Review of the Australian Blood Banking and Plasma Product Sector

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Review of the Australian Blood Banking and Plasma Product Sector

March 2001

A report to the Commonwealth Minister for Health and Aged Care
by a committee chaired by the Rt Hon Sir Ninian Stephen.

Review of the Australian Blood Banking and Plasma Product Sector

The Hon Dr Michael Wooldridge MP
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear Minister

I have pleasure in submitting, on behalf of the Committee, the first and final report of the Review of the Australian Blood Banking and Plasma Product Sector.

Your decision to establish a comprehensive examination of Australia's blood and blood product needs has proved timely in view of the rapidly changing environment in the area of blood and blood products that Australia and other nations face.

Australia has an enviable record in the provision of safe, high quality blood transfusion services and Australian volunteer blood donors have played an important part in this achievement; continuing support of donors in the future is essential.

Two concerns have predominated in the Committee's deliberations - ensuring that Australians continue to have access to safe, high quality blood transfusion services and that Australia is well equipped to meet future challenges. These are crucial public health matters requiring a strong national approach by States, Territories and the Commonwealth.

Over recent years all Australian Governments having been working towards a national approach to blood supply matters. Important initiatives have been put in place. The Review has sought to build on these initiatives and has proposed additional measures which concentrate on strengthened governance and financing arrangements; quality assurance in supply and use and ongoing monitoring and review. We believe that the measures recommended will provide a firm foundation for the future.

The Review thanks all those individuals and organisations who have contributed views and information which have assisted the Committee's understanding and its deliberations. In particular the members of the Committee are grateful indeed for the unfailing enthusiasm and highly professional assistance of the Secretariat throughout the period of the Review.

I commend the report to you.

Sincerely

Ninian Stephen
Chairman
27 March 2001

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Contents

List of tables

List of figures

Executive summary

This is the first and final report of the Review of the Australian Blood Banking and Plasma Product Sector.

The Review has involved a comprehensive examination of that part of the health system responsible for meeting Australia's blood and blood product needs. Activities range from the giving of blood by volunteer donors, collection, testing and banking of blood, through to processing and production of blood and plasma products, and their distribution and clinical use. The sector is funded largely by State, Territory and Commonwealth governments and is subject to governance, financing and legislative arrangements.

Following a previous review of aspects of the sector in 1995 (the McKay Wells review), Australian governments have implemented a series of measures aimed at creating a truly national blood service and assuring the safety and quality of the blood supply.

The current Review was established in 1999 by the Commonwealth Minister for Health and Aged Care to consider developments to date, to assess current and future needs and to advise on areas for improvement.

The Review's terms of reference were as follows.

1 Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best-practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.

2 Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.

3 Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time. Among other things, the advice should cover:

   — the need for and financial impact of new testing procedures and new products;
   — legal and ethical issues where access to products may have to be based on clinical priorities;
   — cost effectiveness of proposed safety improvements;
   — the role of an expert reference laboratory in setting and maintaining a national quality assurance program; and
   — the impact of change on public confidence in the blood supply.

4 Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.

5 Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.

The approach of the Review Committee to its wide-ranging terms of reference was to establish an understanding of the sector, seek views and assess performance, identify and assess Australia's needs, examine how well positioned Australia is to meet these needs, and consider and assess strategies for improvement. The Review did not seek to change two fundamentals — the giving of blood by voluntary donors and the provision of blood and blood products from donated blood free of charge to patients.

Origins and evolution of the sector

The origins of blood banking are linked to the emergence of blood transfusion as therapy for blood loss and deficiencies, and there are continual advances and developments in both fields. Over many years, a complex set of relationships and functions has evolved:

- the volunteer donors who are the foundation of Australia's blood supply;
- the Australian Red Cross, the provider of the national blood service (Australian Red Cross Blood Service);
- the national plasma fractionator, CSL Limited, a public company with contractual obligations to the Commonwealth Government; and
- governments — the States, Territories and Commonwealth — that jointly fund Australia's blood supply, make the laws that deal with the sector, and determine and implement blood policies.

The complexity of the current arrangements is a result of the range of activities and organisations involved, as well as the evolution from separate State and Territory based bodies. While there have been moves towards a national focus, with State and Territory blood transfusion services uniting to form a national blood service in 1996, there remains a division of responsibilities between States, Territories and the Commonwealth.

Drawing the sector together — taking a national approach

During the coming decades, Australia will face a national and international environment that is fast changing and uncertain, posing significant public policy questions. Ensuring access to a safe, secure and affordable supply of blood and blood products and supporting their appropriate use, are important public health matters. To meet Australia's needs, there should be a national approach to the supply of blood and blood products that delivers efficient and effective services, responds promptly to new and emerging developments and develops responsible and responsive policies.

Governance arrangements must be strengthened. The extent of national management and oversight should be increased. There must be recognition of the roles and responsibilities of States, Territories and the Commonwealth within a contemporary governance framework with national accountability. Current approaches to financing and information management should be enhanced. There are substantial efficiency gains to be made.

The Review recommends that a National Blood Authority be established, as a priority, to provide national management and oversight of Australia's blood supply.

New governance and financing arrangements should be simpler, with single lines of accountability and clear, consultative relationships established between governments and key organisations. Specifically, the new arrangements would comprise the following interrelated elements:

- national policy development by Commonwealth, State and Territory governments, with advice drawn where possible from existing arrangements and structures within the health system as well as from the National Blood Authority;
- national supply planning and management by the National Blood Authority;
- independent national regulation of blood supply safety and quality by the Therapeutic Goods Administration;
- national quality assurance in supply and use to ensure quality standards and practices, with national coordination of approaches by a range of organisations; and
- supporting national financing and legislative arrangements by States, Territories and the Commonwealth.

It is important that changes are linked to developments in the health system. Advice on blood matters should be developed in the context of national public health and risk management applicable to Australia's circumstances. Evidence-based assessments should be adopted and results disseminated. Emerging scientific, technological and other developments should be monitored.

Safety and quality of the blood supply

Blood banking is a service where a focus on donors and recipients as well as on manufacturing processes and supply is crucial. There has been significant investment in assuring a safe, high quality blood supply. Material before the Review suggests that, while the Australian blood supply is safer than it has ever been, there is still scope for improvement.

Australia's achievement of near self-sufficiency in its supply of blood and plasma products gives Australia a high level of control over the quality of future supplies. Under these circumstances, continuing high levels of safety and quality should be achievable, as long as careful national policy measures and strong regulatory oversight are maintained.

Uniform national standards for donor selection and for the collection, testing, processing, storage and transport of blood and blood products are critical to assuring the safety and quality of Australia's supply. There should be continuing assessment of the impact of the Commonwealth regulatory regime that took effect from July 2000, with reporting to Australian Health Ministers on requirements to achieve uniform national standards.

Australia has a number of programs providing external oversight of quality assurance in laboratory testing of the blood supply. The Review recommends that they be coordinated nationally.

Safe, high quality use of blood and blood products

Future sustainable improvements in safety and quality of blood transfusion will require quality assurance approaches that cover the spectrum from donors to recipients and that strike a balance between regulatory and other approaches.

Opportunities for significant public health and safety gains lie in the better use of blood and blood products and alternatives. While improvements in the safety and quality of the blood supply will depend largely on national coordination, better use of blood and blood products will rely more on action in hospitals. This will include the adoption of guidelines, policy and program development, data collection, audit, and patient and staff education. All hospitals that regularly perform blood transfusion should have an

appropriately supported group to implement and oversee quality assurance. Establishment of hospital transfusion committees, or their equivalent, should be linked to existing hospital accreditation requirements.

Activities should be supported by national initiatives such as development and implementation of clinical practice guidelines, formal evaluation of interventions to promote better transfusion practice, dissemination of results, and development of performance indicators for monitoring hospital transfusion practice.

The Review also recommends establishment of a national, voluntary, confidential scheme to monitor untoward transfusion events and outcomes in hospitals (a haemovigilance scheme) and to provide data that places Australian transfusion risks in perspective. Efforts in this area should be a component of adverse events monitoring in Australian hospitals and part of a national approach to improve patient safety.

Planning and managing the blood supply

Self-sufficiency in blood and blood products is a national and international obligation and responsibility, and should remain an important national goal for Australia. The Commonwealth Government should monitor the goal's appropriateness, relevance and application in light of scientific, technological and other developments in transfusion medicine and patient care.

Planning and managing Australia's blood supply requires a national strategic approach, not single product approaches. Understanding supply needs, the factors that underpin the donation of blood and drive supply and use, and the most appropriate collection methods and systems is critical. The blood and plasma given by Australia's volunteer donors are sources for many therapeutic products. Reliance on whole blood collections when plasma is the market driving force may result in unused fresh blood components, product wastage and associated ethical concerns. Similarly, plasma is a source of several therapeutic products that are extracted simultaneously. Increased production in one product generally results in a similar production increase in another.

A national blood service is vital. Reflecting the national move towards simpler administrative arrangements, there should be a single service delivery and funding agreement between the Commonwealth and the ARCBS for the provision of the national blood service, with agreements between the Commonwealth and States and Territories regarding supply needs, service requirements and priorities. The Review has made a number of other recommendations to strengthen the national blood service.

There should also be a national arrangement to replace the existing State and Territory based approaches for the provision of imported blood products and related products to achieve equity in access and efficiency in purchasing and administration.

The National Blood Authority should develop a contingency planning strategy for Australia's blood supply. The strategy should draw on Australian and overseas expertise and experience in crisis management and contingency planning, and include monitoring of product markets and developments nationally and internationally.

Plasma fractionation

Australia's future plasma fractionation needs are best met through the national facility operated by CSL. This should be managed through some form of contract similar to the Plasma Fractionation Agreement. The national imperative is that Australia's needs for plasma products are met and that CSL's fractionation of foreign plasma does not pose

any significant risks to the safety and quality of domestic products and to product recipients. Clear lines of responsibility and accountability, and performance monitoring, reporting and review, should be incorporated into the Agreement.

Supply arrangements should enable systematic consideration of new product developments and innovations in patient care. Plasma products and their substitutes should be considered in the same way as other therapeutic goods marketed in Australia. Australian governments should seek expert advice on the potential place and costs of new plasma products and substitutes in the Australian supply from the Pharmaceutical Benefits Advisory Committee. Some supporting legislative and regulatory changes are required.

Future arrangements for the manufacture and supply of a range of diagnostic products for blood testing, typing and cross-matching made by CSL from human blood supplied by the ARCBS also need to be considered.

Information, monitoring and research

A recurring Review theme is the need to enhance information and research capacity within the sector.

The Review encountered a lack of information in the public domain about activities within the existing set of arrangements. The lack of nationally consistent and comprehensive information about many aspects, from donor management through to product usage and patient outcomes, has hampered analysis. While data may be collected regionally or in institutions, there is limited capacity to draw together routinely information from a number of sources and build a national picture of activity and performance.

As well as national information management, important needs include forming links with the wider public health sector (eg in communicable disease surveillance) and improving the evidence base for transfusion practice. As a first step, the National Blood Authority should develop a national information management and reporting plan for the Australian blood sector. This should include development of a range of indicators for monitoring performance.

The way forward — recommendations for action

The Review has involved a comprehensive examination of the blood banking and plasma product sector, with development of recommendations about various aspects as directed by the terms of reference. The primary aim of the recommendations is to ensure that Australia is equipped to meet emerging and future challenges, to provide an adequate and secure supply of safe, high quality blood and blood products and to promote appropriate clinical use.

The recommendations represent an integrated package, with several mechanisms for ongoing monitoring and review. These are essential given the need for Australian governments to respond to the changing national and international environment.

A summary of the recommendations follows, for ease of reference. This is followed by a list of the recommendations against the Review's terms of reference, which cites the sections in specific chapters of the report where the recommendations are given in full, together with the reasoning behind them.

Summary of recommendations

1 A National Blood Authority

A National Blood Authority should be established as a priority as a statutory body under Commonwealth legislation to provide national management and oversight of the Australian blood supply, which will, as in the past, be based on voluntary donation and with the products from donated blood provided free of charge to patients. The Commonwealth Government should provide funding for the establishment and operation of the Authority. (Section 4.2)

The National Blood Authority should comprise a Board with an independent chairman and nominees of State, Territory and Commonwealth governments drawn from the public and private sectors. The Board should ensure close consultative arrangements are established with providers of blood and blood product services, clinicians, professional groups and the community. (Section 4.2)

The National Blood Authority should:

- manage and plan Australia's blood and blood product supply to meet current and future needs;
- develop and implement national contingency planning to manage supply risks;
- administer service delivery and funding agreements established between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and providers of blood and blood products and related services;
- manage and account for public funds provided for the national blood supply;
- monitor and assess local and international markets and developments in the sector;
- plan and implement efficiency and quality improvements in the sector;
- identify information needs and priorities for the sector and provide a national focus for performance monitoring and reporting;
- assist in identifying research needs and priorities with the National Health and Medical Research Council and others; and
- make recommendations and reports to governments on blood supply matters. (Section 4.2)

While the National Blood Authority should be accountable and report to the Commonwealth Health Minister and Parliament, it should also report regularly to Australian Health Ministers on activities, performance of the national supply and emerging matters. (Section 4.2)

2 Establishing effective relationships

The Commonwealth Government should establish mechanisms to ensure effective lines of communication and advice between the National Blood Authority in managing and planning Australia's blood supply and the Therapeutic Goods Administration in regulating its safety and quality. (Section 4.2)

3 New financing arrangements

State, Territory and Commonwealth governments should replace the current administratively complex cost-shared approach to financing Australia's supply of blood and blood products with a simpler arrangement where:

- the Commonwealth funds the national supply as a whole by a Commonwealth appropriation;
- States and Territories reimburse the Commonwealth for their respective contributions; and
- the National Blood Authority manages and accounts for the Commonwealth appropriation. (Section 4.3)

State and Territory financial contributions should be made on a cost-recovery approach, based on product usage in the preceding year and national benchmarks of product costs. National benchmarks of product costs should be revised annually in light of new developments and changing costs. (Section 4.3)

National service delivery and funding agreements should be established between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and providers of blood and blood products and related services. (Section 4.3)

The States, Territories and Commonwealth should establish criteria for responding to new expenditure proposals that may arise between budgets (Section 4.3)

4 Expert advice on blood matters

National blood policy should continue to be developed by the Commonwealth in collaboration with States and Territories. In developing national policies, Australian Health Ministers should draw on advice from the National Blood Authority and from existing health system structures and arrangements. Key sources of expert advice for Ministers and the Authority should include:

Public health and safety

- public health and safety — National Health and Medical Research Council (NHMRC), National Public Health Partnership (NPHP)
- communicable disease surveillance — National Centre for Disease Control, and the NPHP
- safety and quality matters in hospitals including adverse events monitoring and reporting — Australian Council for Safety and Quality in Health Care (ACSQHC).

Clinical practice

- use of blood, blood products and alternatives — NHMRC, professional colleges and societies
- clinical practice improvements — National Institute of Clinical Studies (NICS), professional colleges and societies

Regulation of products and manufacturing processes

- The Therapeutic Goods Administration and associated bodies
  - safety, quality and efficacy of blood products and related products — Australian Drug Evaluation Committee (ADEC)

— safety, quality and performance of medical devices and diagnostic products — Therapeutic Device Evaluation Committee (TDEC), National Serology Reference Laboratory (NRL)

— product standards and good manufacturing practice standards -Therapeutic Goods Committee (TGC)

Cost effectiveness of blood products, substitutes and medical interventions

- plasma products, substitutes, clinical indications — Pharmaceutical Benefits Advisory Committee (PBAC)
- indicative prices for plasma products, substitutes — Pharmaceutical Benefits Pricing Authority (PBPA)
- testing procedures and medical interventions — Medicare Services Advisory Committee (MSAC).

