing out of Advate and Recombinate, as shown in Table 3.14.

TABLE 3.14 *Changes in suppliers of imported plasma and recombinant blood products*

IMPORTED PRODUCT	PREVIOUS ARRANGEMENTS TRADE NAME (SUPPLIER)	NEW ARRANGEMENTS FROM 1 JULY 2011 TRADE NAME (SUPPLIER)
rFVIII	Advate and Recombinate (Baxter) Xyntha (Wyeth)	Not available after a transition period Xyntha (Pfizer) Kogenate FS (Bayer)
rFIX	BeneFIX (Wyeth)	BeneFIX (Pfizer)
APCC	FEIBA (Baxter)	FEIBA (Baxter)
Anti-Rh(D)	WinRho (Baxter)	Rhophylac (CSL)
Protein C	Ceprotin (Baxter)	Ceprotin (Baxter)
pdFVII	Plasma-derived Factor VII (Baxter)#	Plasma-derived Factor VII (Baxter)
pdFXI	BPL Factor XI and LFB Hemoleven (CSL)#	BPL Factor XI (CSL)#
pdFXIII	Fibrogammin P (CSL)#	Fibrogammin P (CSL)

Provided under ad hoc arrangements to meet clinical requirements.

In applying the two-supplier model the outcomes of the tender process will require a significant number of patients to change products. This transition process is being closely managed by the NBA in cooperation with clinical and patient stakeholder groups, jurisdictions and suppliers. It is expected that most patients needing to change products will have done so within the first six months of the new supply arrangements.

The new supply arrangements for imported plasma and recombinant products will formalise the contractual frameworks for the supply of certain products by home delivery to appropriate patients, under the supervision of a haemophilia treatment centre.

The NBA is working closely with members of the Haemophilia Foundation of Australia, the Australian Haemophilia Centre Directors' Organisation (AHCDO), the Australian Haemophilia Nurses Group, the Blood Service and the contracted suppliers, to manage the transition of patients between rFVIII products. Additional funding will be 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.

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 around 110 in-vitro red cell diagnostic reagents by public laboratories and the Blood Service, through the National Blood Agreement.

During 2010–11 the NBA had contracts with four suppliers for the supply of diagnostic reagents to public laboratories: CSL Limited, Lateral Diagnostics, ALS–Abacus and OCD (Johnson & Johnson trading as Ortho-Clinical Diagnostics).

The four contracts were due to expire on 31 October 2009 but, following consideration in 2008–09, were extended for one year. Following further stakeholder consultation, the contracts were extended again to June 2011, to align with the financial year. The NBA successfully negotiated prices for the final period that were lower than the CPI increases for that period.

Funding for diagnostic reagent supply is capped at $4.8 million per year. The NBA manages the cap for all jurisdictions across 70 facilities and our four suppliers.

Figure 3.22 shows that the total market share of each supplier has remained relatively stable during the year.

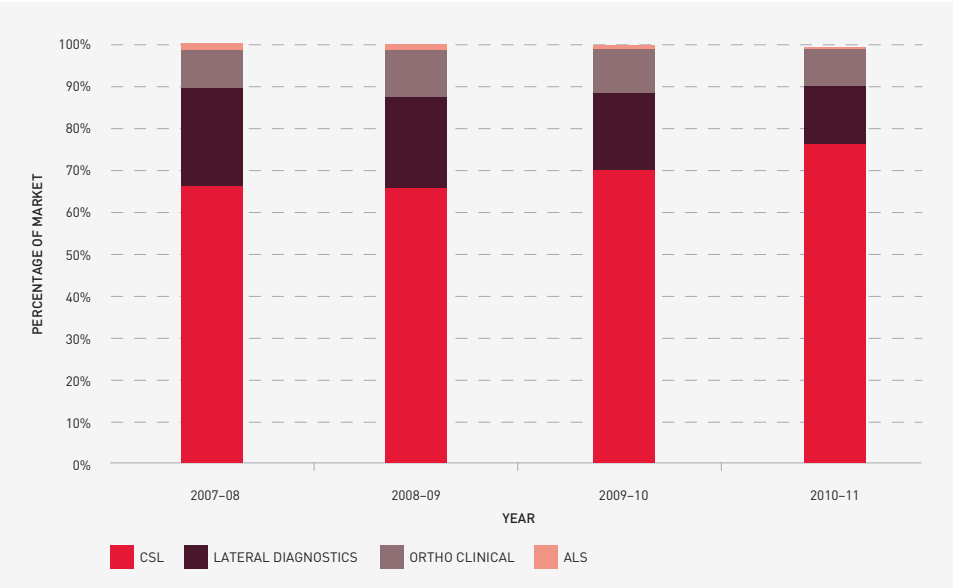


FIGURE 3.22 *Market share for suppliers of diagnostic reagent products, 2007–08 to 2010–11*

The NBA used the same approach to procurement of diagnostic reagents as that used for imported plasma and recombinant products. JBC representatives, a number of public laboratories and current and potential suppliers were all consulted. Feedback was obtained on recent or potential changes to demand for red cell diagnostic reagents, product range, issues with the current standing offer arrangements, the strength of the supplier market and issues around improving the management and allocation of the products.

These consultations highlighted that the TGA regulatory reforms for diagnostic reagents will be a key challenge in the future. In September 2010, the JBC endorsed policy parameters for the tender, as follows:

- establishment of a standing panel to help ensure a commercially competitive supply to public laboratories and the Blood Service of a range of red cell diagnostic reagents that represents value for money
- three-year contracts with options for the NBA to negotiate two additional one year extensions
- arrangements to include an efficient periodic review process to allow for the addition or removal of products or suppliers as a result of regulatory or market changes.

The NBA released the tender in December 2010 and the new arrangements took effect on 1 July 2011. Bio-RAD Laboratories has been added to the four existing suppliers. The new contracts for all suppliers will continue to provide public pathology laboratories with a wide choice of products and the ability to procure the most appropriate diagnostic blood products at competitive prices, quality and service levels.

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 A**).

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 AHMC.

The NBA has 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, DoHA was provided with 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.

Two within-category[1] and non-complex proposals were assessed and will be available through the NSP&B from 1 July 2011.

A number of other applications were received and will be assessed during 2011–12.

1 Within category proposals are defined as changes to products already approved by health ministers and which are already listed on the National Product and Services List

3.3 MANAGEMENT OF RISK AND SECTOR PERFORMANCE IMPROVEMENT

The NBA gives a high priority to managing blood sector risks and contingency planning to ensure that the supply of all required blood and blood products is maintained. A key mechanism to reduce risk that the NBA has focused on during the year is to drive improved data capture and analysis across all aspects of the supply chain.

Key performance indicators	Measure	Results
Management of the National Blood Supply Contingency Plan (NBSCP)	High level of satisfaction of all funding jurisdictions with the NBA's management and implementation as assessed through a survey of JBC members	78% of jurisdictions were very satisfied with the NBA's advice, noting that the implementation of the BloodNet system will further improve timely inventory management. The remaining 22% were unsure. (Page 58)
Number of days the National Blood Supply Contingency Plan is activated for plasma and recombinant products		7 24-30 September 2010, as a precautionary measure to guide the transition to new supply arrangements following the Octagam recall. (Page 59)

Deliverables	Measure	Results
Implement new product levels for national reserve inventories and new supplier contract arrangements	New levels to be implemented by 30 June 2011	Required product inventory levels implemented as an outcome of the transition phases under the CAFA. New tenders for imported IVIg and other imported plasma and recombinant products include enhanced framework for supply security inventories and updated required product inventory levels. Comprehensive updated supply security risk assessment for plasma and recombinant products now to be conducted in 2011–12. (Pages 47–55, 67)
Percentage of recommendations from the *Administrative Review of the National Blood Arrangements 2009*, for which the NBA has responsibility completed[1]	Number of measures from the implementation plan that the NBA was assigned and successfully implemented. ≥95%	3 of 4 (75%) recommendations that the NBA was assigned have been completed. Work on one further recommendation is ongoing together with the JBC and CTEPC.

1 It is expected that all recommendations will be implemented by 2013-14

RISK MANAGEMENT

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 2010–11 was to ensure the most effective risk management arrangements were in place to implement blood policy and to continue to improve sector performance.

Key activities 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.

Risk management for contracted supply arrangements

All supply contracts have a requirement for the suppliers to develop and provide risk management plans to the NBA. These plans detail each supplier's approach to ensuring that risks in providing products and services are identified and avoided or mitigated as far as possible. They provide a basis for discussions on risk management with suppliers.

The CAFA, as the contract dealing with domestic fractionation, also establishes a requirement for an annual risk workshop between CSL and the NBA. Suppliers' risk management plans are taken into account by the NBA in developing its own risk management plans for the contracted supply arrangements for each supply contract or suite of contracts.

In the course of tendering and contracting for blood and blood products the NBA has developed a framework of arrangements relating to supply contracts to provide robust risk management aimed at security of supply. These include:

- notification and reporting processes to identify impending risks
- intensive product management mechanisms
- commitments from suppliers to accord preferred customer status to supply for Australia
- requirements for products to have a specified minimum level of shelf life at the time of supply in Australia
- requirements for the holding of required levels of in-country reserves
- provision for supply of alternative products, if triggered by the NBA
- in some cases, multiple supplier arrangements.

In the tender processes for new contracts for imported IVIg and other imported plasma and recombinant products (see pages 49–53 for more information on these procurements), the NBA has introduced enhanced and additional supply security measures, including:

- a committed global stock requirement for products with a steady demand—a supplier will arrange for a quantity of product held in the normal global supply chain to be specifically earmarked as product available for supply to Australia
- contractual procedures specific to the management of a product recall situation
- alternative minimum inventory requirements to apply for products where low level or highly spasmodic demand for particular products makes the NBA's normal in-country reserve requirements difficult for suppliers to commit to on a sustainable basis.

While these advances in supply risk management have been made, reprioritisation of resources during the year meant that the planned updating of the NBA's supply risk analysis for plasma and recombinant products did not progress. This process will be undertaken during 2011–12.

Financial risks

The new contractual arrangements with commercial suppliers and the implementation of the output based funding model introduce some financial risks for the NBA. Accordingly in the context of developing the 2011–12 NSP&B, the NBA prepared an overall financial reserve strategy, taking into account:

- the completion of risk analysis of plasma and recombinant products and establishment of reserve levels
- an understanding of all potential calls on cash reserves
- a sensitivity analysis of the impact on cash flow of demand changes against the agreed supply plan.

The National Blood Supply Contingency Plan

The National Blood Supply Contingency Plan (NBSCP) was activated during the year due to the voluntary recall of Octagam during September 2010, see page 59, but otherwise inventory levels for all products remained strong.

The NBA liaised closely with suppliers to monitor possible impacts during the Queensland and Victorian floods in January and February 2011 and the Australian-New Zealand air travel interruptions due to volcanic ash in May and June 2011. All suppliers were well prepared and there were no material impacts on any blood or blood product supply arrangements for Australia.

The NBA also reviewed its Standard Operating Procedures for the NBSCP and these were updated to take into account the lessons learnt from the recall of Octagam. An internal education campaign will be undertaken during 2011 to ensure both current and new NBA staff members are aware of their roles and responsibilities during the activation of the NBSCP.

Due to a reprioritisation of internal resources, the annex covering transfusion-transmitted infection for the NBSCP was not completed during 2010–11, although a draft of the roles and responsibilities was prepared.

Management of risk in states and territories

States and territories have constitutional responsibilities for coordinating and planning the response to disasters within their jurisdiction; in turn their emergency management organisations coordinate with Emergency Management Australia.

The extent to which jurisdictions have prepared responses to risks to the blood supply varies depending on their level of knowledge of the total inventory and clinical requirements and the effectiveness of linkages between the NBSCP and state emergency response plans.

Some jurisdictions have developed formal emergency blood management plans or have specific blood sector elements within wider state emergency plans, while others rely on knowledge of the sector and informal networks. Several states have recently conducted exercises to test their procedures.

During 2010–11, the NBA collected information on the preparedness of jurisdictions for emergencies involving blood, and the JBC will consider these early in 2011–12.

VOLUNTARY RECALL— NBA ENSURES IVIG SUPPLY

The NBA ensured that patients currently receiving intravenous immunoglobulin (IVIg) continued to receive products required for their treatment after Octapharma Australia recalled all batches of its Octagam (IVIg) solutions, due to safety concerns, on 24 September 2010. Octapharma issued the voluntary recall in consultation with the TGA, as a result of an increase in adverse events internationally, although none had been reported in Australia at that time.

On the same day, the NBA activated the National Blood Supply Contingency Plan (http://www.nba.gov.au/nbscp/index.html) and the supply of IVIg in response to the recall was managed under this framework in an effective and timely way.

From the several options available to maintain supply, the NBA elected to authorise the use of additional domestic IVIg (Intragam) from CSL inventory, and to trigger the supply of Flebogamma by Lateral Diagnostics. Lateral Diagnostics was very responsive to the additional demand for product and met the supply requirement throughout the period of the Octagam recall.

Because the Blood Service is responsible for the authorisation and distribution of IVIg under the Deed of Agreement with the NBA, the Blood Service had a key role in supporting the increased use of Intragam and the transition to Flebogamma. The Blood Service worked with the NBA and the product suppliers to develop and circulate information to IVIg prescribers, and to manage the necessary logistics within the supply chain. Clinicians were able to switch their Octagam patients to alternative IVIg products with support from the Blood Service, and patients were able to continue their treatment with Intragram or Flebogamma with little, if any, disruption to their care.

International Consensus Conference on risk-based decision-making for blood safety

Blood safety decision-making has become increasingly complex with increasing expectation that aspects including scientific, medical, ethical, legal, regulatory, economic and public policy requirements should be taken into consideration. As blood systems globally focus on the responsible use of healthcare resources, questions arise on the most effective way to manage risk for blood safety that is sustainable. The focus on blood safety is increasingly considering risks beyond product safety towards a concept of 'process integrity'—a 'vein-to-vein' system approach rather than a focus on 'product' alone.

In late October 2010 staff of the NBA attended an international consensus development conference on risk-based decision-making for blood safety that was held in Toronto. The intention of the conference was to seek recommendations and guidance on the creation of a framework for risk-based decision-making. The development of a risk framework for blood safety decision-making can build on knowledge relevant in the evaluation of previous blood safety decisions, haemovigilance data, models developed in other high risk disciplines and industries and leading practices in risk management, risk communication and systems thinking. An independent panel of 12 professionals with experience in the risk industry or health care developed the foundations of a vein-to-vein risk framework by answering pre-set questions designed by the organising committee.

The conference offered many valuable insights into the substantial costs and the very real challenges in developing a more comprehensive risk-based decision-making framework for the blood sector that would move the sector away from a precautionary approach to one based on a more holistic cost-benefit analysis.

The intent of the conference was discussed at the CTEPC Blood Policy forum in March by Adjunct Professor Chris Brook, who had participated on the independent panel. Future coordination of the policy framework and consideration of the issue by governments will be coordinated by DoHA. The NBA will assist in assessing the impact on the security of supply of any changes in the approach to risk for the sector.

SECTOR PERFORMANCE IMPROVEMENT

The NBA has a number of projects and activities designed to improve the overall efficiency of the sector as key strategies to improve affordability and minimise risk. These fall into three broad areas of improvement through:

- increasing capacity in data collection and analysis
- knowledge acquisition and management
- management and accountability initiatives.

Sector improvement through data collection and analysis

The availability of comprehensive, consistent, relevant, timely and robust data, and the capacity to analyse that data, is a powerful tool to identify areas where improvements can be made in supply management and clinical demand. During the year significant progress was made in the capture and analysis of data.

Implementation of BloodNet

Initially known as ORBS, the web-based ordering and receipting 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. During 2010–11, 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. To date the system has been rolled out to all hospitals in Queensland, South Australia, Tasmania, the Northern Territory and three hospitals in Victoria. Jurisdictions expressed satisfaction with the advice and approach taken for the national implementation of BloodNet, and the nature of the reports they receive from the system.

BLOODNET: VALUE ADDING IN THE SUPPLY CHAIN

Australia is already reaping the benefits of the roll out of NBA's BloodNet, Australia's first national, online, blood ordering system.

'The BloodNet system is easy to use and requires little training,' said Sue Williams, Senior Scientist, Transfusion, Queensland Health.

BloodNet replaces the manual ordering systems that relied on faxes and phone calls. Hospitals are now able to place an order for blood and blood products via a customised webpage. Once placed, the order is sent directly to the Blood Service by the click of a button.

The system is quick, easy and secure and the NBA is working with other blood product suppliers to enable them to be part of the online ordering system (see diagram overleaf).

BloodNet enables hospitals to:

- place orders 24 hours a day, 7 days a week and get instant confirmation that the order has been received
- give immediate feedback on receipt of orders, such as whether an item is damaged or close to the expiry date
- by late 2011 it will also allow for the recording and tracking of the fate of blood and blood products that are discarded or transferred to other hospitals.

BloodNet also provides data showing a hospital's history of orders, use and trends over time as well as inventory levels and ordering practices. Hospitals can easily produce weekly, monthly or yearly reports on their blood use and obtain accurate financial details of their orders.

Implementation in private laboratories in Western Australia is scheduled for mid-July 2011, for the ACT and some area health networks in NSW in August and for the public facilities in Western Australia in September. Discussions with the remaining facilities in New South Wales and Victoria in relation to implementation are ongoing.

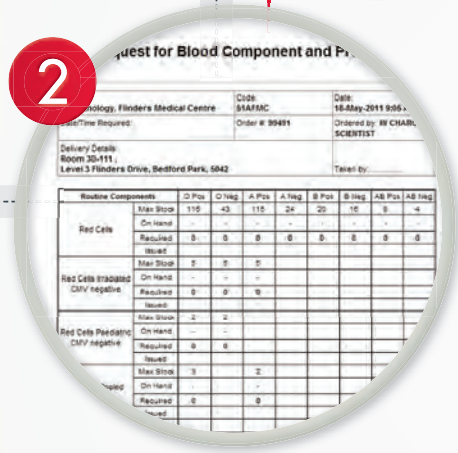
There is no cost to hospitals in introducing the system. The NBA is meeting all costs of implementing, supporting and further developing BloodNet.

Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP (right), was given a live demonstration of BloodNet while on a visit to Darwin by the Royal Darwin Hospital's Senior Scientist Kelly Burns.

BLOODNET IN 7 EASY STEPS

ONE
An order for blood is lodged using BloodNet at Flinders Medical Centre laboratory in Adelaide.

TWO
The order is immediately received at the nearest Blood Service Distribution Centre.



THREE
The ordered items are collected from the storage facilities at the Blood Service.

FOUR
The order is loaded into a courier van for dispatch to Flinders Medical Centre.

FIVE
The ordered items arrive at Flinders Medical Centre.

SIX
The order is receipted in BloodNet and in the hospital's LIS using the existing scanners at Flinders Medical Centre.

SEVEN
The items are stored at the laboratory ready for testing, collection and use.

Australian Bleeding Disorders Registry

The ABDR is deployed to users in all Australian haemophilia treatment centres and clinics. The system is designed to produce data that fulfils the needs of clinicians, patient representative groups and governments within a highly controlled governance framework.

Substantial progress on increased data collection and quality was achieved during the year, with a noticeable increase in the quality of data, enabling the publishing of the first ABDR Annual Report (see www.nba.gov.au/abdr). Eighty-eight per cent of jurisdictional representatives expressed satisfaction with the data provided by the NBA from the ABDR.

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 3.15 below.

TABLE 3.15 *Comparison of the proportion of patients in registers and treated, UK and Australia, major diagnoses 2010*

	FEMALE			MALE		
	IN REGISTER 2009–10	TREATED 2009–10	PROPORTION TREATED	IN REGISTER 2009–10	TREATED 2009–10	PROPORTION TREATED
AUSTRALIA						
HmA (Symp + Asymp)	294	25	8.5%	1631	805	49.4%
HmB (Symp + Asymp)	80	15	18.8%	383	170	44.4%
vWD	1003	96	9.6%	745	87	11.7%
Other conditions	278	9	3.2%	264	13	4.9%
UK						
HmA (Symp + Asymp)	1082	53	4.9%	5346	2863	53.6%
HmB (Symp + Asymp)	332	37	11.1%	1125	618	54.9%
vWD	5588	620	11.1%	3268	363	11.1%

Planning work to further enhance the system commenced in June 2011.

NBA 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 last year, efforts on Big Red have been focussed primarily on data cleansing and integrating data from disparate systems into combined reports.

The technical work to enable secure remote access by jurisdictions to Big Red has been completed and this functionality will be deployed to jurisdictional users later in 2011 once work on the meta-data tool to accompany these data sets is completed. This is a key aspect of the delivery of the full functionality of BloodNet for JBC members allowing them to link data on demand and supply to compare ordering practices across AHPs.

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.

During 2010–11 a series of minor enhancements were undertaken to consolidate the functionality of the system in respect of demand planning and audit trails. Following these enhancements, use of the system continued to rise throughout the year with the system now an integral tool in daily work on contract administration and supply and demand planning.

Work is currently underway to electronically integrate the data from BloodNet relating to order and receipt verification into IDMS processes to validate supplier invoices for blood and blood products before payment. These system enhancements will be implemented in full during 2011–12.

The internal auditor 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. A number of recommendations were made and the NBA is undertaking further analysis of several technical issues and refining how the system interacts with our business processes.

National IVIg management system

The National IVIg Management System (NIMS) will capture information on the use of IVIg in order to support and align with the *Criteria for the clinical use of IVIg in Australia*.

During 2010–11, the NBA planned the infrastructure needed for the system and the linkages between NIMS and other NBA sector systems such as BloodNet and ABDR, in preparation for the development and implementation of the system. Further development work was placed on hold following the decision of CTEPC to undertake an independent review of the management of IVIg (see pages 75–6).

Barcoding

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

The NBA will actively engage with the sector in 2011–12 to determine the specific details of implementation, including an agreed timetable.

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. Part 4 of this report, Horizon scanning, describes just some of the minor, major and simply interesting events that arose during the year. Other activities to build our knowledge base are described below.

The collaboration of national plasma product supply planners (NPPSpa)

The third meeting of the collaboration of national plasma product supply planners was held in Lisbon in March 2011, and chaired by the NBA's General Manager. 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. Issues discussed included:

- patterns of IVIg usage, including sub-cutaneous Ig usage
- quantifying, attributing and funding mechanisms associated with the collection costs of plasma
- demand trends for clotting factors and other plasma products and the difficulty of predicting the budgetary impacts associated with the treatment of high cost patients
- international trade in plasma and IVIg products and supply, demand and price trends
- standards for plasma fractionation, especially in toll manufacturing agreements
- the use and cost effectiveness of solvent detergent pathogen inactivation to treat plasma products
- management of the availability of increasing numbers of product brands available in the haemophilia category, including the criteria for evaluating new proposals
- the ethical considerations associated with plasma collection.

The group agreed that the collaboration continues to be worthwhile and Canada was elected to chair the group in the future. During 2011, further comparative data will be assembled and analysed and the group will meet again in early 2012.

Other overseas intelligence gathering *(see also page 60)*

Two NBA officers visited the United Kingdom and the Republic of Ireland to assess relevant ICT and data systems to inform the further development of the NBA's data activities. This included identifying any systems that could be purchased and used directly, either as a new capability or to replace an existing system with little modification. We were also interested to examine how the use of these systems had changed practice and product consumption.

The General Manager also visited the United Kingdom to:

- investigate operational aspects of blood sector management by the Welsh Blood Service, including inventory, distribution management, service standards and the impact of cost pressures. Of particular interest was the implementation of cell salvage throughout Wales
- explore the experience of the UK National Health Service (NHS) Commercial Medicines Unit in recent procurement of recombinant blood products and investigate the work of the NHS Better Blood Transfusion Program in developing models to predict future demand for red cells and platelets and in benchmarking and auditing safe and appropriate use of fresh blood components.

Staff who attended international conferences also took every opportunity to hold relevant side meetings with suppliers and colleagues in the blood sector from around the world. Key messages emerging from conferences attended are described below:

World Federation of Haemophilia XXIX International Congress

Evidence from around the world indicates that the demand for clotting factor support will continue to increase as a result of haemophilia populations in the developed world living longer and the introduction of more active prophylaxis treatment programs, some of life-long duration.

13th International Haemovigilance Seminar

International data points strongly to the need to focus resources around risks in the transfusion process, rather than implementing further measures to improve the safety of the blood products themselves.

International Plasma Protein Congress

A number of developments in IVIg of relevance to the Australian blood sector were reported including the introduction of an IVIg management program in the United Kingdom; an update on progress in clinical trials on the use of IVIg to treat Alzheimer's disease; and increasing concerns about the incidence of thrombotic events with Immunoglobulin G.

Sector improvement through management and accountability initiatives

The NBA continued to review and assess policies and procedures across aspects of the blood supply chain, in order to increase efficiency and accountability within the blood sector, and internationally.

Performance measures for suppliers

The NBA continued to benchmark performance of contracts with suppliers for price and quality and also to provide reference points for sector performance improvement, as part of contract negotiations, see pages 46–55 & 57.

In particular, the extensive negotiations during the development of the new Deed of Agreement with the ARCS and implementation of output based funding, focused strongly on identifying opportunities to measure and improve performance, see pages 39–41.

Review of distribution arrangements for plasma and recombinant blood products

In 2010–11, stage 3 of the distribution review was implemented by the NBA. This required the NBA to undertake further evaluation of the manufacturer-direct distribution model to assess the costs and benefits for governments and the sector. A project board was established and distribution sites were visited. Key stakeholders were interviewed in Queensland, which agreed to be a site for a trial of the new arrangements.

The board's findings were considered by the JBC in December 2010 which endorsed a two-year program to improve the supply chain for plasma and recombinant products, which would:

- develop an agreed set of commercially-based performance standards and information requirements for this supply chain
- monitor performance against these standards for all commercial suppliers and the Blood Service[1], and initiate improvements where appropriate
- explore opportunities for reducing the inventory of non-fresh products held by the Blood Service, using a risk-based assessment
- consolidate national direct-delivery arrangements for all clotting factors in conjunction with the further development of the ABDR.

AHCDO convened a workshop of haemophilia stakeholders in February 2011 to discuss opportunities and possible directions for supply chain improvements in relation to clotting factors. The outcomes of this discussion are assisting in framing specific options for further work.

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1 As a distributor: the Blood Service is responsible for delivering some blood products other than fresh blood components.

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* has been developed to address the lack of specific accountability obligations, other than general safety and quality issues mandated by other agencies, on health providers such as laboratories in hospitals and clinics and other institutions that receive blood and blood products for dispensing to patients.

The Statement contains a concise description of responsible, sustainable and appropriate use of blood and blood products relevant to handling, storage, administration, usage and capacity to report inventory. It was developed following stakeholder consultation and advice from the JBC and was considered and endorsed by the AHMC on 12 November 2010. At the request of CTEPC, the NBA, in conjunction with JBC representatives, is currently developing a plan to promote and implement the Statement nationally, in conjunction with the ACSQHC National Safety and Quality Health Service Standard on blood and blood product.

Ensuring appropriate company behaviours

In January 2010 and January 2011 meetings were held in Dublin, in the Republic of Ireland, to draft a set of principles to promote the development of ethical and safe systems of blood and plasma collection and the manufacture of safe products for clinical treatment. Participants included both the industry and not-for-profit sectors, national blood authorities and patient and donor organisations. At the end of the initial meeting, a comprehensive statement—the Dublin Consensus Statement—was released which focused on the needs of patients and donors. During 2010 the Statement was published in *Vox Sanguinis*[1]; it has been endorsed by 22 patient groups and received qualified agreement from key global organisations.

At the second meeting the Statement was modified, with discussion around the issues of self sufficiency and a preferred focus on red blood cells and platelet donations. In particular, a number of organisations were concerned to ensure that the Statement should not specifically exclude the possibility of paying plasma donors. All of the participants agreed that the revised Statement was suitable for submitting to their organisations for formal endorsement. The Statement has not yet been endorsed by Australian governments or internationally.

The NBA has responded to the Statement by introducing additional requirements in its documentation to procure plasma-derived blood products. Companies tendering to the NBA for these contracts must now demonstrate that they and their plasma suppliers maintain ethical policies and practices in relation to patients, blood and plasma donors, sector relationships and global use of donated blood and plasma. The new specification is consistent with Commonwealth procurement guidelines and the National Blood Agreement.

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, focusing mainly in the field of acute hospital care. As a result, the language and culture of performance measurement is now well established in the day-to-day life of acute public hospitals.

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1 Mahony BO, Turner A, "The Dublin Consensus Statement on vital issues relating to the collection of blood and plasma and the manufacture of plasma products" Vox Sanguinis 2010 98,447-450

Ongoing development of performance measures is occurring on multiple fronts as part of Australian Government and state and territory initiatives that aim to establish an information infrastructure at the service delivery level. These are designed to:

- support and encourage good practice
- regularly inform about consumer outcomes
- inform judgments about value for money
- produce national and state and territory data on performance to enhance accountability.

The National Blood Agreement requires the NBA to:

- undertake or facilitate national information management, benchmarking and cost and performance evaluation for the national blood supply (paragraph 25(o) of the National Blood Agreement)
- facilitate the development of national information systems for safety and quality issues in relation to the Australian blood sector (paragraph 35(f) of the National Blood Agreement).