Surveying scientific and technological developments and innovations

- scientific and technological developments on the horizon — NHMRC, MSAC

Ethical matters

- ethical matters relating to testing, access to products and treatments, research — NHMRC

(Section 4.5)

5 Intergovernmental agreements

Intergovernmental agreements between the Commonwealth and States and Territories should be established to underpin and formalise recommended governance and financing arrangements. (Section 4.4)

6 National safety and quality standards of blood and related products

There should be uniform national standards for blood and blood products covering donor selection, collection, testing, processing, storage and transport. Australian Health Ministers should monitor and assess the impact of the Commonwealth regulatory regime that took effect from July 2000 under the *Therapeutic Goods Act 1989*, identify gaps and take steps necessary to achieve uniform national standards for the sector. (Section 5.4)

The Therapeutic Goods Administration and the Therapeutic Goods Committee should review regularly national standards for blood and blood products in light of new developments and evidence and in the context of national public health and risk management applicable to Australia's circumstances. (Section 5.4)

Australian governments should put in place, as a matter of urgency, nationally uniform statutory defence laws. (Section 5.5)

The Therapeutic Goods Administration should be the approving body for listing new diseases and new tests for diseases and for varying the donor declaration to ensure a nationally consistent and timely response to changes in national standards. (Section 5.5)

7 External oversight and coordination of the quality of laboratory testing

Arrangements for external oversight of quality assurance in laboratory testing should ensure that:

- national service delivery and funding agreements with providers of blood products and services require participation in, and compliance with, external quality assurance and proficiency programs;
- external quality assurance programs are conducted independently of service delivery;
- aggregate data on testing results are provided to the National Blood Authority, the Therapeutic Goods Administration and other appropriate authorities for monitoring and reporting; and
- evidence-based assessments of proposed safety and quality improvements in the production and supply of blood products consider quality assurance requirements.
  (Section 5.6)

The Commonwealth should establish a mechanism to coordinate nationally activities of external quality assurance providers and specialised programs in laboratory testing. (Section 5.6)

8 Assuring safe and quality use of blood and blood products

All hospitals regularly performing blood transfusion should have an appropriately supported group to implement and oversee quality assurance. At a minimum, the group should be responsible for:

- disseminating national or local guidelines within the institution;
- developing local policies and protocols for blood use and collection;
- auditing use and wastage, and developing related performance indicators;
- risk management, including monitoring adverse or unexpected events and potential errors, analysing underlying system failures, providing timely feedback and advice to management and staff, and overseeing action taken;
- staff and patient education; and
- communication with internal and external bodies (including State Blood User Groups) about quality assurance matters. (Section 12.3)

These functions should be performed by a dedicated hospital transfusion committee or be incorporated within the role of another appropriate quality assurance or risk-management committee as the situation demands. (Section 12.3)

Establishment of hospital transfusion committees should be linked to the hospital accreditation requirements of the Australian Council for Healthcare Standards. (Section 12.3)

Collection and analysis of data related to the reasons for transfusion of blood products should be integrated into relevant hospital information and documentation systems. Hospital transfusion committees (or their equivalent) should take the lead in such developments. (Section 12.6)

The Health Advisory Committee of the National Health and Medical Research Council should lead the development and implementation of evidence-based guidelines to promote appropriate use of blood and blood products in liaison with the Australasian Society of Blood Transfusion, the Haematology Society of

Australia and New Zealand and other professional colleges and societies. (Section 12.5)

The Australian Council for Safety and Quality in Health Care and the National Institute of Clinical Studies should promote initiatives to support better transfusion practice in Australian hospitals including:

- the adoption of interventions (eg guidelines, audit approaches, transfusion committees);
- their formal evaluation; and
- dissemination of results of successful interventions. (Section 12.5)

The National Health Performance Committee should initiate the development of performance indicators for monitoring hospital transfusion practice in liaison with the Australasian Society of Blood Transfusion, the Haematology Society of Australia and New Zealand, the Australian Council for Healthcare Standards and other relevant groups. (Section 12.6)

Australian Health Ministers should commission a discussion paper on promoting appropriate and efficient use of Australia's national blood supply. (Section 12.3)

9 Reducing untoward and unexpected effects of blood transfusion

A national scheme for monitoring untoward transfusion events and outcomes in hospitals (a haemovigilance scheme) should be established as a priority for the purposes of:

- identifying contributory factors;
- providing feedback to enable clinical practice and product improvements; and
- providing data to place Australian transfusion risks in perspective. (Section 13.4)

The haemovigilance scheme should be developed as part of the national approach to improving patient safety being led by the Australian Council for Safety and Quality in Health Care. (Section 13.4)

The Australian Council for Safety and Quality in Health Care, in collaboration with the National Blood Authority, should provide Australian Health Ministers with a detailed implementation plan, timetable, budget and associated funding arrangements for the scheme. The proposal should be developed in liaison with relevant bodies. (Section 13.4)

A voluntary, confidential approach should be adopted for reporting adverse transfusion events in hospitals with appropriate legislative protections. (Section 13.4)

The National Blood Authority, in collaboration with the Australian Council for Safety and Quality in Health Care, should establish a mechanism for collating and analysing information from existing monitoring and surveillance schemes, and the proposed haemovigilance scheme. It should draw together expertise from these schemes to provide regular national reports on safety and quality in the supply and use of blood and blood products. (Section 13.5)

10 National self-sufficiency

Self-sufficiency should remain an important national goal for Australia recognising that it is a national and international obligation and responsibility. (Section 8.4)

The Commonwealth Government should monitor the goal's appropriateness, relevance and application in light of scientific, technological and other developments in transfusion medicine and patient care. (Section 8.4)

11 The ARCBS — the national blood service

A single service delivery and funding agreement should be entered into between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and the ARCBS for the provision by the ARCBS of the national blood service, operational from 2002-03. (Section 9.3)

Budgeting for the ARCBS should move to a triennial basis. (Section 9.3)

There should be an agreement between the Commonwealth and States and Territories regarding supply needs, service requirements and priorities for the national blood service. (Section 9.3)

The National Blood Authority should administer the Agreement with the ARCBS. (Section 9.3)

The National Blood Authority should report regularly to Australian Health Ministers on progress with the administration of the agreement with the ARCBS and outcomes. (Section 9.3)

The National Blood Authority, as part of its national supply planning role, should monitor the implementation of the ARCBS National Blood Management System for national inventory management, with a view to early introduction. (Section 6.1)

The ARCBS should provide the National Blood Authority with an assessment of Australia's experience in developing, implementing and reviewing the role, place and cost effectiveness of plasmapheresis in meeting current and future plasma supply needs. (Section 11.2)

The national service delivery and funding agreement with the ARCBS for the provision of the national blood service should be consistent with, and require compliance with, the obligations of the memorandum of understanding for the National Managed Fund. (Section 9.3)

12 Plasma fractionation

The Commonwealth Government should enter into a second Plasma Fractionation Agreement with CSL at the expiry of the first ten and a half years of the present agreement (at 30 June 2004) to ensure Australia's future needs for plasma products are met. (Section 10.3)

The Agreement should be for a shorter term than the current one. (Section 10.3)

A Plasma Fractionation Agreement should include provisions for:

- establishing an agreed product list and pricing schedule;
- reviewing new products and new clinical indications for existing products for which government funding is sought with expert advice provided by PBAC and with the supplier providing supporting evidence on clinical effectiveness and cost effectiveness;

- establishing product prices, based on the PBPA arrangements, to enable consideration of financial consequences to governments, the Plasma Fractionation Agreement and other agreements; and
- addition and deletion of products in light of evidence about safety, effectiveness and cost effectiveness. (Section 10.4)

Consideration should be given to a two-tiered approach to product pricing that comprises:

- a basic set of products for which an agreed price will be paid; and
- appropriate payment for new products based on PBAC / PBPA criteria and advice. (Section 10.4)

The National Blood Authority should administer the Plasma Fractionation Agreement as part of national supply planning. (Section 10.3)

The National Blood Authority should report regularly to Australian Health Ministers on progress with the administration of the Agreement and outcomes. (Section 10.3)

13 National supply and access arrangements for imported blood products and related products

The States, Territories and Commonwealth should establish a national arrangement to replace the existing State and Territory based approaches for the provision of imported blood products and related products. (Section 11.1)

The national arrangement should provide for:

- evidence-based product lists and associated clinical indications, with expert advice provided by PBAC / PBPA;
- purchasing through national service delivery and funding agreements between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and suppliers;
- national administration;
- information systems to monitor product issue and use; and
- regular review of products and associated clinical indications.(Section 11.1)

The National Blood Authority should administer the arrangement and report to Australian Health Ministers. (Section 11.1)

14 Managing supply risks — contingency planning

The National Blood Authority should develop a contingency planning strategy for Australia's blood supply. The strategy should draw on Australian and overseas expertise and experience in crisis management and contingency planning, and include monitoring of product markets and developments nationally and internationally. The strategy should be reviewed regularly. (Section 11.3)

In the context of national contingency planning:

- the importation of foreign-sourced plasma is not recommended as a strategy for meeting Australia's plasma product shortfalls. The National Blood Authority should keep this approach under review.
- the National Blood Authority should manage the National Reserve of Plasma Products, established to provide short-term security in national supply. The Reserve should be continually monitored and reviewed in light of experience and

changing national needs and circumstances.

- the Commonwealth Government should examine the appropriateness, relevance and feasibility of bilateral agreements with appropriate countries for the supply of blood products. (Section 11.3)

15 Diagnostic products — Diagnostic Products Agreement

The Commonwealth Government, in establishing future supply and delivery arrangements for blood banking related diagnostic products, should consider:

- the range of products and services required to meet future needs;
- the costs (direct and indirect) of current agreement arrangements and their cost effectiveness;
- the ability of suppliers to meet domestic needs;
- approaches for assessing product cost effectiveness and determining product prices; and
- information and performance reporting requirements. (Section 10.5)

16 Information

The National Blood Authority should develop a national information management and reporting plan for the Australian blood sector. (Section 6.1)

As a matter of priority, AHMAC should complete and report on the results of the study examining the costs of the national blood service provided by the ARCBS. (Section 10.3)

17 Research

The National Blood Authority should work with the National Health and Medical Research Council and with other interested parties to identify priorities and develop a research program to strengthen the evidence base for transfusion practice in Australia. (Section 6.4)

Term of reference	Recommendations
1 Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.	**6** National safety and quality standards of blood and related products (see pages 48 and 51) **7** External oversight and coordination of the quality of laboratory testing (see page 53) **8** Assuring safe and quality use of blood and blood products (see pages 114, 118 and 120) **9** Reducing untoward and unexpected effects of blood transfusion (see pages 127 and 128) **16** Information (see pages 56 and 91) **17** Research (see page 59)
2 Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.	**1** A National Blood Authority (see page 35) **2** Establishing effective relationships (see page 36) **3** New financing arrangements (see page 40) **5** Intergovernmental agreements (see page 40)
3 Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time.	**4** Expert advice on blood matters (see page 42)
4 Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.	**10** National self-sufficiency (see page 77) **11** The ARCBS — the national blood service (see pages 56, 81 and 103) **13** National supply and access arrangements for imported blood products and related products (see page 99) **14** Managing supply risks — contingency planning (see page 106)
5 Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.	**12** Plasma fractionation (see pages 91 and 95) **15** Diagnostic products — Diagnostic Products Agreement (see page 97)

Introduction

The Commonwealth Minister for Health and Aged Care, the Hon Dr Michael Wooldridge, MP, announced the Review of the Australian Blood Banking and Plasma Product Sector on 10 May 1999. It is a comprehensive examination of Australia's blood and blood product needs. Its purpose is to advise on principles and directions to guide the sector.

The Review was conducted by a Committee comprising:

- the Right Hon Sir Ninian Stephen — Chairman;
- the Hon Dame Margaret Guilfoyle;
- Professor Robert Beal; and
- Professor Judith Whitworth.

The Review was supported by a Secretariat based in Canberra and funded by the Commonwealth Department of Health and Aged Care.

Details of the Review Committee and Secretariat are at Appendix A and the Minister's media release announcing the Review is at Appendix B.

Background to the Review's establishment

In announcing the Review, the Minister noted that Australia, like other countries, is facing a number of new and emerging challenges in providing a safe and adequate supply of blood and blood products. They include:

- the threat of new infectious agents to the safety of the blood supply;
- rising demand for certain blood products and concerns about product shortages in some areas;
- the availability of new technologies, such as new tests to enhance the safety and quality of the blood supply, new products and new treatments; and
- rising community expectations and demand for products.

Following a previous review of aspects of the sector — *Commonwealth Review of Australian Blood and Blood Product System* (McKay & Wells 1995) — Australian governments have implemented a series of measures aimed at creating a truly national blood service and assuring the safety and quality of the blood supply.

The current Review was established to consider developments to date, to assess current and future needs and to advise on areas for improvement.

The Minister emphasised that the Review would not seek to change two fundamentals of the system: the giving of blood by voluntary donors and the provision of blood and blood products from donated blood free of charge to patients.

Terms of reference

The Review's terms of reference were as follows.

1 Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best-practice standards,

recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.

2 Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.

3 Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time. Among other things, the advice should cover:

- the need for and financial impact of new testing procedures and new products;
- legal and ethical issues where access to products may have to be based on clinical priorities;
- cost effectiveness of proposed safety improvements;
- the role of an expert reference laboratory in setting and maintaining a national quality assurance program; and
- the impact of change on public confidence in the blood supply.

4 Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.

5 Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.

The Review's terms of reference contained some important underlying themes. They include the concepts of safety and quality and managing risk. The Review has adopted broad definitions of safety and quality in keeping with health system developments.

Scope of the Review

The Review has involved a comprehensive examination of the blood banking and plasma product sector, that part of the health system responsible for meeting Australia's blood and blood product needs. The sector covers the donation of blood and its collection, testing and banking through to processing, production of products, distribution and clinical use. It is funded largely by State, Territory and Commonwealth governments and is subject to governance, financing and legislative arrangements.

The Review's five terms of reference were wide-ranging. Their primary aim has been to ensure that Australia is equipped nationally to meet emerging and future challenges, to provide an adequate and secure supply of safe, high quality blood and blood products and to promote appropriate clinical use.

Approaching the terms of reference

The Review divided its activities into two categories — assessing the existing situation and considering possible future courses of action. In broad terms, this involved:

- establishing an understanding of the sector — its history, structure, organisation and activities and recent and emerging developments;
- seeking views;

- assessing performance;
- identifying and assessing Australia's needs;
- examining how well positioned Australia is to meet these needs; and
- considering and assessing strategies for improvement.

Consultation process

The Review canvassed community, industry and professional views through public consultation. Advertisements requesting submissions were placed in the national and capital city newspapers and the medical press over July and August 1999. Letters inviting submissions were sent to a selection of interested groups and organisations. Respondents were asked to comment on all or parts of the Review's terms of reference and to provide supporting evidence. Over 75 submissions were received from a variety of health agencies, government departments, industry, professional organisations, service providers, researchers, interest groups and consumers. A list of respondents is at Appendix C.

The Review conducted a series of consultations with respondents across Australia as well as with experts and relevant organisations. Details of the consultation program are provided in Appendix D.

Review members visited a number of facilities to meet those working in the field and to gain an understanding of the sector's activities. These included blood banks, the CSL plasma fractionation facility at Broadmeadows in Victoria, and public and private hospitals. Further information about the program of site visits is provided at Appendix E.

Information gathering and analysis

Information was gathered from a variety of sources including submissions, published reports and commissioned research. Additional information was sought from several organisations. Systematic literature reviews on key areas associated with the terms of reference were undertaken. Consultants were engaged to undertake industry and market analyses of Australian and global plasma fractionation and of relevant diagnostic products, and to survey new and emerging technologies.

A feature of the Review has been the lack of information in the public domain about activity related to the blood supply. The Review has sought to address these matters in its recommendations.

Review boundaries

Some matters fell outside the scope of the Review, in particular, the two policy principles: the voluntary nature of the donor system and the provision of blood and blood products from donated blood free of charge to patients.

In addition, some submissions raised scientific and technical issues, often matters being addressed by other bodies. Since the Review was not established as a technical expert group, it has not itself dealt with these matters in this Review but, as they arose, has drawn them to the attention of relevant bodies. They have included:

- leucodepletion of fresh blood products;
- technical aspects of the question of donor deferral in response to the potential threat of variant Creutzfeldt Jakob Disease (CJD);

- the role and place of autologous collections and directed donations;
- implementation of the National Health and Medical Research Council's (NHMRC) *Guidelines on the Prophylactic Use of Rh D Immunoglobulin (anti-D) in Obstetrics* (NHMRC 1999); and
- release and implementation of the Australian Health Ministers'Advisory Council (AHMAC) Blood and Blood Products Committee's *Review of the Use and Supply of Intravenous Immunoglobulins in Australia* (AHMAC 2000a).

For several reasons, the area of cord blood banking also fell outside the scope of the Review. The special feature of cord blood is that it is rich in stem cells that behave like bone marrow and can, in certain circumstances, be used instead of bone marrow when the patient would otherwise require a bone marrow transplant. Arrangements for collecting and storing cord blood and the uses to which it may be put are different from those relating to blood donations. Australia's arrangements for cord blood banking are being examined jointly by the Commonwealth, States and Territories through AHMAC.

Measuring and assessing performance

One of the Review's major tasks was to assess the performance of the blood sector. The Review found this difficult for several reasons.

While many submissions raised the concept of 'international best practice' or 'world's best practice', the concept was not defined clearly. It was often viewed narrowly as the adoption of a particular procedure or process. The Review had reservations about the usefulness of this approach since circumstances, needs and risk profiles vary from nation to nation. Variations in the prevalence of blood-borne diseases, as well as differences in national policies, the organisation, funding and management of national blood programs and health systems make comparisons difficult. Proper performance assessment requires a focus on outcomes as well as on structures and processes. Additionally, performance assessment requires the development of agreed performance indicators for comparison against attainable or desirable standards (benchmarks).

The Review found few agreed performance indicators for the blood sector. A systematic review of the international, peer-reviewed literature relating to the organisation, operations and performance of national blood programs was undertaken. Only a handful of studies was identified. Few of these provided agreed performance indicators. Most of those available relate to scientific and technical performance, rather than informing policy. The ARCBS provided the Review with information about a benchmarking study it commissioned comparing the performance of the ARCBS against that of a sample of similar blood services. Recognising the difficulties and inherent limitations of benchmarking studies, the Review considers this is an important first step in the direction of performance assessment and service accountability.

For much of the sector, performance information is not readily available, systematically collected or reported. The Review, therefore, developed a three-stage approach to assess performance and to provide a rationale for its findings, conclusions and recommendations. This involved examination of perceptions of the sector as reported in submissions to the Review or in other consultations, analysis of available information against defined national goals and outcomes and, where possible, comparisons with other nations.

Changes during the course of the Review

Over the course of the Review, the Committee has been struck by the changing environment. It has noted the sector's response to a variety of matters including:

- the first case of transfusion-acquired HIV since 1985 and its effect on public support and confidence;
- the introduction of new screening tests for pathogens in blood that have relatively small safety gains but high direct expenditure costs;
- demands for increased access to imported products;
- the adoption of procedures designed to reduce the need for blood;
- the variation in policies in different countries to new potential threats to the blood supply such as variant CJD;
- establishment of a national indemnification scheme for the Australian Red Cross Blood Service (ARCBS); and
- extension of national regulation to all ARCBS activities.

The Review has sought to provide a framework to assist in considering these types of matters in the future and to build on current achievements.

The Review has also observed the commencement and / or further development of a number of activities including clinical guidelines for the use of blood products, national inventory management by the ARCBS and haemovigilance. They are important developments. The Review has sought to place them in a strategic framework as well as to advise on future directions.

Structure of the report

This is the first and final report of the Review. It comprises five parts:

- Part A (Chapters 1-3) gives an overview of the sector, summarising its evolution and organisation and discussing recent and emerging developments and trends internationally and in Australia;
- Part B (Chapters 4-6) addresses terms of reference 1 to 3, discussing the need for a national approach to governance and financing, for national standards and regulation to ensure a safe, high quality blood supply, and for mechanisms to improve national information management and research capacity;
- Part C (Chapters 7-11) addresses terms of reference 4 and 5 and discusses Australia's goal of self-sufficiency in blood and plasma products, the importance of a national strategic approach to planning and managing the blood supply, the role of the national blood service and plasma fractionation industry and ways to balance better the supply of plasma products;
- Part D (Chapters 12-13) broadly addresses term of reference 1 and examines ways to improve transfusion practice, promote better use of blood and blood products, and monitor nationally adverse outcomes of transfusion; and
- Part E (Chapter 14) presents the overall conclusions of the Review.

A set of appendices providing supporting information and material is included at the end of the Report.

Part A — Overview

1 Origins and evolution of Australia's blood banking and plasma product sector

The blood banking and plasma product sector comprises a wide range of activities, from the giving of blood by volunteer donors and the collection, testing and banking of blood, through to processing and production of blood and plasma products, and their distribution and clinical use.

The origins of blood banking are linked to the emergence of blood transfusion as therapy for blood loss and deficiencies, and there are continual advances and developments in both fields. Over many years, the sector has evolved to comprise a complex set of relationships and functions:

- the volunteer donors who are the foundation of Australia's blood supply;
- the Australian Red Cross, originally a provider of emergency relief, now also the provider of the national blood service;
- a national plasma fractionator, CSL Limited, originally set up as a public sector entity to ensure Australia's supply of biological reagents and, since 1994, a public company which produces plasma products under a long-term contract with the Commonwealth; and
- governments — the States, Territories and Commonwealth — that fund and support blood transfusion services.

This chapter presents an overview of the sector's origins, evolution and organisation, beginning with a description of the main blood products used in transfusion medicine. More detail and analysis of particular aspects is provided in Parts B to D.

1.1 Blood transfusion and blood products

Blood transfusion emerged as an essential part of medical care for treating blood loss and deficiencies during the 20th century. Organised blood transfusion services first emerged in the 1920s and 1930s with the establishment of donor panels. Initially, only whole blood was used for transfusion. Along with a number of other significant scientific and medical advances, the development of blood separation and fractionation technologies allowed the treatment of specific conditions with the required blood component or blood fraction.

Today, whole blood is rarely transfused. Modern practice is to administer the specific blood components that are needed. A fundamental aspect of blood banking and blood product manufacture is the separation of blood into its components which are then supplied to hospitals and clinicians for use. Specific components may also be collected in a single procedure through the process of apheresis.

Fresh blood products are perishable with short shelf lives (red cells 35-42 days and platelets 5 days). Production therefore involves fast turn-around times. Single blood donations are the starting point for manufacture. Products are used by a large and diverse group of patients, predominantly in emergency and acute care. In most cases, the recipient receives product from a small number of donors once only. Cellular components cannot be sterilised so freedom from infectious agents depends on the quality of blood as donated and tested.

Red cells are the mostly widely used fresh blood product. The major fresh blood products and their main clinical uses are shown in Table 1.1.

Table 1.1 Major fresh blood products

Product	Main uses
Red cells	Replacement of blood loss in trauma and surgery, and occasional treatment of anaemia
Platelets	Control of bleeding related to platelet deficiencies caused by disease (eg leukaemia) or following severe haemorrhage or as a result of treatment of an underlying malignant disorder
Cryoprecipitate	Treatment of clotting factor and fibrinogen deficiencies
White cells	Treatment of sepsis, regeneration of blood cells after chemotherapy

Plasma includes three groups of proteins — albumin (which is important in maintaining blood volume), immunoglobulins (which combat infection and are important in immunity) and clotting factors (which have specific functions in the clotting mechanism).

Plasma products have longer shelf lives (one to three years) than fresh blood products and fall into two categories:

- those made from normal plasma from large batches of thousands of donations; and
- those made from hyperimmune plasma donated by relatively small cohorts of donors with high levels of specific antibodies such as Rh D immunoglobulin, tetanus and zoster.

Plasma may be collected by two methods — by separating plasma from whole blood donations or by plasmapheresis where only the plasma is collected from the donor. Steps are taken at the blood service and the plasma fractionation facility to minimise the risks of viral contamination.

Albumin is the most abundant product of plasma fractionation. With the development of recombinant factors VIII and IX (products which are not derived from plasma), intravenous immunoglobulin (IVIg) replaced plasma-derived clotting factors as the major driver in plasma collection and plasma product manufacture. Table 1.2 shows the principal plasma products and their main clinical uses.

Table 1.2 Principal plasma products

Product	Main uses
Albumin (various concentrations)	Treatment of shock, burns, liver disease and kidney disease
Immunoglobulin for intramuscular injection (IMIg)	Temporary protection against infectious diseases such as measles, rubella and hepatitis A
Immunoglobulin for intravenous injection (IVIg)	Replacement therapy for primary immune deficiency disorders; Guillain-Barré; Kawasaki disease
Immunoglobulin preparations with high levels of specific antibody (hyperimmune globulins)	Treatment of tetanus or prevention of hepatitis B, chicken pox, haemolytic disease of the newborn or cytomegalovirus
Factor VIII concentrate (a specific clotting factor)	Haemophilia A
Other clotting factors, or mixtures of them	Bleeding disorders such as haemophilia B

1.2 Development and organisation of the sector

The origins and development of blood banking in Australia are closely linked with the Australian Red Cross and its humanitarian efforts in wartime and with Australia's desire, as an island continent, to safeguard its population in times of crisis.

By the 1960s, blood banks were an established feature of the health services of developed countries, either as hospital departments or distinct entities. Over the next 20 years, blood collection agencies tended to become detached from the hospital environment and developed the characteristics of production agencies. Product safety and quality and good manufacturing practice requirements brought blood banks and plasma fractionators under regulatory oversight similar to the pharmaceutical industry.

Increasing awareness of the potential for transfusion-transmitted infections, particularly in light of the HIV / AIDS crisis of the 1980s, focused attention in laboratory testing on viral screening. Testing for blood-borne diseases began as tests became available. In recent years, much effort has been concentrated on the development and introduction of more sensitive tests, the investigation of newly emerging pathogens, the development through biotechnology of synthetic products such as recombinant products and methods to reduce blood loss in surgery.

Australian Red Cross involvement

In 1929, the Australian Red Cross established Australia's first organised blood transfusion service in Victoria. This was followed by the establishment of similar services in all States. These were developed on a State and Territory basis reflecting the organisation of the Red Cross with its eight separate State and Territory Divisions. The service was based on voluntary donation.

During World War II, a National Emergency Blood Transfusion Service was formed along with a scientific advisory committee, the National Blood Transfusion Committee. After the war, State and Territory blood transfusion services continued to operate under the umbrella of the Red Cross. State and Territory laws were introduced to prevent the sale of blood and blood products and coordination was maintained through the National Blood Transfusion Committee. The blood transfusion services were not the only providers of homologous blood for transfusion. Blood banks were also run by some hospitals that maintained their own donor panels and collections. Many of these were subsumed gradually by the Red Cross blood transfusion services.

The 1990s saw a move towards a national focus for blood transfusion services in Australia. In 1995, the Commonwealth commissioned a review of the Australian blood and blood product system. That review examined consultative mechanisms, coordination and management at the national level, the future role of the Australian Red Cross in blood banking, and the impact of pricing signals and charging on the supply and demand for blood and blood products. The review's report (McKay & Wells 1995) provided the impetus for a number of reforms and related initiatives, one of these being the formation of a national blood service run by the Australian Red Cross. The aim of this was to rationalise and streamline functions and allow free transfer of products across State and Territory boundaries.

The Australian Red Cross Blood Service

In 1996, the blood transfusion services of the States and Territories united to form a national blood service, the ARCBS. The governance arrangements of the Australian Red Cross were reorganised and the ARCBS was established as an operating division of the Australian Red Cross. An ARCBS Board of Management was created, responsible for providing strategic direction and accountable directly to the Australian Red Cross National Council which has ultimate legal responsibility for the blood service. A Chief Executive Officer was appointed to manage the delivery of the service, accountable to the ARCBS Board.

The ARCBS is organised into five strategic business units — Queensland; New South Wales / Australian Capital Territory; Victoria / Tasmania; South Australia; and Western Australia / Northern Territory — and has a national office, based in Melbourne. Today, the ARCBS is the predominant part of the activities of the Australian Red Cross, accounting for some 60 per cent of the organisation's total operating revenue in 1999-00 (Australian Red Cross 2000).

CSL involvement

Just as the Australian Red Cross involvement in the sector grew out of war, so did that of CSL. The Commonwealth Serum Laboratories, as CSL was named originally, was established in 1916 to ensure Australia had a continuing supply of biological reagents, in response to:

- Australia's wartime isolation and dependence on overseas supplies for vaccines, sera and other biological products;
- significant medical advances, particularly the emergence of vaccines for the treatment of infectious diseases;
- the handing over of quarantine administration by the States to the Commonwealth from 1 July 1909; and
- emerging support for the concept of a government vaccine institute for public health purposes.

The Commonwealth Serum Laboratories initially produced vaccines and sera for treating a variety of illnesses including diphtheria, tetanus, typhoid, cholera, plague, whooping cough, smallpox and influenza. Gradually, its activities expanded.

In 1949, the Commonwealth Government decided that fractionation should be undertaken in Australia and that the Commonwealth Serum Laboratories was the most suitable institution to perform this role. It was also agreed that funding of the initiative was the responsibility of the Commonwealth Government. This decision paved the way for the Australian plasma fractionation industry. Production of albumin and immunoglobulin commenced in 1953-54. Factor VIII preparations became available shortly afterwards.

The Commonwealth Serum Laboratories has undergone a number of transformations reflecting changing government policy towards public business enterprises. In 1961, it became a statutory body, the Commonwealth Serum Laboratories Commission under the CSL Act 1961; in 1991, the Commission was corporatised and converted into a public company, CSL Limited, while remaining wholly owned by the Commonwealth; and in 1994, it was privatised and became a listed public company.

The Commonwealth protected the national interest by entering into two long-term contracts with CSL — the Plasma Fractionation Agreement and the Diagnostic Products Agreement — to ensure the continued supply of plasma products and certain diagnostic products to the Australian community. The Plasma Fractionation Agreement has a term of ten and a half years — from 1 January 1994 to 30 June 2004. It provides for the processing of plasma products from Australian-sourced plasma collected by the ARCBS from volunteer donors. The Diagnostic Products Agreement has a term of seven and a half years. It provides for the production, supply and distribution of a range of diagnostic products for blood testing, typing and cross-matching made from human blood supplied by the ARCBS. Both agreements may be extended by the Commonwealth.

Today, CSL develops, manufactures and markets pharmaceutical products of biological origin. Products include human and veterinary pharmaceuticals, notably vaccines as well as plasma and plasma products. As well as providing plasma fractionation and diagnostic product services to the Australian community, CSL processes plasma supplied by the national blood services of New Zealand, Hong Kong, Singapore and Malaysia into a range of products for return to those countries. In 2000, CSL purchased the plasma fractionation assets and business of Schweizerische Rotkreuzstiftung Zentrallaboratorium Blutspendedienst (SRK-ZLB), a Swiss corporation, making it one of the largest plasma fractionators in the world. ZLB is affiliated to the Swiss Red Cross.

Government involvement

An ongoing factor in the development of blood transfusion services in Australia has been the appropriate division of responsibility between the Commonwealth and States and Territories, as is true for the health system generally.

Under the Australian Constitution, legislative power with respect to health was not conferred on the Commonwealth and so remained with the States. The blood transfusion services were developed on a State and Territory basis reflecting the organisation and funding of public health services in Australia as well as the basic organisation of the Australian Red Cross.

In 1946, the Constitution was amended (S.51xxiiiA) giving the Commonwealth power to provide pharmaceutical, sickness and hospital benefits and medical and dental services. In the 1950s, the Commonwealth and State governments agreed to fund jointly the majority of the costs of the Australian Red Cross in providing blood transfusion services for Australia. In 1954, cost-shared funding arrangements came into operation, with the proportions changing over time. Financing is discussed further in Chapter 2.

The McKay Wells review (1995) led to the development of a national approach by Australian governments to the supply of blood and blood products. Efforts have focused on strengthening national policy coordination by the formation of a government policy forum, the Blood and Blood Products Committee of AHMAC. The Committee provides a national policy focus for blood matters and brings together the States, Territories and Commonwealth. Terms of reference of the Committee are included at Appendix F.

A series of reforms and measures have been put in train. These are discussed further in Chapter 3.

2 Australia's blood supply today

Australia's blood supply is founded on two important principles. These are voluntary, non-remunerated donation of blood and plasma, and self-sufficiency in products derived from human blood and plasma as far as practicable, rather than routine dependence on imported products.

The ARCBS and CSL play central roles. These organisations depend upon the volunteer donors and upon each other — the ARCBS relies on CSL for plasma fractionation and supply of plasma products, and CSL relies on the ARCBS for plasma collection from donors and for the distribution of manufactured plasma products.

This chapter gives an overview of current arrangements for Australia's blood supply — the fundamental principles on which it is based, the products and their providers, and current governance and financing arrangements.

2.1 Voluntary donation and self-sufficiency

In 1975, in response to ethical and humanitarian concerns about the impact of plasma shortages in the developed world on developing countries, the World Health Assembly passed an important resolution (WHA 1975). The resolution sought to promote the health and safety of blood donors and recipients of blood and blood products and included:

- that whole blood donation and supplementary plasmapheresis (to the extent that it was necessary for national self-sufficiency in plasma) be voluntary and unpaid;
- that nations try to become self-sufficient in blood and blood products;
- that donors not be compensated for giving whole blood or plasma; and
- that nations enact legislation to regulate the collection, processing, distribution, export and import of blood and blood products.