The NBA is developing a framework that will allow a set of key performance indicators, aligned with the national health performance framework, to be developed for use in benchmarking and monitoring the blood sector.

There are a number of measures that could be drawn from the blood sector to contribute to the overall understanding of the health status of the Australian population. For example, morbidity due to bleeding disorders and measures of the burden of disease for people with bleeding disorders would provide good insight into health outcomes for a defined population group. These may include years lived with disability, impairment rating, disability-adjusted life expectancy, years of life lost and cause of death.

Community capacity to meet the needs of people with bleeding disorders such as the distance to a haemophilia treatment centre, the rate of prophylaxis and the rates of haemophilia could be measured in the 'determinants of health' domain. The rate of occurrence of haemophilia was used as an example of an appropriate indicator for this domain in the initial report of the National Health Performance Committee. Data is now available for these types of measures to facilitate international comparisons.

The central tasks for this project are to interpret how the national health system performance framework aligns with types of information within the blood sector, and propose indicators for adoption at the national level. There are three types of information for the blood sector:

- *management*—focusing on demonstrating achievement of the objectives of governments, including value for money
- *clinical*—focusing on patient outcomes and safety and quality of processes used to deliver these outcomes. The clinical domain comprises measures of the impact of health care on a patient and indicators of this type are often described as the 'gold standard' of service effectiveness indicators
- *supply*—focusing on the degree to which suppliers to the sector are fulfilling the expectations of governments in the most efficient and effective manner.

During 2011–12, the draft measures will be further developed to reflect data that is currently available or will be available over time. A discussion paper will then be circulated to the sector for comment.

3.4 APPROPRIATE PATIENT BLOOD MANAGEMENT AND SAFE USE OF BLOOD AND BLOOD PRODUCTS

The NBA contributes to promoting the safe, high quality management and use of blood and blood products and services by working with stakeholders and other experts to develop clinical practice and product use guidelines that support effective and appropriate clinical practice.

In 2010–11 key areas of work included:

- national patient blood management guidelines and initiatives
- review of the criteria for the clinical use of IVIg
- national haemovigilance program
- National Safety and Quality Health Service Standard for blood and blood product
- red cell data usage project
- education initiatives.

Key performance indicators	Measure	Results
Quality advice provided to guide promotion of safe, high quality patient blood management and use of blood and blood products	High level of satisfaction of the NBA's advice on the promotion of patient blood management and use of blood and blood products as assessed through a survey of JBC	88% of the jurisdictions were satisfied with the NBA's advice on the process undertaken to develop patient blood management guidelines and the IVIg criteria, noting the need for further evaluation of cost-effectiveness. (Pages 71–5)
	Numbers of downloads of guidelines and criteria from NBA website (www.nba.gov.au)	Guidelines–329 Criteria–253 (Pages 71–5)

Deliverables	Measure	Results
Provide clinicians with evidence-based information on safe and appropriate blood management by releasing two elements of the National Health and Medical Research Council Clinical Practice Guidelines for Patient Blood Management	Two guidelines released by 30 June 2011	PBM Guideline module on Critical Bleeding/Massive Transfusion released on 31 March 2011 PBM Guideline module on Perioperative public consultation process closed on 1 April 2011 (Pages 71–3)

PATIENT BLOOD MANAGEMENT GUIDELINES AND INITIATIVES

Internationally, patient blood management is a well-established approach which aims to avoid unnecessary transfusion and the associated risks, and to optimise the use of donor blood. The NBA has developed a wide-ranging program to implement these objectives, which includes updating guidelines, developing national outcome and performance measures, and supporting the development and national roll-out of successful educational initiatives.

Clinical practice guidelines for patient blood management

Using interest monies approved by the JBC, the NBA is managing the development of evidence-based Patient Blood Management Guidelines. The interest monies 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.

Members of the Clinical Reference Group for the Perioperative PBM Module: Dr Hilary Cadman, Dr Suzanne Campbell, Dr Craig French, Associate Professor Larry McNicol, Ms Tracy Merlin, Dr Richard Seigne, Mr Daryl Teague and Dr Amanda Thomson, with NBA staff Dr Chris Hogan, Dr Paul Hyland, Ms Jennifer Roberts and Ms Leia Earnshaw. Missing were Professor Zsolt Balogh, Mr Shannon Farmer, Professor Russell Gruen and Dr John Vinen

The guidelines will comprise a set of six separate modules that are being developed sequentially and will focus on different patient populations: Critical Bleeding/Massive Transfusion; Perioperative; Medical; Critical Care; Obstetrics; and Paediatrics/Neonates. NHMRC approval will be sought on completion of each module. Combined, the suite of six modules will replace the NHMRC/Australian and New Zealand Society for Blood Transfusion, *Guideline on the use of blood components (2001).*

In 2009–10 the systematic reviews and public consultation processes were completed for both the Critical Bleeding/Massive Transfusion and Perioperative Modules. After peer review and an independent AGREE II assessment, the Critical Bleeding/Massive Transfusion module was approved by NHMRC on 12 November 2010 and released on 31 March 2011.

Public consultation for the Perioperative Module closed on the 1st April 2011 with 25 submissions being received. The module is expected to be finalised for independent peer review and AGREE II assessment in July prior to consideration by the NHMRC at its meeting in October 2011.

The systematic review and writing of the Medical and Critical Care modules are progressing and are expected to be released for public consultation early in 2012.

NEW ADVICE TO GUIDE CLINICAL PRACTICE

The release of the revised Critical Bleeding/Massive Transfusion module on 31 March 2011 represented the culmination of nearly three years of work on the part of the NBA and its knowledge network of clinical specialists and practitioners.

'I believe this is an important body of work and the Society is pleased to continue to have the opportunity to be involved in guideline development with the Authority,' said Associate Professor Michael O'Leary of the Australian and New Zealand Intensive Care Society.

Publication of the module in 2009–10 was delayed due to the complexity and volume of material generated by the review and its release now heralds significant improvements in the evidence for, and quality of, patient blood management standards.

The previous protocols recommended transfusion of a large number of red cells, which assisted in replacing blood loss but did not take into account the need to stop the blood loss. The information in the new module consolidates evidence that supports more comprehensive management of critical bleeding incidents and promotes local adaptation and use of a massive transfusion protocol.

The module is one of six that together will form the Clinical Practice Guidelines for Patient Blood Management. They will replace the NHMRC/Australian and New Zealand Society for Blood Transfusion, *Guideline on the use of blood components (2001).*

Dr Bronwen Ross, Deputy CEO, Royal College of Pathologists of Australasia acknowledged *'...the significant work that has gone into producing this document. The College appreciates the opportunity to be involved in the development of these guidelines...'*

The Critical Bleeding/Massive Transfusion module sets out the material in a logical way and is currently available in both electronic and print format, free of charge. Copies can be obtained or ordered from the NBA website at http://www.nba.gov.au/guidelines/module1/index.html.

Demand for the module has been high. In order to make the information more accessible to health practitioners, the development of an iPad/iPhone application for the modules of the Patient Blood Management Guideline is underway.

No.	Grade	Recommendation
R1	C	It is recommended that institutions develop an MTP that includes the dose, timing and ratio of blood component therapy for use in trauma patients with, or at risk of, critical bleeding requiring massive transfusion (Grade C).[4,5]
R2	B	C	The routine use of rFVIIa in trauma patients with critical bleeding requiring massive transfusion is not recommended because of its lack of effect on mortality (Grade B)[6] and variable effect on morbidity (Grade C).[6]

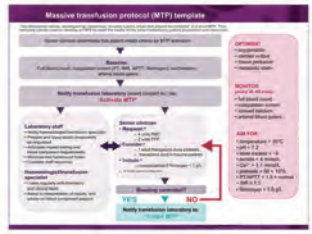
Patient Blood Management Guidelines: Module 1

Critical Bleeding Massive Transfusion

Massive transfusion protocol template

An editable electronic template MTP is available on the NBA's website www.nba.gov.au.

The MTP template is also shown in Appendix G. Chapter 4 discusses local adaptation of the template MTP (s. 10.1) and the development of guidelines on activation and cessation of the MTP (s. 10.2).



Summary of practice points

The CRG developed practice points where, as was commonly the case, the systematic review found insufficient high-quality data to produce evidence-based recommendations, but the CRG felt that clinicians require guidance to ensure good clinical practice. These points are based on consensus among the members of the committee.

No.	Practice point	Relevant section of document
PP1	In patients with critical bleeding requiring massive transfusion, the following parameters should be measured early and frequently: • temperature • acid–base status • ionised calcium • haemoglobin • platelet count • PT/INR • APTT • fibrinogen level. With successful treatment, values should trend towards normal.	6.1
PP2	Values indicative of critical physiologic derangement include: • temperature < 35°C • pH < 7.2, base excess > –6, lactate > 4 mmol/L • ionised calcium < 1.1 mmol/L • platelet count < 50 × 10⁹/L • PT > 1.5 × normal • INR > 1.5 • APTT > 1.5 × normal • fibrinogen level < 1.0 g/L.	6.1
PP3	In critically bleeding patients requiring, or anticipated to require, massive transfusion, an MTP† should be used. A template MTP is provided within this module.‡ †The use of the word 'protocol' in 'massive transfusion protocol' throughout this report is not strictly prescriptive. ‡The template MTP is intended for local adaptation.	6.2
PP4	In patients with critical bleeding requiring massive transfusion, insufficient evidence was identified to support or refute the use of specific ratios of RBCs to blood components.	6.2
PP5	In patients with critical bleeding requiring massive transfusion, haemoglobin concentration should be interpreted in the context of haemodynamic status, organ perfusion and tissue oxygenation.	6.3

No.	Practice point	Relevant section of document
PP6	In patients with critical bleeding requiring massive transfusion, the use of RBC and other blood components may be life saving. However, transfusion of increased volumes of RBC and other blood components may be independently associated with increased mortality and ARDS.	6.6
PP7	In patients with critical bleeding requiring massive transfusion, the use of an MTP to facilitate timely and appropriate use of RBC and other blood components may reduce the risk of mortality and ARDS.	6.6
PP8	An MTP should include advice on the administration of rFVIIa when conventional measures – including surgical haemostasis and component therapy – have failed to control critical bleeding. NB. rFVIIa is not licensed for this use. Its use should only be considered in exceptional circumstances where survival is considered a credible outcome (see Template MTP example).	6.6
PP9	When rFVIIa is administered to patients with critical bleeding requiring massive transfusion, an initial dose of 90 µg/kg is reasonable.	6.6
PP10	In patients with critical bleeding requiring massive transfusion, suggested doses of blood components are* • FFP: 15 mL/kg • platelets: 1 adult therapeutic dose • cryoprecipitate: 3–4 g. *Or as directed by the haematologist/transfusion specialist in specific clinical situations (such as cirrhotics).	6.8

APTT, activated partial thromboplastin time; ARDS, acute respiratory distress syndrome; FFP, fresh frozen plasma; INR, international normalised ratio; MTP, massive transfusion protocol; PT, prothrombin time; RBC, red blood cell; rFVIIa, recombinant activated factor VII

CRASH-2†	
In trauma patients with or at risk of significant haemorrhage tranexamic acid (loading dose 1 g over 10 minutes, followed by infusion of 1 g over 8 hours) should be considered.	6.9
The CRASH-2 trial was published on 14 June 2010 after the cut-off date of the systematic review.[7] No systematic review was conducted on tranexamic acid in critical bleeding/massive transfusion. The study population was not restricted to critical bleeding requiring massive transfusion.	

National patient blood management initiatives

Internationally, hospitals that have introduced patient blood management (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. The NBA established a National Patient Blood Management Steering Committee (NPBMSC) in 2009 to provide advice to governments on patient blood management initiatives.

In providing advice, the NPBMSC referred to the research emerging from the systematic review being conducted to support the production of the patient blood management guideline modules. The NPBMSC has proposed a set of national outcome and performance measures and the development of a Patient Blood Management Toolkit to support the introduction of patient blood management at the local level.

The measures and toolkit concepts were considered by JBC and the CTEPC in March 2011. Work on the toolkit will commence early in 2011–12.

Key achievements include:

- definition of anaemia management priorities by the Anaemia Management Working Group, a sub-group of the NPBMSC including:
  - engagement of the Royal College of Pathologists Australia to standardise information included in pathology reports relating to anaemia
  - engagement of the National Prescribing Service to include anaemia in their educational offerings
  - liaison with the TGA on issues relating to availability of iron products
- incorporation of PBM content into education programs supported by the JBC including the BloodSafe eLearning Program and Melbourne University's Post Graduate Certificate in Transfusion Practice
- contribution to the DoHA Review of the Funding of Pathology Services in Australia to encourage appropriate stewardship of blood and blood products
- provision of detailed guidance to, and sector coordination of, input on all aspects of the National Safety and Quality Health Service Standard for blood and blood product.

CRITERIA FOR THE CLINICAL USE OF INTRAVENOUS IMMUNOGLOBULIN

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.

Review of the *Criteria for the clinical use of IVIg in Australia* (the Criteria)

The Criteria identifies the indications for which IVIg is funded under the national blood arrangements by all Australian governments. Regular review of the Criteria is required to align funded access to IVIg with the latest evidence, or in the case of limited evidence, a consensus of expert opinion.

A triennial review of the Criteria was conducted by the National IVIg Criteria Review Working Group (NICRWG) established and supported by the NBA. The working group received and considered 28 formal submissions in 2010 and a systematic review was conducted for indications where sufficient evidence was available.

An exposure draft was developed and approved by the NICRWG and the JBC for public consultation and released on 25 June 2011 for a period of eight weeks. The NICRWG will consider the feedback prior to submission of the revisions through the JBC to health ministers for approval.

It is anticipated that the second edition of the Criteria will be finalised and released on 1 July 2012.

Review of the management of IVIg

In response to concerns at the need for a higher level of cost effectiveness to be applied to the use of IVIg, the NBA, working with the government members of the NICRWG, commenced an analysis of the existing management arrangements for IVIg and alternatives that could be applied.

This analysis showed that in 2009–10, the cost of subsidised IVIg was $275 million, which represented 31per cent of the blood budget. In 2003–04, this cost was $134 million. Both figures include the cost of plasma collected by the Blood Service for the locally manufactured product. Between the two periods, the average cost per patient increased by 25 per cent from approximately $20,000 to $25,000. In the period 2003–04 and 2007–08, prior to the release of the Criteria, growth in IVIg usage was approximately 14 per cent per annum.

Since then, growth has averaged 11.5 per cent per annum. While contemporary data on the amount and cost of treating chronic versus acute diseases with IVIg are not readily available, a number of observations can be made. For example, certain conditions such as primary immunodeficiency disease (PID) which accounts for about 17 per cent of total IVIg issued, requires IVIg for life, commencing in early childhood. For a typical adult PID patient the cost per year for IVIg is approximately $30,000. The biggest change in demand from 2004–05 to 2009–10 has been for the treatment of conditions where there is convincing evidence of benefit; see Part 4, pages 101–3.

The range of indications for which IVIg therapy demonstrates some clinical benefit is expanding, with the product's immunomodulatory effects being the current mode of action of greatest interest. For example, Baxter International Inc. is currently undertaking multi-centre trials on the use of IVIg in the management of Alzheimer's disease. The potential for a significant and ongoing growth in demand coupled with an ever expanding list of indications poses challenges for both supply security and affordability. The key challenge in determining the cost effectiveness of IVIg for other conditions, which affect only small patient numbers, is the lack of supporting data.

Preliminary analysis has found that the current authorisation arrangements are not consistent across jurisdictions. They 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.

In May 2011, CTEPC determined that the NBA, with the JBC, should coordinate an independent review of IVIg management arrangements, with the following goals:

- ensuring that funded IVIg use reflects best clinical practice and is cost effective
- ensuring that the outcomes of decision-making regarding access to IVIg funded under the national blood arrangements are consistent with the current Criteria
- improving the capture of information on the effectiveness of IVIg usage to improve the evidence base that will inform future changes as to what is regarded as best practice in IVIg use and prescribing.

Work on this project will commence in August 2011.

NATIONAL HAEMOVIGILANCE PROGRAM

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. These systems are known as haemovigilance systems.

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

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

In 2010, HAC published the second Australian Haemovigilance Report, http://www.nba.gov.au/haemovigilance/index.html based on the agreed National Haemovigilance Data Dictionary. The report collated 294 serious adverse incidents reported between July 2008 and June 2009 and made 12 key recommendations in the areas of data quality, procedural errors and national blood quality and safety initiatives.

During the year HAC met to consider a strategy for addressing Recommendation 2 of the 2010 Haemovigilance report on improving reporting and recognition of serious adverse events such as transfusion-associated circulatory overload (TACO) and transfusion related acute lung injury (TRALI). See Figure 3.23 for images of TRALI-affected and recovered patient chest x-rays.

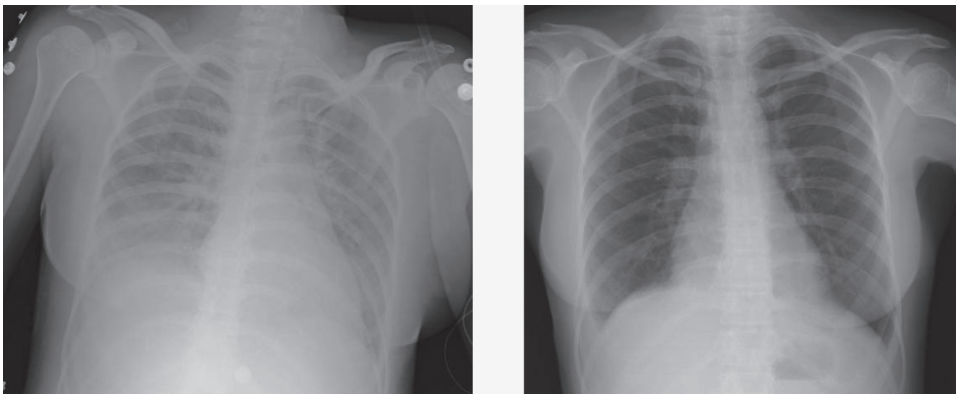


FIGURE 3.23 *TRALI: chest x-ray findings (a) at the time of acute symptoms and (b) after weaning from a ventilator (Transfusion related acute lung injury presenting with acute dyspnoea: a case report. Journal of Medical Case Reports 2008, 2:336. doi:10.1186/1752-1947-2-336)*

HAC agreed that a consensus guideline on the Recognition and Management of Acute Transfusion Related Adverse Events should be developed and that this document should include sections on TACO and TRALI. The NBA has worked with the HAC out of session to develop the structure of the guideline and will seek assistance from an expert society to draft the content of the report.

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

The NBA contributed to the development of the draft National Safety and Quality Health Service Standard for blood and blood product. The standard has been developed by the ACSQHC after consideration of the NBA's request to include a blood specific standard in their suite of 10 key standards. The NBA has assisted the ACSQHC in consulting widely with the blood sector over the past three years in the development of this important Standard.

The Standard is built around four key elements:

- the governance and quality improvement systems—health services should have in place systems that are safe and minimise waste at all stages of the provision, use, storage and distribution of blood and blood products
- the documentation of patient information—the clinical workforce should accurately record a patient's blood and blood product use including transfusion history and indications for treatment
- communicating with patients—the clinical workforce should inform patients and carers about the options and risks for any treatment plan that may include the use of blood and blood products
- blood and blood product management processes—health services should have systems in place to obtain, store, prescribe, transport and administer blood appropriately, efficiently and safely.

The draft standard was made available for a period of public consultation, which ended on 8 October 2010. The NBA provided two formal submissions to the ACSQHC; one to the public consultation process and another to inform the estimate of regulatory impacts associated with implementing the national standards and accreditation framework.

The new Standard is expected to be made available during 2011 for full implementation from January 2013. The NBA will continue to work closely with the ACSQHC to ensure that we communicate the principles of the *Statement on national stewardship expectations for the supply of blood and blood products* (see page 68) in alignment with this Standard.

RED BLOOD CELL USAGE PROJECT

The use of red blood cell products has been shown to be highly variable, with some patients receiving transfusions that are not required. Although jurisdictions have safety and quality programs aimed at improving the rate of clinically appropriate transfusions, these programs have limited access to data on blood use drivers and trends.

The purpose of the National Data Linkage Project is to facilitate jurisdictional-based data linkage with the aim of producing a nationally consistent dataset of, and ultimately a national report on, blood product use in Australia.

The diagram in Figure 3.24 illustrates how the data linkage will be implemented.

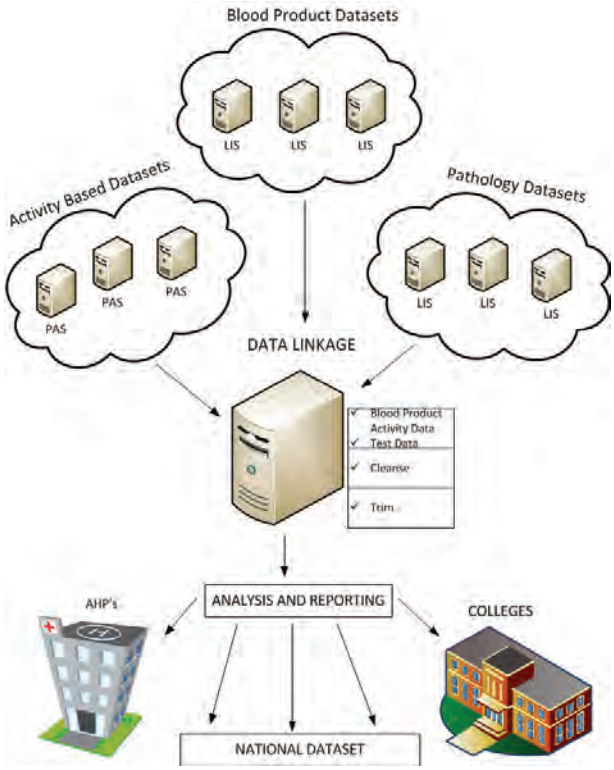


FIGURE 3.24 *Red cell data linkage datasets*

During 2010–11 good progress was made towards this aim with the completion of a detailed methodology and most states and territories confirming the scope of activity required to achieve this data linkage.

The data linkage project is expected to deliver three major benefits for the sector namely:

- improved understanding of blood product use and trends generally
- improved information to support clinical practice improvements
- improved information to support compliance with current and future sector standards.

The project is focused on providing data as shown in Table 3.16.

TABLE 3.16 *Focus of the red cell data linkage project*

ANALYSIS AREA	KEY QUESTIONS	BROAD INDICATORS
Pattern of Transfusion by Specialty Groups (broad 'data screening' step for overall trends and drivers)	Which specialty areas are key users of blood and blood products (SRG codes)? How have blood use trends changed over time? - by specialty and by hospital? - by day and overnight patients? - by emergency and elective patients? - by medical and surgical patients? - by age and gender of patients? How do hospitals compare with blood use —overall and by specialty?	Overall volumes Admissions with/without transfusion (no & %) Average units/volume per patient (transfused and all patients) Single unit transfusion rates Pre and post-transfusion Hb levels Pre-operative HB levels Other test values for products of interest
Specialty Group Targeted Analysis (more detailed regular analysis following from initial data screening above)	Which conditions/diagnoses/procedures are key users of blood and blood products within the target specialty (DRG, ICD codes)? (Clinician engagement to identify appropriate clinical groupings is essential) How do hospitals compare with blood use by the relevant clinical sub-groupings?	
Supporting Clinical Practice Improvement Initiatives (more adhoc and tailored analysis)	What is the incidence of pre-operative anaemia in the target group? What are the triggers for the decision to transfuse? (utilising pathology test results) Does the data show potential diversion from nationally endorsed clinical guidelines for transfusion?	

Notes:
SRG—Service-related group
DRG—Diagnosis-related group
ICD—International classification of diseases

A workshop has been scheduled for early August 2011 to determine how best to report and present the data at a local and state level and to determine which data to consolidate into a national report. It is expected that a national report on red cell data usage, and to some extent other fresh product usage, will be produced by June 2012.

EDUCATION INITIATIVES

The NBA considers education initiatives an important tool in implementing patient blood management and improving the safety, quality and efficiency of the clinical use of blood and blood products. Using interest monies approved by the JBC, the NBA has facilitated and supported the development of local programs to make them available nationally.

Bloodsafe e-learning 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 *Clinical Transfusion Practice* course available on the BloodSafe e-Learning Australia website continues to be very popular throughout Australia with over 90,000 people having registered for the program up to the end of June 2011, and a completion rate of approximately 74 per cent.

Interest in the e-Learning website has continued throughout the year, with an average of at least 2,500 user registrations per month. Nurses are the largest users at around 90 per cent of all registrations. User support and evaluation data demonstrate high levels of user satisfaction.

During 2010–11, work continued on development of new courses for 'postpartum haemorrhage' and 'iron deficiency anaemia', which will supplement the existing *Clinical Transfusion Practice* course. These are expected to be available by October and December 2011 respectively.

In addition, strategies were developed to evaluate the BloodSafe e-Learning Australia website and to promote its use.

Graduate program in transfusion practice

The NBA entered into an agreement with the Victorian Department of Health to revise the Graduate Certificate in Transfusion Practice to update the course content to incorporate key patient blood management concepts. The update was completed and the revised course content has been implemented.

The aim of the course is to develop and educate health professionals who have roles in improving transfusion safety and appropriateness of use of blood and blood products within hospitals. The foundation of the work is the translation of national best practice guidelines into every day transfusion practice. It is offered as a four subject online course, facilitated by an experienced online nurse educator. The course is endorsed by the Blood Matters program of the Victorian Department of Health, and the Blood Service. This is the only graduate e-certificate online blood transfusion course in the southern hemisphere.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PART 4: HORIZON SCANNING

4.1 INTRODUCTION

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. 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 ongoing focus is on national and international information on:

- issues that may have an impact on global supply, demand and pricing—for example, changes in company structure, capacity, organisation and ownership
- diseases or pandemics (including those that are endemic to and those that are not yet detected in Australia) that may have an impact on supply or risks to the safety of products.
- developments in testing methods, vaccines and disease control strategies that could potentially mitigate risks to supply
- new product developments and applications
- global regulatory and blood practice trends, including donor safety
- emerging risks that could potentially put financial or other pressures on the Australian sector.

This part of the report gives a summary of the core developments that have come to our attention during the year. The detail and the breadth of the coverage continue to be influenced by the very positive feedback we receive from this chapter annually.

The NBA collects a large volume of material. The material which is included here is not intented to be comprehensive nor a complete depiction of the issues. Rather, we have provided extracts, snippets and examples to illustrate the vast array of factors that are or may impact on international and domestic blood supplies and industry operations. In particular, we have assumed a level of understanding of some issues and events that have been covered in previous annual reports. To view annual reports from previous years, go to: www.nba.gov.au/About us/Publications/NBA Annual Report. Selected acronyms are contained in **Appendix 12.**

Given the extent of the footnotes for Part 4: Horizon scanning we have organised them as endnotes which can be located at the end of the chapter.

Figure 4.1 identifies the themes covered in this part of the report.

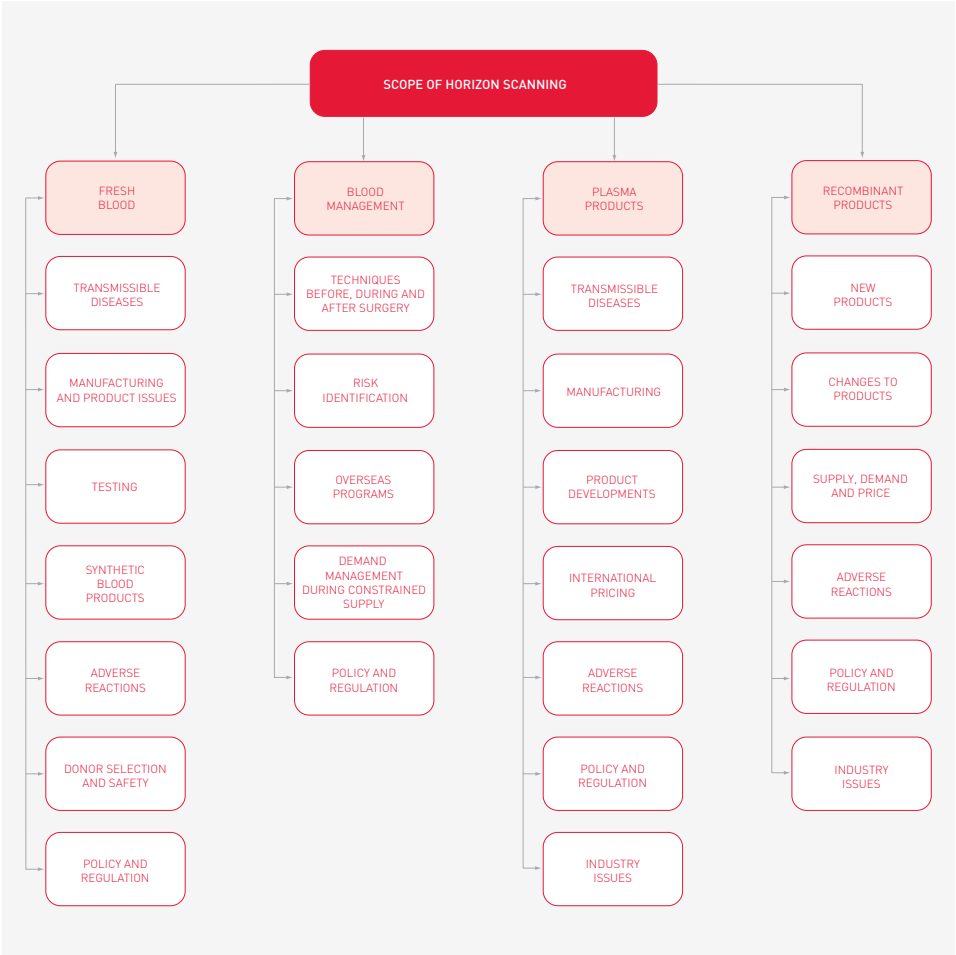

FIGURE 4.1 *Scope of the NBA's horizon scanning*

4.2 FRESH BLOOD

TRANSMISSIBLE DISEASES

Transmissible diseases, whether endemic to Australia, newly emerging, or potential arrivals, are of concern to the NBA due to their potential to impact on both the safety and the supply of product. The impacts may be regional or national. The NBA monitors global experience with a number of diseases.