Voluntary donation

As a signatory to the 1975 World Health Assembly resolution (WHA 1975), Australia remains committed to maintaining a voluntary, non-remunerated donor base. This principle is expressed in State and Territory Human Tissue Acts that prohibit the sale of organs and tissue, including blood (see Appendix G). It has been inherent in the development of blood transfusion services by the Australian Red Cross.

In keeping with this principle, Australia's volunteer, non-remunerated donors meet almost all of the nation's blood product needs. In 1999-00, the ARCBS reported some 944,000 homologous donations (blood donations given for transfusion to an unknown recipient), representing over 95 per cent of all recorded blood and blood component collections for that year. Other less common types of donations are autologous collections (involving blood taken from patients for their own use before a medical procedure) and directed donations (involving blood donated by another for use by a particular patient).

An overview of available information on blood donors in Australia and overseas, and some principles for future monitoring and research to improve donor management practice are given in Chapter 7.

Self-sufficiency

Self-sufficiency in supply covers collection of human blood and plasma and production, including a national plasma fractionation capacity. Self-sufficiency was seen as in the national interest as well as an international responsibility. Australia's response to the World Health Assembly resolution (WHA 1975) was to impose constraints on imported products by declining to register any foreign plasma product unless it has a demonstrably significant clinical advantage over the local product. This policy is enunciated in Appendix 19 of the *Australian Guidelines for the Registration of Drugs* (see Appendix H).

One of the Review's tasks (under its fourth term of reference) was to examine the self-sufficiency principle (see Section 8.4).

2.2 Products, providers and distribution

The blood supply provides three broad groups of products — fresh blood, locally made plasma, and imported products. The domestic market through the activities of ARCBS and CSL meets almost all of Australia's blood and blood product needs.

As whole blood cannot generally be stored for longer than a few weeks, the separation and processing of cellular components is done on a regional basis near the point of donation. The ARCBS collects donations of whole blood or blood components from donors and separates and further processes the cellular components into a range of fresh blood products, which are supplied direct to hospitals and clinicians for use. Most of the plasma collected by the ARCBS is sent to CSL, but some is kept for use in the blood bank and in the preparation of fresh frozen plasma for treating certain clotting disorders.

A small quantity of fresh blood is collected either in hospitals, for specific purposes (such as the production of platelets for use in cancer treatment), or in remote areas where special donor panels are used in case of emergencies. Autologous collection services are provided by the ARCBS and by pathology services in the public and private sectors.

The ARCBS also provides other (non-core) services for individual State and Territory governments which are beyond the scope of this Review, such as tissue typing, bone marrow registry, stem cell cryopreservation and cord blood banking.

Product safety and quality standards

Measures and steps used in the production and supply of blood and blood products are critical to ensuring recipient safety and improved transfusion outcomes. Australia has four sources of supply — domestic homologous donations, autologous collections, directed donations and imported products. A mix of strategies is in place to ensure safety and quality in products supplied from these sources. The measures vary according to the source of supply but there is some overlap in approach. The strategies and mix of providers involved are detailed in Appendix I. Regulatory strategies include product manufacturing principles, audits of compliance and testing to minimise the potential for infectious disease transmission in the community.

Today, the vast majority of production activities (involving the ARCBS and CSL) come under a single, Commonwealth regulatory regime. Administered by the Therapeutic Goods Administration (TGA), the regime regulates the activities of the two major providers to ensure product safety, quality and efficacy for use on the Australian market as well as ensuring the safety, quality and efficacy of registered imported products. The

regime's aim is to protect the health and safety of donors, recipients and the community and to optimise use of scarce national resources by enabling products to move across State and Territory boundaries.

The fresh blood activities of the ARCBS were brought under Commonwealth regulation from July 2000. Previously, they were regulated at a State / Territory level while ARCBS plasma collection activities were regulated by the TGA.

States and Territories regulate the activities of the few non-ARCBS blood banks and blood collection agencies. A national accreditation system for pathology laboratories operates. Participation is mandatory for providers (public and private) funded under the Medicare Benefits Scheme. A number of quality assurance activities and arrangements apply to providers. They vary depending on the provider, the regulatory regime and funding mechanism, and cover both internal and external quality assurance activities.

Imported products

Australia imports certain plasma products (eg factors VII, IX, XI and XIII, and factor VIII inhibitor bypass agent [FEIBA]), plasma product substitutes (such as recombinant factors VIIa and VIII) and some other related products (eg porcine factor VIII). Importation is for several reasons — it is uneconomical for CSL to manufacture some products where the volumes required are small; CSL does not have the technology to make the complete range of products; and Australia does not have recombinant manufacturing technology. Product importers include CSL and other private companies. Imported products represent, in volume, a very small part of Australia's supply, although in 1999-00, because they are costly, they accounted for about 6 per cent of government expenditure on blood and blood products.

Special Access Scheme arrangements, administered by the TGA, allow individuals with serious conditions access to certain drugs including imported blood products not registered for marketing in Australia. Products provided under the scheme are not subject to TGA evaluation and are funded by governments, hospitals or patients with requests initiated by the patient's medical practitioner.

Inventory management and distribution

The distribution of fresh blood products and most locally made plasma products is managed by the ARCBS through its regional business units in conjunction with hospitals, pathology laboratories and clinicians. The ARCBS is responsible for national inventory management including maintaining working reserves of products to meet fluctuations in demand. Some products are transferred between States and Territories to balance peaks and troughs in local demand. CSL supplies one locally made plasma product, normal intramuscular immunoglobulin (IMIg), directly to hospitals and clinicians.

Imported products are managed through a mix of systems reflecting different purchasing arrangements. There are two State / Territory and Commonwealth government 50:50 cost-shared arrangements: one covers the purchase of imported recombinant factor VIII; and the other concerns the provision of certain high cost imported blood products and related products for people with rare coagulation disorders. Arrangements are State and Territory based. For recombinant factor VIII, some States / Territories are moving to joint purchasing arrangements.

Users

Virtually all blood, blood products and their recombinant substitutes are funded by government and provided free of charge to patients. Hospitals and clinicians in the public and private sectors are responsible for their use and for ensuring patient safety. The ARCBS works closely with the Australian Defence Force in meeting the military's blood product needs during training and peacekeeping operations.

2.3 Governance, financing and legislation

Governance

The sector is largely government funded with cost-shared arrangements in place between two levels of government — the Commonwealth and States and Territories. Underlying this is the understanding that access to safe and high quality blood and blood products is a public health responsibility in which government has a key role.

Responsibility for the provision of blood transfusion services is shared by many organisations from the government, private and voluntary sectors (see Table 2.1). Underpinning these arrangements is a plethora of advisory bodies from within the sector and from the broader health system.

At a government level, planning and management is achieved through a range of inter-agency and intergovernment committees. As outlined in Chapter 1, the Blood and Blood Products Committee of AHMAC has primary carriage of the coordination of policy across governments, operating within health policy fora of State, Territory and Commonwealth governments. As Appendix F indicates, the Blood and Blood Products Committee's terms of reference are wide ranging. Activities have concentrated on particular aspects such as establishing the ARCBS, and improving access and use arrangements for certain products, rather than upon sector-wide management.

Table 2.1 The Australian blood sector

Function	Examples of individuals / groups involved
Voluntary donation of blood	Volunteer donors, ARCBS
Financing	State, Territory and Commonwealth governments
Legislation	State, Territory and Commonwealth governments
Regulation	Therapeutic Goods Administration (TGA) and associated advisory committees — Australian Drug Evaluation Committee (ADEC), Therapeutic Goods Committee (TGC), Therapeutic Device Evaluation Committee (TDEC); Australian Quarantine and Inspection Service (AQIS); and States and Territories
Quality assurance	National Serology Reference Laboratory (NRL), National Pathology Accreditation Advisory Council (NPAAC), National Association of Testing Authorities (NATA), Royal College of Pathologists of Australasia (RCPA), Australian Council for Safety and Quality in Health Care (ACSQHC), Australian Council for Healthcare Standards (ACHS), Standards Association of Australia (SAA), International Standards Organisation (ISO)
National blood policy coordination	AHMAC Blood and Blood Products Committee
Population health and safety	National Health and Medical Research Council (NHMRC), National Public Health Partnership (NPHP), Commonwealth and State and Territory health departments, Intergovernmental Committee on AIDS and Related Diseases (IGCARD), Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD), National CJD Registry
Provision of blood and blood services	ARCBS, CSL, pharmaceutical companies, public and private hospitals, pathology companies
Use of blood and blood products	NHMRC, hospitals and clinicians, professional colleges and societies, Australian Defence Force

Financing

In 1999-00, States, Territories and the Commonwealth spent some $333 million on the production and supply of blood and blood products under cost-shared arrangements. Information on other aspects of expenditure is not available routinely. Hospital, medical and other costs associated with the use of blood and blood products in patient care are funded by governments (eg through the Australian Health Care Agreements, Medicare Benefits Scheme), private health insurers and patients. Other costs include administration by governments, public health related measures and research.

Over the last decade, blood supply expenditure has increased steadily from around $107 million in 1990-91 to $218 million in 1995-96, up to the present figure of $333 million. Over the last five years (1995-96 to 1999-00), expenditure has grown by around 11 per cent per annum in nominal terms. Expenditure growth is the result of increased demand, implementation of new initiatives and the high cost of specific new measures aimed at securing a safe and sufficient national supply.

The Commonwealth Government's share of funding has increased steadily over the last 10 years from 59 per cent in 1990-91 to 67 per cent in 1999-00. Figure 2.1 shows the sources of funding for 1999-00.

Figure 2.1 Australia's blood supply, sources of funding, 1999-00

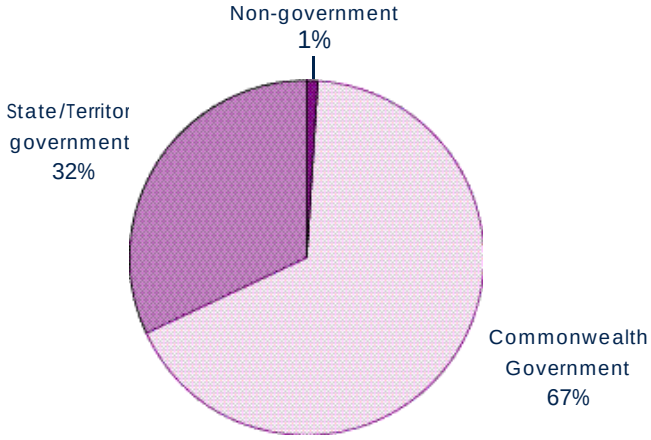
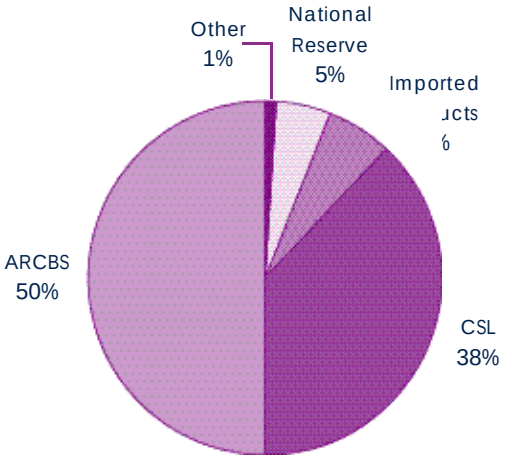


Figure 2.2 shows areas of expenditure in 1999-00. As the figure highlights, the largest single area of expenditure is the ARCBS national blood service at around 50 per cent, followed by CSL for plasma fractionation and diagnostic product services (38 per cent) and imported blood products and related products (6 per cent).

Figure 2.2 Australia's blood supply, areas of expenditure, 1999-00



Funding responsibilities vary across areas of expenditure. While the Commonwealth, States and Territories share the costs of the ARCBS providing some $165 million (or 99.4 per cent of its expenditure) in 1999-00, States and Territories are major funders contributing $98 million (59 per cent).

In contrast, the Commonwealth fully funds the plasma fractionation activities of CSL ($119 million in 1999-00) as well as the diagnostic products that CSL manufactures and supplies under the Diagnostic Products Agreement ($6 million in 1999-00).

States, Territories and the Commonwealth share the funding of an agreed range of imported products on a 50:50 basis. In 1999-00, government expenditure amounted to almost $21 million for these products. Expenditure has doubled from just over $9 million in 1995-96.

The newly established National Reserve of Plasma Products is fully funded by the Commonwealth. Establishing the Reserve over the three years 1998-99 to 2000-01 is estimated to cost some $26 million.

Service delivery and funding agreements

Government funding is distributed through a mix of service delivery and funding agreements between governments and service providers. In all, there are over 30 agreements with others being finalised. The essential features of the arrangements are:

- cost-shared funding agreements between the Commonwealth and States and Territories for the ARCBS under the Red Cross Blood Transfusion Service Assistance Program;
- a separate agreement between each State and Territory government and the ARCBS;
- a Plasma Fractionation Agreement between the Commonwealth and CSL;
- a Diagnostic Products Agreement between the Commonwealth and CSL;
- recombinant factor VIII purchasing agreements between the Commonwealth and States and Territories;
- imported blood products and related products agreements between the Commonwealth and States and Territories for high-cost products;
- a separate set of agreements between the Commonwealth and product and service providers underpinning the National Reserve of Plasma Products; and
- a single memorandum of understanding between States, Territories, the Commonwealth and the ARCBS for the National Managed Fund.

There is also an agreement between the ARCBS and CSL that covers their relationship in supply and delivery of plasma and the manufacture and delivery of plasma products. The Commonwealth also provides certain indemnities to CSL for product liability claims that may result from the use of particular CSL products manufactured before the CSL sale (Indemnity Agreement).

A memorandum of understanding was established between Commonwealth and the Australian Red Cross to provide funding (from States, Territories and the Commonwealth) to assist with the transition to and creation of the ARCBS as a national body.

Legislation

A range of State and Territory and Commonwealth laws deals with the blood sector. All States and Territories have some form of legislation controlling the use of human tissue including blood. The number of pieces of legislation and their names vary across States and Territories, as do their provisions. They focus on consent to the removal of blood for therapeutic, medical or scientific purposes, and in all States and Territories except Queensland, statutory defences to protect donors, suppliers and medical practitioners against actions brought in relation to the transmission of diseases such as HIV through the use of blood and blood products. The Commonwealth also has a range of legislation falling within the health field (*Therapeutic Goods Act 1989, National Health Act 1953 and Health Insurance Act 1973*) or more broadly based (*CSL Sale Act 1993, Customs Act 1901 and Trade Practices Act 1974*). Legislation relating to the blood supply is summarised in Appendix G.

2.4 Activity in the sector

The Review has compiled a set of statistical information on activities and expenditure. Information has been drawn from a number of sources. It covers statistics on donors, collections, production and product issue as well as expenditure statistics. The information is provided in Appendix J, along with a discussion of information sources and associated matters of interpretation.

In 1999-00, the ARCBS collected blood from around 463,000 donors. The ARCBS produced and issued over 700,000 units of red cells and well over 300,000 units of platelets. As well, over 238,000 kg of plasma were sent by the ARCBS to CSL for fractionation into a variety of plasma products. During the same year, CSL manufactured over 5,000 kg of albumin; 946 kg of IVIg; 47 million IU (international units) of factor VIII; and nearly 16 million IU of factor IX. Additionally, some 13.7 million IU of recombinant factor VIII was imported into Australia in 1999-00, up from 5.8 million IU in 1996-97.

The Review confined its activity analysis to the four years since the formation of the ARCBS (1996-97 to 1999-00). Reasons for this included: limitations in the availability of consistent time-series information on the sector nationally; and the Review's focus on recent and future developments and directions for the sector. As this four-year period precedes the decision by Australian Health Ministers to adopt a donor deferral policy in relation to variant CJD, any changes resulting from this policy will not be reflected in these statistics.

While information on aspects of the sector's activities is reported under various State and Territory and Commonwealth service delivery and funding agreements, it is not drawn together routinely and systematically to provide a national picture. Broad level information is published by the ARCBS on the activities of the national blood service. For other aspects of the sector, little information is available in the public domain.

Subsequent chapters of the Report contain statistics for particular aspects of the sector.

3 The changing environment

The Review aims to ensure that Australia can respond nationally to emerging developments and changing needs, within the context of the Australian health system. This chapter surveys recent and emerging developments and trends. Later chapters explore their implications for Australia.

3.1 Global developments and trends

The HIV / AIDS crisis of the 1980s greatly increased public awareness and perceptions of blood transfusion risks, sparking immense interest in the safety and adequacy of blood supplies worldwide. This has resulted in a range of measures including structural reform, increased safety measures, regulatory approaches and policy reform. Product developments have also brought changes to the plasma fractionation industry.

Structural reform

A number of countries have undertaken reviews of the organisation and management of their blood programs, ranging from judicial inquiries to continual ongoing review. One of the most prominent of these was Canada's Commission of Inquiry on the Blood System, which reported finally in 1997 (Krever 1997). A series of judicial inquiries into the transmission of HIV was conducted in France. The United Kingdom, the United States, Germany, the Netherlands and New Zealand have also reviewed their programs.

These reviews have led to significant reorganisation and structural reform of blood services in many countries. There is no single preferred approach across countries, as the focus has been on the optimal reform for each country. Common themes, however, do exist: rationalisation, consolidation and integration as well as clarification of roles and responsibilities and system-wide approaches to achieving improved management, accountability and performance as part of risk management.

Today, the structure of blood programs varies greatly across nations, from highly centralised to highly regional. Many rely on the Red Cross for the administration of the blood supply but in some countries the Red Cross has ceased to play any role in the blood sector (eg Canada). The United States has a pluralistic system. Sweden relies on hospital-based programs. Finland and New Zealand have single national programs, with the former run by the Red Cross while the New Zealand Blood Service is a not-for-profit government enterprise. In the United Kingdom, there are blood services covering England and Wales, Northern Ireland, and Scotland. Funding arrangements also vary widely. In some countries patients, and no doubt insurers, bear the balance of costs for blood products transfused.

Safety of the blood supply

Many countries, including Australia, are striving for increased blood safety and a 'zero-risk' blood supply. The latter, however, is unattainable. Measures have taken a variety of forms (eg more attention to the selection and retention of lower risk donors, use of new and more sensitive tests to detect blood-borne pathogens and the introduction of techniques to inactivate blood-borne pathogens). Measures have tended to focus on the supply side. However, this is starting to change with attention turning to improving the clinical use of blood and blood products.

Regulatory approaches

Over the past two decades, regulatory approaches increasingly have been adopted for blood collection, testing, processing, storage, transport and use. Considerable effort and resources have been directed towards adopting and enforcing good manufacturing practices, overseen by strong national regulatory authorities. The aim has been to assure product consistency, safety and efficacy and protect the health and safety of recipients.

International regulation

An international regulatory environment for blood safety matters has emerged as part of trends in market globalisation and harmonisation. There are moves towards internationalisation of regulatory standards for the blood sector (eg the European Union); however, there are differing views about the nature and extent of harmonisation. The international regulatory environment is heavily influenced by two agencies — the Food and Drug Administration in the United States (FDA) and the European Medicines Evaluation Agency of the European Union (EMEA). The two agencies do not necessarily have identical views and may promulgate different regulatory standards.

Australia's regulatory approaches are closely linked to those of Europe, reflecting a similar tradition in blood transfusion services based on voluntary, non-remunerated donors and public health funding. Australia's current basic legal standard for therapeutic goods is the British Pharmacopoeia which, in turn, is subject to the European Pharmacopoeia Commission. The EMEA, through its Committee for Proprietary Medicinal Products (CPMP), develops scientific guidelines in key areas affecting blood products. While Australia is not obliged to follow these guidelines and standards, it has tended to adopt them.

Industry regulation

The plasma fractionation industry has come under increased regulatory oversight, scrutiny and control in developed countries. Attention has concentrated on good manufacturing practice established by national regulatory authorities. Dedicated viral inactivation and removal techniques have become mandatory steps in fractionation schemes. Initial viral testing of plasma by nucleic acid amplification methods detects viruses at an early stage and reduces the 'window period' between infection and detection. Recall procedures are mandatory for products derived from plasma pools potentially contaminated by pathogens that are unable to be eliminated by testing and / or inactivation procedures or where there are other breakdowns in good manufacturing practice. Limiting the size of plasma pools from which plasma products are manufactured has been used in some countries to reduce the risks of viral transmission (see Section 11.2).

The plasma fractionation industry, like the pharmaceutical industry, has undergone significant transformation. More stringent regulatory requirements and viral safety and compliance costs have altered the logistics and economics of plasma fractionation. For example, dedicated viral inactivation steps involve chemical, heat and radiation treatments designed to disable the virus without damaging the essential plasma proteins. While virus levels are reduced by these treatments, so are product yields.

The shift in political philosophy in many countries to the corporatisation and privatisation of government businesses has also affected the industry. Plasma fractionation plants of a number of Red Cross blood services have been commercialised.

The number of plasma fractionation plants worldwide has been reduced. There has been consolidation, greater commercialisation and diversification into other areas such as biotechnology (see Section 10.1).

Policy

A major debate among developed nations concerns the application of the precautionary principle to the formation of blood policy. The principle has been an accepted risk-management strategy in several fields where there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health and when the lack of scientific information precludes a detailed scientific evaluation (European Commission 2000a). In blood safety policy, precautionary approaches have been adopted in the face of scientific uncertainty (eg tightening of donor selection criteria to reduce the theoretical risk of variant CJD). While different countries and organisations may agree on the available facts, they may differ widely in their interpretation of how risks should be translated into a balanced health protection policy.

Product developments

Alternatives to plasma products have been developed and marketed. One example is recombinant factor VIII, which has displaced demand for plasma-derived clotting factors in some countries and altered the market outlook and economics of the plasma fractionation industry. The plasma product market in many developed countries has also changed with consumption and production shifting from factor VIII to IVIg.

3.2 Recent developments in Australia's blood sector

Over recent years, Australian governments have embarked on a series of initiatives to develop a national approach to the supply of blood and blood products and to managing supply risks. Efforts have focused on the blood service, clarifying roles and responsibilities of key agencies, strengthening national policy coordination, improving accountability, and supply and access arrangements for certain products. They have occurred in response to a number of factors:

- international developments and the problems some countries faced about the safety, quality and governance of their blood supplies;
- pressure of market globalisation and harmonisation in regulation, highlighting the need for national, rather than State and Territory based, approaches to supply and regulation;
- concerns about shortages in certain products in some parts of the country;
- concerns about rising levels of government outlays;
- increasing focus on efficiency and best use of available resources;
- growing recognition that a fragmented approach to management matters posed potential risks for the blood service, governments, donors, recipients and the community; and
- concerns that Australia's dependence on a single plasma fractionator and a policy of strict import constraints create potential risks to the supply of plasma products.

Structural changes

The McKay Wells review (1995) provided the impetus for many structural changes, the most significant being the formation of the ARCBS as a national blood service and the

establishment of the Blood and Blood Products Committee. A series of other measures aimed at providing funding, legislative and regulatory infrastructure necessary for a national blood service have been developed or put in train. Implemented measures include:

- extension of Commonwealth regulation to the manufacture of fresh blood components by the ARCBS since July 2000 so that a single national regulatory regime now applies to the activities of the two dominant providers and the vast majority of the sector; and
- a national indemnification scheme for the ARCBS (National Managed Fund) from July 2000 to support its operations as a national blood service and to better manage financial risks of government.

Measures still under development are:

- uniform national statutory defence legislation to operate in association with the new national indemnity arrangement; and
- new financing arrangements for the ARCBS.

Improved product supplies and access arrangements

Measures have been undertaken to improve supply and access for particular products. In 1995-96, State, Territory and Commonwealth governments provided additional funding to the ARCBS to increase plasma collection for factor VIII production. A 50:50 cost-shared program for the purchase of recombinant factor VIII was introduced at the same time. In 1997, States, Territories and the Commonwealth agreed to nationally coordinated cost-shared provision of certain imported blood products and related recombinant products for people with haemophilia who develop inhibitors (antibodies) to factors VIII and IX and for patients with other rare blood coagulation disorders. Previously, States and Territories funded products required for emergency use while the Commonwealth paid for those required for elective procedures. The memoranda of understanding for these new arrangements are being finalised by governments.

Managing supply risks

Two other initiatives are the National Reserve of Plasma Products and the Blood Product Replacement List. These were developed in response to concerns that potential supply risks for plasma products could result from Australia's dependence on a single national plasma fractionator and policy of strict import constraints.

A national reserve of major plasma products is presently being established. Announced in August 1998, the Reserve aims to provide short-term security in the supply of major plasma products in the event of natural disasters and failures in blood and plasma collection systems or the plasma fractionation process. The Reserve is being established through a mix of strategies — collection of additional plasma from Australian donors and resulting domestic fractionation, and through importation of IVIg. It will hold a three-month supply of major plasma products such as IVIg, factor VIII and factor IX. The Reserve is being established over several years, reflecting the time required to amass sufficient product while meeting ongoing needs. The Reserve is further discussed in Section 11.3.

The Blood Product Replacement List was announced by the TGA in 1997 as a contingency response to short-term problems in domestic manufacture. Its aim was to

establish a list of suitable foreign-sourced products that could be imported as needed. The impact of this initiative is discussed in Section 10.4.

National Managed Fund

Recently, a National Managed Fund was established to cover future blood and blood product liability claims against the ARCBS. The Fund replaces the previous State and Territory insurance arrangements and addresses problems the ARCBS had experienced in obtaining commercial insurance in some States. This new national indemnification arrangement for the ARCBS is supported by the payment of premiums by all States and Territories, the Commonwealth and the ARCBS. It provides uniform liability cover and central management. A memorandum of understanding sets out the respective roles, responsibilities and obligations of the parties.

Response to concerns about variant CJD and blood transfusion

A major development that has unfolded during the Review has concerned responses to the possible risk of acquiring variant CJD through blood transfusion. Variant CJD was first reported in the United Kingdom in 1996 and is thought to be contracted by eating beef infected with the prion that causes bovine spongiform encephalopathy (BSE), commonly known as 'mad cow disease'.

In December 2000, the ARCBS implemented the decision of Australian Health Ministers to defer blood donors who have lived in the United Kingdom for a cumulative period of six months or more between 1980 and 1996 as a precautionary measure against variant CJD. Similar donor deferral policies have been implemented in some other countries (eg Canada, New Zealand and United States). Australian Health Ministers took this decision in light of published scientific data suggesting that, in an experimental setting, variant CJD can be transmitted by blood between animal species. No cases of variant CJD transmitted by blood transfusion have been reported in Australia or elsewhere. Countries have taken this action as a precautionary measure to the possible risk of transmission of variant CJD through blood transfusion. The donor deferral measure is an example of the public health and safety policy balance between risks to the safety of the blood supply and risks to the adequacy of the supply.

The ARCBS has estimated that the measure is expected to result in an initial reduction in donations of 5-10 per cent, leading to some 30,000 donors eventually being deferred (Commonwealth Department of Health and Aged Care 2000). Australian governments have provided additional funding to the ARCBS to recruit new and lapsed donors and encourage current donors to donate more frequently to cover the resulting reduction in donors and whole blood and plasma donations.

An NHMRC expert committee was established in December 2000 to provide expert advice to Australian governments on matters necessary to prevent the spread of variant CJD and other transmissible spongiform encephalopathies (TSEs) in Australia.

3.3 Developments and trends in Australia's health system

Australia's health system like those of other similar countries has been changing. Some of the key trends are summarised below:

- a shift in policy focus from providers and inputs of health care to patients and the outcomes of care;
- a move away from government as funder, purchaser, provider and regulator of health services, with governments entering into contracts with providers to supply services, and regulation being undertaken by a third party;
- a search for ways to improve efficiency and effectiveness of service delivery and quality of health care, in the face of concerns about rising levels of government expenditure on health and resulting pressures on budgets;
- growing recognition that safety and quality improvement are central functions of health care systems, and establishment of bodies to provide national leadership, including the ACSQHC and the National Institute of Clinical Studies (NICS);
- increasing focus on risk management as an integral part of good business practice;
- increasing use of technology assessments to provide information on the benefits, risks and costs of health interventions to assist decisions about the funding, delivery and organisation of new and existing health care technologies;
- strengthening information systems and evidence to improve performance monitoring and assessment and to provide reliable information to consumers, providers and governments; and
- recognition of the need for access to high quality research and development and cost-effective ways to disseminate and translate research findings into practice.

3.4 Future developments

Scientific, technological and other developments

Developments in scientific knowledge and technologies will continue, probably at an ever-increasing rate. Even over the course of the Review, the Committee has seen the introduction of nucleic acid amplification testing for HIV and hepatitis C, as well as debate about the merits of leucodepletion of fresh blood products. Further development of technologies to improve the safety, quality or shelf life of blood and blood products (including new testing and processing methods) can be expected and some of these may have an impact on the availability of blood and blood products. New types of products that may increase supply and reduce risk are under development, such as modified red cells and platelets or substitutes for plasma products. Other approaches to reduce the need for blood and blood products, such as the use of naturally occurring substances to stimulate the production of specific blood components, are being developed (eg use of the hormone erythropoietin to increase red cell production). Trials are also being undertaken on new ways of using blood or modified blood products to treat illness and disease.

The effect of these developments on the blood supply is difficult to predict. They do, however, highlight the importance of developing ways to promote technological transfer across the Australian health system.

Product needs

There is escalating demand for certain products, particularly IVIg. This, together with the impact of donor deferral and other policies on the supplies of products in individual countries, is likely to result in a tightening global supply of plasma products. Adequacy and security of supply are emerging as key concerns for nations.

Rising community and consumer expectations

Consumer and community expectations about the blood supply and the health system generally, and the range of services provided, their safety and quality, access and costs, are likely to continue to rise. Maintaining public support and confidence are important policy objectives for governments, providers and regulators.

Emerging infectious agents

The blood sector and health system also need to be capable of dealing with new and emerging infectious agents. Following recognition of diseases due to viruses (eg HIV and hepatitis C), there has been a trend towards increasingly stringent testing of blood and adoption of donor deferral policies in a number of nations including Australia. There is concern in some quarters that these types of policy responses bring with them only marginal gains in safety, often at high direct and indirect costs.

Changing demographics

Australia's geography and pattern of settlement present particular challenges for the national delivery of health services, as does its changing demographics. Australia's population of around 19 million is both unevenly distributed across the continent and highly mobile. The ability to collect blood and plasma from donors varies across the nation as do needs for blood and blood products.

Australia's population is ageing and this trend will continue. At the same time, the rate of Australia's population growth is expected to continue to decline, largely as a result of increasing numbers of deaths occurring in an ageing population as well as low and declining fertility. The Australian population is estimated to reach between 22.1 and 23.1 million by 2021 (ABS 2000).

3.5 Implications for Australia

The impact of these developments and trends on Australia's blood and blood product needs are uncertain as are estimates of future demand. They mean that, during the coming decades, Australia will face a national and international environment that is complex, fast changing and uncertain, posing significant public policy questions. Ensuring Australians' access to a safe, secure and affordable supply of blood and blood products and their alternatives, and supporting their appropriate use, are public health matters requiring a national approach. This national approach should deliver efficient and effective services, respond to new and emerging developments and develop responsible and responsive policies.

Australia's blood banking and plasma product sector is in transition. It is moving from State and Territory based approaches to a national one for the supply of blood and blood products. It is an ambitious but important reform program. The Review has sought to build on these developments, while focusing on the broader need for a national approach for the whole sector. The Review's principal aim is a national approach that recognises the roles and responsibilities of States, Territories and the Commonwealth in a contemporary governance framework with national accountability. It has sought to

identify structural and other impediments to achieving a national approach and to recommend measures to overcome them.

The Review has used the following national goals and outcomes to assess performance and to provide a rationale for its findings, conclusions and recommendations. They are based on work initiated by AHMAC (1998) and are an integration of the following:

- provision of an adequate and secure supply of safe, high quality blood and blood products in the right mix;
- access based on clinical need;
- promotion of appropriate use of blood and blood products and their alternatives;
- best use of available resources;
- maintaining the capacity to respond rapidly to changing circumstances and needs;
- ensuring public support and confidence; and
- financial accountability.

The rest of this report sets out the Review's views on and recommendations for a national approach.

Part B — Meeting Australia's needs into the future

Term of reference 1

Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best-practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.

Term of reference 2

Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.

Term of reference 3

Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time. Among other things, the advice should cover:

- *the need for and financial impact of new testing procedures and new products;*
- *legal and ethical issues where access to products may have to be based on clinical priorities;*
- *cost effectiveness of proposed safety improvements;*
- *the role of an expert reference laboratory in setting and maintaining a national quality assurance program; and*
- *the impact of change on public confidence in the blood supply.*

4 Governance arrangements: taking a national approach within a federal system

The governance needs of Australia's blood banking and plasma product sector are central Review themes. The Review was asked to:

- recommend how the system might best be drawn together to ensure it meets Australia's needs into the future; and
- consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on issues of safety, quality and supply.