Mosquito-borne diseases—dengue and chikungunya

Occurrence

Both dengue and chikungunya have been strongly in evidence in warmer parts of the world and have also appeared in places where they have not been recorded in recent years. In Australia, for example, the Northern Territory Health Department reported the first case of dengue fever in 70 years, Queensland faced imported and local cases of dengue in the north, including both type-two and type-four dengue, and a Perth-based doctor contracted dengue fever from a needle stick injury, the first recorded case of its kind in Australia.

Internationally, locally-acquired dengue returned to continental USA in 2010, specifically Florida, the first outbreak since the mid-1930s. Entomologists found a small colony of *Aedes aegypti* in the Netherlands, on and near facilities of a company that imports used tyres from the southern part of the USA. *Aedes aegypti* carries yellow fever as well as dengue and chikungunya. The World Health Organization (WHO) has warned that India and parts of South East Asia face the threat of yellow fever virus, carried by the mosquito that carries dengue.

During the year, good advances in understanding the diseases were made.

Daily temperature fluctuations, not just high temperatures, play a significant role in the transmission of dengue, according to research led by French, Thai and USA scientists[1].

A statistical study of 1,500 individuals[2] has shown that chikungunya infections were higher in Rh positive individuals compared with their Rh negative counterparts. Results also indicated more infections in adults over 30 years of age and more in males than females enrolled in this study.

The Singapore Immunology Network, an institute of the Agency of Science, Technology and Research, and Vivalis, a French biopharmaceutical company, announced the discovery of two new fully human monoclonal antibodies which could battle chikungunya, a disease that currently has no available vaccine or specific treatment[3].

Vaccine development

A successful dengue vaccine needs to protect against all four types of dengue and work continues by many scientists, research institutes and pharmaceutical companies on a variety of vaccines. Chikungunya vaccines are also under development.

Sanofi Pasteur has conducted Phase III trials of its dengue vaccine on an industrial scale with expectations that the vaccine may be launched in 2015. GlaxoSmithKline (GSK) also had a live, weakened dengue vaccine in clinical trials.

There were a number of Phase I human clinical studies underway including:

- Hawaii Biotech with a tetravalent dengue vaccine
- three vaccines developed by the USA National Institutes of Health (NIH)
- the Colombia Trial of Inviragen's lead vaccine candidate, DENVax, which is expected to protect against all four serotypes of dengue fever
- In Port St. Lucie, the Vaccine and Gene Therapy Institute is engineering cytomegalovirus to express the important parts of the four dengue strains.

Controlling the vector

Insecticide-based strategies for dengue control may result in worse future epidemics due to increased insecticide resistance and lower herd immunity, according to research published in *The Lancet* on 3 May 2011. Innovative strategies not relying on insecticide are being actively pursued:

- the Eliminate Dengue Project, backed by the Bill and Melinda Gates Foundation, went live in Cairns in January with the release of about 40 mosquitoes infected with Wolbachia bacteria in every fourth home in Yorkey's Knob weekly for 12 weeks. The bacteria, which is designed to spread through breeding mosquitos, prevents the transmission of dengue. If successful it will be trialled in much larger sites
- British scientists said a small-scale trial of the strategy of releasing sterile male mosquitoes, carried out in the Cayman Islands, had cut mosquito numbers by 80 per cent in six months
- Tulane University researchers have been deploying small traps with a mix of chemicals to convince the disease-carrying female mosquitoes they have found the perfect place to lay their eggs.

Other Mosquito-Borne Diseases

Over the summer, Victoria and South Australia saw increased incidence of Ross River virus and Barmah Forest virus.

Murray Valley encephalitis virus infection (MVEV) is a mosquito-borne illness that occurs periodically in humans in Australia and is endemic in the Northern Territory and northern Western Australia. In previous years 14 MVEV cases were notified to the National Notifiable Diseases Surveillance System (NNDSS) from WA (9), South Australia (2), the NT (2) and NSW (1). Two of the 14 notified cases died. In addition a Canadian resident with a recent travel history to the NT died as a result of MVEV. Public health authorities continue to monitor this season's MVEV activity given the increased rainfall, mosquitoes and amplifying hosts across Australia. There were no cases of MVEV notified in 2010.

More broadly, an increased number of insect-borne viral infections causing neurological or musculoskeletal disease have been reported in horses in NSW, Victoria and South Australia since February 2011.

The West Nile Virus (WNV) continues to spread. It has been isolated in Sarawak in the form of the Kunjin virus which was reclassified as a subtype of WNV in 2000. WNV is thought to have caused encephalitis in northern Greece with transfusions and blood donations banned in the affected regions. Scientists have successfully sequenced the genetic code of the *Culex* mosquito that transmits WNV, aiming to elucidate how the insect carries and transfers the virus that it picks up after feeding on infected birds and then disabling the specific genes that allow transmission. Researchers from Purdue University have discovered that when a certain antibody binds to the WNV, it manages to lock up the infection mechanism and neutralise it. This could be a step towards developing a vaccine.

Work on potential vaccines and treatment for malaria continues round the world. In a promising development, scientists have identified how to stop the malaria parasite from infecting red blood cells, with carbohydrate molecules similar to heparin. A new oral treatment for malaria, containing a synthetic, modified version of heparin, could result.

The PATH Malaria Vaccine Initiative is a global program established in 1999, through a grant from the Bill and Melinda Gates Foundation, to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. In June 2011 the program began collaborating with Crucell and GSK to develop a second-generation vaccine bringing together two promising approaches.

Influenza/Avian influenza

Influenza has made fewer headlines than during the H1N1 influenza pandemic ('swine flu') in 2009. Avian influenza (H5N1) continues to infect bird flocks on a major scale, and although there are humans affected, person-to-person transmission does not appear to have increased.

The viruses

Chinese researchers have shown that the H1N1 pandemic virus, which originated in pigs, is capable of going back into pigs and trading genes with other flu viruses to generate more virulent strains. Pigs are known as mixing vessels for flu viruses, because they can be infected with human, avian and swine strains.

A team from China and the USA has found evidence suggesting southern China as the origin of multiple clusters of the human H5N1 avian influenza viruses[4]. The group proposed that the virus spread into Southeast Asia and western and northern China and then made a final spread across Eurasia and into the Middle East and Africa. The initial spread from southern China into India was followed by transmission into Indonesia.

A team which discovered that pigs in Indonesia have been infected with the disease since 2005[5] said that bird flu virus may be evolving the ability to spread from mammal to mammal. The European Union (EU) is funding a scientific collaboration called FLUPIG, to study how bird flu adapts to pigs and how swine flu spreads to people.

Vaccines

A meeting, coordinated by WHO, agreed to a framework for sharing influenza virus samples during a pandemic. This includes binding legal regimes for WHO, national influenza laboratories and industry in both developed and developing countries. It should increase and expedite access to essential vaccines, antivirals and diagnostic kits for lower-income countries. The International Federation of Pharmaceutical Manufacturers and Associations, which represents 26 research-based drug makers, welcomed the plan and confirmed its members' commitments.

Research on possible vaccines has focused on developing a capacity to protect against all strains of influenza:

- a vaccine developed at the Australian National University is being trialled in Indonesia
- Inovio Pharmaceuticals has been trialling its H5N1 vaccine SynCon VGX-3400X, Inovio Pharmaceuticals and the University of Pennsylvania received a grant from the NIH to fund development
- Dynavax Technologies Corporation has also been trialling its universal flu vaccine.

vCJD

Prion diseases and in particular variant Creutzfeldt-Jakob Disease (vCJD) remain a concern to those responsible for the safety of the blood supplies round the world.

The UK Health Protection Agency said 1 in 9,160 tonsil samples tested showed evidence of vCJD.

Transmission

Research is improving the understanding of transmission of prions:

- Spanish scientists have confirmed that Creutzfeldt-Jakob disease can be transmitted through general surgery
- NIH-funded research at Brown University[6] noted that, in yeast, it is the size of prion complexes, not their number, that determines their efficiency in spreading. They suggest the findings may relate to other neurodegenerative diseases that depend on misfolding proteins, such as Alzheimer's disease (AD) or Parkinson's disease.

Policy

The EU's executive arm proposed an end to the systematic killing of entire herds when a sick cow is discovered, in mid-July 2010. The Commission has also proposed to relax a 2001 ban on animal protein used in pig and poultry feed, to allow pig meal to be fed to poultry and poultry meal to be fed to pigs.

Test

A blood test for vCJD has been developed by British scientists. The lead author of the research, Dr Graham Jackson of the Medical Research Council's Prion Unit, said,

This test could potentially go on to allow blood services to screen the population for vCJD infection, assess how many people in the UK are silent carriers and prevent onward transmission of the disease.

But the sensitivity must be improved and the specificity confirmed in much larger studies before the test could be used to screen asymptomatic individuals, the researchers cautioned in *The Lancet*.[7]

NDM-1

In 2010 in the UK, USA and Canada there was alarm about the global spread of bacteria that had been made resistant to nearly all antibiotics by a new gene. The North American cases involved people who had recently received medical care in India, where the problem was regarded as widespread. A British medical journal[8] revealed the risk in an article describing dozens of cases in Britain of people who had gone to India for medical procedures. To date, the gene called NDM-1 has mostly been found in bacteria that cause gut or urinary infections and is carried by bacteria that can spread hand-to-mouth.

Other

International travel and the spread of new diseases pose an ongoing challenge to blood services to screen and actively manage donor risks. In 2010 these challenges included:

- travellers returning from the World Cup who carried measles from South Africa
- an outbreak of whooping cough in Queensland
- an increased number of new HIV cases in Australia
- legionnaires' disease in Australians who had returned from holidays in Bali
- tick-borne diseases such as babesiosis that has been transmitted by blood transfusion in the USA
- a peak in the number of tuberculosis cases in the UK (at their highest level in 30 years) with drug-resistant cases doubling in a decade
- an outbreak of monkeypox in Central Africa.

Progress in detection and management research is promising, for example:

- synthetic nucleotides injected into monkeys can block the replication of Ebola and Marburg viruses, suggesting it eventually may be possible to protect humans against these agents. Morpholino oligomer are the first drugs approved by the USA Food and Drug Administration (FDA) to go into clinical non-human trials against the viruses
- research by Immunetics of Boston through a grant from the National Institute of Allergy and Infectious Diseases (NIAID) is looking to bring a confirmatory test for Chagas disease to clinical trials
- a new online mapping tool, Predict, will enable scientists and the public to track outbreaks of animal diseases that might jump to humans. Predict will be at www.healthmap.org/predict.

DONOR SELECTION AND SAFETY

New guidelines in Australia mean people who receive a tattoo, piercing or acupuncture can now donate blood after six months, down from the previous waiting period of 12 months.

Two issues under active debate in the past year in a number of countries have been:

- under what guidelines, if any, should blood donations be accepted from men who have sex with men (MSM)
- whether donations from people who have, or have had, chronic fatigue syndrome (CFS) should be accepted.

MSM

The Blood Service guidelines require a 12 month ban on donation after engaging in homosexual intercourse. In 2010 the Blood Service announced an independent review of its current policies, taking into account the most recent scientific evidence. This is due to be finalised in late 2011.

Policies do differ internationally:

- the USA Department of Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability agreed by a 9–6 vote to continue the current donor policy, which rejects blood donations from any man who has had sex with another man (MSM)
- the Canadian Blood Services offered funding to support research on the appropriate restriction for men who have sex with men as blood donors
- in the UK, it was reported the ban on gay men donating blood would be lifted because the rule could be discriminatory and might breach equality legislation. However, gay men would be permitted to donate only if they have not had sexual intercourse for a decade.

Chronic fatigue syndrome (CFS) and the XMRV debate

Research published late in 2009 had suggested a link between CFS and Xenotropic Murine Leukemia Virus-Related Virus (XMRV)[9]. Decisions taken on the evidence available at the time moved swiftly around the world. Several countries, including Canada, Australia, New Zealand and the UK, moved to ban donors who had current or previous CFS infection. A task force formed by the American Association of Blood Banks (AABB) said that people diagnosed with CFS should not donate blood. In December 2010, the European Medicines Agency (EMA) called on Europe's Health Ministers to initiate an immediate Europe-wide prohibition of blood donation from people who have been diagnosed with myalgic encephalomyelitis (ME/CFS). This followed the decision by the UK government to issue a permanent, lifetime ban on all ME patients (including those who have 'recovered') giving blood. The American Red Cross implemented indefinite deferral for donors with a history of a medical diagnosis of CFS following consideration by the FDA Blood Products Advisory Committee (BPAC).

Controversy continued in 2011 on whether XMRV is in fact linked to CFS and on how to test for XMRV. Some researchers reported they were unable to find any evidence of XMRV in various groups, including those diagnosed with CFS. A number of studies indicated that previous research that associated the XMRV virus with CFS and prostate cancer may have involved contaminated samples and chemicals.

On 2 June 2011 the NIH issued a news bulletin concerning recent research on XMRV. It concluded that:

Delineation of the origin of the retrovirus known as XMRV from the genomes of laboratory mice indicates that the virus is unlikely to be responsible for either prostate cancer or chronic fatigue syndrome (CFS) in humans, as has been widely published. The virus arose because of genetic recombination of two mouse viruses. Subsequent infection of lab experiments with XMRV formed the basis of the original association.

Editors of the journal *Science* asked the co-authors of the 2009 paper that linked CFS with the retrovirus XMRV to retract the paper voluntarily. The letter said two additional papers that 'cast further doubt' on the 2009 paper's findings would be published on 2 June in *Science* and *Science* would be publishing an editorial expression of concern. In a written response, study coauthor Judy A. Mikovits of the Whittemore Peterson Institute for Neuro-Immune Disease said 'it is premature to retract our paper.'

Donor safety

The issue of donor vigilance—or the careful monitoring and management of the impact on the health of donors arising from their donations—gained prominence in 2010–11, especially through the Dublin Consensus Statement[10] (referred to on page 68). Inter alia, the Statement declared that:

- all donors must be provided with clear and accessible information prior to their donation, which should include information on the potential risks to them of donating blood or plasma
- the health of the donor should not be compromised by their donation.

While blood services have for a long time understood the potential risk of iron depletion to their donors, and have implemented a range of strategies to address these concerns, two other issues relating to donor vigilance have attracted debate during the year in Australia and overseas.

The first relates to the additional intervention that mid-term saline replacement procedures may have on plasmapheresis donors. There is increasing interest in ensuring that the adverse events of this form of donation are fully understood and managed with appropriate attention to the health of the donor. Interestingly, the effect of the saline infusion on the second stage plasma collection is uncertain and there is not yet robust data internationally to determine the impact of the concentration of immunoglobulins of this form of donation.

The second issue has implications for product recipients as well as regular apheresis donors. During 2010–11, concern has been expressed that Di(2-ethylhexyl)phthalate (DEHP) could be harmful[11]. DEHP is commonly contained in plastic blood bags and tubing sets. The EU has said that DEHP poses no general risk to human health[12]. However, an EU Scientific Review examining whether there may be any risk from the use of DEHP in certain medical applications (children and neonates undergoing long-term blood transfusion and adults undergoing long-term haemodialysis) suggested that alternatives were available and relative toxicities could be explored[13].

Jordi Segura, head of a Barcelona laboratory accredited by the World Anti-Doping Agency (WADA), was among 12 researchers to publish a joint study which found the concentration of residue from DEHP 'significantly' differs in a person's urine after a transfusion. Segura said he is leading research to validate a test for the compound, which could be used to pursue doping violations in cyclist samples dating back eight years, under WADA rules.

TESTING

Safety systems

During the year, the Caridian BCT Mirasol Pathogen Reduction Technology (PRT) System was chosen by the Poland government for FFP, and the Belgian Red Cross-Flanders for platelets.

The Cerus INTERCEPT Blood System was approved for the use of plasma components by Swiss regulators and the FDA granted Cerus Corporation orphan drug status for plasma prepared for treatment of thrombotic thrombocytopenic purpura (TTP).

Cerus was also awarded a further grant from the USA Department of Defense (DoD) to support advanced development of the company's pathogen inactivation technology for red blood cells, and received USA government funds to support the development of the INTERCEPT Blood System for platelets.

ProMetic's P-Capt filter incorporates the prion-specific affinity resin that was developed by Pathogen Removal and Diagnostic Technologies Inc. and is supplied by ProMetic to MacoPharma. The P-Capt filter is a single-use sterile device which has been CE-marked[14] since 2006 for the removal of prion infectivity from red blood cell concentrate prior to transfusion.

The UK's Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) recommended that the Department of Health adopt the P-Capt filter subject to the completion of the PRISM (prion-filtered versus standard red cells in surgical and multi-transfused patients) study. In Ireland, P-Capt has been used routinely in one pilot hospital and is currently undergoing a health technology assessment in relation to national policy and adoption. Macau has a blood transfusion service that has started to use P-Capt to remove vCJD from red blood cell concentrates donated by Caucasians thought to be at risk of carrying the prion.

Tests

The FDA has approved the first rapid hepatitis C virus test for patients 15 years and older. The OraQuick HCV Rapid Antibody Test is claimed to read oral and blood samples for hepatitis C in 20–40 minutes with 99 per cent accuracy.

Standard tests for HIV cannot identify people very recently infected with the virus, but a more sensitive test has now been developed. By testing for HIV's genetic material in addition to antibodies against the virus in more than 3,000 people, Dr Sheldon R. Morris of the University of California San Diego and colleagues identified 15 HIV-infected patients whom the standard test would have missed[15].

The cobas TaqScreen MPX Test test is a qualitative *in vitro* test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA and Hepatitis B Virus (HBV) DNA in human plasma. Roche announced that the cobas TaqScreen MPX Test, version 2.0 for use on the cobas s 201 system is now commercially available in Europe. This test is intended for use to screen samples of donations of human whole blood and blood components including source plasma.

Other

In the USA, the only recorded case of HIV transmission from a blood transfusion in eight years has been linked to a Missouri blood donor, according to the USA Centers for Disease Control and Prevention (CDC). The man's HIV positive status was not confirmed until after he donated blood a second time.

A boy with a peanut allergy had a severe anaphylactic reaction after receiving a platelet transfusion that may have contained undigested peanut protein, according to a report in the 18 May issue of the *New England Journal of Medicine*.

The boy was given adrenalin and recovered. Three of the five platelet donors admitted eating several handfuls of peanuts less than 24 hours before donating blood. However the report's authors say it is premature to encourage blood donors not to eat peanuts before giving blood or for questions about diet to become part of the screening process.

MANUFACTURING

Red Cell shelf life

Interest in the extent to which the age of product influences its efficacy and its risk to patients, if at all, is strong and there are many large and small studies becoming available:

- A study in Canada concluded that in hospitalised patients with a major diagnosis of cardiovascular disease, there is a modest independent association between increasing duration of storage of red cells and risk of death[16].
- Another study[17] found that the transfusion of red blood cells stored between 30–42 days was associated with a five per cent excess mortality.
- In the USA, the National Heart, Lung, and Blood Institute (NHLBI) is funding nine research grants to improve the safety of red blood cell transfusions[18].
    - One grant will support a large, multicentre, randomised clinical trial to compare outcomes in heart surgery patients who receive transfusions of red blood cells stored for shorter or longer amounts of time. This Red Blood Cell Storage Duration Study (RECESS) plans to enrol about 1,830 patients.
    - Wake Forest University Professor Daniel Kim-Shapiro and Mark Gladwin, of the University of Pittsburgh will study why the quality of stored blood degrades over time and investigate ways to make transfusions using older blood safer.
    - Researchers at the University of Alabama at Birmingham will focus on the mechanisms by which red blood cell storage time affects blood flow through capillaries and whether the storage age impacts the interaction between banked red cells and nitric oxide produced in the body.
- The potential relationship between red blood cell storage time and patient morbidity and mortality was discussed at the 2010 AABB Annual Meeting. An overview of previous clinical studies was followed by the description of two ongoing, randomised, controlled clinical trials designed to provide more definitive data—the Age of Blood Evaluation Trial (ABLE) and the RECESS study.

- A retrospective study of isolated coronary artery bypass surgery in a Netherlands hospital concluded that the storage time of transfused red blood cells is not a risk factor for early or late mortality in patients who undergo coronary artery bypass grafting[19].
- British research suggests significant differences between new and old red blood cells used for transfusions[20]. Dr. Jay Mehrishi says recent trials on cardiac surgery patients demonstrated that transfused blood more than 14 days old produced serious side effects. More than 40,000 patients were involved.
- In Australia, an abstract of a retrospective Hunter New England Health study of more than 20,000 blood transfusions administered over the previous 10 years suggested that patients who receive blood more than 14 days old are up to four times more likely to develop potentially lethal infections.

Platelets

A study by the Hovon cooperative group[21], *Clinical effectiveness of leucoreduced, pooled donor platelet concentrates, stored in plasma or additive solution with and without pathogen reduction,* concluded that despite the potential advantages of pathogen (and leucocyte) inactivation of amotosalen–HCl/UVA–treated platelet products, their clinical efficacy is inferior to platelets stored in plasma, warranting a critical reappraisal of employing this technique for clinical use.

Entegrion is working on Stasix, derived from blood platelets and developed to stop internal bleeding. It is freeze-dried, extending shelf-life, but could be quickly rehydrated.

A study[22] published in the November 2010 issue of *Transfusion* explored whether the use of platelet additive solution for platelet storage would enable more efficient bacterial screening. The authors examined the effect of selected bacterial species on measurable platelet quality variables over time as well as on biofilm-forming ability. Their study showed that platelet additive solution-based platelet storage allows for faster detection of *Serratia liquefaciens*, and potentially other species such as the closely related *Serratia marcescens*.

Whole blood

The Blood Service is working with the Australian Defence Force to freeze blood for troops in remote locations. New research on the cryopreservation of blood is expected to provide Australian troops in Afghanistan with home-sourced blood within two years, rather than relying on American and Dutch supplies.

Core Dynamics received a grant from the USA Army Foundation for the Advancement of Military Medicine, Telemedicine & Advanced Technology Research Center, for development of freeze-dried blood. It is expected that the result will be individual freeze-dried blood units that can be carried into the battle field and, upon rehydration with sterile water, transfused.

Plasma

At the annual Advanced Technology Applications for Combat Casualty Care Conference, in the USA haemorrhage was a major topic. Two products showcased at the conference, namely freeze-dried plasma (which is already in human trials) and spray-dried plasma, may be approved for use within three to five years.

Army doctors are also encouraging the interosseous catheter technique for administering intravenous fluids directly into bone marrow, which can be done in low-lighting or combat conditions. Dried plasma can be given this way.

Entegrion is one of several companies developing a dried plasma product and received two grants from the DoD. Entegrion's Resusix (dehydrated human plasma) is a shelf-stable alternative to FFP and does not need to be thawed in emergency situations.

SYNTHETIC BLOOD PRODUCTS AND OXYGEN CARRIERS

Interest in artificial blood arises from concern about the availability of donors, possible infection from donations and, for military purposes, the need for access to significant supplies in battlefield locations. Trials have continued, for example on perfluorocarbon-based and haemoglobin-based blood substitutes.

Governments are starting to commit funding to manufacture synthetic products although production costs are high. However, some associated risks have been identified and it is unclear when any products will be able to be marketed.

- Scientists have now turned embryonic stem cells, cells from cord blood and a pinch of human skin into red blood cells.
- British scientists turned stem cells from IVF embryos into red blood cells as a first step towards industrial manufacture of synthetic blood on an industrial-scale.
- Arteriocyte continues to develop artificial blood from the stem cells of discarded umbilical cords. One umbilical cord can provide enough blood for three transfusions.
- A team at the University of Queensland is also growing red blood cells from umbilical cord stem cells. *The blood that we get from a single cord from one baby has enough potential to make 10,000 units (one unit is 450 millilitres) of red blood cells*, said Professor Nielsen
- Oxygen Biotherapeutics is continuing its Phase IIb trial of Oxycyte to evaluate its safety and tolerability in patients with severe non-penetrating traumatic brain injury. Oxycyte requires no cross matching and contains no biological components, therefore there is no risk of viral transmission. Its effects on the immune system, platelet function and distribution, as well as the safety and efficacy of platelet transfusion, often essential for patients with traumatic brain injury and related polytrauma, are also being studied.
- University of North Carolina-Chapel Hill researchers used tiny particles of human skin that have the same shape and flexibility as red blood cells to turn skin cells from humans into pro-clotting cells (platelets).
- The NIH has awarded funds to further develop and broaden the uses of synthetic platelets, using biodegradable polymers and the technology that makes them work; and also to explore the potential of protein-induced pluripotent stem (iPS) cells as a source of universal red blood cells and platelets for transfusion, using a method designed to rule out the risk of cancer.
- Other research initiatives include producing red blood cells from iPS cells, developing a universal blood product that would eliminate the need for matching blood groups before transfusion, a nano-size biological capsule carrying haemoglobin.
- Scientists are developing a universal blood product that would do away with the necessity of matching blood groups before transfusion. Maryam Tabrizian and colleagues from McGill University in Canada discovered a way to encase living, individual red blood cells within a multilayered polymer shell. The shell serves as a cloaking device, making the cell invisible to a person's immune system and able to evade detection and rejection. Oxygen can still penetrate the polymer shell, however, so the red blood cells can carry on their main business of supplying oxygen to the body.
- Professor Mark Fitzgerald, director of trauma services at the Alfred Hospital, Melbourne, faced with losing a patient who was unable to accept human blood transfusions due to religious beliefs, sought a haemoglobin carrier from the USA[23]. He had been involved in trials of the product in the USA. It is derived from bovine blood. Professor Fitzgerald says it just carries haemoglobin, it doesn't need to be cross-matched, and it can be left on the shelf for three years.

- Two Colorado researchers say they have developed a new method in which they use their proprietary blood stem-cell lines from cord blood to generate mature, adult red blood cells in the lab in 14 days. They hope for clinical trials in humans in five years.
- A scientist from the University of Oklahoma College of Pharmacy is developing a nano-size carrier of haemoglobin. He has created a miniaturized delivery system, like a tiny form of the soft gel that protects medications until it can reach the right place in the body. He places haemoglobin inside these biological capsules that carry oxygen through the body. The capsules are the key because pure haemoglobin outside the capsule is toxic.
- Researchers at the Harvard Stem Cell Institute in Boston published experiments showing that synthetic biological signals can quickly reprogram ordinary skin cells into entities that appear virtually identical to embryonic stem cells. The same strategy can then turn those cells into ones that could be used for transplants. Derrick J. Rossi of the Children's Hospital Boston, who led the research said, *We now have an experimental paradigm for generating patient-specific cells highly efficiently and safely and also taking those cells to clinically useful cell types.*

4.3 BLOOD MANAGEMENT

Western Australia became the first jurisdiction in the world to adopt a system-wide program of patient blood management. It includes blood tests several weeks before scheduled surgery so anaemia can be treated and emphasis on surgical techniques which minimise blood loss. This program is credited with reducing WA's use of red blood cells per 1,000 population from 30 in 2007–08 to 28.49 in 2010–11. This compares to a national average of 35.

USE OF ANAEMIA DRUGS

Caution continues in the use of erythropoiesis-stimulating agents (ESAs):

- The American Society of Hematology and the American Society of Clinical Oncology updated their recommendations. According to their joint guidelines[24], physicians need to use caution when giving ESAs to cancer patients who have anaemia caused by chemotherapy; and with rare exceptions, ESAs should not be given to cancer patients who are not receiving chemotherapy[25].
- In June 2011 the FDA made a safety announcement, Modified dosing recommendations to improve the safe use of ESAs in chronic kidney disease. This recommended more conservative dosing.
- Researchers from the University of Minnesota, led by Hassan N. Ibrahim, say that while blood transfusions increase the risk of adverse outcomes in anaemic renal transplant recipients, treatment with ESAs does not[26].

Nevertheless, product developments in this space continue strongly.

- Affymax says that four late-stage trials for its anaemia drug Hematide showed that the therapy is non-inferior to Amgen's Epogen and Aranesp, putting it on a path to file for FDA approval. However, cardio-risks in a patient subgroup captured the attention of analysts who expected the FDA to require another clinical trial.
- Lipoxen revealed encouraging Phase II trial results for its long-acting erythropoietin (EPO) candidate ErepoXen. It is being developed as a long acting form of EPO for the treatment of anaemia in renal disease patients.
- ProMetic Life Sciences presented data on its orally active PBI-1402 compound at the 15th Congress of the European Hematology Association held in Spain in June 2010. It demonstrated a reduction in the need for blood transfusions in chemotherapy-induced anaemic patients.

RISK IDENTIFICATION

Activities to raise awareness of the importance of the appropriateness of the use of products emerged on different products and from a number of studies.

- An analysis of more than 31,000 patients who underwent isolated coronary artery bypass grafting (CABG) surgery showed that receiving one or more blood transfusions conferred a nearly threefold increased risk of operative mortality, compared to not receiving a transfusion.
- In October 2010, the UK National Patient Safety Agency (NPSA) issued new guidance aimed at reducing delays in providing blood for patients in emergency situations. Acute care organisations are advised to draw up a local protocol for dealing with massive blood loss and agree a trigger phrase understood by all staff to activate the protocol (see page 71–3 on the Australian Patient Blood Management Critical Bleeding/Massive Transfusion Guideline module).
- The Critical Care Canada Forum in Toronto heard that clinicians were failing to adhere to clinical guidelines regarding frozen plasma transfusions and that the requirement to use a standard order form increased compliance.
- In the USA the Centers for Biologics Evaluation and Research distributed the summary of transfusion fatality reports received by the FDA for the period 1 October 2009–30 September 2010. They judged 40 of the fatalities to be transfusion-related, while in 24 further instances transfusion could not be ruled out as the cause. There were instances of TRALI. There were still fatal reactions to bacterial-contaminated platelet transfusion, although the USA has platelet concentrate microbial screening. However, there were no bacterial contamination fatalities from apheresis derived platelet pools. There were two ABO haemolysis deaths, one due to clerical error.

CHEMICAL AGENTS TO LIMIT BLEEDING FROM TRAUMA OR PROCEDURE

Novo Seven

Although its principal use is as a clotting agent in the treatment of haemophilia patients, rFVIIa is also used as an aid to coagulation in non-haemophilia patients.

A recent study reviewed the use of rFVIIa in patients without haemophilia[27]. It concluded that clinically significant benefits of rFVIIa as a general haemostatic agent in patients without haemophilia remain unproven. Given its potential risks, such use cannot be recommended and in most cases it should be restricted to clinical trials.

Two studies[28] reported in the *Annals of Internal Medicine* on 19 April again raised concerns about off-label use of rFVIIa. One concluded that off-label use of rFVIIa in the [USA] hospital setting far exceeds use for approved indications. These patterns raise concern about the application of rFVIIa to conditions for which strong supporting evidence is lacking. The second concluded that limited available evidence for five off-label indications suggests no mortality reduction with rFVIIa use. For some indications, it increases thromboembolism.

PHYSICAL BARRIERS

Sealants and clotting bandages can both assist in reducing blood loss. There have been several new developments during the year.

Genetic factors

French doctors announced the country's first 'saviour sibling', conceived through in-vitro fertilisation and genetically selected to ensure he did not carry the gene for beta-thalassemia but was a close enough match to provide his sibling's treatment cells from his umbilical cord blood.

A patient with beta-thalassemia became transfusion-free after gene therapy. Researchers fixed the faulty gene responsible for the condition in some of the patient's own bone marrow stem cells and re-infused them. The team at Brigham and Women's Hospital and Harvard Medical School in Boston and at the University of Paris now plan to treat patients who have sickle cell disease with gene therapy.

PATTERNS OF TRANSFUSION

New research[29] suggests patients having heart surgery who receive fewer blood transfusions do just as well as those who receive more.

A researcher has suggested that in patients requiring large volumes of blood products or displaying coagulopathy after injury, early and aggressive administration of blood component therapy may actually reduce the aggregate amount of blood required[30].

A study of 81 patients treated with platelet-rich plasma after total knee replacement surgery found that only 2.4 per cent of the patients needed a blood transfusion, compared with the typical transfusion rates of 30–50 per cent[31].

Dr Henry Cryer, UCLA Chief of trauma and emergency surgery, received a research grant from the National Trauma Institute (NTI) to study the use of fresh whole blood for transfusions at civilian trauma centres. Recent military studies indicate that transfusion of fresh whole blood may be more beneficial than individual blood components in patients with severe haemorrhage.

Scientists have developed a mathematical model reflecting how red blood cells change in size and haemoglobin content during their four-month lifespan. They said their research may allow prediction of who is likely to become anaemic, using routine hospital tests.

Iron deficiency is common during pregnancy. Intravenous iron given just once over a one-hour infusion was found to be effective and safe for iron-deficient women in a single-centre study reported at a poster session of the American Congress of Obstetricians and Gynecologists 59th Annual Clinical Meeting[32].

PLATELETS

Of particular interest is the UK-led trial of prophylactic platelet study (TOPPS) currently underway. This two-stage, randomised controlled trial of prophylaxis versus no-prophylaxis platelet transfusions in haematology/oncology patients following chemotherapy is investigating to what extent prophylactic platelet transfusions are clinically effective. Doses of platelets for this indication are a significant proportion of the total number of platelets transfused in Australia. If the findings are positive the level of demand for platelets could change.

The Canadian Cardiovascular Society has provided evidence-based recommendations on the use of antiplatelet therapy across all indications. These first-ever guidelines give physicians and other health professionals clear procedural recommendations, including how long a patient should take dual antiplatelet therapy, with appropriate use beyond a year. The full guidelines appeared in the *Canadian Journal of Cardiology* in 2011.

Platelets in the blood arise from cells known as megakaryocytes. Researchers at the Children's Hospital of Philadelphia found that mature megakaryocytes infused into mice could generate platelets of normal size and function. They hope it might be possible to treat individuals with thrombocytopenia through mature megakaryocyte infusion

4.4 PLASMA AND RECOMBINANT PRODUCTS

PLASMA

In the UK, Health Minister Edwina Hart ruled that the Welsh Blood Service and NHS Blood and Transplant (which collects blood for North Wales and England) can sell discarded plasma for non-clinical use, with safeguards in place to ensure that products can be used only for ethical purposes and a policy is under development about the sale of plasma.

In August 2010, Octapharma announced successful completion of clinical development of Uniplas, a blood group independent, universally applicable, prion depleted, solvent/detergent treated, human pooled plasma for infusion. OctaplasLG is the only commercially available prion-reduced plasma for transfusion, manufactured by Octapharma and relying on PRDT's prion capture technology used at industrial scale. This industrial application of the prion capture technology is also being expanded for use in Uniplas.

IMMUNOGLOBULINS

Strong activity and global interest in these important products continued throughout the year.

Product recall

Octapharma

The FDA announced in August 2010 that Octapharma was voluntarily recalling selected batches of Octagam because of increased rates of thromboembolic events. Thirty-one batches were recalled. By 8 September the recall had been extended to a further five batches in France, two batches in Mexico and one batch in Germany. This was subsequently expanded to further EU nations.

By 22 September 2010, Sweden and France had quarantined or withdrawn the product and Germany had withdrawn its licence. The Octapharma IVIg product represented ~8 per cent of the USA market and ~13% of the global market. CSL and Baxter share prices rose on the assumption that their respective market shares would increase.

By late September 2010, Octapharma had withdrawn all its 5 per cent liquid preparation from the USA market at the request of the FDA, *until a root cause of the previously reported thromboembolic events can be determined*.

The EMA recommended suspending the marketing authorisation for Octagam 5 and 10 per cent throughout the EU and initiating a recall of all Octagam 5 and 10 per cent batches from the EU market. The suspension was to remain in place until the problem had been rectified.

Octapharma believed that an unexpected increase in Factor XIa in the final products played a role in the increase of the rate of thromboembolic events; and that, having identified the cause of the increased incidence, it could take prompt corrective action. The company said it assumed the issue could be resolved by the end of 2010.

On 31 May 2011, Octapharma announced that the European Commission had lifted the EU-wide suspension of the marketing authorisations of both Octagam 5 and 10 per cent subject to certain conditions including that each batch released would have a thrombin generation assay carried out and that post-marketing studies would be implemented in order to confirm the safety of the product.

There was a minor impact in Australia at that time (see page 49 & 59) or Australia's response.

CSL

The USA FDA received post-marketing reports of serious thrombotic adverse events associated with use of Vivaglobin manufactured by CSL Behring. Vivaglobin was indicated for treatment of Primary Humoral Immunodeficiency and was administered subcutaneously. It was not approved for intravenous use and inadvertent intravenous use of Vivaglobin may carry a higher risk. CSL Behring informed the FDA that in-house research testing revealed procoagulant activity in Vivaglobin.

Risk factors identified in post-marketing thrombotic event reports for Vivaglobin included pre-existing cardiovascular disorders, prior thrombotic event, obesity, oral estrogen use, hyperlipoproteinemia, in-dwelling catheter and immobility.

Hyperviscosity, hypercoagulable disorders, and multiple cardiac risk factors may also confer thrombosis risk in the setting of immune globulin product administration. Marketing of the product in the USA was discontinued from 4 April 2011.

Regulatory

Activities in market coverage of leading immunoglobulin products included:

- The European Commission granted marketing authorization for CSL's Hizentra, subcutaneous [human] immunoglobulin 20 per cent solution. It is used for subcutaneous injection in the treatment of patients diagnosed with primary immunodeficiency as well as secondary immunodeficiencies. In addition, the FDA approved an application to extend the shelf life of Hizentra from 18 months to 24 months
- Baxter submitted its subcutaneous immunoglobulin for FDA approval and is concluding a late-stage trial of another product that may let patients administer a monthly dose with one injection at home
- Talecris received approval from the FDA in October 2010 for Gamunex®-C (Immune Globulin Injection [Human], 10% Caprylate/Chromatography Purified) for subcutaneous administration in the treatment of primary immunodeficiency disease. It contains half the antibody concentration of Hizentra. The FDA also approved Talecris' Gamunex®-C for intravenous delivery to treat primary immunodeficiency, chronic inflammatory demyelinating polyneuropathy (CIDP), and idiopathic thrombocytopenic purpura (ITP)
- The EMA granted Grifols a licence to market Flebogamma dual inactivation and nanofiltration (DIF) 100mg/ml, which features a ten per cent concentration level. This new version of the treatment, which was also approved in the USA follows the 2008 launch of Flebogamma DIF 50 mg/ml, which is a 5 per cent concentration.

Product Developments

According to data presented at the XIVth Meeting of the European Society for Immunodeficiencies, CSL's Privigen 10 per cent liquid intravenous immunoglobulin therapy stabilized with proline is effective and well tolerated in patients with several primary and secondary immunodeficiencies and offers significant protection against infection. Privigen is approved in the EU, Switzerland, Canada and the USA for treating patients diagnosed with PID and ITP. In Europe, Privigen is also approved for treating Guillain-Barre Syndrome and Kawasaki-Syndrome.

At the same meeting, Baxter presented interim data from a Phase III clinical trial of HyQ. HyQ is an immunoglobulin therapy facilitated subcutaneously by recombinant human hyaluronidase, a dispersion and permeation enhancer. Interim analyses showed that 28 out of 29 HyQ-treated study participants with PID were able to infuse immunoglobulin under the skin, using a single injection site, at infusion volumes, intervals and rates equivalent to their previous intravenous administration of immunoglobulin.

In June 2011, Baxter announced that the Committee for Medicinal Products for Human Use of the EMA had issued a positive opinion for extension of the therapeutic indications of KIOVIG[33] to include a new indication for multifocal motor neuropathy (MMN), a severe, debilitating disorder requiring lifelong treatment. Baxter has been granted Orphan Drug Designation for this indication in the USA.

Treatments alternative to immunoglobulin

Immunoglobulin is used to treat a range of conditions. The NBA follows with interest any alternative treatments that are developed as they may reduce pressure on supply and price. This year we have specifically focused on developments for the treatment of chronic immune thrombocytopaenia.

During 2010–11 a number of studies were released:

- a study sponsored by Amgen on romiplostim (Nplate) showed no new safety issues, no increase in adverse events over time and stability in both dose and efficacy
- a similar extension analysis of eltrombopag (Promacta) supported by GSK, also demonstrated continued efficacy in increasing platelet counts and reducing bleeding while showing no new safety signals[34]
- results of a Phase II trial of Rozrolimupab were released—this is a fully human anti-RhD monoclonal antibody mixture, designed as a modern counterpart to the plasma-derived anti-RhD immunoglobulins currently used in the treatment of ITP
- Octapharma published data from a clinical study to illustrate the benefits Octagam 10 per cent can deliver for sufferers of ITP
- In June 2010, GSK's Revolade was not approved for funding on the UK NHS to treat chronic ITP. The National Institute for Health and Clinical Excellence's (NICE) preliminary recommendation said that it was very unclear about how many health benefits eltrombopag would provide compared with other existing treatments, adding that the price was also far greater than what is normally considered a cost effective use of NHS resources.

NICE did however agree that Nplate could be used on the NHS in England and Scotland to treat adults: with chronic forms of the condition when they are unresponsive to standard active treatments and rescue therapies; in patients who have severe disease; or those at high risk of bleeding requiring frequent courses of rescue therapies. The product had already been approved in the USA Europe and Japan.

However, GSK and the FDA notified a new safety finding in patients with chronic liver disease whose thrombocytopenia was treated with eltrombopag. The ELEVATE study was terminated following the identification of an imbalance of thrombosis of the portal venous system in the patients treated with eltrombopag versus matching placebo. Healthcare professionals were reminded that Promacta was not indicated for the treatment of thrombocytopenia in patients with chronic liver disease.

In June 2011, Shire announced that the Pulmonary-Allergy Drugs Advisory Committee of the FDA recommended, that the efficacy and safety data provides substantial evidence to support approval of Firazyr (icatibant) for the treatment of acute attacks of hereditary angioedema in patients 18 years and older. The Committee also recommended self-administration of the drug by patients.

Potential new or extended uses for immunoglobulin

The interest in proving efficacy of immunoglobulin for AD continued. Baxter released positive results from a Phase II clinical study of Gammagard in patients with mild-to-moderate AD, and its Phase III clinical trial will run into 2012. Grifols is trialling therapeutic plasmapheresis and the administration of human albumin and IVIg at different doses and frequencies. The preliminary results suggested a trend toward disease stability in the treatment group.

A positive result from either or both of these studies could have a major impact on global demand for immunoglobulin, with consequent supply shortages and price rises. However it is interesting to note that USA companies alone currently have around 100 drugs, not just immunoglobulins, for use in the treatment of AD either in clinical trials or awaiting regulatory review. The NBA is following all of the activities around alternative therapies for AD because of their potential effect on the market.

Scientists developing treatments for Creutzfeldt-Jakob Disease (CJD) have unexpectedly blocked the onset of AD. Two antibodies studied in relation to CJD may also have an effect on AD[35], by blocking the damaging effects of the toxic protein 'amyloid beta', which accumulates and becomes attached to the nerve cells in the brain.

COAGULATION (CLOTTING) FACTORS

GBI Research recently estimated that by 2016 the world coagulation disorders market will reach $US 7.7 billion, demonstrating a cumulative annual growth rate of 5 per cent between 2009–16.

Product developments

The same report notes that Baxter and Bayer control 56 per cent of the market. Novo Nordisk has third position with Pfizer and CSL Behring controlling 15 per cent and 8 per cent respectively. On future developments, GBI reports that the current coagulation disorders pipeline contains 90 projects across five major indications. Haemophilia A and haemophilia B, currently accounting for more than two-thirds of the total coagulation disorders market, are the key therapy areas of focus in the current pipeline, with approximately 64% of the current coagulation disorders pipeline concentrating on these two indications. About 20 molecules, representing 22% of the current coagulation disorders pipeline, are in early stages of development for haemophilia.

In July 2010, the World Federation of Haemophilia Congress was held in Buenos Aires. Suppliers used the occasion to describe their projects.

Biogen Idec and Swedish Orphan Biovitrum AB announced results from a Phase I/IIa study of their long-lasting, fully-recombinant FIX Fc fusion protein (rFIXFc) in haemophilia B patients. The product demonstrated a threefold increase in half-life compared with historical data for BeneFIX. The product is now in Phase III development, along with a FVIII product. This long-lasting, fully-recombinant Factor VIII Fc fusion protein (rFVIIIFc) has been granted orphan drug designation by the European Commission.

Pfizer presented the results of a pre-clinical study in mice indicating that recombinant FXa therapy may provide a unique way to bypass deficiencies in the intrinsic pathway. Other results suggest that a recombinant FVIIa molecule with increased activity and duration may improve inhibitor outcomes. Other haemophilia research outlined by Pfizer included:

- a new model of antibody-induced haemophilia A to assess bypass therapies
- a prospective registry of European haemophilia B patients receiving BeneFIX for usual use
- two-year interim results of a non-interventional trial to assess the safety and efficacy of treatment with rFIX
- safety and efficacy of B-domain-deleted recombinant FVIII—final results of a 10 year pharmacovigilance study.

Bayer HealthCare presented data from a Phase I study of its rFVIIa variant (BAY 86-6150) in haemophilia A or B, with or without inhibitors. Novo Nordisk researchers advised that N7-GP, now in Phase II clinical trials, may offer a less frequent dosing schedule for prophylaxis in haemophilia patients with inhibitors.

According to pooled results from four studies, an ultrapure form of plasma-derived FIX concentrate (Nonafact) appears to stop bleeding in haemophilia patients, whether bleeding occurs spontaneously or due to surgery.

In other developments:

- Inspiration Biopharmaceuticals was awarded two USA Government grants, to advance the clinical development of two products—IB1001 is a factor IX product, while OB1 is a recombinant porcine factor VIII, which can be given over a short infusion time. It is designed for people with inhibitors against human FVIII. The European Commission has granted orphan drug status for OBI-1
- during 2011, CSL expects to commercialise both a FXIII product and Beriplex, a treatment for reversing the effects of blood thinning drug Warfarin quickly
- Biogen Idec and Swedish Orphan Biovitrum began a global registrational clinical trial of their long lasting recombinant FVIII Fc fusion protein. The EMA's Paediatric Committee agreed to the paediatric investigational plan for the companies' long lasting, fully recombinant Factor IX Fc fusion protein (rFIXFc). The FIX product is designed to stay in the body up to three times longer than existing drugs
- CSL Behring was granted Orphan Drug Designation[36] by the European Commission for the development of its recombinant fusion protein linking coagulation rFVIIa with albumin (rVIIa-FP) for haemophilia A and haemophilia B patients with inhibitors[37]. CSL Behring's CSL 627, a single chain rFVIII, is receiving Phase I testing.

At the annual meeting of the American Society of Hematology researchers reported that about two-thirds of patients with acquired haemophilia appear to find the disorder resolves itself[38].

Results from the European Acquired Hemophilia Registry indicate that more than 70 per cent of patients diagnosed with acquired haemophilia who successfully eradicate FVIII inhibitors survive for at least five years[39].

A survey of haemophilia treatment centres suggested that only half were treating children according to guidelines, with prophylaxis three times a week[40].

Novo Nordisk reported rFVIII shows the potential to become a safe and effective treatment. The company submitted a Biologic License Application to the FDA seeking approval of its rFXIII compound for congenital factor XIII deficiency.

Baxter reported that recombinant von Willebrand factor or rVWF may be safe and well tolerated in patients with type 3 and severe type 1 von Willebrand disease, the most common inherited bleeding disorder worldwide.

In Israel, Prolor's Factor IX-CTP demonstrated a significantly longer duration of clotting activity in the haemophilic mice model compared with commercially available Factor IX.

Safety

The USA FDA recently approved revised labelling for Grifol's Alphanate blood-clotting agent to show steps taken to prevent the compound leading to infections of vCJD.

According to Jerzy Windyga of the Institute of Hematology and Transfusion Medicine in Warsaw[41], the improved rFVIII Xyntha is safe and effective for surgical haemostasis in patients with haemophilia A undergoing major orthopaedic surgery.

A European registry that enrolled patients with haemophilia B being treated with rFIX (Benefix) found that the reformulated version of the product was associated with fewer adverse events compared with the original formulation[42].

Presentation

Pfizer received approval from the FDA for the use of a prefilled dual-chamber syringe for administration of XYNTHA Antihemophilic Factor (Recombinant) Plasma/Albumin-Free for haemophilia A.

Novo Nordisk announced that the FDA had approved NovoSeven RT rfVIIa (room temperature stable) in an 8 mg vial size. The FDA extended the shelf life for all vial sizes from 24 to 36 months at room temperature (at/below 77 degrees Fahrenheit).

Regulatory

Significant changes in market access included:

- the FDA granted orphan drug exclusivity for Wilate (von Willebrand Factor/Factor VIII Concentrate, Human) and approved Wilate for the treatment of spontaneous or trauma-induced bleeding episodes in patients with severe von Willebrand's Disease as well as in patients with mild or moderate forms of the illness in whom the use of desmopressin is known or suspected to be ineffective or contraindicated
- the FDA approved CSL Behring's Corifact, intended to prevent bleeding in people with congenital Factor XIII deficiency. Corifact received Orphan Drug Designation by the FDA because it is intended for use in a rare disease or condition. Corifact is already in use in twelve other countries as Fibrogammin.

OTHER PLASMA PRODUCTS

Alpha(1)-antitrypsin (AAT) deficiency

A Danish study claimed that expensive treatments for AAT deficiency should be withdrawn because the drugs have no benefit. The study reviewed data from two trials on 140 patients. It considered treatments developed by Kamada, Talecris, CSL, and Baxter. The report called recommendations by the American Thoracic Society and European Respiratory Society 'misguided', however, Talecris funded a study[43] which it says demonstrates that augmentation therapy with Alpha(1)-Proteinase Inhibitor (Human) (A1PI) significantly reduces lung tissue loss in patients with emphysema related to AAT deficiency.

Octaplex

The FDA approved Octapharma USA's Investigational New Drug Application for Octaplex (human prothrombin complex, freeze dried) as a fast track product for 'reversal of anticoagulation therapy in patients under vitamin K antagonist therapy with the need for urgent surgery or invasive procedures'. The FDA had previously granted orphan drug exclusivity for Octaplex in this indication. Octaplex is a double virus-inactivated concentrate with a balanced level of Vitamin K-dependent coagulation factors and protein C and S.

Plasmin

A blood clot treatment being developed by Talecris Biotherapeutics received an Orphan Drug Designation from European regulators. Talecris is studying Plasmin in Phase II clinical trials to assess its ability to treat acute peripheral arterial occlusion. The condition occurs when blood flow to the extremities, usually the legs, is blocked by a blood clot. It is most common in people with underlying peripheral artery disease.

OTHER

ProFibrix, of the Netherlands, contracted with CSL Behring for clinical and commercial supply of plasma-based fibrinogen and thrombin. Its product Fibrocaps is currently being studied for treatment of bleeding during surgery and after trauma. A dry powder based on a mixture of fibrinogen and thrombin, Fibrocaps is a ready-to-use preparation designed to be stable at room temperature and applied in different formats, including sprays and bandages. A large Phase II trial is currently underway with final results expected in 2011.

Platelet-rich plasma (PRP) is a promising biologic treatment for myocardial infarction according to researchers at the Stanford University School of Medicine. PRP has already been identified as a novel biologic treatment for wound healing and sports-related injuries but it was only recently that scientists began studying PRP's potential in repairing damaged cardiovascular tissue. Studies indicate PRP stimulates cell repair via growth factor release and by attracting reparative cells[44].

INDUSTRY STRUCTURE AND MARKET CONDITIONS

The NBA undertakes the procurement of imported IVIg and other plasma and recombinant products within a global market of multinational suppliers. The industry remains active and expanding, in both production capacity and new product development, and is generally seen as a strong sector for investment.

Talecris/Grifols

In June 2010, Grifols, Europe's largest maker of plasma products, agreed to buy Talecris Biotherapeutics for over $US3 billion to expand its share of the $US7 billion market to almost a third, the same as Baxter's and more than CSL's 29 per cent share[45]. However, the agreement was subject to approval by Spanish and USA regulatory authorities, as well as shareholders and the USA Federal Trade Commission (FTC). The approval took a year and was subject to a consent agreement regarding disposal of assets. The FTC was said to fear the merger would reduce supplies and raise prices. The three products for which the FTC had concern were immunoglobulin, albumin and plasma-derived factor VIII (pdFVIII)[46].

The FTC conditions for approval introduced Italian company Kedrion to increased competition in the USA market. Grifols will sell both the Talecris fractionation facility in Melville, New York, and Grifols' plasma collection centres in Mobile, Alabama, and Winston-Salem, North Carolina, to Italian company Kedrion. Grifols is required to sell Talecris' Koate pdFVIII business, including the Koate brand name in the USA, to Kedrion, and to manufacture private-label immunoglobulin, private-label albumin and Koate for seven years for Kedrion to sell in the USA.

Grifols is starting construction of a new plant in Barcelona with the capacity to fractionate one million litres of plasma a year (with potential to expand to two million) allowing the group to double its existing fractionation capacity in Spain. The construction work is scheduled to take 18 months after which the process of obtaining licenses from the FDA and EMA will begin. The Grifols plant in Los Angeles currently has a capacity of 2.2 million litres, giving group total capacity of 6.3 million litres in 2014. The combined company's USA and Spanish fractionation plants will receive plasma from about 150 plasma collection centres.

CSL

CSL is spending $A235 million over five years on a large scale biotechnology facility at its Victorian Broadmeadows site, focussed on the late-stage development of new therapies for cancer, bleeding disorders, inflammation and infection.

In mid-February 2011, CSL reported a 19 per cent drop in first half net profit from a year earlier because of the much stronger Australia dollar[47]. The CEO, Brian McNamee, said the company's underlying business had continued to grow, including licensing into new geographic and patient markets. In the CSL Behring business, sales grew 8 per cent from a year ago on a constant-currency basis to $US1.6 billion.

Baxter

Analysts said Baxter had benefited from the temporary absence of Octagam from the market and its return could mean Baxter could not maintain its growth.

Baxter acquired the haemophilia-related assets of Archemix. The lead product is ARC19499, a synthetic, subcutaneously-administered haemophilia therapy whose Phase I clinical trial was conducted in the UK.

Novo Nordisk

Novo Nordisk plans to invest in a new biologics manufacturing facility at its Kalundborg site, the largest in the group's production network. The new capacity will be used to manufacture biopharmaceuticals such as FVIIa and will be available for manufacturing haemophilia drugs in the pipeline.

Nearest to the market is Novo's recombinant factor XIII drug NN1841, designed to treat a rare bleeding disorder that affects about 600–1,000 patients worldwide. The drug was filed for approval in the USA in February. An improved FVIII called N8 is in Phase III trials for haemophilia A, as is a long-acting formulation of FIX for haemophilia B.

Other

Terumo Corporation of Tokyo announced its acquisition of CaridianBCT. Terumo entered the blood transfusion market in the 1960s and has grown into the number five blood transfusion player globally. The rising global demand for blood transfusion products is in part due to the ageing of the population in developed nations and, in emerging economies, the rapid development of healthcare infrastructure. The transaction will allow Terumo to offer a wider range of blood processing technologies and greatly expand Terumo's geographic presence, particularly in North America.

Bayer Schering Pharma aims to deliver a successor to its Factor VIII product and to create drugs to treat bleeding and optimise bypass therapy. The rFVIIa compound BAY 86-6150 shows promise in this respect with a pivotal Phase II/III study of the drug.

Cangene has merged and rebranded its USA subsidiaries as Cangene Plasma Resources. The company owns and operates three FDA licensed plasma-collection facilities and Cangene Plasma Resources Winnipeg. Cangene recently announced that the Biomedical Advanced Research and Development Authority (BARDA), the agency within the HHS that administers its bio-defence stockpiling contracts, will exercise options under a botulism antitoxin supply contract. This should generate $US61million in additional revenue for Cangene over three to four years.

Germany's Biotest AG acquired Brazil's Marcos Pedrilson Produtos Hospitalares Ltda. The Brazilian company, located in Rio de Janeiro, was Biotest's distributor and holds all plasma protein registrations of Biotest for the Brazilian market. Biotest contracted to sell its global Microbiological Monitoring business to Merck, so it can focus on its plasma proteins business.

GTC Biotherapeutics, developer of ATryn, the first product developed, approved and manufactured in the USA and EU using GTC's transgenic technology, is now a subsidiary of LFB Biotechnologies. Interest continues in the FVIIa development.

Bio Products Laboratory in the UK changed ownership status following the completion of its transfer to a limited company. This follows a transfer of the business away from NHS Blood and Transplant into Plasma Resources UK, a Department of Health-owned entity. The Bio Products Laboratory is now run by the same holding company and operational board as its plasma supplier DCI.

ProMetic, via its new subsidiary, NewCo, entered into a long-term lease with Quebec's *Institut National de la Recherche Scientifique* for an existing state-of-the-art facility. NewCo will undertake the development and manufacturing of high-value plasma-derived therapeutic biosimilars for ProMetic's current and future clients. This facility will have a targeted processing capacity of 150,000 litres. The plant is expected to begin operations by the end of 2011 and reach full capacity by 2014.