Key matters considered by the Review included the drawing together of the sector nationally and the financing framework and legislative requirements to support the new governance arrangements.

One of the Review's major conclusions is that governance arrangements must be strengthened in order to provide the national approach required for Australia's future needs. This conclusion is supported by universal acknowledgment across Review submissions and consultations. There is also wide agreement about areas requiring improvement. However, there are differing views on how areas of need should best be met. As with many other areas of health and public policy, developing a national approach within a federal system of government is challenging.

The Review has sought to identify functions and define roles and responsibilities.

In this chapter, principles and arrangements for a national approach are recommended. Subsequent chapters discuss the implications of a national approach for particular aspects.

It is important that changes are linked to developments in the health system and public health and risk management applicable to Australia's circumstances. The Review has considered the context within which decisions will be made and advice will be sought, and developed principles and approaches for assessing options, developing advice and providing a rationale for recommendations.

4.1 Limitations of current governance arrangements

A recurring theme in Review submissions and consultations was the lack of clarity in responsibilities between governments and resulting fragmented management approaches.

Division of responsibility

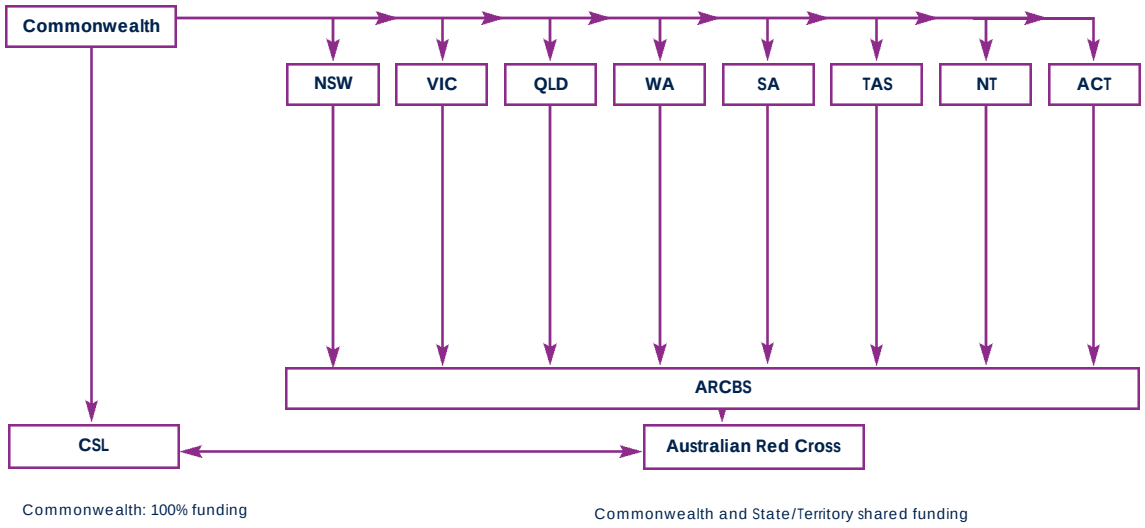
States, Territories and the Commonwealth share a number of roles and responsibilities. They make the laws that deal with Australia's blood supply, determine blood policies and are responsible for their implementation. They jointly fund the provision of blood transfusion services and indemnify against product liability claims through the National Managed Fund.

Today, the Commonwealth is the major funder, contributing over 67 per cent of expenditure on the supply of blood and blood products. While the ARCBS is funded jointly, it is States and Territories that have major responsibility for the supply and delivery of the national blood service by the ARCBS. In contrast, the Commonwealth is

the sole funder of CSL and has primary responsibility for national plasma fractionation and diagnostic product services provided by CSL. CSL depends on plasma provided by the ARCBS and its plasma product distribution services. The ARCBS relies on the plasma product manufacturing services of CSL.

As Figure 4.1 illustrates, all this is accomplished through a complex set of arrangements.

Figure 4.1 Australian blood banking and plasma product sector service delivery and funding arrangements — domestic homologous blood supply



The division of responsibilities is also reflected in the series of arrangements between States, Territories and the Commonwealth for funding imported blood products and related products and in the State, Territory and Commonwealth legislation that deals with the sector (see Appendix G). As well, States, Territories and the Commonwealth fund hospital, medical, and other services associated with the provision of blood transfusion services to patients.

Many respondents considered that current governance arrangements are major impediments to the ARCBS becoming a truly national blood service and Australia acquiring a national supply approach. The Review supports this view. The multiplicity of agreements that underpins the flow of products and funds within the sector leads to a fragmented approach to supply planning, priority setting and management, service delivery, performance reporting and accountability. They impede capacity to respond quickly and effectively to new needs and circumstances, as changes require negotiation with many parties. The high cost of maintaining the current arrangement, which is borne by governments and ultimately by taxpayers, is not the most cost-effective use of available resources.

Lack of national management and oversight

Currently, supply planning and management largely occur at an agency or component level, with coordination through a range of inter-agency and intergovernment committees.

As discussed in Chapter 2, the AHMAC Blood and Blood Products Committee provides some policy coordination across governments. It has concentrated on particular aspects rather than overall management.

Review submissions and consultations saw the establishment of this Committee as an important development, with many commenting on its significant work in a range of areas. These include increased access to products to improve the treatment of patients with haemophilia and other rare coagulation disorders; and investigating questions such as uniform national statutory defence, product liability insurance and alternatives to homologous donation. However, respondents questioned the Committee's capacity, authority and resources to provide national management and rapid response to new developments and pressures.

Suggested solutions from Review respondents

There is general agreement that current arrangements need to be strengthened and an overall framework developed to draw together the sector's activities, provide clarity in roles, responsibilities and accountabilities and ensure effective national management. There are differing views about how to achieve this. Most submissions focused on proposed mechanisms rather than on an overall framework that might give a strategic focus and purpose. Suggestions ranged from altering the structure and increasing the membership of the AHMAC Blood and Blood Products Committee, to establishing a national agency responsible for Australia's blood supply that would have the capacity to take action rather than merely coordinate. The importance of a national agency having effective State and Territory representation was emphasised, with either accountability to State, Territory and Commonwealth governments, or a single, clear line of reporting to one Minister.

A few submissions proposed that the Commonwealth should assume full responsibility for the funding and provision of Australia's blood supply. While the Review supports strong national governance, such a proposal is inappropriate given constitutional and practical limits. Australia requires national strategies to secure sufficient supply, to optimise use, to ensure efficient and effective use of available resources and to manage technological change. No one government has the necessary policy and infrastructure capacity to achieve these outcomes.

It is critical that any new governance arrangements enable States, Territories and the Commonwealth to work together on blood matters.

4.2 Developing a national approach

Drawing the sector together nationally

Ensuring a safe, secure and affordable supply of blood and blood products and alternatives requires national supply management, planning and oversight. Because the sector is largely government funded, governments need to work together to ensure financial accountability and optimal use of available resources. Agreements need to be considered and set in the broader context of national supply policies and arrangements, organisation, costs and performance measures and as part of national oversight. A national approach also allows clear lines of responsibility and accountability.

National product availability and access arrangements for patients and uniform standards and provisions to protect public health and safety are also needed. The differences between States and Territories in access arrangements for certain products

and the availability of certain procedures that reduce the need for blood and blood products were a common concern in submissions and consultations. These matters are discussed further in later chapters.

Critical to the new governance arrangements is a capacity to consolidate and integrate activities and to provide strong national management. Important considerations for the Review included developing an effective national management approach while ensuring administrative efficiency. Achieving such an approach is not easy given the complexity and nature of the blood sector and the matters of public health and safety involved. However, the need is undoubted.

Strengthening the structures

No advisory committee arrangement can provide the integrated management approach required. A national advisory committee can only recommend, not mandate action or change. It has limited capacity to deliver national management and administration. National accountability is not guaranteed. An advisory committee does not provide the ready capability that governments need to deliver national responses to new and emerging concerns and to protect public health and safety. The Review considers that advisory committee arrangements are neither appropriate nor sufficient to meet Australia's needs. A new approach is required.

A better alternative is a national blood authority that has overall carriage and responsibility for the national blood supply with statutory status and statutory powers.

The role of a National Blood Authority

A National Blood Authority would provide a national management structure, a rapid national response capability and a ready reporting mechanism for Australia's blood supply. As a statutory body with statutory powers, the Authority would have the necessary influence and status to deliver required national actions and policy outcomes. It would enable governments to control better their funding position in the sector and enhance national productivity. It would emphasise the importance of the blood supply as a matter of national interest. It would recognise constitutional and other legislative responsibilities of States and Territories within the health system and for statutory defence.

The Authority would be responsible for planning and managing Australia's blood and blood product supply needs; administering service delivery and funding agreements with blood product providers; managing associated government funds; monitoring and supervising operational efficiency and effectiveness; national information developments; and national reporting on supply activities, performance and emerging matters. It would also provide a national reference point for governments on blood matters. Subsequent chapters discuss in detail recommended roles and responsibilities of the National Blood Authority.

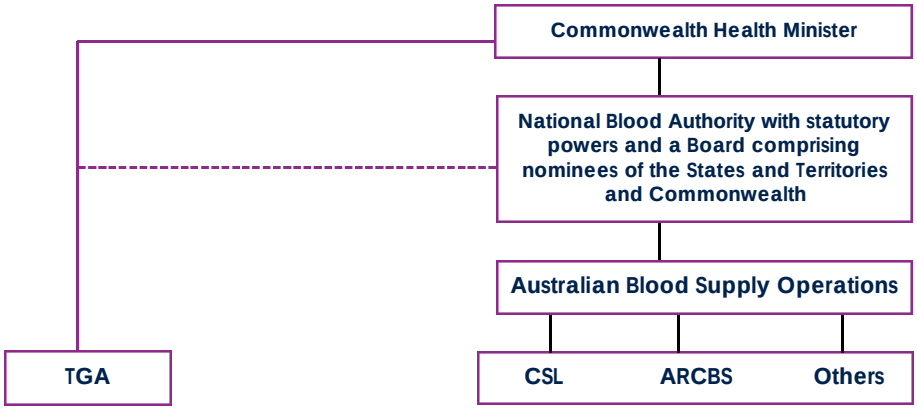
The Authority would comprise a Board with an independent chairman and nominees of State, Territory and Commonwealth governments from the public and private sectors. To be effective, the Board should comprise a small number of members drawn from the public administration, business and financial management, clinical and community areas. The Authority would need to be adequately resourced.

Clear lines of reporting and accountability

An integral part of implementing a National Blood Authority would involve simplifying current arrangements and establishing clear lines of government responsibility and accountability. This has been a key concern for the Review.

The Review considers that the National Blood Authority should be a Commonwealth statutory body reporting to the Commonwealth Health Minister and Parliament. The recommended approach is illustrated in Figure 4.2. At the same time, it is important that the Authority report regularly to Australian Health Ministers on the Authority's activities, performance of the national supply and emerging matters.

Figure 4.2 A national approach



The National Blood Authority should be established under its own Commonwealth enabling legislation in order to provide it with a separate existence and to set out its functions. As the Authority would manage public funds, it would be a statutory body under the *Financial Management and Accountability Act 1997*.

Relationships with providers of blood and blood products

Within the overall framework, the respective roles and responsibilities of providers of blood and blood product services to the proposed National Blood Authority need to be defined. A unique feature of Australia's blood supply is its arrangements, with governments as funders and the ARCBS and CSL as sole providers of blood and blood product services. The Review considers that it would be inappropriate for providers to be appointed to the Board of the Authority. Any such representation could pose potential conflicts of interest, as the National Blood Authority would be administering funding agreements with providers.

At the same time, the Review recognises the importance of drawing upon the expertise, experience and viewpoints of providers, along with other groups such as clinicians, professional groups and consumers, in development and in implementation matters. It is critical that the national approach encourages new ideas and innovation from all parties.

Relationship between National Blood Authority and the TGA

The relationship between the National Blood Authority and the TGA needs to be examined carefully. The independent national regulatory oversight administered by the TGA is an important attribute of Australia's blood supply. It provides a critical external

check and advises on policy in relation to product regulation matters including standards.

There is universal support for the important role that an 'arm's length' regulator such as the TGA can play in assuring public confidence. It is important that this role is not compromised, while ensuring that standards, including regulatory standards, are set in the context of public health policy and risk management. Again, clear lines of communication and advice need to be established.

Defining roles and responsibilities

Overall, the new governance arrangements recommended by the Review would comprise the following interrelated elements:

- national policy development by Commonwealth, State and Territory governments, with advice drawn where possible from existing arrangements and structures within the health system as well as from the National Blood Authority;
- national supply planning and management by the National Blood Authority;
- independent national regulation of blood supply safety and quality by the TGA;
- national quality assurance in supply and use to ensure quality standards and practices, with national coordination of approaches by a range of organisations; and
- supporting national financing and legislative arrangements by States, Territories and the Commonwealth.

Recommendations

- **A National Blood Authority should be established as a priority as a statutory body under Commonwealth legislation to provide national management and oversight of the Australian blood supply, which will, as in the past, be based on voluntary donation and with the products from donated blood provided free of charge to patients. The Commonwealth Government should provide funding for the establishment and operation of the Authority.**
- **The National Blood Authority should comprise a Board with an independent chairman and nominees of State, Territory and Commonwealth governments drawn from the public and private sectors. The Board should ensure close consultative arrangements are established with providers of blood and blood product services, clinicians, professional groups and the community.**
- **The National Blood Authority should:**
  - **manage and plan Australia's blood and blood product supply to meet current and future needs;**
  - **develop and implement national contingency planning to manage supply risks;**
  - **administer service delivery and funding agreements established between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and providers of blood and blood products and related services;**
  - **manage and account for public funds provided for the national blood supply;**
  - **monitor and assess local and international markets and developments in the sector;**
  - **plan and implement efficiency and quality improvements in the sector;**
  - **identify information needs and priorities for the sector and provide a national focus for performance monitoring and reporting;**
  - **assist in identifying research needs and priorities with the National Health and Medical Research Council and others; and**
  - **make recommendations and reports to governments on blood supply matters.**

- **While the National Blood Authority should be accountable and report to the Commonwealth Health Minister and Parliament, it should also report regularly to Australian Health Ministers on activities, performance of the national supply and emerging matters.**
- **The Commonwealth Government should establish mechanisms to ensure effective lines of communication and advice between the National Blood Authority in managing and planning Australia's blood supply and the Therapeutic Goods Administration in regulating its safety and quality.**

4.3 Financing framework

An efficient, effective and responsive national financing framework is required to support the proposed new governance arrangements.

As already stated, Australia's blood supply is largely government funded with cost-shared arrangements between the States, Territories and Commonwealth. The financing framework reflects Australia's federal system and the history and evolution of the ARCBS and CSL as national service providers. Agreements between the States and Territories and the Commonwealth, and between governments and service providers, underpin the flow of funds and products in the sector. Agreements vary in type, with most based on historical costs and activity rather than outputs and outcomes. Review submissions and consultations called for a simpler and more flexible cost-shared approach to government funding.

Recent developments

Current funding arrangements for the ARCBS reflect the previous State and Territory based organisational structure for the production and consumption of blood and blood products. The need for a new financing approach was highlighted by the McKay Wells review (1995), with a range of recommendations for change made. Since 1998, AHMAC has been developing a new funding system for the ARCBS that aims to be efficient, transparent and accountable and reflects the new responsibilities of the parties within a national framework and national production requirements. The intention is to move from funding on a historical input-costs basis to funding on outputs, with States and Territories funding fresh blood products and the Commonwealth funding plasma products. This approach is often referred to as the two-product line funding approach. The AHMAC Blood and Blood Products Committee is gathering detailed information regarding the costs of the blood service to develop an output cost model.

Two elements not to be changed are that blood and plasma be given by volunteer, unpaid donors and that blood and blood products from donated blood be provided free of charge to patients.

Need for financing reform

The need for financing reform was a common theme in Review submissions and consultations, several of which, including those of governments, questioned the appropriateness of the proposed two-product line funding approach for the ARCBS. However, few respondents put forward alternatives or suggested principles that should underpin new arrangements. Many referred to structural imbalances and inequities in current, largely State and Territory based arrangements, when they are based on production, not consumption, models. Some focused on the level of funding provided by governments, calling for additional funds, rather than changes to current financing arrangements.