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46 According to the FTC, Grifols and Talecris had around 8.4 percent and 22.8 percent of the US immunoglobulin market, respectively, and their merger would have meant effectively only three manufacturers with nearly all US sales. In albumin, the companies had US market shares of approximately 13 percent each, and the acquisition would have left four significant competitors. In the market for pdFVIII, Grifols and Talecris accounted for 23 percent and 3.6 percent respectively and after their merger there would have been only three main competitors

47 In April, CSL's CEO was reported to have warned that the rising Australian dollar could see Australian companies send jobs offshore.


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PART 5: CORPORATE GOVERNANCE

5

5.1 GOVERNANCE STRUCTURE

The National Blood Authority senior executive management team comprises the following staff:

- General Manager and Chief Executive Officer, Dr Alison Turner
- Principal Medical Officer, Dr Chris Hogan
- Deputy General Manager, Sector Coordination, Systems and Corporate, Ms Stephanie Gunn
- Deputy General Manager, Fresh Blood and Clinical Development, Mr Andrew Mead
- General Counsel and Deputy General Manager, Commercial Contracts, Mr Michael Stone.

Brief biographies of these staff are given in **Appendix 8.**

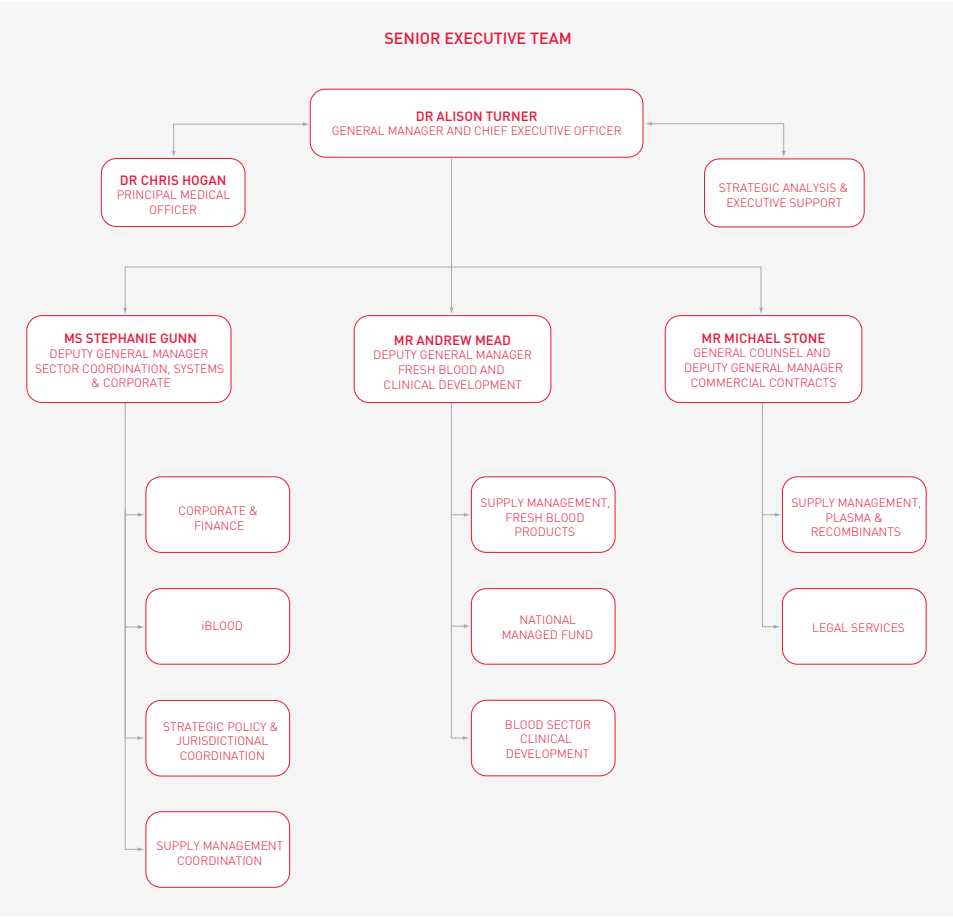

FIGURE 5.1 *NBA's organisational structure as at 30 June 2011*

GOVERNANCE

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 9** for 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 two 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 supply coordination are effectively linked and that data and systems development activities are prioritised to best meet internal and external priorities.

AUDIT COMMITTEE

The Audit Committee's work program progressed well during 2010–11. Activities included:

- reviewing and making minor recommendations to the CEO on the 2009–10 annual financial statements
- reviewing and making recommendations to the CEO on the Certificate of Compliance
- reviewing and providing advice on the Strategic Risk Management Plan, specifically in relation to financial risk management strategies
- reviewing and making recommendations on the development of the internal audit work program and monitoring the progress of implementation activities to address findings
- providing advice on business continuity planning, financial management, risk management, the Fraud Control Plan and accountability issues
- providing an overview of the effectiveness of the NBA control framework including consideration of testing against the business continuity plan, fraud risk assessment and the new fraud risk management plan and risk against the risk management plans of projects.

The committee met six times in 2010–11.

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 is now implementing key recommendations, including ensuring a more comprehensive accountability framework for contracts.

The internal auditor conducted a review of the IDMS 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. A number of recommendations were made and the NBA is undertaking further analysis of several technical issues and refining how the system interacts with our business 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 the 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's strategic risk management plan for 2011–12 was drafted. The plan identifies six 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 provided input into the draft plan which is expected to be finalised in August 2011.

The NBA participated in the 2011 Comcover Risk Management Benchmarking Survey and received a benchmarking score of 7.2 out of a possible 10. This benchmarking score places the NBA at a 'structured' maturity level. The average score achieved by all participating agencies was 6.4 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. The existing NBA fraud control plan expired in late 2010. KPMG was appointed to undertake the fraud risk assessment and develop a fraud control plan for 2010–12.

The findings of the 2010 fraud risk assessment indicated that there were no significant risks to the NBA, with a universally strong control environment in operation. No significant gaps were identified in the NBA's fraud controls.

However, the Audit Committee did note that there were two moderate fraud risks. In response to these, the NBA is reviewing improved control measures.

Under its current 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 Australian National Audit Office (ANAO), in 2010–11. This assistance enabled the NBA to ensure compliance and appropriate accountability and to identify scope for continual improvement in our activities.

The ANAO continued its performance audit of NBA activities. The objective of the 2010–11 audit is *to assess whether the NBA's governance and contractual arrangements are effective in ensuring sufficient blood supply and services*. The ANAO has undertaken field work *to examine whether the NBA demonstrates:*

- *sound governance and administrative systems to support blood and blood product supply, including arrangements to assess and consider value for money*
- *accountable and responsive contract management of the ARCS Deed of Agreement to meet legislative requirement, government policy and improve national supply and*
- *sound performance information, including links to higher level outcomes, to assess the effectiveness of contractual arrangements in meeting national blood supply needs.*

Finalisation of the audit is expected in the latter half of 2011.

Other external scrutiny

There were no judicial decisions or decisions of administrative tribunals that impacted on the operations of the NBA during 2010–11. There were no reports of the agency by a Parliamentary committee or the Commonwealth Ombudsman.

5.2 PLANNING AND SERVICE DELIVERY

OPERATIONAL PLANNING

In 2010–11, the NBA delivered 84 per cent of activities against the planned outcomes. Table 5.1 demonstrates the overall trend in the NBA's delivery against our operational plans over the past five years.

TABLE 5.1 *NBA performance in achieving objectives of its operational plans, 2006–07 to 2010–11*

YEAR	2006–07	2007–08	2008–09	2009–10	2010–11
Performance (%)	85%	81%	95%	91%	84%

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 2011–12 operational plan

Through its 2011–12 operational plan, drafted during the year, 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.

Key challenges for the coming year include:

- ensuring effective management of, and successful transition to, the new supply contracts for plasma, recombinants and diagnostic reagent products and finalisation of new procurement arrangements for imported IVIg and rFVIIa to meet domestic demand
- managing the Blood Service Deed under rollover arrangements, including finalising the Payment and Substitution Rules and National Service Standards
- implementing national roll out of BloodNet and the redevelopment of ABDR
- printing and publishing the Perioperative module of the Patient Blood Management guideline
- completing the review of the *Criteria for the clinical use of IVIg in Australia.*

CORPORATE

During 2010–11, 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*. JBC members were unanimously satisfied with the quality and timeliness of support provided.

A total of 98.25 per cent of papers prepared by the NBA were provided to the JBC at least seven days before the meetings and 88 per cent of recommendations in the NBA papers were agreed by the JBC.

The NBA Secretariat helped to organise the inaugural CTEPC Blood Policy Forum, held on 8 March 2011. One recommendation arising from the review was an increased policy role for CTEPC in the blood sector. Another was the establishment of a blood policy forum, which was seen to be a key component in the development of a strategic agenda for blood policy in Australia. The forum program consisted of presentations on priority issues followed by workshop discussions. Attendees included CTEPC and JBC members and representatives from the NBA, the Blood Service, NHMRC, ACSQHC, HealthPACT, the Australia and New Zealand Society of Blood Transfusion (ANZSBT) and the Haemophilia Foundation of Australia (HFA).

Secretariat services were also provided to a joint meeting between the JBC and the CTEPC, held immediately after the Blood Policy Forum. At that meeting agreement was reached to undertake further work on the management of IVIg, patient blood management, risk-based decision-making for blood safety and on effective communication of the *Statement on national stewardship expectations for the supply of blood and blood products,* and the ACSQHC National Safety and Quality Health Service Standard for blood and blood product. The joint meeting also agreed that the forum should be held on an annual basis in future. The JBC Secretariat has been tasked to work with the CTEPC Secretariat to organise these meetings.

Secretariat services were also provided to the NBA Board, which met four times during 2010–11. All NBA Board meetings were held in Canberra.

Customer Service Charter

The NBA is committed to providing a professional, high-quality, 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.

5.3 PEOPLE MANAGEMENT

OUR VALUES

The NBA has four values that are central to our workplace. We:

- actively listen, think and encourage engagement
- criticise sparingly, praise generously
- be 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 48 in 2009–10 to 50 at the end of June 2011, although of these one person was on extended long service leave and another was on long-term leave without pay. Short-term, non-ongoing staff are regularly used to meet deliverables. Table 5.2 shows NBA staff numbers, by classification.

TABLE 5.2 *Number of NBA staff at 30 June 2011*

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				1	1
EL 2	3*	1	4		8
EL1 Legal		1			1
APS 6 Legal					0
EL 1	7	1	10		18
APS 6	8**		2		10
APS 5	2	1	1		4
APS 4	2				2
APS 3		1			1
TOTAL					**50**

* One employee on extended Long Service Leave
** One employee on long-term leave without pay

Workforce planning, staff turnover and retention

Staff turnover in 2010–11 decreased significantly from 25 per cent in 2009–10 to 17 per cent, which is within the average range for the APS.

The average length of service for NBA staff is now approximately three and a half years. Forty per cent of staff have been with the NBA for more than four years. We are fortunate that our staff profile contains a diverse range of skills, experience and backgrounds.

In early 2011, the NBA conducted two surveys—one to assess current staff skills and capabilities and the other to gauge staff satisfaction. As very similar surveys were conducted in 2008–09, the NBA is now in a position to measure the areas where its strategies have been successful and also to identify areas where greater focus is required. In addition, once the APS *State of the Service Report 2010–11* is published, the NBA will be able to use particular aspects of the Report to benchmark against other agencies.

Skills and capabilities

The skill survey showed that we had been successful in improving skills in core areas such as statistical modelling and research and analysis with good developing skills in the discipline of cause and effect and general administrative efficiencies. It also showed a steady continual increase in our clinical knowledge of blood and blood products. This is due largely to our ongoing program of lectures by the Principal Medical Officer, which provides non-clinically trained staff with a detailed insight into specific elements of transfusion medicine and how each of the products provided through the supply plan interacts with the coagulation process.

Staff satisfaction

A staff satisfaction survey was conducted in April 2011. There was an 81 per cent response rate. The survey replicated, in part, the 2009 NBA Organisational Staff Survey with 83 of the 99 questions being identical or similar to questions in the earlier survey.

The results of the survey show that there are many areas where the organisation is performing strongly and has increased satisfaction rates. In particular, staff feel that their work is interesting and challenging, that the NBA is a good organisation to work for and they are proud to do so. Staff also feel that team-work is encouraged in the Agency and people within teams put substantial effort into their work and have a strong sense of working as a team. Staff also report that they understand their role within the NBA and that their managers are knowledgeable and responsive to problems.

Finally, staff feel that they have sufficient autonomy, access to the equipment they need and that the NBA is sensitive to family responsibilities.

The staff participation forum continues to provide a good representation of the views of staff 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 establishing the Health and Fitness Promotion Program, awareness of occupational health and safety obligations, review of the Knowledge Management Forum program, and the activities of the social club.

PRODUCTIVITY GAINS

There have been delays in implementing the electronic records and document management system due to some technical interface issues that needed to be addressed by the vendor. These are now resolved and the system will be implemented following the transition of the NBA to the Department of Human Services gateway arrangements. The new arrangements are expected to result in considerable savings in staff time and resources relating to records management and the efficiency of our internal knowledge transfer.

The NBA continued to deliver an increased range of services and more complex contract management requirements within existing services.

FEATURES OF EMPLOYMENT TOOLS

Employment tools

Table 5.3 shows numbers of NBA employees covered by the NBA Enterprise Agreement 2010–11, Common Law agreements, Section 24 determinations, and Australian Workplace Agreements, at 30 June 2011.

TABLE 5.3 *Numbers of NBA staff on types of employment agreements*

STAFF	ENTERPRISE AGREEMENT	AUSTRALIAN WORKPLACE AGREEMENT	COMMON LAW OR SECTION 24 AGREEMENT
SES	Nil	Nil	3
Non–SES	38	7	1

NBA enterprise agreement

The National Blood Authority Enterprise Agreement 2010–11 took effect on 20 August 2010. Table 5.4 provides detail of the classification against salary levels.

TABLE 5.4 *Salary levels of NBA staff at 30 June 2011*

CLASSIFICATION	MINIMUM	MAXIMUM
Executive Level 2	102,160	115,146
Executive Level 1	85,625	97,675
EL1 Legal	85,628	103,674
APS 6 Legal	68,515	76,591
APS Level 6	69,678	78,606
APS Level 5	63,162	66,664
APS Level 4	58,071	61,361
APS Level 3	51,255	56,815

In March 2011, the NBA received ministerial approval to begin negotiating an enterprise agreement to start on 1 July 2011, at the earliest. The nominated bargaining representatives entered negotiations on behalf of staff and subsequently a draft agreement was approved by the Minister. A total of 85 per cent of eligible staff voted on the agreement and 93 per cent of these voted 'yes'. Fair Work Australia approved the agreement, to take effect from 1 July 2011.

Non-salary benefits

The Enterprise Agreement 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 NBA Enterprise Agreement, available on the NBA website. In summary they 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 (not all officers)
- flexible working arrangements with time off in lieu where appropriate, including recognition of travel time
- access to laptop computers, dial-in facilities, and mobile phones (not all officers)
- support for professional and personal development
- provision of eyesight testing and reimbursement of prescribed eyewear costs specifically for use with screen-based equipment
- influenza vaccinations for staff and families
- annual close-down.

For SES staff and others on Australian Workplace Agreements, common law agreements or s.24 determinations:

- all the forgoing benefits except flex-time
- car parking (not all officers)
- airport lounge membership (not all officers)
- vehicle leasing arrangements made available for office duties during work hours or salary in lieu (not all officers).

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 benchmark 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.

An important vehicle for professional development at the NBA is the individual personal development plan. Personal development plans help the organisation to meet the objectives of its operational plan by focusing on what individual staff members must deliver in order to meet goals outlined in the plan. Each staff member has an individual meeting with his or her manager on a quarterly basis. At the beginning of each quarter, a clear agreement is reached between staff members and their managers on the support and skills needed by the staff members if they are to achieve these goals. At the end of each quarter, the staff members and managers discuss progress in obtaining the required skills and the relevance and value of the training provided.

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 provided staff with the opportunity to increase their knowledge and 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, recordkeeping, 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 Carol Koski, University of Maryland Medical Systems—the clinical use of IVIg in neurology
- Mr Gianluca Anguillesi, Octapharma—an update on registered immunoglobulin products and their features
- Ms Jennifer Williams, CEO, Australian Red Cross Blood Service—the Blood Service's year in review
- Dr Lisa Michaels, Kogente/Bayer—on the haemophilia pipeline
- Mr Jan Bult, Plasma Protein Therapeutics Association—on the global industry and challenges for the future
- Mr Jim Bacon, Talecris—insight into the cold chain processes
- Dr Ian Prosser, TGA—an update on regulatory matters.

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

In addition, our Principal Medical Officer, Dr Chris Hogan, made a number of presentations to staff including an update on haemophilia, thalassaemia, iron metabolism, milestones in the history of transfusion medicine and the coagulation cascade.

Dr Alison Turner also briefed staff on intelligence gathered during her recent visits to the UK National Health Service Commercial Medicines Unit, the Welsh Blood Service, the Dublin Consensus Conference, the meeting of the collaboration of national plasma product supply planners and the International Plasma Protein Congress.

Other staff who travelled to participate in conferences provided detailed written or oral briefings to staff on key emerging issues.

During the year a Journal Club was established as a forum for NBA staff to analyse and discuss current journal articles relevant to our work.

The effectiveness of all training is assessed as part of discussions between staff and managers in the quarterly personal development plan meetings described above.

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 2010–11, a new NBA Health and Fitness Promotion Program was established. 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. Highlights included:

- two teams participated in the Camp Quality VertiCool Challenge
- lunchtime yoga classes
- donation of blood to the Blood Service
- participation in training on occupational health and safety and stress management, which are seen as key contributors to a healthier workplace.


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ANNUAL REPORT

PART 6: FINANCIAL MANAGEMENT AND ACCOUNTABILITY

6

6.1 BUDGET AND FINANCIAL MANAGEMENT

This section provides an overview of the NBA's financial management and outcome in 2010–11.

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*, the *Australian 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 National Managed Fund (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 National Managed Fund (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 6.1 summarises the NBA's revenue and expenditure for the year.

TABLE 6.1 *Overall funding and expenditure for the NBA in 2010–11: a summary*

	FUNDING INCL. APPROPRIATIONS ($M)	EXPENDITURE ($M)
Departmental—NBA Operations	10.022	9.784
Administered—national blood and blood product supply	941.016	938.264

OVERVIEW OF FINANCIAL PERFORMANCE IN 2010–11

This section provides a summary of the NBA's financial performance for 2010–11. Details of departmental and administered results are shown in the audited financial statements, and this summary should be read in conjunction with those statements.

Audit report

The NBA received an unqualified audit report for 2010–11.

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 patient blood management and the safe use of blood and blood products.

Although all planned initiatives in these areas are well under way, several factors have caused delays in implementation. As a result, funds provided for those initiatives have not yet been fully spent.

These unspent funds were drawn on to meet the staffing and other costs of completing these initiatives in 2010–11 and will be accessed similarly in 2011–12, so operating deficits will occur in those financial years. These deficits have been 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 2010–11 operating surplus of $0.238 million, compared with an operating surplus of $0.048 million in 2009–10. Table 6.2 shows the key results for the period 2008–11.

TABLE 6.2 *Key results in financial performance, 2010–11, 2009–10 and 2008–09*

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

Income statement

Revenue

Total departmental revenue received in 2010–11 amounted to $10.022 million: $5.948 million in funding from the Australian Government; $3.980 million in contributions received from the states and territories and other revenue; and $0.094 million for resources received free of charge. This represents an increase of $0.498 million (5.2 per cent) on revenue received in 2009–10. 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 2010–11 amounted to $9.784 million, 3 per cent higher than in 2009–10.

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 $0.036 million at 30 June 2011. 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. The funds represent amounts intended to be used for implementing key information technology projects and for consultancies on the quality and appropriate use of blood products in Australia, as well as being surpluses from prior years.

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 $0.616 million, down from $2.5 million in 2010.

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 AHMC approves an annual NSP&B, which is formulated by the NBA from demand estimates provided by the states and territories.

Revenue

Total estimated revenue for 2010–11 is presented in Table 6.3. Because funding is provided to meet the cost of supplying blood and blood products, the increase of $68.0 million in funding (8 per cent) for the current financial year reflects the increasing demand for products and contractually agreed increases in prices.

TABLE 6.3 *Administered revenue, 2010–11, 2009–10 and 2008–09*

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

Expenses

Table 6.4 shows the NBA's administered expenses for 2008–09 to 2010–11.

TABLE 6.4 *Key results of administered expenses, 2010–11, 2009–10 and 2008–09*

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

Administered expenses for 2010–11 increased by 9.2 per cent over those for 2009–10. Total payments to commercial suppliers increased by 9.5 per cent and payments to the Blood Service increased by 8.9 per cent.

Administered assets and liabilities

Administered assets comprise the following:

- short term investments made in relation to the National Managed Fund
- 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.

Net administered assets and liabilities increased by $119.6 million during 2010–11 mainly as a result of drawings from the Official Public Account to undertake the investments for the National Managed Fund and the prepayment to the Blood Service.

Unspent funds received from jurisdictions are transferred to the Official Public Account and are not classified as administered assets.

6.2 PURCHASING

The National Blood Authority 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 were consistently favourable in relation to complying with mandatory processes and 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 2010–11.

Three funding agreements entered into with jurisdictions, using interest monies from administered funds approved by the JBC, continued in 2010–11. 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 of 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 2010–11 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 2010–11.

Consultants

In 2010–11, nine new consultancy contracts were entered into, involving total actual expenditure of $473,819 (GST inclusive). In addition, seven ongoing consultancy contracts were active during the year, involving actual expenditure of $925,272 (GST inclusive). Total expenditure on consultancies in 2010–11 was $1,399,091.

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 policies and procedures for selecting consultants and approving the required expenditure are set out in chief executive and management instructions and key business processes. These processes adhere to the principles of the Commonwealth Procurement Guidelines and Best Practice Guidance.

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

Table 6.5 shows total expenditure on all consultancy services from 2007–11, covering both new contracts let in the applicable year and ongoing contracts let in previous years.

TABLE 6.5 *Expenditure on consultancy services, 2007–08 to 2010–11*

	NO. LET	TOTAL EXPENDITURE ON NEW AND EXISTING CONSULTANCIES ($)
2010–11	9	1,399,091
2009–10	3	492,033
2008–09	14	997,076
2007–08	9	1,624,081

Table 6.6 provides details of consultancy contracts let by the NBA in 2010–11 and the value of contracts over their entire life. Contracts with a value of less than $10,000 have not been included, in line with the annual reporting requirements of the Joint Committee of Public Accounts and Audit.

TABLE 6.6 *Consultancy services of $10,000 or more, 2010–11*

CONSULTANT NAME	DESCRIPTION	CONTRACT PRICE (GST INCL.)	SELECTION PROCESS	JUSTIFICATION
Biotext Pty Ltd	Systematic Reviewer for the 2010 review of the IVIg Criteria for Use	150,000.00	Open Tender	A
Gaudin Consultancy Limited	Provision of professional services to provide independent advice for Output Based Funding Model	60,000.00	Direct Source	B
Health Technology Analysts Pty Limited	Procurement of a Systematic Reviewer and Technical Writer Services	1,415,000.00	Open Tender	A
IMS Australia Pty Ltd	Procurement of a Systematic Reviewer	304,175.00	Open Tender	A
Ken Barker Consulting Pty Ltd	Consultancy services for an independent member of the National Blood Authority's Audit Committee	22,000.00	Direct Source	B
Morison Consulting Pty Ltd	Consultancy services for an independent member of the National Blood Authority's Audit Committee	48,400.00	Direct Source	B
The Loch Group Pty Limited	Consultancy services for an independent member of the National Blood Authority's Audit Committee	41,800.00	Direct Source	B
Australian Healthcare Associates Pty Ltd	Provision of professional services to undertake comparative studies of demand management frameworks in the health sector	94,380.00	Select Tender	A
Pricewaterhouse Coopers	Provision of consultancy services to provide Management and Advice Support Services for the National Managed Fund	1,066,073.00	Open Tender	B
Gaudin Consultancy Limited	Provision of professional services to provide an independent review for the cost attribution process of the Output Based Funding Model	50,000.00	Direct Source	B
Globin Global	Procurement of technical expertise in the procurement of diagnostic reagents	10,924.99	Direct Source	A
Ernst & Young	Provision of professional services to provide independent advice on inventory management and distribution by the Blood Service	179,817.00	Select Tender	B
KPMG	Provision of professional services to provide independent advice on Fraud risk assessment and a Fraud Control plan	37,007.85	Direct Source	B

CONSULTANT NAME	DESCRIPTION	CONTRACT PRICE (GST INCL.)	SELECTION PROCESS	JUSTIFICATION
Marsh Pty Ltd	Procurement of technical expertise in the review of insurance	25,768.39	Direct Source	A
Dr Louise Morauta	Provision of professional services to identify options for increasing the consistency in which blood and blood products are used nationally	25,000.00	Direct Source	A
UXC Connect Pty Limited	Procurement of technical expertise to undertake a review of ICT infrastructure	27,277.00	Direct Source	A

Notes:
'open tender'—a procurement procedure in which a request for tender is published inviting all businesses that satisfy the conditions for participation to submit tenders.
'select tender'—a procurement procedure in which the procuring agency selects which potential suppliers are invited to submit tenders in accordance with the mandatory procurement procedures.
'direct sourcing'—a procurement procedure, available only in defined circumstances, in which an agency may contact a single potential supplier or suppliers of its choice and for which conditions for direct sourcing apply under the mandatory procurement procedures.
Justification for decision to use consultancy: A—requirement for specialist expertise not available within the NBA; B—requirement for independence considered essential.

6.3 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 2010–11, desktop computers, laptops and blackberries were replaced and audio-visual equipment was upgraded to better support the increased demand for teleconferencing.

6.4 FINANCIAL STATEMENTS

Australian National Audit Office

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 2011, 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; Schedule of Contingencies; Schedule of Asset Additions; Schedule of Administered Items 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 National Blood Authority's Chief Executive 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 the Chief Executive determines is necessary to enable the preparation of the financial statements that 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 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 evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made by the National Blood Authority's Chief Executive, 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.

GPO Box 707 CANBERRA ACT 2601
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 2011 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

8 August 2011

National Blood Authority
Financial Statements
For the year ended 30 June 2011

Statement by the Chief Executive and Chief Financial Officer

In our opinion, the attached financial statements for the year ended 30 June 2011 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.

A J Turner
Chief Executive Officer

8 August 2011

Ashley Jackson
Chief Financial Officer

8 August 2011

NATIONAL BLOOD AUTHORITY
STATEMENT OF COMPREHENSIVE INCOME
for the year ended 30 June 2011

	Notes	**2011 $'000**	2010 $'000
EXPENSES			
Employee benefits	3A	**5 869**	5 636
Supplier expenses	3B	**3 114**	2 677
Depreciation and amortisation	3C	**795**	973
Write-down and impairment of assets	3D	**-**	188
Losses from asset sales	3E	**6**	1
Total expenses		**9 784**	9 475
LESS:			
OWN-SOURCE INCOME			
Own-source revenue			
Sale of goods and rendering of services	4A	**487**	193
Other	4B	**3 493**	3 539
Total own-source revenue		**3 980**	3 732
Gains			
Other	4C	**94**	80
Total gains		**94**	80
Total own source income		**4 074**	3 812
Net cost of services		**5 710**	5 663
Revenue from Government	4D	**5 948**	5 712
Surplus attributable to the Australian Government		**238**	49
OTHER COMPREHENSIVE INCOME			
Changes in asset revaluation reserves		**-**	191
Total other comprehensive income		**-**	191
Total comprehensive income		**238**	240
Total comprehensive income attributable to the Australian Government		**238**	240

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

NATIONAL BLOOD AUTHORITY
BALANCE SHEET
as at 30 June 2011

	Notes	2011 $'000	2010 $'000
ASSETS			
Financial Assets			
Cash and cash equivalents	5A, 9	**36**	210
Trade and other receivables	5B	**8 769**	8 622
Total financial assets		**8 805**	8 832
Non-Financial Assets			
Leasehold improvements	6A, 6C	**37**	141
Property, plant and equipment	6B, 6C	**334**	254
Intangibles	6D, 6E	**1 295**	1 610
Other	6F	**64**	57
Total non-financial assets		**1 730**	2 062
Total Assets		**10 535**	10 894
LIABILITIES			
Payables			
Suppliers	7A	**427**	644
Other	7B	**1 424**	1 823
Total payables		**1 851**	2 467
Provisions			
Employee provisions	8A	**1 213**	1 194
Total provisions		**1 213**	1 194
Total Liabilities		**3 064**	3 661
Net Assets		**7 471**	7 233
EQUITY			
Contributed equity		**812**	812
Reserves		**206**	206
Retained surplus		**6 453**	6 215
Total Equity		**7 471**	7 233

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 2011

Item	Retained Earnings		Asset revaluation reserve		Contributed equity/capital		Total equity	
	2011 $'000	2010 $'000	**2011 $'000**	2010 $'000	**2011 $'000**	2010 $'000	**2011 $'000**	2010 $'000
Opening balance								
Balance carried forward from previous period	**6 215**	6 166	**206**	15	**812**	812	**7 233**	6 993
Adjusted opening balance	**6 215**	6 166	**206**	15	**812**	812	**7 233**	6 993
Comprehensive Income								
Other comprehensive income	**-**	-	**-**	191	**-**	-	**-**	191
Surplus for the period	**238**	49	**-**	-	**-**	-	**238**	49
Total comprehensive income	**238**	49	**-**	191	**-**	-	**238**	240
of which:								
Attributable to Australian Government	**238**	49	**-**	191	**-**	-	**238**	240
Closing balance as at 30 June	**6 453**	6 215	**206**	206	**812**	812	**7 471**	7 233
Closing balance attributable to the Australian Government	**6 453**	6 215	**206**	206	**812**	**812**	**7 471**	7 233

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

NATIONAL BLOOD AUTHORITY
CASH FLOW STATMENT
for the year ended 30 June 2011

	Notes	**2011** **$'000**	2010 $'000
OPERATING ACTIVITIES			
Cash received			
Appropriations		**5 608**	5 523
Goods and services		**3 933**	3 577
Net GST received		**366**	263
Total cash received		**9 907**	9 363
Cash used			
Employees		**5 626**	5 441
Suppliers		**3 353**	2 888
Section 31 receipts transferred to OPA		**640**	162
Total cash used		**9 619**	8 491
Net cash flows from (used by) operating activities	9	**288**	872
INVESTING ACTIVITIES			
Cash received			
Proceeds from sales of intangibles		**24**	-
Total cash received		**24**	-
Cash used			
Purchase of property, plant and equipment		**188**	32
Purchase of intangibles		**298**	652
Total cash used		**486**	684
Net cash flows used by investing activities		**(462)**	(684)
Net increase (decrease) in cash held		**(174)**	188
Cash and cash equivalents at the beginning of the reporting period		**210**	22
Cash and cash equivalents at the end of the reporting period	5A	**36**	210

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

NATIONAL BLOOD AUTHORITY
SCHEDULE OF COMMITMENTS
as at 30 June 2011

	2011 $'000	2010 $'000
BY TYPE		
Commitments receivable		
Net GST recoverable on commitments	**67**	145
Total commitments receivable	**67**	145
Commitments payable		
Capital commitments		
Intangibles [1]	**1**	209
Total capital commitments	**1**	209
Other commitments		
Operating leases [2]	**164**	671
Other	**576**	716
Total other commitments	**740**	1 387
Net commitments by type	**674**	1 451
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**67**	118
From one to five years	**-**	27
Total other commitments receivable	**67**	145
Commitments payable		
Capital commitments		
One year or less	**1**	209
Total capital commitments	**1**	209
Operating lease commitments		
One year or less	**164**	503
From one to five years	**-**	168
Total operating lease commitments	**164**	671
Other commitments		
One year or less	**576**	584
From one to five years	**-**	132
Total other commitments	**576**	716
Net commitments by maturity	**674**	1 451

NB: Commitments are GST inclusive where relevant.

[1] The nature of capital commitments is further deployment of internally developed software.

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

Nature of lease	*General description of leasing arrangement*
Lease for Canberra office accommodation	The current lease for office accommodation expires on 31 October 2011.
Lease for Melbourne office accommodation	The current lease for office accommodation expires on 31 October 2011.

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

NATIONAL BLOOD AUTHORITY
SCHEDULE OF CONTINGENCIES
as at 30 June 2011

Quantifiable Contingencies
None

Unquantifiable but material contingencies are disclosed in Note 10: Contingent Liabilities and Assets

SCHEDULE OF ASSET ADDITIONS
for the year ended 30 June 2011

The following non-financial non-current assets were added in 2010-11:

	Other property, plant and equipment	Intangibles	Total
	$'000	$'000	$'000
Additions funded in the current year			
By purchase - appropriation ordinary annual services			
Ordinary operating costs	119	188	307
By purchase - other	69	110	179
Total funded additions funded in the current year	**188**	**298**	**486**
Total additions	**188**	**298**	**486**

The following non-financial non-current assets were added in 2009-10:

	Other property, plant and equipment	Intangibles	Total
	$'000	$'000	$'000
Additions funded in the current year			
By purchase - appropriation ordinary annual services			
Ordinary operating costs	20	452	472
By purchase - other	12	266	278
Total funded additions funded in the current year	**32**	**718**	**750**
Total additions	**32**	**718**	**750**

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

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS
for the year ended 30 June 2011

Income administered on behalf of Government *for the year ended 30 June 2011*	**Notes**	**2011** **$'000**	2010 $'000
Revenue			
Non-taxation revenue			
Funding from governments	14A	**939 212**	871 195
Interest	14B	**1 629**	-
Other	14C	**175**	1 354
Total income administered on behalf of Government		**941 016**	872 549
Expenses administered on behalf of Government *for the year ended 30 June 2011*			
Grants	15A	**-**	456 881
Supplier expenses	15B	**937 954**	402 143
Depreciation and amortisation	15C	**310**	128
Total expenses administered on behalf of Government		**938 264**	859 152

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

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Assets administered on behalf of Government *as at 30 June 2011*	**Notes**	**2011** **$'000**	2010 $'000
Financial assets			
Cash and cash equivalents	16A	**41 157**	389
Trade and other receivables	16B	**14 702**	10 210
Other investments	16C	**40 611**	-
Total financial assets		**96 470**	10 599
Non-financial assets			
Inventories	16D	**55 024**	67 212
Property, plant and equipment	16E	**30**	-
Intangibles	16F	**371**	445
Other	16G	**75 401**	12
Total non-financial assets		**130 826**	67 669
Total assets administered on behalf of Government		**227 296**	78 268
Liabilities administered on behalf of Government *as at 30 June 2011*			
Payables			
Suppliers	17A	**68 934**	39 496
Total payables		**68 934**	39 496
Total liabilities administered on behalf of Government		**68 934**	39 496

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

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Administered Cash Flows
for the year ended 30 June 2011

	Notes	2011 $'000	2010 $'000
OPERATING ACTIVITIES			
Cash received			
Commonwealth contributions		**591 889**	548 057
State and territory contributions		**347 323**	323 138
Interest		**546**	-
Net GST received		**96 682**	85 464
Other		**198**	410
Total cash received		**1 036 638**	957 069
Cash used			
Grant payments		**-**	501 150
Suppliers		**1 071 831**	441 797
Total cash used		**1 071 831**	942 947
Net cash flows from (used by) operating activities		**(35 193)**	14 122
INVESTING ACTIVITIES			
Cash used			
Purchase of property, plant & equipment		**36**	-
Purchase of intangibles		**230**	75
Investments		**40 611**	-
Total cash used		**40 877**	75
Net cash flows (used by) investing activities		**(40 877)**	(75)
Net Increase (Decrease) in Cash Held		**(76 070)**	14 047
Cash and cash equivalents at the beginning of the reporting period		**389**	-
Cash from Official Public Account for:			
- Appropriations		**5 750**	7 707
- Special accounts		**1 163 441**	943 037
		1 169 191	950 744
Cash to Official Public Account for:			
- Special accounts		**1 052 353**	964 402
		1 052 353	964 402
Cash and cash equivalents at the end of the reporting period	20A	**41,157**	389

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

NATIONAL BLOOD AUTHORITY
SCHEDULE OF ADMINISTERED ITEMS (continued)

Administered Commitments *as at 30 June 2011*	**2011** **$'000**	2010 $'000
BY TYPE		
Commitments receivable		
Net GST recoverable on commitments	**275 254**	287 342
Total commitments receivable	**275 254**	287 342
Commitments payable		
Capital commitments		
Intangibles [1]	**261**	157
Total capital commitments	**261**	157
Other commitments		
Other [2]	**3 027 529**	3 160 602
Total other commitments	**3 027 529**	3 160 602
Net commitments by type	**2 752 536**	2 873 417
BY MATURITY		
Commitments receivable		
Other commitments receivable		
One year or less	**84 519**	94 201
From one to five years	**128 601**	107 651
Over five years	**62 134**	85 490
Total other commitments receivable	**275 254**	287 342
Commitments payable		
Capital commitments		
One year or less	**261**	127
From one to five years	**-**	30
Total capital commitments [1]	**261**	157
Other commitments		
One year or less	**929 449**	1 036 079
From one to five years	**1 414 610**	1 184 133
Over five years	**683 470**	940 390
Total other commitments [2]	**3 027 529**	3 160 602
Net commitments by maturity	**2 752 536**	2 873 417

NB: 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 ITEMS (continued)

Administered Contingencies
as at 30 June 2011

There were no quantifiable administered contingent liabilities as at 30 June 2011.

Unquantifiable but material contingencies are disclosed in Note 19.

Statement of Activities Administered on Behalf of Government

The major activities of the NBA are directed towards managing national blood arrangements, ensuring sufficient supply and to provide a new focus on the safety and quality of blood products and services.

The NBA manages and coordinates Australia's blood supply in accordance with the National Blood Agreement agreed by the Commonwealth, States and Territories. Under this agreement, the Commonwealth contributes 63 per cent of blood supply funding and the States and Territories provide 37 per cent. The funding for blood and blood products is funded from a special account established under the National Blood Authority Act 2003.

Details of planned activities for the year can be found in the Agency Portfolio Budget Statements for 2010 - 11 which have been tabled in Parliament.

Administered Asset Additions
for the year ended 30 June 2011

The following non-financial non-current assets were added in 2010-11:

	Property, plant & equipment	Intangibles	Total
	$'000	$'000	$'000
Additions funded in the current year			
By purchase - other	**36**	**230**	**266**
Total funded additions funded in the current year	**36**	**230**	**266**
Total additions	**36**	**230**	**266**

The following non-financial non-current assets were added in 2009-10:

	Property, plant & equipment	Intangibles	Total
	$'000	$'000	$'000
By purchase - other	-	75	75
Total funded additions funded in the current year	**-**	**75**	**75**
Total additions	**-**	**75**	**75**

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 2011

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 appropriations 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, States and Territories. Under this agreement, the Australian Government contributes 63 per cent of blood supply funding and the States and Territories 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.

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 2010; 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.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

1.2 Basis of Preparation of the Financial Statements (cont..)

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

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.

Administered revenues, expenses, assets and liabilities and cash flows reported in the Schedule of Administered Items and related notes are accounted for on the same basis and using the same policies as for departmental items, except where otherwise stated at Note 1.18.

1.3 Significant Accounting Judgments and Estimates

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 accounting 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.

The following new standards (including reissued standards) were issued prior to the sign-off date, were applicable to the current reporting period and had a financial impact on the NBA:

- AASB 7 Financial Instruments: Disclosures
- AASB 132 Financial Instruments: Presentation

Other new standards, revised standards, interpretations and amending standards that were issued prior to the sign-off date and are applicable to the current reporting period did not have a 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 and amending standards were issued by the Australian Accounting Standards Board prior to the sign-off date, which are expected to have a financial impact on the NBA for future reporting periods.

Other new standards, revised standards, interpretations and amending standards that were issued prior to the sign-off date and are applicable to the future reporting period are not expected to have a future financial impact on the NBA.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

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.

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 in that year.

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 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 apply 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 2011. The estimate of the present value of the liability takes into account expected 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 by the Department of Finance and Deregulation as an administered item.

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 represents outstanding contributions as at 30 June 2011.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

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.

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.

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.

1.11 Financial Assets (cont..)

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.

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 agency's accounts immediately prior to the restructuring.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

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 are carried at fair value less subsequent accumulated depreciation and accumulated impairment losses. Valuations are conducted with sufficient frequency to ensure that the carrying amounts of assets do not differ materially from the assets' fair values as at the reporting date. The regularity of independent valuations depends upon the volatility of movements in market values for the relevant assets. All valuations are conducted by an independent qualified valuer and are undertaken by the Australian Valuation Office.

Revaluation adjustments are made on a class basis. Any revaluation increment is credited to equity under the heading of asset revaluation reserve except to the extent that it reverses a previous revaluation decrement of the same asset class that was previously recognised in the surplus/deficit. Revaluation decrements for a class of assets are recognised directly in the surplus/deficit except to the extent that they reverse 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.

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	**2010-11**	2009-10
Infrastructure, Plant and Equipment	**3 to 7 years**	3 to 7 years
Leasehold improvements	**Lease term**	Lease term

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

1.15 Property, Plant and Equipment (cont..)

Impairment
All assets were assessed for impairment at 30 June 2011. 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	**2010-11**	2009-10
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 2011.

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
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

1.18 Reporting of Administered Activities

Administered revenues, expenses, assets, liabilities and cash flows are disclosed in the schedule of administered items 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 statement of cash flows in the schedule of administered items and in the administered reconciliation table in Note 18.

Revenue
All administered revenues are revenues relating to the course of ordinary activities performed by the NBA on behalf of the Australian Government.

All administered revenues are recognised on the basis of cash received.

Collectability of debts is reviewed at balance date. Allowances are made when collection of the debt is judged to be less rather than more likely.

Amounts appropriated during the year for administered interest are recognised in the balance sheet.

Grants
The NBA administers a number of grant schemes on behalf of the Government. Grant liabilities are recognised to the extent that (i) the services required to be performed by the grantee have been performed or (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.

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.

National Managed Fund
The National Managed Fund was established to manage the liability risks of the ARCBS 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.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

1.18 Reporting of Administered Activities (cont..)

The Fund came into effect on 1 July 2000 and to date, no claims have been made against the fund. The balance of the fund as at 30 June 2011 is $82,843,378 (30 June 2010: $74,448,609). Refer to Note 22.

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.

NOTE 2: Events after the Reporting Period

There were no significant events occurring after 30 June 2011.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

	2011 $'000	2010 $'000
NOTE 3: Expenses		
Note 3A: Employee Benefits		
Wages and salaries	**4 189**	3 822
Superannuation:		
Defined contribution plans	**344**	267
Defined benefit plans	**393**	410
Leave and other entitlements	**720**	898
Separation and redundancies	**-**	50
Other employee expenses	**223**	189
Total employee benefits	**5 869**	5 636
Note 3B: Suppliers		
Goods and services		
Consultants	**401**	317
Contractors	**291**	202
Stationery	**22**	17
Travel	**314**	294
Committees, board and conferences	**37**	40
Audit and legal	**360**	221
IT and communications	**918**	699
Property expenses	**97**	123
Other expenses	**168**	241
Total goods and services	**2 608**	2 154
Goods and services are made up of:		
Provision of goods - external parties	**145**	193
Rendering of services - related entities	**206**	503
Rendering of services - external parties	**2 257**	1 458
Total goods and services	**2 608**	2 154
Other supplier expenses		
Operating lease rentals - external parties:		
Minimum lease payments	**461**	465
Workers compensation expenses	**45**	58
Total other supplier expenses	**506**	523
Total supplier expenses	**3 114**	2 677
Note 3C: Depreciation and Amortisation		
Depreciation:		
Property, plant and equipment	**102**	321
Leasehold improvements	**104**	63
Total depreciation	**206**	384
Intangibles:		
Computer Software	**589**	589
Total amortisation	**589**	589
Total depreciation and amortisation	**795**	973

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

	2011 $'000	2010 $'000
NOTE 3: Expenses (cont..)		
Note 3D: Write-Down and Impairment of Assets		
Asset write-downs and impairments from:		
Impairment on intangible assets	**-**	166
Revaluation decrements:		
Property, plant and equipment	**-**	22
Total write-down and impairment of assets	**-**	188
Note 3E: Losses from Asset Sales		
Property, plant and equipment:		
Proceeds from sale	**-**	-
Carrying value of assets sold	**6**	1
Intangibles:		
Proceeds from sale	**24**	-
Carrying value of assets sold	**24**	-
Total losses from asset sales	**6**	1
NOTE 4: Income		
REVENUE		
Note 4A: Sale of Goods and Rendering of Services		
Rendering of services - related entities	**39**	160
Rendering of services - external parties	**448**	33
Total sale of goods and rendering of services	**487**	193
Note 4B: Other Revenue		
Funding from State and Terrritory governments	**3 493**	3 539
Total funding from State and Territory govenments	**3 493**	3 539

Funding from State and Territory governments includes $199,893 revenue (2010: $111,000) which had been previously received and recognised as unearned revenue.

Gains

Note 4C: Other Gains		
Resources received free of charge	**94**	80
Total other gains	**94**	80

REVENUE FROM GOVERNMENT

Note 4D: Revenue from Government		
Appropriations:		
Departmental appropriation	**5 948**	5 712
Total revenue from Government	**5 948**	5 712

Departmental outputs includes $340,358 revenue (2010: $189,000) which had been previously received and recognised as unearned revenue.

	2011 $'000	2010 $'000
NOTE 5: Financial Assets		
Note 5A: Cash and Cash Equivalents		
Cash on hand or on deposit	**36**	210
Total cash and cash equivalents	**36**	210
Note 5B: Trade and Other Receivables		
Goods and Services:		
Goods and services - related entities	**-**	31
Goods and services - external parties	**1**	-
Total receivables for goods and services	**1**	31
Other receivables:		
GST receivable from the Australian Taxation Office	**49**	85
Special Account - cash held in the OPA	**8 719**	8 506
Total other receivables	**8 768**	8 591
Total trade and other receivables (gross)	**8 769**	8 622
Total trade and other receivables (net)	**8 769**	8 622
Receivables are expected to be recovered in:		
Less than 12 months	**8 769**	8 622
Total trade and other receivables (net)	**8 769**	8 622
Receivables are aged as follows:		
Not overdue	**8 769**	8 622
Total receivables (gross)	**8 769**	8 622

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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	2011 $'000	2010 $'000
NOTE 6: Non-Financial Assets		
Note 6A: Leasehold improvements		
Fair value	**157**	157
Accumulated depreciation	**(120)**	(16)
Total leasehold improvements	**37**	141

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	**467**	293
Accumulated depreciation	**(133)**	(39)
Total property, plant and equipment	**334**	254

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 (2010: $108,005) and no increments for plant and equipment (2010: $83,668) were credited to the asset revaluation reserve by asset class and included in the equity section of the balance sheet. No Decrements were expensed (2010: $21,540).

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.

Note 6C: Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2010-11)

	Leasehold improvements $'000	Other property, plant and equipment $'000	Total $'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 *	-	188	188
Depreciation expense	(104)	(102)	(206)
Disposals:			
Other		(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**

* Disaggregated additions information are disclosed in the Schedule of Asset Additions.

NOTE 6: Non-Financial Assets (cont..)

Note 6C: Reconciliation of the Opening and Closing Balances of Property, Plant and Equipment (2009-10) (cont..)

	Leasehold improvements	Infrastructure plant and equipment	Total Property, Plant and Equipment
	$'000	$'000	$'000
As at 1 July 2009			
Gross book value	265	1 135	1 400
Accumulated depreciation and impairment	(169)	(652)	(821)
Net book value 1 July 2009	**96**	**483**	**579**
Additions *	-	32	32
Revaluations and impairments recognised in other comprehensive income	108	83	191
Revaluations recognised in the operating result	-	(22)	(22)
Depreciation expense	(63)	(321)	(384)
Disposals:			
Other disposals	-	(1)	(1)
Net book value 30 June 2010	**141**	**254**	**395**
Net book value as of 30 June 2010 represented by:			
Gross book value	157	293	450
Accumulated depreciation and impairment	(16)	(39)	(55)
	141	**254**	**395**

* Disaggregated additions information are disclosed in the Schedule of Asset Additions.

	2011	2010
	$'000	$'000
Note 6D: Intangibles		
Computer software		
Internally developed - in use	**2 566**	2 453
Purchased	**527**	660
Total computer software (gross)	**3 093**	3 113
Accumulated amortisation	**(1 798)**	(1 503)
Total computer software (net)	**1 295**	1 610
Total intangibles	**1 295**	1 610

Apart from the matter referred to in Note 3D, 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
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for the year ended 30 June 2011

NOTE 6: Non-Financial Assets (cont..)

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 *	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**

* Disaggregated additions information are disclosed in the Schedule of Asset Additions.

Note 6E (Cont..): Reconciliation of the Opening and Closing Balances of Intangibles (2009-10)

Item	Computer software internally developed	Computer software purchased	Total
	$'000	$'000	$'000
As at 1 July 2009			
Gross book value	1 839	555	2 394
Accumulated amortisation and impairment	(337)	(410)	(747)
Net book value 1 July 2009	**1 502**	**145**	**1 647**
Additions *	613	105	718
Impairments recognised in the operating result	(166)	-	(166)
Amortisation	(467)	(122)	(589)
Net book value 30 June 2010	**1 482**	**128**	**1 610**
Net book value as of 30 June 2010 represented by:			
Gross book value	2 453	660	3 113
Accumulated amortisation and impairment	(971)	(532)	(1 503)
	1 482	**128**	**1 610**

* Disaggregated additions information are disclosed in the Schedule of Asset Additions.

NATIONAL BLOOD AUTHORITY
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	2011 $'000	2010 $'000
NOTE 6: Non-Financial Assets (cont..)		
Note 6F: Other Non-Financial Assets		
Prepayments	**64**	57
Total other non-financial assets	**64**	57
Total other non-financial assets are expected to be recovered in :		
No more than 12 months	**64**	57
Total other non-financial assets	**64**	57
No indicators of impairment were found for other non-financial assets.		
NOTE 7: Payables		
Note 7A: Suppliers		
Trade creditors and accruals	**427**	644
Total supplier payables	**427**	644
Supplier payables expected to be settled within 12 months:		
Related entities	**38**	23
External parties	**389**	621
Total supplier payables	**427**	644
Settlement is usually made within 30 days.		
Note 7B: Other Payables		
Salaries and wages	**130**	98
Unearned income from States and Territories	**438**	638
Unearned income from Commonwealth	**856**	1 087
Total other payables	**1 424**	1 823
Total other payables are expected to be settled in:		
No more than 12 months	**1 424**	1 823
Total other payables	**1 424**	1 823
NOTE 8: Provisions		
Note 8A: Employee Provisions		
Leave	**1 213**	1 194
Total employee provisions	**1 213**	1 194
Employee provisions are expected to be settled in:		
No more than 12 months	**498**	559
More than 12 months	**715**	635
Total employee provisions	**1 213**	1 194

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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	2011 $'000	2010 $'000
NOTE 9: Cash Flow Reconciliation		
Reconciliation of cash and cash equivalents as per Balance Sheet to Cash Flow Statement		
Cash and cash equivalents as per:		
Cash flow statement	**36**	210
Balance sheet	**36**	210
Difference	**-**	-
Reconciliation of net cost of services to net cash from operating activities:		
Net cost of services	**(5 710)**	(5 663)
Add revenue from Government	**5 948**	5 712
Adjustments for non-cash items		
Depreciation / amortisation	**796**	973
Net write-down of non-financial assets	**-**	188
Loss on disposal of assets	**6**	1
Changes in assets and liabilities:		
(Increase) / decrease in net receivables	**(147)**	(86)
(Increase) / decrease in non-financial assets	**(5)**	18
Increase in employee provisions	**16**	10
Increase / (decrease) in supplier payables	**(51)**	195
(Decrease) in other payables	**(565)**	(476)
Net cash from operating activities	**288**	872

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NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

NOTE 10: Contingent Liabilities and Assets

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

	2011	2010
	$	$
Short-term employee benefits:		
Salary	**983 219**	831 523
Annual leave accrued	**40 119**	8 921
Performance bonuses	**-**	34 819
Vehicle allowances	**64 050**	55 322
Retention bonuses	**-**	35 000
Total short-term employee benefits	**1 087 388**	965 585
Post-employment benefits:		
Superannuation	**153 984**	139 266
Total post-employment benefits	**153 984**	139 266
Other long-term benefits:		
Long-service leave accrued	**36 423**	37 806
Long-service leave taken	**24 902**	14 256
Total other long-term benefits	**11 521**	23 550
Total	**1 252 893**	1 128 401

Notes
Note 11A was prepared on an accrual basis and excludes acting arrangements and part-year service where remuneration expensed was less than $150,000.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

Note 11B: Average Annual Remuneration Packages and Bonus Paid for Substantive Senior Executives as at the end of the Reporting Period

	as at 30 June 2011					as at 30 June 2010				
Fixed Elements and Bonus Paid [1]	**Senior Executives No.**	**Fixed Elements Salary $**	**Allowances $**	**Total $**	**Bonus Paid [2] $**	**Senior Executives No.**	**Fixed Elements Salary $**	**Allowances $**	**Total $**	**Bonus Paid [2] $**
Total remuneration (including part-time arrangements):										
$150,000 to $179,999						2	143,891	29,680	173,571	-
$180,000 to $209,999	2	161,357	30,423	191,780	-	1	206,700	-	206,700	-
$210,000 to $239,999	2	201,120	15,836	216,956	-	1	180,000	31,000	211,000	-
$240,000 to $269,999	1	265,202	-	265,202	-	1	256,209	-	256,209	34,819
Total	5					5				

Notes

1. This table reports on substantive senior executives who are employed by the entity as at the end of the reporting period. Fixed elements are based on the employment agreement of each individual - each row represents an average annualised figure (based on headcount) for the individuals in that remuneration package band (i.e. the 'Total' column).

2. Represents average actual bonuses paid during the reporting period. The 'Bonus paid' is excluded from the 'Total' calculation, (for the purpose of determining remuneration package bands). The 'Bonus paid' within a particular band may vary between financial years due to factors such as individuals commencing with or leaving the entity during the financial year.

Variable Elements:

With the exception of performance bonuses, variable elements are not included in the 'Fixed Elements and Bonus Paid' table above. The following variable elements are available as part of senior executives' remuneration package:

(a) On average senior executives are entitled to the following leave entitlements:
• Annual Leave (AL): entitled to 20 days (2010: 20 days) each full year worked (pro-rata for part-time SES);
• Personal Leave (PL): entitled to 18 days (2010: 18 days) or part-time equivalent;
• Long Service Leave (LSL): in accordance with Long Service Leave (Commonwealth Employees) Act 1976;

(b) Senior executives are members of one of the following superannuation funds:
• Commonwealth Superannuation Scheme (CSS): this scheme is closed to new members, and employer contributions currently average 28.3 per cent (2010: 24 per cent) (including productivity component). More information on CSS can be found at http://www.css.gov.au;
• Health Super. More information on Health Super can be found at http://www.healthsuper.com.au;
• UniSuper. More information on UniSuper can be found at http://www.unisuper.com.au.

(c) Various salary sacrifice arrangements are available to senior executives including superannuation, motor vehicle and expense payment fringe benefits.

NATIONAL BLOOD AUTHORITY
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Note 11C: Other Highly Paid Staff

During the reporting period, apart from the senior executives disclosed in Note 11A and Note 11B, there were no employees whose salary plus performance bonus was $150,000 or more.

	2011 $'000	2010 $'000
NOTE 12: Remuneration of Auditors		
Financial statement audit services were provided free of charge to the NBA.		
The fair value of the services provided was	**94**	80
	94	80

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	**36**	210
Trade and other receivables	**1**	31
Carrying amount of financial assets	**37**	241
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**427**	644
Carrying amount of financial liabilities	**427**	644

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'.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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NOTES TO THE SCHEDULE OF ADMINISTERED ITEMS

NOTE 14: Income Administered on Behalf of Government	**2011 $'000**	2010 $'000
Revenue		
Non-Taxation Revenue		
Note 14A: Funding from Governments		
Commonwealth contributions	**591 889**	548 057
State & Territory contributions	**347 323**	323 138
Total funding from governments	**939 212**	871 195
Note 14B: Interest		
Deposits	**1 629**	-
Total interest	**1 629**	-
Note 14C: Other Revenue		
Other contributions	**175**	1 354
Total other revenue	**175**	1 354

NOTE 15: Expenses Administered on Behalf of Government		
Expenses		
Note 15A: Grants		
Private sector:		
Non-profit organisations	**-**	456 881
Total grants	**-**	456 881

The nature of the grants in 2010 is Deeds for the provision of services relating to blood and blood related products and bleeding disorders and related activities.

Note 15B: Supplier Expenses		
Purchases of blood products	**936 120**	400 508
Consultants	**1 114**	1 039
Other goods and services	**720**	596
Total goods and services	**937 954**	402 143
Goods and services are made up of:		
Provision of goods - external parties	**936 195**	400 536
Rendering of services - external parties	**1 759**	1 607
Total suppliers expenses	**937 954**	402 143
Note 15C: Depreciation and Amortisation		
Depreciation:		
Property, plant and equipment	**6**	-
Amortisation		
Intangibles	**304**	128
Total depreciation and amortisation	**310**	128

NOTE 16: Assets Administered on Behalf of Government	2011 $'000	2010 $'000
Financial Assets		
Note 16A: Cash and Cash Equivalents		
Cash on hand or on deposit	**41 157**	389
Total cash and cash equivalents	**41 157**	389
Note 16B: Trade and other receivables		
Goods and services receivable - external parties	**3 037**	3 037
Other receivables:		
Interest	**1 083**	-
GST receivable from Australian Taxation Office	**13 619**	10 210
Total other receivables	**14 702**	10 210
Total trade and other receivables (gross)	**17 739**	13 247
Less impairment allowance account:		
Goods and services	**(3 037)**	(3 037)
Total trade and other receivables (net)	**14 702**	10 210
Receivables are expected to be recovered in:		
No more than 12 months	**14 702**	10 210
Total trade and other receivables (net)	**14 702**	10 210
Receivables were aged as follows:		
Not overdue	**14 702**	10 210
Overdue by:		
More than 90 days	**3 037**	3 037
Total receivables (gross)	**17 739**	13 247
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)
Goods and services receivables are with entities external to the Australian Government.		
Credit terms are within 30 days from date of invoice (2010: 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)

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NOTE 16: Assets Administered on Behalf of Government (cont…)	2011 $'000	2010 $'000
Note 16C: Other investments		
Deposits [1]	**40 611**	-
Total other investments	**40 611**	-
Investments are expected to be recovered in:		
No more than 12 months	**40 611**	-
Total other investments	**40 611**	-

[1] Monies invested in term deposits with the Commonwealth Bank of Australia with a term exceeding 90 days.