The current mix, number and diversity of funding arrangements are outmoded and present a number of problems. They do not promote national supply planning, priority setting and management. They are administratively inefficient, do not facilitate timely responses and outcomes, and do not promote national accountability and reporting. An efficient and effective approach consistent with a national management approach with national accountability is required.

The Review considers that the financing framework for Australia's blood supply should:

- maintain cost-shared funding of the supply by States, Territories and the Commonwealth within a simplified arrangement;
- be compatible with proposed governance arrangements;
- support strategic national management;
- be efficient and transparent;
- promote efficiencies in the use of resources;
- promote national accountability and reporting; and
- be responsive to new developments and enable associated organisational and delivery changes.

The Review has approached its task in the following way. It has considered firstly the financing approach and secondly the flow of funds. It has then considered the relative contributions of States, Territories and the Commonwealth; national service delivery and funding agreements with providers of blood and blood product services; and the need for financial flexibility.

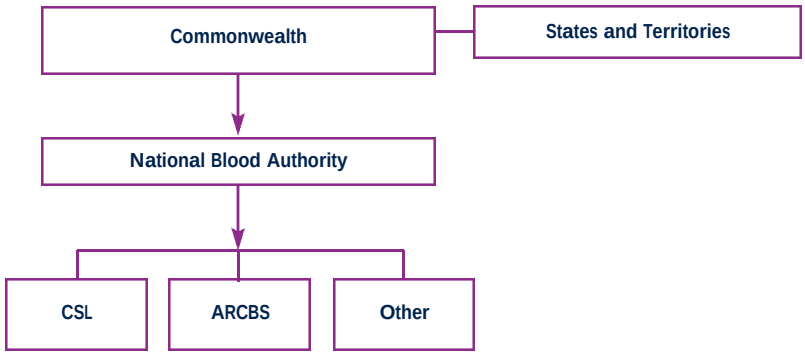
Financing approach

The financing framework should be in line with the proposed new governance arrangements. One of the arguments for establishing a National Blood Authority is strong national management including financing. The Authority would have a financial management role in administering single national service delivery and funding agreements with providers (ARCBS, CSL and other product and service providers) and reporting to Australian Health Ministers on progress and performance. A simpler and more efficient cost-shared funding arrangement based on the National Blood Authority and which promotes cost-effective use of available funds and national accountability is required.

Financing mechanism

The National Blood Authority could receive all funds directly by a Commonwealth appropriation with the Commonwealth being reimbursed by States and Territories. A second approach would involve the Authority being funded directly by each government for that government's share. However, the Review considers that the first approach provides a much clearer and simpler arrangement for the Authority. It is illustrated in Figure 4.3.

Figure 4.3 Flow of funds



Financial contributions of State, Territory and Commonwealth governments

The Review has reservations about the appropriateness and relevance of a two-product line approach for funding the ARCBS, for several reasons. The approach is based on a view that the two sets of products (fresh blood and plasma products) have unique features that enable them to be treated separately. The Review considers that this is an artificial way of considering blood products as in reality, the two are interrelated. They come from a common source (Australian blood donors) with collection, production, supply and distribution in one linked closely to those of the other. It is important that the two are managed jointly and that production and consumption needs are matched, otherwise excess products or product shortfalls may result. Supply management and planning should not be divorced from other sets of products such as imported products and product substitutes. Also, the two-product line approach is based on the assumption that plasma collection and plasma production are drivers of costs in the Australian blood supply.

The Review found it difficult to assess the validity of this assumption because of a lack of information on product costs and use. The Review considers that the two-product line approach would perpetuate a fragmented approach to supply management and planning, which is inconsistent with the proposed new governance arrangements for Australia's national blood supply.

The Review has sought, therefore, to establish some principles to guide the determination of the respective financial contributions of States and Territories and the Commonwealth. The Review considers that, as a starting point, the Commonwealth should maintain the relative proportion of its financial contribution (currently around 67 per cent). States and Territories should make their contributions on a cost-recovery approach, based on product usage, not on production as presently. This will require a set of national benchmarks of product costs that may be revised in light of new developments and changing costs. For administrative and accountability reasons, State and Territory contributions should be based on product usage in the previous year.

The Review acknowledges that national product usage and national product costing information is not collected routinely. It has noted the work being done through AHMAC to obtain a better understanding of the outputs of the ARCBS and to establish national benchmarks.

Chapter 6 presents a number of recommendations about the development of a national information strategy by the National Blood Authority and the importance of improved national inventory management systems in providing better information on product issue and usage. The Review considers that national inventory management systems

provide a ready means of addressing current information gaps on product usage. In the meantime, however, methods other than product usage are available. The current financial splits could be used to determine financial contributions. Alternatively, the work that AHMAC has initiated to obtain a better understanding of the outputs of the ARCBS may assist in establishing a new cost-shared allocation mechanism and cost-recovery charges.

National service delivery and funding agreements

As a general principle, the Review recommends the adoption of single national service delivery and funding agreements with providers of blood and blood product services (eg the ARCBS, CSL and other product and service providers). National agreements are required to support an efficient, effective and responsive national supply planning and management system. They would streamline arrangements, maximise use of available public funds, provide national implementation, availability and access arrangements, and promote national accountability and performance. They would also enable governments to control better their funding position in the sector.

National service delivery and funding agreements would be established between the Commonwealth, on behalf of States, Territories and the Commonwealth, and providers. The National Blood Authority would administer and report on agreements as part of its national supply management role and responsibilities. The agreements established with service providers should:

- be based on a set of consistent and contemporary business and public administration principles;
- be output based;
- set out the obligations, responsibilities and accountabilities of all parties;
- specify core service requirements;
- require compliance with national safety and quality standards and requirements for the provision of products and services; and
- require regular performance reporting.

These matters and recommendations for specific agreements are addressed in Part C.

Financing flexibility

The financing framework needs to be responsive to new developments and changing needs and circumstances. A recurrent concern across submissions was the annual nature of most agreements, making service delivery, supply planning and management and financial budgeting difficult for all parties and for a national blood supply. Negotiation involving nine governments with different budgetary cycles is inefficient and does not facilitate timely outcomes and responses. There were calls for greater financial flexibility to enable national responsiveness. At the same time, there is a need to ensure public accountability.

As a general principle, the Review considers that public funding should be based on evidence of cost effectiveness. The Review has recommended the use of evidence-based assessments for the provision of expert advice on the benefits, risks and costs of proposed blood policies. In other areas of health policy, there is some flexibility outside annual budgetary cycles to bring forward proposals for consideration by government provided they meet certain requirements. This involves provision of evidence of cost effectiveness

following expert-based assessment and proposed annual spending falling within certain financial limits.

Recommendations

- **State, Territory and Commonwealth governments should replace the current administratively complex cost-shared approach to financing Australia's supply of blood and blood products with a simpler arrangement where:**
  - **— the Commonwealth funds the national supply as a whole by a Commonwealth appropriation;**
  - **— States and Territories reimburse the Commonwealth for their respective contributions; and**
  - **— the National Blood Authority manages and accounts for the Commonwealth appropriation.**
- **State and Territory financial contributions should be made on a cost-recovery approach, based on product usage in the preceding year and national benchmarks of product costs. National benchmarks of product costs should be revised annually in light of new developments and changing costs.**
- **National service delivery and funding agreements should be established between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and providers of blood and blood products and related services.**
- **The States, Territories and Commonwealth should establish criteria for responding to new expenditure proposals that might arise between budgets.**

4.4 Formalising new arrangements

To underpin and formalise recommended governance and financing arrangements, the Commonwealth and States and Territories should establish intergovernmental agreements.

Recommendation

- **Intergovernmental agreements between the Commonwealth and States and Territories should be established to underpin and formalise recommended governance arrangements.**

4.5 Decisions about blood matters

The changes to governance arrangements will have implications for national policy development. Many of the decisions about blood matters are similar to those encountered in other areas of health. The difference is in community perceptions and attitudes to blood transfusion risks. This has been experienced worldwide and has resulted in extremely cautious decisions about blood matters in some countries.

In Australia, there is debate about priorities for resource allocation, as reflected by differences and tensions in Review submissions and consultations. It is important that decisions are made in the light of health system developments and public health and risk management applicable to Australia's needs and circumstances. To guide future decisions, the Review has sought to provide principles and approaches for assessing options, developing advice and providing a rationale for recommendations.

Risk management

In the blood sector, as in other areas of the health system, there has been a move towards risk management as an integral part of system-wide management. Strengthening risk management has been a key concern in AHMAC activities and reforms over the last six years and within individual organisations (eg ARCBS, CSL), as well as for the Review.

Options for managing risks need to be assessed against national public health interests. While the experience of other countries should be considered, their policies and practices may not be relevant to Australia's needs. It is important that national differences are taken into account in the development of Australian policies and that they are stated explicitly as part of the rationale for advice and decisions.

Proposals should be considered in the context of the entire blood sector, from donors through to recipients of blood and blood products. Individual measures and steps in one area may have 'flow on' effects in other areas. Introducing a new testing procedure may affect the adequacy and availability of supply as well as safety. For example, the introduction of nucleic acid amplification testing improves recipient safety; however, for platelets, which have a short shelf life of five days, the additional testing is at the expense of shelf life and utility. If these effects are not considered, there may be unforeseen and perhaps costly consequences.

Proposals should also be considered within the wider picture of government policies and programs. Action in other areas of health may have an impact on the blood supply (eg communicable disease control in the community), as may actions in areas outside health (eg agriculture, quarantine and trade) and vice versa. Balanced health protection policies require collaborative approaches.

Evidence should be drawn from a variety of sources including medical and scientific research; perceptions of donors, patients and the community; cost and use of resources; and wider social and ethical matters. In addition, advice should consider feasibility, timing and implementation.

Integral to improving risk management is the use of evidence-based assessments as policy tools. Assessing the benefits, risks and costs of policy options provides a clear and transparent way to communicate the basis of advice and decisions. Assessments should consider and appraise available research. They should be broad based, considering impacts on the blood supply, wider health system and other sectors. Assessment tools should include risk analyses, cost-benefit analyses and cost-effectiveness analyses.

Expert advice

Australia's health system already has a strong expert advice capacity that covers a range of areas. Government advisory bodies and departments, professional colleges, societies and other organisations provide expertise, capacity and infrastructure. Experts from a variety of fields are drawn on and a wide range of views canvassed.

In developing national blood policies, Australian Health Ministers will require advice across a range of areas including public health and safety matters; national supply; product access and availability; blood and blood product usage; innovations and developments; and mechanisms for continuing improvement. Where possible, they should draw this advice from existing health system structures rather than create new arrangements. This will help to integrate the blood sector into the health system of which it is a part, optimise existing expertise, capacity and infrastructure, minimise

fragmentation and facilitate technological transfer across the health system. This already occurs in some areas, is beginning in some areas and needs to be strengthened in others.

The National Blood Authority will be a source of advice on blood supply matters. The advice of various groups will be needed to facilitate the role of the Authority in national supply planning, management and oversight. Advice arrangements need to include an intelligence gathering capacity to allow national responses to change (eg new knowledge, new scientific and technological developments and innovations, new diseases and changing disease patterns). The NHMRC should provide this capacity and report regularly on areas of change.

Important sources of expert advice on blood matters are listed in the recommendations box below. Subsequent chapters discuss the specific roles and contributions of these various bodies in meeting Australia's needs for expert advice across a range of areas.

Recommendations

National blood policy should continue to be developed by the Commonwealth in collaboration with States and Territories. In developing national policies, Australian Health Ministers should draw on advice from the National Blood Authority and from existing health system structures and arrangements. Key sources of expert advice for Ministers and the Authority should include:

Public health and safety

- **public health and safety — National Health and Medical Research Council (NHMRC), National Public Health Partnership (NPHP)**
- **communicable disease surveillance — National Centre for Disease Control, and the NPHP**
- **safety and quality matters in hospitals including adverse events monitoring and reporting — Australian Council for Safety and Quality in Health Care (ACSQHC).**

Clinical practice

- **use of blood, blood products and alternatives — NHMRC, professional colleges and societies**
- **clinical practice improvements — National Institute of Clinical Studies (NICS), professional colleges and societies**

Regulation of products and manufacturing processes

- **The Therapeutic Goods Administration and associated bodies**
  - **safety, quality and efficacy of blood products and related products — Australian Drug Evaluation Committee (ADEC)**
  - **safety, quality and performance of medical devices and diagnostic products — Therapeutic Device Evaluation Committee (TDEC), National Serology Reference Laboratory (NRL)**
  - **product standards and good manufacturing practice standards — Therapeutic Goods Committee (TGC)**

Cost effectiveness of blood products, substitutes and medical interventions

- **plasma products, substitutes, clinical indications — Pharmaceutical Benefits Advisory Committee (PBAC)**
- **indicative prices for plasma products, substitutes — Pharmaceutical Benefits Pricing Authority (PBPA)**
- **testing procedures and medical interventions — Medicare Services Advisory Committee (MSAC).**

Surveying scientific and technological developments and innovations

- **scientific and technological developments on the horizon — NHMRC, MSAC**

Ethical matters

- **ethical matters relating to testing, access to products and treatments, research — NHMRC**

5 Assuring safe, high quality blood and related products

The Review was asked, under its first term of reference, to examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health system, and to identify impediments and recommend strategies to bring about sustainable improvements. This chapter examines the capacity of existing arrangements to ensure safety and quality in the production and supply of blood and blood products. It discusses ways to improve safety and quality within a national system, focusing on national standards and frameworks. Moves to promote safety and quality in the use of blood and blood products will rely more on action in hospitals, supported by national initiatives. These are discussed in Part D.

The Review was further asked to consider the need for mandatory compliance with a national quality assurance program and the role of an expert reference laboratory in setting and maintaining a national quality assurance program. Section 5.6 examines current quality assurance programs and mechanisms to encourage compliance with them, and recommends greater coordination of existing systems.

5.1 Recent developments and strategies

The range of measures implemented over the past two decades to improve the safety and quality of the blood supply and to minimise the risks of infectious disease transmission has been extensive and involved many groups within the health system. Some of these have been structural and organisational in nature, for example, the construction of the new CSL plasma fractionation facility at Broadmeadows in 1994, and the move to establish the ARCBS in 1996. Others have been of a regulatory nature. They include the introduction of Commonwealth regulatory controls for plasma collection and production in 1991 and for fresh blood products in 2000, accompanied by the development of and modifications to associated codes of good manufacturing practice. On the broader public health and disease prevention front, there has been a series of national strategies to combat HIV and hepatitis C.

As new viral hazards (eg hepatitis B, HIV, hepatitis C) have been recognised, the Australian health system has been quick to respond. Australia was an international leader in the area of public health interventions to minimise the spread of HIV / AIDS, once its modes of transmission were identified. New donor selection criteria have been developed and adopted in response to viral hazards, and testing of donations has been introduced as new tests became available. Initiatives in the testing area have included:

- the introduction of testing nationally for hepatitis B in 1970, for HIV in 1985, for hepatitis C in 1990, and for human T-lymphotropic virus 1 (HTLV-1) in 1993;
- establishment of the NRL in 1985 initially to evaluate test kits for HIV and to set criteria for interpretation of HIV test results, and gradually extended to hepatitis C testing and quality assurance in other areas of serology testing; and
- introduction of nucleic acid amplification testing for hepatitis C RNA in plasma pools by CSL in 1999, followed by nucleic acid amplification testing by the ARCBS for HIV and hepatitis C in fresh blood products in 2000.

Extensive quality assurance systems have been put in place within the ARCBS and CSL so that their products are both safe and fit for their intended uses.

Appendix I describes strategies in place to ensure safety and quality of the blood supply.

5.2 Assessing the safety and quality of the Australian blood supply

Safety and quality improvement are recurring Review themes. Definitions vary according to people's perceptions of risk and acceptable risk. The Review adopted broad definitions of safety and quality.

Perceptions expressed in submissions and consultations

Many submissions to the Review commented that Australia's blood supply is 'safe' and of high quality, although few of these submissions defined what they meant by a safe blood supply.

Most submissions also agreed that there is room for improvement, and a range of current problems and impediments to better practice and outcomes were identified. Many were relatively minor, or related to detailed technical matters falling outside the scope of the Review. Where the Review felt further action was necessary, it referred the matters to the appropriate authorities.

Referring to the viral hazards of transfusion, some submissions made the comment that the supply has never been safer, although published data to support these claims were not provided. With a few exceptions, other aspects of safety (eg bacteriological safety) and general product quality were rarely mentioned.