Non-Financial Assets		
Note 16D: Inventories		
National Reserve inventory held for distribution	**37 996**	40 143
Other inventory held for distribution	**17 028**	27 069
Total inventories	**55 024**	67 212

During 2010-11, $475,998 of inventory held for distribution related to a net write-off of damaged and expired stock and was recognised as an expense (2010: $1,247,277). 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 16E: Property, plant and equipment		
Other property, plant and equipment:		
Fair value	**36**	-
Accumulated depreciation	**(6)**	-
Total property, plant and equipment	**30**	-

No revaluation increments for plant and equipment (2010: $nil) were credited to the asset revaluation reserve. No decrements (2010: $nil) were expensed.

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.

TABLE A: 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/amortisation and impairment	-	-
Net book value 1 July 2010	**-**	**-**
Additions*	36	36
Depreciation/amortisation 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**

* Disaggregated additions information are disclosed in the Schedule of Administered Asset Additions.

NOTE 16: Assets Administered on Behalf of Government (cont…)	2011 $'000	2010 $'000
Note 16F: Intangibles		
Computer software		
Internally developed - in use	**868**	638
Total computer software (gross)	**868**	638
Accumulated amortisation	**(497)**	(193)
Computer software (net)	**371**	445
Total intangibles (non-current)	**371**	445

TABLE B: 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 depreciation/amortisation and impairment	(193)	(193)
Net book value 1 July 2010	**445**	**445**
Additions*	230	230
Depreciation/amortisation expense	(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 depreciation and impairment	(497)	(497)
	371	**371**

* Disaggregated additions information are disclosed in the Schedule of Administered Asset Additions.

Reconciliation of the Opening and Closing Balances of Intangibles (2009-10)

	Computer software internally developed $'000	Total $'000
As at 1 July 2009		
Gross book value	563	563
Accumulated depreciation/amortisation and impairment	(65)	(65)
Net book value 1 July 2009	**498**	**498**
Additions*	75	75
Depreciation/amortisation expense	(128)	(128)
Net book value 30 June 2010	**445**	**445**
Net book value as of 30 June 2010 represented by:		
Gross book value	638	638
Accumulated depreciation and impairment	(193)	(193)
	445	**445**

* Disaggregated additions information are disclosed in the Schedule of Administered Asset Additions.

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NOTE 16: Assets Administered on Behalf of Government (cont…)	2011 $'000	2010 $'000
Note 16G: Other Non-Financial Assets		
Prepayments [1]	**75 401**	12
Total other non-financial assets	**75 401**	12

[1] In 2011, this includes a prepayment to transition the Blood Service to the Output Based Funding Model (OBFM) arrangements.

NOTE 17: Liabilities Administered on Behalf of Government

Payables

Note 17A: Suppliers		
Trade creditors and accruals [2]	**68 934**	39 496
Total suppliers	**68 934**	39 496

[2] In 2011, this includes accrued invoices from the Blood Service under the OBFM arrangements.

Supplier payables expected to be settled within 12 months:		
Related entities	**-**	26 615
External parties	**68 934**	12 881
Total suppliers	**68 934**	39 496
Settlement is usually made within 30 days		
Total liabilities administered on behalf of Government	**68 934**	39 496

NOTE 18: Administered Reconciliation Table

Opening administered assets less administered liabilities as at 1 July	**38 772**	39 033
Plus: Administered income	**941 016**	872 549
Less: Administered expenses (non CAC)	**(938 264)**	(859 152)
Administered transfers to/from Australian Government:		
Appropriation transfers from OPA:		
Annual appropriations for administered expenses (non CAC)	**5 750**	7 707
Special account:		
Transfers from OPA	**1 163 441**	943 037
Transfers to OPA	**(1 052 353)**	(964 402)
Closing administered assets less administered liabilities as at 30 June	**158 362**	38 772

NOTE 19: Administered Contingent Liabilities and Assets

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.

The Deed of Indemnity between the Red Cross and the NBA indemnifies the Red Cross in relation to the NSW and ACT Principal Sites (NAPS) and Victoria and Tasmania Principal Site (VTPS) development funding arrangements. If the NAPS or VTPS funding arrangements cease in respect of a NAPS or VTPS 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 NAPS or VTPS contract after the date when the Red Cross no longer has sufficient NAPS or VTPS funding to meet the funded obligations as a result of the cessation of the NAPS or VTPS funding.

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	2011 $'000	2010 $'000
NOTE 20: Administered Financial Instruments		
NOTE 20A: Categories of Financial Instruments		
Financial assets		
Held-to-maturity:		
Deposits	**40 611**	-
Total	**40 611**	-
Loans and receivables:		
Cash on hand or on deposit	**41 157**	389
Trade and other receivables	**1 083**	-
Total	**42 240**	389
Carrying amount of financial assets	**82 851**	389
Financial Liabilities		
At amortised cost:		
Trade and other creditors	**68 934**	39 496
Carrying amount of financial liabilities	**68 934**	39 496

Note 20B: 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 20C: 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 20D: 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 20E: 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'.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
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Note 21 Appropriations

Table A: Annual Appropriations ('Recoverable GST exclusive')

	2011 Appropriations							Appropriation applied in 2011 (current and prior years) [3] $'000	Variance $'000
	Appropriation Act			*FMA Act*					
	Annual Appropriation $'000	Appropriations reduced [1] $'000	AFM [2] $'000	Section 30 $'000	Section 31 $'000	Section 32 $'000	Total appropriation $'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:

1. Appropriations reduced under Appropriation Acts (No. 1,3,5) 2010-11: sections 10,11,12 and 15 and under Appropriation Acts (No. 2,4,6) 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.
2. Advance to the Finance Minister (AFM) - Appropriation Acts (No. 1,3,5) 2010-11: section 13 and Appropriation Acts (No. 2,4,6) 2010-11: section 15.
3. Appropriation applied for administered items reflects the transfer to the Special Account which was established under the FMA Act 1997 section 21.

	2010 Appropriations								Appropriation applied in 2010 (current and prior years) [3] $'000	Variance $'000
	Appropriation Act				*FMA Act*					
	Annual Appropriation $'000	Appropriations reduced [1] $'000	AFM [2] $'000	Section 14 (Act No. 1) $'000	Section 30 $'000	Section 31 $'000	Section 32 $'000	Total appropriation $'000		
DEPARTMENTAL										
Ordinary annual services	5,523	-	-	-	-	162	-	5,685	5,685	-
Other services										
Equity	-	-	-	-	-	n/a	-	-	-	-
Loans	-	-	-	-	-	n/a	-	-	-	-
Previous years' outputs	-	-	-	-	-	n/a	-	-	-	-
Total departmental	5,523	-	-	-	-	162	-	5,685	5,685	-
ADMINISTERED										
Ordinary annual services										
Administered items	7,707	-	-	-	-	n/a	-	7,707	7,707	-
Payments to CAC Act bodies	-	-	-	-	-	n/a	-	-	-	-
Total administered	7,707	-	-	-	-	n/a	-	7,707	7,707	-

Notes:

1. Appropriations reduced under Appropriation Acts (No. 1,3) 2009-10: sections 10,11 and 12 and under Appropriation Acts (No. 2,4) 2009-10: sections 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.
2. Advance to the Finance Minister (AFM) - Appropriation Acts (No. 1,3) 2009-10: section 13 and Appropriation Acts (No. 2,4) 2009-10: section 15.
3. Appropriation applied for administered items reflects the transfer to the Special Accounts which were established under the FMA Act 1997 sections 20 and 21.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

Note 21 Appropriations (cont…)

Table B: Unspent Departmental Annual Appropriations ('Recoverable GST exclusive')
Table B is blank for financial years 2010 and 2011.

Table C: Special Appropriations ('Recoverable GST exclusive')
Table C is blank for financial years 2010 and 2011.

Table D: Disclosure by Agent in Relation to Annual and Special Appropriations ('Recoverable GST exclusive')
Table D is blank for financial years 2010 and 2011.

Table E: Reduction in Administered Items ('Recoverable GST exclusive')
Table E is blank for financial years 2010 and 2011.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

	2011 $	2010 $

NOTE 22: Special Accounts

THE NATIONAL BLOOD ACCOUNT
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.

National Blood Account - Departmental

Balance brought forward from previous period	**8 716 068**	8 507 242
Appropriation for reporting period	**5 608 000**	5 523 000
Other receipts - State and Territory contributions	**3 292 943**	3 249 478
Other receipts	**663 797**	162 382
Total increase	**9 564 740**	8 934 860
Available for payments	**18 280 808**	17 442 102
Payments made to employees	**5 626 351**	5 441 731
Payments made to suppliers	**3 898 972**	3 284 303
Total decrease	**9 525 323**	8 726 034
Total balance carried to the next period and represented by:	**8,755,485**	8 716 068
Cash - held in the Official Public Account	**8 719 019**	8 505 743
Cash - held by the NBA	**36 466**	210 325
Total balance carried to the next period	**8 755 485**	8 716 068

National Blood Account - Administered

Balance brought forward from previous period	**170 173 030**	159 270 493
Appropriation for reporting period	**5 750 000**	4 746 000
Other receipts - Commonwealth contributions	**586 952 925**	543 120 946
Other receipts - State and Territory contributions	**344 424 339**	320 239 195
Other receipts - External parties	**14 829**	233 664
Total increase	**937 142 093**	868 339 805
Available for payments	**1 107 315 123**	1 027 610 298
Payments made to suppliers	**975 244 970**	857 437 268
Total decrease	**975 244 970**	857 437 268
Total balance carried to the next period and represented by:	**132 070 153**	170 173 030
Cash - held in the Official Public Account	**132 070 153**	169 784 434
Cash - held by the NBA	**-**	388 596
Total balance carried to the next period	**132 070 153**	170 173 030

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

	2011 $	2010 $

NOTE 22: Special Accounts (cont..)

NATIONAL MANAGED FUND (BLOOD AND BLOOD PRODUCTS)
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.

National Managed Fund (Blood and Blood Products) - Administered

Balance brought forward from previous period	**74 448 609**	63 597 682
Appropriation for reporting period	**-**	2 961 000
Other receipts - Commonwealth contributions	**4 936 113**	4 936 113
Other receipts - State and Territory contributions	**2 898 987**	2 898 987
Other receipts - External parties	**705 645**	159 900
Total increase	**8 540 745**	10 956 000
Available for payments	**82 989 354**	74 553 682
Payments made to suppliers	**145 977**	105 073
Investments made from the special account (FMA Act section 39)	**81 767 756**	-
Total decrease	**81 913 733**	105 073
Total balance carried to the next period and represented by:	**1 075 621**	74 448 609
Cash - held in the Official Public Account	**1 075 621**	74 448 609
Total balance carried to the next period	**1 075 621**	74 448 609

OTHER TRUST MONEY SPECIAL ACCOUNT
On 12 October 2010, the Minister for Finance and Deregulation issued Determination 2010/13 abolishing the "Other Trust Moneys - National Blood Authority Special Account" which had been established under section 20 of the *Financial Management and Accountability Act 1997*. *During* the financial years 2010 and 2011, the account had a nil balance and there were no transactions debited or credited to it.

NOTE 23: Compensation and Debt Relief

Administered
No 'Act of Grace' expenses were incurred during the reporting period. (2010: 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* . (2010: no waivers)

No ex gratia payments were provided during the reporting period. (2010: no payments)

Departmental
No payments were made under the Defective Administration Scheme during the reporting period. (2010: no payments)

No payments were made under section 73 of the *Public Service Act 1999* during the reporting period. (2010: no payments)

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

Note 24: Reporting of Outcomes

Note 24A: Net Cost of Outcome Delivery

Particulars	Outcome 1	
	2011	2010
	$'000	$'000
Expenses		
Administered	**938 264**	859 152
Departmental	**9 784**	9 475
Total expenses	**948 048**	868 627
Income from non-government sector		
Administered		
Activities subject to cost recovery	**-**	-
Other	**349 127**	324 492
Total administered	**349 127**	324 492
Departmental		
Activities subject to cost recovery	**-**	-
Other	**4 074**	3 812
Total departmental	**4 074**	3 812
Total	**353 201**	328 304
Other own-source income		
Administered	**-**	-
Departmental	**-**	-
Total	**-**	-
Net cost / (contribution) of outcome delivery	**594 847**	540 323

The National Blood Authority operates under one outcome and one output. Transactions reported under this output are reported in 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 are eliminated in calculating the actual Budget Outcome. Refer to Outcome 1 Resourcing Table in this Annual Report.
Costs recovered include contributions from State and Territory governments.

Note 24B: Major Classes of Departmental Expense, Income, Assets and Liabilities by Outcomes

Particulars	Outcome 1	
	2011	2010
	$'000	$'000
Departmental Expenses		
Employees	**5 869**	5 636
Suppliers	**3 114**	2 677
Depreciation and amortisation	**795**	973
Other expenses	**6**	189
Total	**9 784**	9 475
Departmental Income		
Income from government	**5 948**	5 712
Sales of goods and services	**3 980**	3 732
Other non-taxation revenue	**94**	80
Total	**10 022**	9 524
Departmental Assets		
Cash and cash equivalents	**36**	210
Trade and other receivables	**8 769**	8 622
Leasehold Improvements	**37**	141
Infrastructure, plant and equipment	**334**	254
Intangibles	**1 295**	1 610
Other non-financial assets	**64**	57
Total	**10 535**	10 894
Departmental Liabilities		
Suppliers	**427**	644
Other payables	**1 424**	1 823
Employee provisions	**1 213**	1 194
Total	**3 064**	3 661

Outcome 1 is described in Note 1.1. Net costs shown include intra-government costs that are eliminated in calculating the actual Budget Outcome.

NATIONAL BLOOD AUTHORITY
NOTES TO AND FORMING PART OF THE FINANCIAL STATEMENTS
for the year ended 30 June 2011

Note 24: Reporting of Outcomes (cont…)

Note 24C: Major Classes of Administered Expenses, Income, Assets and Liabilities by Outcomes

Particulars	Outcome 1	
	2011	2010
	$'000	$'000
Administered expenses		
Grants	**-**	456 881
Suppliers	**937 954**	402 143
Amortisation	**310**	128
Total	**938 264**	859 152
Administered income		
Provision of goods - related entities	**591 889**	548 057
Provision of goods - external parties	**347 323**	323 138
Interest	**1 629**	-
Other	**175**	1 354
Total	**941 016**	872 549
Administered assets		
Cash and cash equivalents	**41 157**	389
Receivables	**14 702**	10 210
Investments	**40 611**	-
Inventories	**55 024**	67 212
Property, plant and equipment	**30**	-
Intangibles	**371**	445
Other non-financial assets	**75 401**	12
Total	**227 296**	78 268
Administered liabilities		
Suppliers	**68 934**	39 496
Total	**68 934**	39 496

Outcome 1 is described in Note 1.1.

APPENDICES

APPENDIX 1. 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 products and blood-related 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 2. 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 products including:

- 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:

- Octapharma Australia and Lateral Diagnostics for the provision of overseas-sourced intravenous immunoglobulin (IVIg)
- Baxter Healthcare, Pfizer Australia and Novo Nordisk Pharmaceuticals Pty Ltd, for the provision of a range of imported plasma-derived and recombinant blood products
- CSL Limited, Lateral Diagnostics, Johnson & Johnson Medical (trading as Ortho-Clinical Diagnostics) and Abacus ALS Pty Ltd, 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*.

Australian Health Ministers' Conference

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. In 2010–11 health ministers:

- approved the *2010–11 to 2012–13 Statement of Expectations for the Australian Red Cross Blood Service*
- endorsed the proposed combined government response and plan to implement the recommendations of the *Administrative Review of the National Blood Arrangements 2009*
- approved the *Statement on national stewardship expectations for the supply of blood and blood products*
- agreed to the recommended nominations for membership to the NBA Board
- approved the NSP&B 2011–12
- approved the policy principles of the output based funding model.

The Hon Catherine King MP, Parliamentary Secretary to the Minister for Health and Ageing, the Hon Nicola Roxon MP, had executive responsibility for the NBA within the Australian Government health portfolio from 14 September 2010. Prior to this date the Hon Mark Butler MP was Parliamentary Secretary for Health and Ageing.

Australian Health Ministers' Advisory Council

The Australian Health Ministers' Advisory Council (AHMAC) provides support to the AHMC. 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 AHMC. The Council has no statutory power and decisions are reached by consensus.

Clinical, Technical and Ethical Principal Committee

The Clinical, Technical and Ethical Principal Committee (CTEPC) was established in 2006 to provide advice to the Australian Health Ministers' Advisory Council on a range of issues, such as:

- the 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.

Jurisdictional Blood Committee

Australian, state and territory governments are represented on the JBC, which was established by the National Blood Agreement in 2003. The JBC 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 AHMC 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*, communication links between CTEPC and the JBC were strengthened by appointing a representative of CTEPC to attend JBC meetings. During 2010–11 Dr Stephen Christley attended JBC meetings. In addition, the chair of the JBC attends relevant CTEPC 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 long-standing members stepped down including Mr Bill Heiler (NSW) and Mr Tony Sansom (Tas). Ms Bedford of WA was due to retire early in July 2011.

The members of the committee at 30 June 2011 were:

Ms Mary McDonald (Chair)	Commonwealth
Ms Donna Burton	Commonwealth
Ms Carolyn Duck	Australian Capital Territory
Ms Kim Stewart	New South Wales
Ms Kelly Burns	Northern Territory
Mr Geoff Simon	Queensland
Ms Susan Ireland	South Australia
Dr Priya Dubey	Tasmania
Ms Karen Botting	Victoria
Ms Joan Bedford	Western Australia

APPENDIX 3. NATIONAL BLOOD AUTHORITY AGENCY RESOURCE STATEMENT

The Agency Resource Statement provides details of the funding sources that the NBA drew upon in 2010–11. In addition it provides information about special accounts balances to be carried over to 2011–12.

	Actual Available Appropriations for 2010–11 ($'000)	Payments Made 2010–11 ($'000)	Balance Remaining 2010–11 ($'000)
Ordinary Annual Services			
Departmental appropriation			
Departmental appropriation	5 608	5 608	-
Total	**5 608**	**5 608**	**-**
Administered expenses			
Outcome 1:	5 750	5 750	
Total	**5 750**	**5 750**	
Total ordinary annual services	**11 358**	**11 358**	
Special Accounts			
Opening balance	253 338		
Appropriation receipts	11 358		
Non-appropriation receipts	943 890		
Payments made		1 066 685	
Closing Balance			141 901
Total Resourcing and Payments	1 208 586	1 066 685	

RESOURCES FOR OUTCOMES

This table is intended to provide details of the total funding for each outcome.
In 2010–11 the NBA operated under a single outcome.

Outcome 1— Australia's blood supply is secure and well managed

	Budget 2010–11 ($'000)	Actual Expenses 2010–11 ($'000)	Variation 2010–11 ($'000)
Output Group 1			
Special Accounts			
Administered Items	964 872	938 264	26 608
Departmental Outputs	10 918	9 784	1 134
Total for Outcome 1	975 790	948 048	27 742
Average Staffing level (number)		45	

APPENDIX 4. BIOGRAPHIES OF NBA BOARD MEMBERS

Board members are selected by the AHMC. 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 terms of appointment for all members of the Board concluded on 11 May 2011. A new Board was appointed to take up office as from 12 May 2011.

CONTINUING MEMBERS

Mr Ken Barker—financial expert

In July 2009, Mr Ken Barker retired from full-time employment as Chief Financial Officer with New South Wales Health. In that position Mr Barker was responsible for controlling and monitoring recurrent expenditure and revenue, establishing New South Wales Health's financial management policy and strategy and overseeing the business management services involving insurance, risk management, taxation, benchmarking of public hospital support services and independent financial review of public and private sector initiatives.

Mr Barker worked for New South Wales Health for 24 years and had some 42 years of experience in the New South Wales Government. He is now director of his own company, which specialises in financial management and 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 has been involved in the former New South Wales Blood Transfusion Service, nationalisation and establishment of the Australian Red Cross Blood Service, establishing national indemnity arrangements for blood and blood products, providing input into defending claims for blood-acquired HIV in New South Wales, providing input into the Stephen Review of the Australian Blood Banking and Plasma Product Sector, establishing the National Blood Authority, 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.

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 Coordination in the South Australian Department of Health. He has served as a CEO of three separate area health services in New South Wales. He is a medical practitioner and has previously 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 also a member of CTEPC.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.

She was re-appointed as Commonwealth representative to the NBA Board in May 2011.

RETIRING MEMBERS

Mr Garry Richardson—chair

Mr Garry Richardson has extensive experience in the health and financial services sectors and is a Fellow of the Australian Institute of Company Directors. Before retiring from his executive career at the end of 1997, Mr Richardson was Managing Director of National Mutual Health Insurance Pty Ltd (now known as BUPA Australia) for seven years. He was concurrently Vice President of the Australian Health Insurance Association and Board member of the International Federation of Health Funds (based in the United Kingdom).

Since retiring, Mr Richardson has been appointed to several boards in the state, Commonwealth, private and not-for-profit sectors. Mr Richardson was Chair of the NBA Board between May 2007 and May 2011. He serves as Chair of Health Super Pty Ltd, Chair of Health Super Financial Services Ltd, Independent Chair of the City of Stonnington's Audit Committee, Board member of Calvary Ministries Limited and Board member of Defence Health Limited.

Mr Rob Christie—community representative

Mr Rob Christie has a long history of community service and experience as a health consumer representative in Australia in connection with blood and blood products and the needs of patients with bleeding disorders and their families.

Mr Christie's commitment to the blood sector as a Board member of Haemophilia Foundation Australia from 1997 to 2006 resulted in his appointment as Life Governor. He spent four years as its National President, was President of Haemophilia Foundation South Australia and Board member from 1995 to 2008. He was also a member of the Coagulation User and Advisory Group with the Australian Red Cross South Australia.

He is currently the Vice-President Finance of the World Federation of Hemophilia, Montreal, Canada. Mr Christie was appointed Community Representative on the NBA Board in May 2007.

Dr Peter Lewis-Hughes AM—state and territory representative

Dr Peter Lewis-Hughes joined the Commonwealth Department of Health in 1986, working in the Australian Capital Territory and Queensland until 1995, when he was recruited by Queensland Health.

His role with Queensland Health was to implement structural reform agendas in key services such as pathology, biomedical engineering services and public health and forensic laboratory sciences. Following the Forster Review of Queensland Health in 2005, he was appointed Executive Director of Clinical and State-wide Services with responsibility for development and reform of the Queensland Health blood program, radiology services, medication services and the oral health program.

With wide-ranging experience in the health care industry at Australian Government and state levels, Dr Lewis-Hughes is especially interested in contemporary health issues as they relate to strategic and business planning for clinical services across Queensland. In 2009 he received a Queensland Health Australia Day Achievement Award for Clinical and State-wide Services. Later that year Dr Lewis-Hughes left Queensland Health but continues to provide advice on all aspects of health policy, service delivery, review and reform.

In 2010 his contribution to clinical administration and services to public pathology were nationally recognised in the Australia Day Honors List and he was made a Member of the Order of Australia.

Dr Lewis-Hughes was appointed Public Health Expert on the NBA Board in 2003 and state and territory representative in 2007.

NEW MEMBERS

Ms Gayle Ginnane—chair

Ms Gayle Ginnane was the Chief Executive Officer (CEO) of the Private Health Insurance Administration Council until her retirement in May 2008. Ms Ginnane has spent 29 years working in the public sector, including the Australian Taxation Office, the Australian Bureau of Statistics, the Department of Defence, the Department of Immigration and Ethnic Affairs, the Department of Foreign Affairs and Trade and the Department of Health and Ageing.

Ms Ginnane has served on the Management Committee of the Muscular Dystrophy Association ACT Branch, the Council of the Institute of Public Administration and was Chair of the St Jude's Family Service Management Committee. 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 to the Board of the National Childcare Accreditation Council in June 2008, is a member of the Board of the ACT Division of General Practice and is in a similar position on the Police Health Fund.

Ms Ginnane was appointed as Chair of the NBA Board in May 2011.

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 & Chief Investment Officer for the Mercantile Mutual (ING) Group in Sydney from 1987-1995. 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 career experience includes directorships of many ING owned companies in Australia and also many companies offshore, primarily in Canada, Japan, Malaysia and New Zealand. As CEO of ING Australia, Mr Bedbrook was an active director of the ING Charitable Foundation and he also served as a director of the industry organisation, the Investment and Financial Services Association from 2004-2008. He brings a wealth of senior executive, board governance and financial services knowledge and experience.

Mr Bedbrook was appointed community representative on the NBA Board in June 2011.

Adjunct Professor Chris Brook PSM—state and territory representative

Adjunct Professor Chris Brook is the Executive Director, Wellbeing, 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. This portfolio is responsible for expenditure of around $3 billon per annum, 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 AHMC meetings and is 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 (ISQua) 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 George Rubin MB BS (Hons) FRACP FAFPHM FAChAM—public health expert

Professor Rubin has been on the executives of the South Eastern Sydney and the Illawarra Area Health Services (now with the South Eastern Sydney Local Health District), first as Director of Population Health, Planning and Performance and since 2009, as Director of Clinical Governance. He is Professor of Public Health at both the Universities of Sydney and NSW and is the immediate past President of the Australasian Faculty of Public Health Medicine and Board member of the Royal Australasian College of Physicians.

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 1997-2005 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 U.S. Centers for Disease Control and Prevention and with the Ford Foundation in Bangladesh. 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.

APPENDIX 5. FRESH BLOOD COMPONENTS SUPPLIED UNDER CONTRACT BY THE BLOOD SERVICE IN 2010–11

PRODUCT NUMBER	PRODUCT NAME
1a	Whole Blood
1b	Whole Blood—Leucodepleted
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 2010–11

List of 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

List of imported IVIg products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS OR JURISDICTIONAL BLOOD ORDERS
Octapharma Australia	Octagam	Used to reduce susceptibility to infections and manage many immune system disorders (not available September 2010–June 2011)
Lateral Diagnostics	Flebogamma	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

List of imported rare bleeding and blood disorder plasma products

Baxter Healthcare	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
	WinRho	Used in the prevention of a potentially fatal form of anaemia in newborn babies of Rh (D) negative mothers
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

List of imported rare bleeding and blood disorder recombinant products

SUPPLIER	PRODUCT TYPE/TRADE NAME	CLINICAL USE APPROVED UNDER THE NATIONAL BLOOD ARRANGEMENTS
Novo Nordisk Pharmaceuticals	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	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
Wyeth Australia Pty Ltd	rFVIII/Refacto/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

APPENDIX 7. UNITS OF RED CELLS, PLATELETS AND IVIG ISSUED PER 1000 HEAD OF POPULATION BY STATE AND TERRITORY 2007–08 TO 2010–11

FIGURE A7.1 *Units of red cells issued per 1000 head of population by state and territory, 2007–08 to 2010–11*

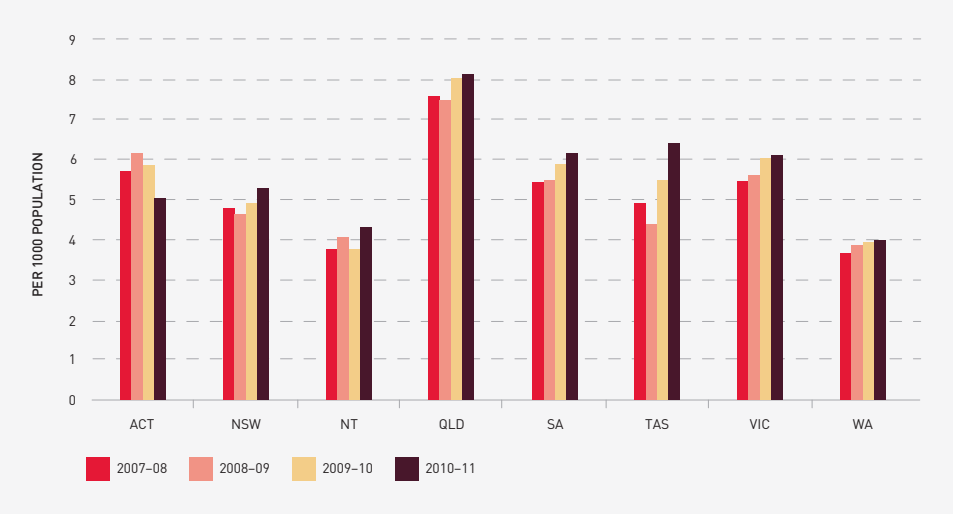

FIGURE A7.2 *Units of platelets issued per 1000 head of population by state and territory, 2007–08 to 2010–11*

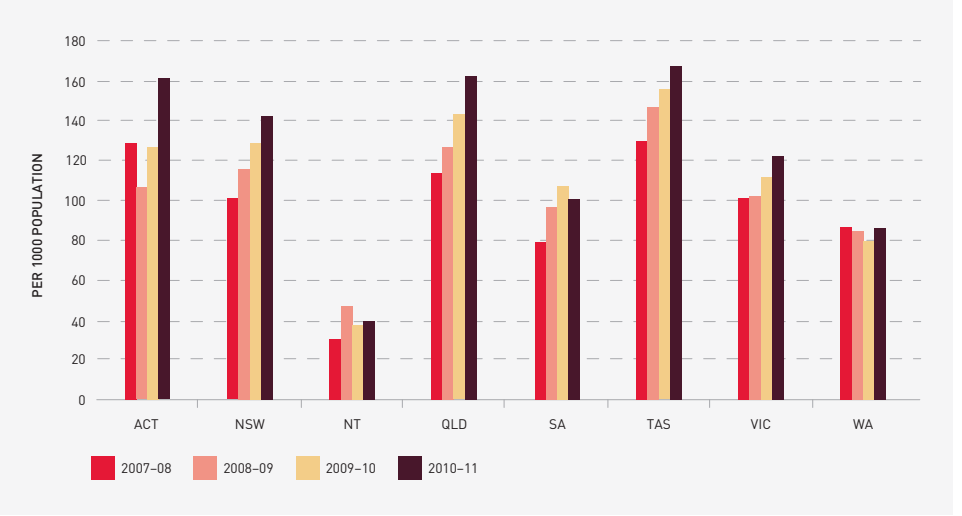

FIGURE A7.3 *Units of IVIg issued per 1000 head of population by state and territory, 2007–08 to 2010–11*

APPENDIX 8. BIOGRAPHIES OF NBA SENIOR MANAGERS

Dr Alison Turner, BVs, MSc, FAICD, General Manager and Chief Executive Officer

Dr Alison Turner was appointed General Manager and Chief Executive Officer of the NBA in August 2003. From 1997 to 2003 she was Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority. Before that she had held a number of senior government positions in the health and primary industries sectors and had represented Australia internationally. Dr Turner has been a director of government and not-for-profit organisations and is currently a councillor of the Australian Institute of Public Administration (ACT).

Ms Stephanie Gunn, BA(Hons), Deputy General Manager, Sector Coordination, Systems and Corporate

Ms Stephanie Gunn is the NBA's Sector Coordination, Systems and Corporate Deputy General Manager. She has qualifications in economics and 25 years of experience in the public service in areas ranging from industry taxation and regional economic and community development. Ms Gunn joined the Department of Health and Ageing in 1996, working in the Minister's office. She then moved to senior management roles in Ageing and Community Care and Corporate Management, focusing on corporate governance, procurement and planning.

Since joining the NBA in November 2003, Ms Gunn has been continuously responsible for corporate and compliance activities. At various times she has been responsible for the relationship with the Blood Service, the clinical development program, and most recently our data and information activities.

Mr Andrew Mead, DipAppSc (Nursing), BHlthSc, MHlthServMgt, Deputy General Manager, Fresh Blood and Clinical Development

Mr Andrew Mead is the NBA's Deputy General Manager for Supply Management (Fresh Blood) and Blood Sector Clinical Development. He has qualifications in health services management and nursing.

Before joining the NBA, he was responsible for risk management and audit at the Australian National University. He has also held positions as General Manager of Griffith Base Hospital and Albury Base Hospital. Over the past 27 years, Mr Mead has worked in various administrative and clinical roles in the acute health care setting, including in tertiary referral and regional and rural hospitals. He has also held academic appointments at Charles Stuart University in health management and paediatrics. He has been involved in the delivery of health service management development programs in Indonesia.

Mr Mead joined the NBA in July 2008.

Mr Michael Stone, BEc, LlB, Grad. Dip. Legal Practice General Counsel and Deputy General Manager, Commercial Contracts

Since January 2010, Mr Michael Stone has been the NBA Deputy General Manager responsible for the establishment and management of commercial product supply contracts, associated supply planning and management and relationship management with the NBA's commercial suppliers. He is also the NBA's General Counsel and has worked on all major blood supply tendering and contracting processes conducted by the NBA since its establishment in 2003.

Mr Stone is admitted to legal practice and has extensive experience in providing legal advice and services for a wide range of Australian Government agencies in the fields of commercial and public law, agency governance and accountability, and the development and implementation of legislation and administrative schemes. He has previously had substantial legal experience with the Australian Government Solicitor and worked on the development of the National Blood Agreement and establishment of the NBA in the Legal Services Branch of the Australian Government.

Mr Stone has worked with the NBA since its inception in 2003.

Dr Chris Hogan MB, BS, BSc(Hons), FRCPA, Principal Medical Officer

Dr Hogan is a consultant haematologist. He brings to the NBA role of Principal Medical Officer a long-term sub-specialist expertise and experience in transfusion medicine, from both a clinical and laboratory perspective. Dr Hogan provides expert medical advice across the breadth of NBA projects and responsibilities.He also has a key role in championing improvements in the appropriate use of blood and blood products for the sector. Dr Hogan continues his part-time position as consultant haematologist at the Royal Melbourne Hospital where he pursues his special interest in ABO-mismatched organ transplantation and in teaching.

Dr Hogan also sits on the Blood Matters Advisory Committee and is a member of the Royal Melbourne Hospital Blood Transfusion and Trauma Advisory Committees. He is chair of the Australian National Haemovigilance Advisory Committee and is the Australian representative on the International Haemovigilance Network. Dr Hogan is a member of the Australian Red Cross Blood Service Research Advisory Committee, the Victorian Blood User Group and IVIg User Group and the National Blood Transfusion Committee. He is a member of the Clinical Reference Groups for the Critical Bleeding, Perioperative and Medical modules of the new Patient Blood Management Guidelines. He is a member of the Education Committee of the Australian & New Zealand Society of Blood Transfusion, a NATA assessor and is an examiner in haematology for the RCPA.

Dr Hogan became the NBA's first Principal Medical Officer in 2008.

APPENDIX 9. RESPONSIBILITIES AND COMPOSITION OF NBA 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 Principal Medical Officer.

The committee is responsible for:

- identifying, considering and agreeing on strategic directions for key emerging policy issues to ensure that 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
- Mr Andrew Mead

Representatives from the Australian National Audit Office and 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 30 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 10. MANDATORY REPORTING

CHANGES TO DISABILITY REPORTING IN ANNUAL REPORTS

Since 1994, Commonwealth departments and agencies have reported on their performance as policy adviser, 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 are 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.

OCCUPATIONAL HEALTH AND SAFETY (OHS)

Comcare determined that the NBA was compliant with Section 16(2) (d) of the *Occupational Health and Safety Act 1991*, following a desktop audit of the NBA as part of its National Proactive Campaign on Health and Safety Management Arrangements (HSMA) for Commonwealth Agencies.

One reportable incident was required to be logged with Comcare during the year.

Other initiatives that were undertaken by the NBA during the year to maintain our ongoing commitment to a safe and secure workplace included:

- reports on OHS issues and wider HSMA issues being provided to our Staff Participation Forum on a regular basis
- the conduct of OHS knowledge management session (including showing an OHS video)
- the update of Material Safety Data Sheets that were made available to all staff
- the conduct of a staff participation survey, which included OHS questions (the survey results will be available early in 2011–12).

This year, the NBA implemented a new health program to assist staff in maintaining and improving their health (see page 123). The NBA also offered employees allowances for screen-based spectacles, software for assistance in managing keyboard requirements, the provision of hand sanitiser equipment upon entry to our premises and flu/swine-flu vaccinations.

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 'intergenerational principle')
- improved valuation, pricing and incentive mechanisms should be promoted (the 'valuation principle').

These principles are most relevant to our purchasing activities. In 2010–11, major improvements were made within our blood product supply contracts, with suppliers' commitments including:

- maintaining a corporate commitment to environmental health and sustainability
- increasing the recyclability of packaging of clotting factors
- investigating the feasibility of using recyclable cold chain packaging and the collection of returnable esky bags
- using reasonable endeavours to select subcontractors who commit to environmental sustainability initiatives
- recycling and landfill reduction strategies
- using plastics that are able to be recycled
- product modification to reduce packaging.

During 2010–11, the NBA continued to focus on activities aimed at maintaining and improving our environmental performance outcomes.

In relation to internal purchasing, the NBA moved from carbon neutral white A4 paper to recycled material. Sole sourcing of renewable energy for the office was maintained.

The NBA offset air travel through the GreenFleet program, which is a carbon offsetting program, reducing the impact of greenhouse gas emissions on the environment. This is achieved through the planting of native trees to soak up the gas emissions.

Feasibility studies to move key NBA committees from paper to electronic agenda papers commenced. This initiative is likely to be implemented in early 2011–12 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.

Staff continued their ongoing commitment to recycling with the result that:

- all toner cartridges and associated parts were recycled (87kgs diverted from landfill)
- there was an increase in general office recycling.

Awareness raising

The NBA has formally trained Green ICT personnel to monitor progress and raise awareness levels within the organisation. As an example, Earth Hour was again publicised within the NBA; the office was fully compliant and all staff were encouraged to participate.

In summary, the table below provides information on the impact our activities have on the natural environment and measures taken and planned to further reduce these impacts.

A number of measures introduced in 2009–10 have been maintained during the year. Some of these steps included:

- reducing energy consumption: by shutting down tenancy lighting after hours and having energy efficient lights installed and connected to movement sensors
- recycling into three streams of waste—co-mingled material, paper and printer cartridges
- ensuring that computers are defaulted to print in black and white and double sided
- encouraging staff to recycle existing stationery stock in preference to the purchasing of new items.

TABLE A9.1 *NBA Environmental performance indicators*[1]

THEME	PERFORMANCE MEASURE	INDICATOR(S)	2009–10	2010–11
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 ($/kWh)	139,701 kWh	140,900 kWh
		Amount of gas purchased/consumed ($/MJ)	0 MJ	0 MJ
		Amount of other fuels purchased/consumed ($/kWh/MJ/L)	2,356 L	0[2]
		Air travel distances (km)	543,492 km	825,716 km[3]
	Total consumption of green energy—this includes the purchase of energy from sustainable resources	Amount of green energy purchased/consumed ($/kWh) during the reporting period	139,701 kWh	140,900 kWh
	Greenhouse gas emissions	Amount of greenhouse gases produced (tonnes)	169.3 tonnes	20.22 tonnes[4]
	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%
		Amount of total energy purchased/consumed ($/kWh) per employee	2,910 kWh	2,818 kWh

1 Note that all measures are best estimates only, and are likely to change substantially as measurement capacities improve.

2 There was no amount associated with other fuels purchased/consumed in 2010–11 due to the NBA no longer having a leased car.

3 Increase is due to deployment of national ICT systems throughout Australia requiring travel for trainers, and the intensive consultation phase for clinical guideline development.

4 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.

THEME	PERFORMANCE MEASURE	INDICATOR(S)	2009–10	2010–11
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
	Un-recyclable waste production—this includes all wastes that are not re-used or recycled	Amount of gas purchased/consumed ($/MJ)		3.69 tonnes
	Recyclable waste production (excluding office paper)	Amount of waste going to recycling facilities (tonnes)		1.335 tonnes
	Paper waste production	Amount of waste paper going to recycling facilities (tonnes)		2.615 tonnes
		Amount of paper sourced from recyclable sources (tonnes)		1.99 tonnes
		Percentage of paper sourced from recyclable sources (per cent)		76%
	Use of renewable/recyclable products	Amount of products sourced from renewable/recyclable sources (tonnes)		76%
	Relative waste production	Amount of total waste (tonnes) per employee		0.15 tonnes
Water	Total consumption of water—this includes all water consumed when undertaking the functions of the agency	Amount of water purchased/consumed ($/L)	680,000 L	493,000 L[5]
	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
		Amount of grey water recycled (L	0 L	0 L
		Amount of grey water re-used(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
		Amount of captured rainwater used (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

5 The decrease in reported water consumption reflects more accurate measurement of allocation of water of our joint tenancy.

FREEDOM OF INFORMATION

From 1 May 2011 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. An agency plan showing what information is published in accordance with the IPS requirements will be accessible from agency websites.

Before the IPS commenced on 1 May 2011, subsection 8(1) of the FOI Act required each Minister responsible for an agency to publish a statement setting out details of the agency's organisation, functions and powers, public consultation arrangements, categories of documents held, and arrangements for public access to agency documents in the agency's possession. Paragraph 8(1)(b) required the Minister to publish an annual update of the agency statement. Subsection 8(3) required both the first statement and the annual updates to be published in the Agency's annual report.

The NBA must provide this information in its 2010–2011 annual report, even though this obligation will for practical purposes have been overtaken by the IPS.

The former requirement under section 8 of the FOI Act included that Australian Government agencies, amongst other things, publish information about:

- functions and decision-making powers that affect the public
- arrangements for public participation in the formulation of policy
- the categories of documents that are held by the agency
- how these documents can be accessed by the public.

In 2010–2011 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.

National Blood Authority functions and powers

Information on the NBA's structure and functions is included in this publication at pages 2, 112 and 188, as is performance information (Part 3 of this report).

Ministers and the NBA's General Manager exercise decision-making powers under the *National Blood Authority Act 2003*. The NBA operates as an Australian Government agency in which staff exercise functions and powers under Acts such as the *Financial Management and Accountability Act 1997* and the *Public Service Act 1999*. Many decisions are given effect through NBA-administered contracts with suppliers.

Arrangements for public participation

Under the National Blood Agreement, the primary responsibility for policy in the national blood sector rests with the Australian Health Ministers' Conference, supported by the JBC.

In the performance of its functions, the NBA has established consultative forums, among them a Professional and Community Forum and a Suppliers Forum. The NBA issues public consultation papers on elements of its work, including before most major blood procurement activities. The NBA also consults with a range of other expert bodies and interested parties in relation to specific projects.

Categories of documents

The NBA maintains records pertaining to the performance of its functions. Records are retained for varying periods, depending on their administrative and historical value, and are disposed of in accordance with the standards and practices approved by the National Archives of Australia under the *Archives Act 1983*. Table A9.3 shows the categories of documents held by the NBA.

TABLE A9.3 *Categories of documents held by the National Blood Authority*

CATEGORY	DESCRIPTION
Program documents	The NBA holds documents relating to: contracts and tendering processes; dealings with Australian Government and state and territory ministers, committees and other government agencies under the National Blood Agreement; and the performance of its functions under the *National Blood Authority Act 2003*.
Working files	The NBA holds working files including correspondence, analysis and advice by NBA staff, documents received from third parties, and drafts of these and other documents.
Internal administration records	The NBA holds personnel records, organisational and staffing records, financial and expenditure records and internal operating documentation such as office procedures, instructions and indexes.
Documents open to public access subject to a fee or other charge	The NBA holds no documents in this category.
Documents available for access or purchase subject to a fee or other charge	The NBA holds no documents in this category.
Documents customarily available free of charge on request	Annual reports and other documents relating to the NBA are available on the internet at www.nba.gov.au.

Procedures and contact details

A request for access to documents under the FOI Act must be in writing. Applicants must state that the request is an application for the purposes of the FOI Act, provide such information as is reasonably necessary to enable a responsible officer of the Agency, or the Minister, to identify it and provide details of how notices can be sent. There is no longer an application fee that applies to requests for information under the FOI Act.

To enable a prompt response and to help the NBA meet its obligations under the FOI Act, applicants should provide as much information as possible about the document(s) sought. We also ask that the applicant include a telephone number or an electronic mail address to allow NBA staff handling a request to seek clarification if necessary. Applicants might be liable to pay charges at rates prescribed by the *Freedom of Information (Charges) Regulations 1982*.

Inquiries about making a formal request under the Act should be made in writing to the NBA's Freedom of Information Coordinator.

Facilities for access

Physical access to documents at the NBA's premises can be arranged. Inquiries should be directed to the Freedom of Information Coordinator:

Freedom of Information Coordinator
National Blood Authority
Locked Bag 8430
CANBERRA ACT 2601

APPENDIX 11. ERRATA

Front cover—Blood Facts text—the final word should read 'material'

Page 21 Table 1.1—the asterisked footnote should read 'Includes $6 million of interest monies allocated by the Commonwealth to the Special Account'

Page 73 Photograph—the photograph included was that of the Clinical Reference Group—Medical module. The correct photograph of the Clinical/Consumer Reference Group—Perioperative module is given on page 71 of this Report.

Page 149–150 Table 7.4—the final column on the right '2010–11' should not have appeared; the data contained in it merely duplicates that in the previous column

APPENDIX 12. GLOSSARY OF TERMS AND ACRONYMS

ACRONYMS

AABB	American Association of Blood Banks
ABDR	Australian Bleeding Disorders Registry
ABS	Australian Bureau of Statistics
ACHS	Australian Council on Healthcare Standards
ACSQHC	Australian Commission on Safety and Quality in Healthcare
AD	Alzheimer's disease
AHCDO	Australian Haemophilia Centre Directors' Organisation
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Council
AHP	Approved Health Provider
ANAO	Australian National Audit Office
ANZSBT	Australian and New Zealand Society of Blood Transfusion
ARCBS	Australian Red Cross Blood Service (the Blood Service)
ARCS	Australian Red Cross Society
AWA	Australian Workplace Agreement
BARDA	Biomedical Advanced Research and Development Authority (USA)
BPAC	[FDA] Blood Products Advisory Committee (USA)
CAFA	CSL Australian Fractionation Agreement
CDC	Centers for Disease Control and Prevention (USA)
CFS	Chronic Fatigue Syndrome
CoE	Council of Europe
CSL Limited	(CSL Ltd, CSL) 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
DEHP	Di(2-ethylhexyl)phthalate
DIF	dual inactivation and nanofiltration

DoD	Department of Defense (USA)
DoHA	Australian Department of Health and Ageing
EMA	European Medicines Agency
ESA	Erythropoiesis (red blood cell) stimulating agent
EU	European Union
FDA	Food and Drug Administration (USA)
FEIBA	Factor Eight Inhibitor Bypass Agent
FFP/FP	fresh frozen plasma/frozen plasma
FOI	Freedom of Information
FTC	Federal Trade Commission (USA)
GSK	GlaxoSmithKline
GST	goods and services tax
H1N1	Pandemic influenza 2009 ('swine flu')
H5N1	avian influenza
HAC	Haemovigilance Advisory Committee
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HFA	Haemophilia Foundation of Australia
HHS	Department of Health and Human Services (USA)
HIV	human immunodeficiency virus
HmA	Haemophilia A
HmB	Haemophilia B
HSMA	Health and Safety Management Arrangements
IDMS	Integrated data management system
Ig	immunoglobulin
IPS	Information Publication Scheme
ITP	Idiopathic thrombocytopenic purpura
IU	International unit
IV	intravenous
IVIg	Intravenous immunoglobulin
IVF	in vitro fertilisation
JBC	Jurisdictional Blood Committee

KPI	key performance indicator
kWh	kilowatt hour
LIS	Laboratory information system (of AHPs)
ME	Myalgic encephalomyelitis
MMN	Multifocal motor neuropathy
MSAC	Medical Services Advisory Committee (Australia)
MSM	men who have sex with men
MVEV	Murray Valley encephalitis virus
NBA	National Blood Authority
NATA	National Association of Testing Authorities (of Australia)
NBSCP	National Blood Supply Contingency Plan
NHLBI	National Heart, Lung and Blood Institute (USA)
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
NIAID	National Institute of Allergy and Infectious Diseases (part of NIH)
NICE	National Institute for Health and Clinical Excellence (UK)
NICRWG	National IVIg Criteria Review Working Group
NIH	National Institutes of Health (USA)
NIMS	National IVIg Management System
NMF	National Managed Fund
NNDSS	National Notifiable Diseases Surveillance System
NPBMSC	National Patient Blood Management Steering Committee
NPPSpa	[collaboration of] National plasma product supply planners
NPSA	National Patient Safety Agency (UK)
NSP&B	National Supply Plan and Budget (Australia)
NTI	National Trauma Institute (USA)
OBFM	Output based funding model
OHS	Occupational Health and Safety
ORBS	Ordering and Receipting Blood System
PBM	Patient blood management
pd	plasma-derived
PID	primary immunodeficiency disease

PRP	platelet-rich plasma
PRT	pathogen reduction technology
RCPA	Royal College of Pathologists of Australasia
rFVIIa	recombinant Factor seven (A)
rFVIII	recombinant Factor eight (clotting factor)
rFIX	recombinant Factor nine (clotting factor)
RNA	Ribonucleic acid
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs (UK)
SES	Senior Executive Service
TACO	Transfusion-associated circulatory overload
TGA	Therapeutic Goods Administration (Australia)
TOPPS	Trial of prophylactic platelets study (UK-led study)
TRALI	Transfusion related acute lung injury
TTP	Thrombotic thrombocytopenic purpura
UCLA	University of California Los Angeles
vCJD	variant Creutzfeldt-Jakob Disease
vWD	von Willebrand disease
WADA	World Anti-Doping Agency
WHO	World Health Organization
WNV	West Nile virus
XMRV	Xenotropic Murine Leukaemia Virus-related virus

GLOSSARY OF TERMS

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
allogeneic transfusion	A transfusion of product taken from different individuals of the same species
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
capillary leak syndrome	A rare medical condition where the number and size of the pores in the capillaries are increased which leads to a leakage of fluid from the blood to the interstitial fluid, resulting in low blood pressure, oedema and multiple organ failure due to limited perfusion
Chagas disease	An infection caused by a protozoan parasite (Trypanosoma cruzi) that can result in acute inflammatory skin changes
Chikungunya	A disease resembling dengue fever, seen mainly in Africa, the Indian subcontinent, and Southeast Asia, caused by an arbovirus transmitted by Aedes mosquitoes
Chronic fatigue syndrome	A complex disorder characterized by profound fatigue that is not improved by bed rest and that may be worsened by physical or mental activity
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
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
Desmopressin	A drug used to treat mild von Willebrand's disease
diagnostic reagent products	Products used in blood typing and cross matching
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
Erythropoietin	A substance produced by the kidney that leads to the formation of red blood cells in the bone marrow
follow-on biologics	A term used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product
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
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 (HLA) 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
intravenous immunoglobulin	A product 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
lean body weight dosing	Dosing regimes using lean body weight calculations
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
nitric oxide scavenging	An adverse impact of blood substitutes
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
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 finding model	A funding arrangement whereby the supplier is paid for product receipted, rather than on a grant basis
Parvovirus B19	A virus infection characterised by low-grade fever, fatigue, a 'slapped cheeks rash' and a rash over the whole body. Parvovirus B19 can temporarily decrease or halt the body's production of red blood cells, causing anaemia
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
perioperative 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
pharmacokinetic dosing indicators	Dosing levels indicated by evidence from pharmacokinetic studies
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)
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
sequaelae	A pathological condition resulting from a prior disease, injury, or attack
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
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
toll manufacturing agreements	Arrangements in which a firm with specialised equipment processes raw materials or semi manufactured goods for another company. In the blood sector these arrangements are used to process plasma from specific countries into products for that country
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
West Nile virus	The mosquito-borne virus that causes West Nile fever
Xenotropic murine leukaemia virus	A virus from the Retroviridae family and the genus gammaretrovirus. It has a single-stranded RNA genome that replicates through a DNA intermediate
Yellow fever	An acute systemic illness caused by a virus from the Flavivirus genus

APPENDIX 13. LIST OF REQUIREMENTS

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
		Letter of transmittal	Mandatory	iii
		Table of contents	Mandatory	iv-vii
		Index	Mandatory	231
App. 12		Glossary of terms and acronyms	Mandatory	218
		Contact officer(s)	Mandatory	ii
		Internet home page address and Internet address for report	Mandatory	ii
	REVIEW BY SECRETARY			
2.2		General Manager's Overview	Mandatory	14
2.1 & 2.2		Summary of significant issues and developments	Suggested	12
2.2		Overview of department's performance and financial results	Suggested	
2.2		Outlook for 2011–12	Suggested	15,19
–		Significant issues and developments—portfolio	Suggested	Not applicable
	DEPARTMENTAL OVERVIEW			
1.1–1.5		Overview description of department	Mandatory	2
1.1, App. 1		Role and functions	Mandatory	2,188
5.1		Organisational structure	Mandatory	112
3.1		Outcome and program structure	Mandatory	24
–		Where outcome and program structures differ from PB 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
1.4		Portfolio structure: part of Health and Ageing portfolio	Mandatory	8

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
	REPORT ON PERFORMANCE			
2 & 3		Review of performance during the year in relation to programs and contribution to outcomes	Mandatory	12, 13, 24–80
3		Actual performance in relation to deliverables and KPIs set out in PB Statements/PAES or other portfolio statements	Mandatory	25, 56, 70
–		Where performance targets differ from the PBS/ PAES, details of both former and new targets, and reasons for the change	Mandatory	Not applicable
2.1–2.4 & 3		Narrative discussion and analysis of performance	Mandatory	12–25, 25–81
3.2		Trend information	Mandatory	9, 26, 28–36, 37, 39, 43, 46–7, 54
3.2 & 3.3, App. 5 & 6		Performance of purchaser/provider arrangements	If applicable, suggested	37–55, 199–202
		Significant changes in nature of principal functions/ services	Suggested	60
2.2 & 3.3		Factors, events or trends influencing departmental performance	Suggested	14–15, 26–36 & 84–109
3.3 & 5.1		Contribution of risk management in achieving objectives	Suggested	40, 44, 46–55, 56–60
5.3 & App. 10		Social inclusion outcomes	If applicable, mandatory	118, 210
5.2		Performance against service charter customer service standards, complaints data, and the department's response to complaints	If applicable, mandatory	52, 117
6		Discussion and analysis of the department's financial performance	Mandatory	126
–		Discussion of any significant changes from the prior year or from budget	Suggested	Not applicable
App. 3		Agency resource statement and summary resource tables by outcomes	Mandatory	192
–		Developments since the end of the financial year that have affected or may significantly affect the department's operations or financial results in future	If applicable, mandatory	Not applicable

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
	MANAGEMENT ACCOUNTABILITY			
Letter of transmittal		Agency heads are required to certify that their agency comply with the Commonwealth Fraud Control Guidelines	Mandatory	iii
5.1 & App. 2		Statement of the main corporate governance practices in place	Mandatory	112–5, 189–91
5.1		Names of the senior executive and their responsibilities	Suggested	112
5.1 & App. 9		Senior management committees and their roles	Suggested	113, 208
5.2		Corporate and operational planning and associated performance reporting and review	Suggested	116
5.1		Approach adopted to identifying areas of significant financial or operational risk	Suggested	114
5.3		Policy and practices on the establishment and maintenance of appropriate ethical standards	Suggested	118
5.3		How nature and amount of remuneration for SES officers is determined	Suggested	122
	EXTERNAL SCRUTINY			
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5.1		Judicial decisions and decisions of administrative tribunals	Mandatory	115
5.1		Reports by the Auditor-General, a Parliamentary Committee or the Commonwealth Ombudsman	Mandatory	115
	MANAGEMENT OF HUMAN RESOURCES			
5.3		Assessment of effectiveness in managing and developing human resources to achieve departmental objectives	Mandatory	119

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
5.3		Workforce planning, staff turnover and retention	Suggested	119
5.3		Impact and features of enterprise or collective agreements, individual flexibility arrangements (IFAs), determinations, common law contracts and AWAs	Suggested	120
5.3		Training and development undertaken and its impact	Suggested	122
5.3 & App. 10		Occupational health and safety performance	Suggested	123, 210
5.3		Productivity gains	Suggested	120
5.3		Statistics on staffing	Mandatory	118, 119
5.3		Enterprise or collective agreements, IFAs, determinations, common law contracts and AWAs	Mandatory	120
5.3		Performance pay	Mandatory	122
	ASSETS MANAGEMENT			
6.3		Assessment of effectiveness of assets management	If applicable, mandatory	135
	PURCHASING			
6.2		Assessment of purchasing against core policies and principles	Mandatory	131
	CONSULTANTS			
6.2		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 (additional information—refer attachment D of Guidelines—to be available on the internet or published as an appendix to the report. Information must be presented in accordance with the pro forma as set out in attachment D of the Guidelines)	Mandatory	132

REF	PART OF REPORT	DESCRIPTION	REQUIREMENT	PAGE REFERENCE
	AUSTRALIAN NATIONAL AUDIT OFFICE ACCESS CLAUSES			
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	EXEMPT CONTRACTS			
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	FINANCIAL STATEMENTS			
6.1		Financial Statements	Mandatory	136
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App. 10		Freedom of Information for the period 1 July 2010 to 30 April 2011 inclusive (see term of subsection 8(1) of the *Freedom of Information Act 1982* as it existed prior to 1 May 2011)	Mandatory	215
6.2		Advertising and Market Research (Section 311A of the *Commonwealth Electoral Act 1918*) and statement on advertising campaigns	Mandatory	132
App. 10		Ecologically sustainable development and environmental performance (Section 516A of the *Environment Protection and Biodiversity Conservation Act 1999*)	Mandatory	211
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App. 10		Disability reporting—explicit and transparent reference to agency-level information available through other reporting mechanisms	Mandatory	210
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SAVING & IMPROVING
AUSTRALIAN LIVES
THROUGH A WORLD-CLASS
BLOOD SUPPLY

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