Some respondents felt that Australia falls short of international best practice in not having introduced universal, pre-storage leucodepletion and viral inactivation technologies for fresh plasma, and in not having provided greater access to certain recombinant products viewed as safer than human plasma-derived products. Others, however, questioned the value of spending more money to improve the already very high safety and quality profile of blood and blood products, on cost effectiveness and public health grounds, advocating that money would be better spent in reducing other disease risks in the community. Many of these expressed concerns that uncritical adoption of further safety measures might reduce access to products by decreasing supply or by delaying the release of products, thus reducing their useable shelf-life, particularly in the case of platelets. Other concerns focused on approaches to the setting of quality standards for the sector, with a number of submissions considering that standards set by the TGA are developed without wide consultation and may be being achieved at the expense of an adequate and secure supply of products.

While some of these comments reflect the inherent tensions that exist between regulatory bodies and those being regulated, they also highlight the need for standards to be set with a full appreciation of public health and risk management that is applicable to Australian needs and circumstances.

How safe is Australia's blood supply?

Analysis of the improvements that have occurred in the Australian blood supply over time is hindered by the current fragmented approach to data collection and performance measurement. Comparison with an external standard or benchmark may be helpful in establishing how well Australia performs against international practice and outcomes, although the magnitude and difficulty of international comparisons has been acknowledged in the literature (eg McCullough 1996; Petricciani 1999). A few reviews and studies have attempted to collect comparative data in a systematic and consistent manner. Most took a broad approach, focusing on the structural and procedural

arrangements in place to secure an adequate supply of safe, high quality blood and related products and tended to avoid evaluation of the effectiveness of blood programs in different countries. The data in some published reviews are now out of date, reflecting policies and regulatory regimes of a previous era.

Rates of viral markers in blood donations are useful indicators of the effectiveness of population disease prevention strategies and donor recruitment and selection processes. Some international comparative studies have been published on viral safety (ECEMA 2000; Muller-Breitkreutz 2000). Muller-Breitkreutz (2000) reported results from viral marker screening for hepatitis C, HIV and hepatitis B in 11 million unpaid donations from Europe, the United States and Australia. The study indicated that marker rates from repeat donations in Europe and Australia were significantly lower than those for United States volunteer donor populations in the 1990s. Also, the probability of a window period donation for these viral agents in Australia was within the ranges measured in Europe. However, the Australian data provided for this study did not include information for either New South Wales or Western Australia, so is not representative of the national donor population.

Submissions to the Review acknowledged the actions taken in recent years to safeguard the blood supply, and the Review noted the implementation of additional safety measures as new hazards were recognised, or as new testing technology became available. However, this should not lead to complacency. Both Australian and international experience over the past five decades with blood-borne infectious diseases such as hepatitis and AIDS is a salutary reminder of the need for continued vigilance.

Australia's achievement of near self-sufficiency in its blood supply and possession of its own plasma fractionation facility at the CSL Broadmeadows plant give Australia a high level of control over the quality of future supplies. Under these circumstances, continuing high levels of safety and quality should be achievable, as long as careful national policy measures and strong regulatory oversight are maintained.

5.3 Opportunities for sustainable improvement

The Review considers that safe, high quality blood and blood products require the following measures, some of which are already in place:

- national definition of quality standards for all processes and products and their regulation;
- mechanisms for 'horizon scanning' for new technologies and regulatory developments, and for ensuring that new developments are appropriately assessed before implementation;
- systems to monitor compliance with national standards, including both internal and external quality assurance; and
- information collection and coordinating mechanisms to ensure that performance data are reported upon routinely and feedback given to service providers and funders to improve performance.

Most of the opportunities for improvement identified by the Review fall within these areas. They appeared as recurring themes in the submissions and other materials examined by the Review. The key policy matters include:

- national standards for collection, testing and processing of blood components;

- the need for national consistency in donor screening and selection criteria, linked to a uniform national statutory donor declaration and uniform statutory defence laws; and
- quality assurance in laboratory testing, with an assessment of the need for a mandatory 'national quality assurance program'.

An analysis of these matters follows, together with some principles and the Review's recommendations for future action. Data collection and information needs are discussed in Chapter 6.

5.4 National standards and regulation

As discussed, Australia now has national standards and a national regulatory regime covering almost all domestic production. Standards cover aspects such as donor selection, collection and testing of donations, and subsequent processing and handling of plasma for fractionation and fresh blood components. Administered by the TGA, the regime's aim is to protect the health and safety of donors, recipients and the community.

The *Therapeutic Goods Act 1989* provides the legislative basis for Australia's national standards for blood and plasma products. The issuing of national standards is the responsibility of the Commonwealth Minister for Health and Aged Care, on advice from the TGA and associated committees, including the TGC.

National standards and a national regulatory regime are critical to assuring the safety and quality of Australia's blood supply and optimising use of scarce national resources by facilitating cross-border transfers of products. The nature of blood-borne communicable diseases, and the likelihood of new threats to the supply, also dictate the need for a flexible, rapid response capacity. Australia also needs to respond in a timely and effective way to new knowledge and technological developments.

Harmonisation between Australian and international standards

Australian standards for fresh blood components are linked to Council of Europe guidelines (TGA 2000). Plasma products are subject to the relevant sections of the British Pharmacopoeia. Two departures from European recommendations relate to the acceptance criteria for haemoglobin / haematocrit levels and United Kingdom residency status of donors. Currently, the ARCBS is exempt from the requirements related to haemoglobin levels. This exemption is under review. In addition, Australian requirements are in place that exclude donors with a history of six months residency in the United Kingdom between 1980 and 1996 from giving blood, in response to concerns about variant CJD and blood transfusion.

Harmonisation of Australian standards with international standards is a desirable national policy goal to facilitate the import / export of products and to facilitate regulatory efficiency. However, this should not occur without comprehensive and detailed assessment of local needs and circumstances. Australia's national interest may not always be best served by adoption of standards developed for other countries where population health status (eg diet-related conditions, infectious disease rates) and the policy environment differ from those in Australia. For example, the Council of Europe guidelines place greater restrictions on donors coming or returning from tropical areas than do national donor selection guidelines developed by the ARCBS. A recent commentary on this matter notes that while no European land is located within the

tropics, a substantial proportion of Australia's landmass falls within this zone, affecting a significant number of ARCBS collection centres (RCPA 2000).

Variability in regulatory standards

There is wide support in Review submissions and consultations for uniform national standards and processes for the collection, testing, processing, storage and transport of blood and blood products. There is universal support for a national regulator at 'arm's length' from implementation in order to assure public support and confidence. The main source of debate concerns the level and form of regulation that should apply to other aspects of the sector (eg hospital blood banks) and associated costs.

In 1998, AHMAC acknowledged that proper regulation of all elements of the blood and blood products system is an imperative for greater effectiveness, efficiency and accountability (AHMAC 1998). In 1998, AHMAC did not accept proposals for Commonwealth regulation of the whole blood banking and plasma product sector, thus excluding some hospital blood banking and related activities.

Gaps in safety and quality standards may exist in other sources of supply. There have been moves to improve standards for autologous collections and directed donations through the AHMAC Blood and Blood Products Committee (AHMAC 2000b). Several groups provided information to the Review on initiatives to improve safety standards for emergency transfusion in some rural and remote areas.

National standards should apply regardless of the provider, the setting and funding arrangements. This is important for risk management. It is imperative that standards continue to be monitored to ensure that uniformity is achieved.

National criteria for donor selection

Donor screening processes and selection criteria play an important role both in protecting the well-being of donors and in ensuring product safety and quality for recipients. Donor questionnaires are one of the key strategies used to achieve these aims (Appendix I).

An effective and safe national blood service requires development and timely implementation of evidence-based national criteria for donor screening and selection as part of donor management. Standards should be revised regularly in light of new evidence from relevant disciplines, including basic and applied research in the field of communicable diseases and human behaviour.

A multiplicity of arrangements and relationships exists relating to standards for donor screening and selection. Before 1995, donor screening and selection criteria were developed by the National Blood Transfusion Committee of the Australian Red Cross in consultation with the TGA. When the National Blood Transfusion Committee was disbanded in 1995 as part of the move to the ARCBS, its donor safety and selection functions transferred to the Donor and Product Safety Committee of the ARCBS. This committee issued *National Guidelines for the Selection of Blood Donors* in February 1999. The ARCBS advised the Review that these were revised in December 2000. Throughout there has been concurrent State / Territory legislation covering donor screening and selection, linked to statutory defence provisions (see Section 5.5). National regulatory arrangements for donor screening and selection, first introduced for plasma products in 1991, were extended to fresh blood products manufacturing by the ARCBS in July 2000, linked to the Council of Europe guidelines.

While inconsistencies exist between individual State / Territory provisions relating to donor selection, none of the State and Territory provisions exceed Commonwealth regulatory requirements in this area. However, this could happen in the future. Such inconsistency is not desirable for risk management within a national blood service. Under current arrangements, the ARCBS could choose to develop a more stringent donor selection framework and criteria than dictated by regulation. The cost implications of such action in what is essentially a fully government-funded service need to be considered.

There was a lack of clarity about roles and responsibilities for developing national donor selection criteria. It is now clearly part of the TGA's responsibilities in setting and reviewing national standards.

Donor selection is an integral part of the regulation of safety and quality. As with other standards, developing an appropriate framework and criteria for donor selection must occur within the context of public health and safety and risk-management approaches applicable to Australia's circumstances. It is important that donors' privacy and confidentiality are protected.

Managing safety and quality improvements

A related matter concerns how best to manage the assessment and introduction of safety and quality improvements. Australians should expect that national safety and quality standards will be based on the best available evidence and that they will be revised regularly in light of new evidence. Assessment should occur in terms of national public health and risk management applicable to Australia. The process should involve public consultation and results should be published and disseminated.

Australian standards for the production and supply of blood and blood products have evolved to accommodate new knowledge and emerging infectious or other threats. New, more sensitive tests and improved manufacturing processes will continue to be developed. Investment in further technological developments in laboratory testing needs to be balanced with investment in other facets of safety and quality in the sector, for example, haemovigilance systems to monitor adverse transfusion outcomes.

The cost effectiveness of all proposed improvements needs critical examination. Assessments should be broadly based. Timing, feasibility and implementation matters such as quality assurance requirements should be considered. All such measures should be subject to review.

The 'horizon scanning' function proposed to be undertaken by the NHMRC (see Chapter 4) will be an important way to keep abreast of developments in the blood supply and related areas.

Recommendations

- **There should be uniform national standards for blood and blood products covering donor selection, collection, testing, processing, storage and transport. Australian Health Ministers should monitor and assess the impact of the Commonwealth regulatory regime that took effect from July 2000 under the Therapeutic Goods Act 1989, identify gaps and take steps necessary to achieve uniform national standards for the sector.**
- **The Therapeutic Goods Administration and the Therapeutic Goods Committee should review regularly national standards for blood and blood products in light of new developments and evidence and in the context of national public health and risk management applicable to Australia's circumstances.**

5.5 Uniform national donor declaration and statutory defence laws

Donor declarations

Legislation in all States and Territories, other than Queensland, has required a declaration from donors that their answers to key questions in donor questionnaires are truthful. As part of the Commonwealth regulatory regime, it is mandatory for donors across Australia to complete a declaration form.

The donor declaration is a crucial element of statutory defence. A uniform donor declaration is essential for nationally uniform statutory defence.

Uniform national statutory defence

All States and Territories other than Queensland have legislation in place that provides a limited statutory defence to legal proceedings brought in relation to the transmission of certain diseases through the use of blood and blood products. This defence can protect the suppliers of blood and blood products, hospitals, medical practitioners and blood donors from civil liability where a recipient is infected with a disease such as HIV.

Statutory defence laws must strike a balance between the private interests of individuals to pursue their legal rights when injured as a result of use of blood or blood products, and the public interest in ensuring the ongoing availability of blood products through the protection of donors, the ARCBS, hospitals and medical practitioners from unreasonable litigation.

The defence is only available when the steps or procedures outlined in the relevant State / Territory legislation have been taken. The key elements of the defence are:

- that donors have been selected on the basis of an approved declaration form;
- that donated blood has been tested in accordance with approved testing methods; and
- the supplier, hospital or medical practitioner must take steps to ensure that the blood is not used if there is a basis for believing that it could be infected.

Areas of inconsistency in the current statutory defence laws of the States and Territories include:

- the diseases covered by the defence;
- who is able to claim the benefit of the defence;
- the minimum standards required to be met to attract the protection of the defence;
- the approval processes for tests;
- approval of the methods of screening blood donors;
- the situations in which the defence is not available; and
- special requirements for emergency transfusion.

Originally, statutory defence laws were developed to address difficulties experienced by the Red Cross in obtaining insurance in relation to AIDS. They now serve a wider risk-management purpose in the form of indemnity against AIDS-related claims arising from transmission through blood and blood products, in most of the States / Territories that have enacted such legislation. Over time, the laws have been amended by some States and Territories to widen the range of diseases covered.

Provision of an adequate and secure supply of safe, high quality blood and blood products in the right mix is an important national objective. Achieving this objective requires a viable and effective national blood service. An effective national blood service, in turn, requires the flexibility to transfer blood products across State / Territory boundaries. Interstate transfers provide the capacity to cater for fluctuations and disparities between supply and demand and to ensure product access in cases of established clinical need, without fear of the potential legal implications. The interests of the national blood service and the public would be best served by the enactment of nationally uniform statutory defence laws. National uniform statutory defence laws are desirable on a number of other grounds:

- to ensure that all users of blood and blood products are treated equally by the law;
- to support risk management and to provide certainty and clarity for the ARCBS that the defence will apply if it complies with agreed national standards; and
- to support the effective and efficient operation of the National Managed Fund and to ensure that it can achieve value for the public monies expended in obtaining insurance for the ARCBS.

The need for uniform 'blood shield' or statutory defence legislation was initially canvassed in the McKay Wells review (1995). That review recommended protection for the ARCBS preferably by Commonwealth legislation. However, nationally uniform laws have not yet been enacted. They are a critical part of a national legislative scheme for Australia's blood supply. They are required urgently.

Policy, constitutional and other matters surrounding efforts to achieve national uniformity in the area of public health and safety legislation have been considered extensively under the banner of the NPHP (Centre for Comparative Constitutional Studies 1999). Since the McKay Wells review (1995), detailed work relating to national statutory defence has been progressed by the AHMAC Blood and Blood Products Committee. Options to achieve uniform national statutory defence include the following approaches, each of which has its own advantages and disadvantages:

- *referral of States' powers* — States could legislate to refer their powers under the Constitution in this area to the Commonwealth, thus enabling the Commonwealth to legislate exhaustively in relation to civil proceedings for all categories of those to be protected by the legislation;
- *enactment of mirror legislation* — with each State or Territory enacting identical laws in relation to all possible statutory defence;
- *template legislation* — where the Commonwealth or one State or Territory acts as a 'host' and enacts the agreed legislation within its jurisdiction. All other jurisdictions then pass a law stating that the legislation of the host jurisdiction applies to bodies or persons within that State or Territory. A precedent for this approach exists in Corporations Law and in the Competition Code of the Trade Practices Act where the States and Territories have agreed and legislated to apply the Commonwealth Act as their own law; and
- *complementary legislation* — where the Commonwealth would legislate to the full extent of its Constitutional powers, and the States / Territories would enact identical legislation that would apply to those persons or bodies to which the Commonwealth law does not apply.

The original statutory defence laws were based on the mirror legislative approach, with all States and Territories apart from Queensland introducing laws based on the model legislation. Approval processes for listing new diseases and new tests for diseases vary across States and Territories. Current arrangements are administratively complex, inefficient and costly.

The national blood service operates in a changing national and international environment. The legislative and regulatory framework underpinning the service must be able to accommodate timely, efficient, effective and national responses to new diseases, new knowledge and technological developments.

Uniform statutory defence laws and a national approval mechanism for updating the defence laws and varying the donor declaration in response to changes in national standards are critical. The TGA is best placed to be the national approving body as part of its role in setting and reviewing standards for the Australian blood supply.

Recommendations

- **Australian governments should put in place, as a matter of urgency, nationally uniform statutory defence laws.**
- **The Therapeutic Goods Administration should be the approving body for listing new diseases and new tests for diseases and for varying the donor declaration to ensure a nationally consistent and timely response to changes in national standards.**

5.6 Quality assurance in laboratory testing

The Review was asked to examine the 'role of an expert reference laboratory in setting and maintaining a national quality assurance program' and the need for 'mandatory compliance' with such a program. The Review has interpreted these aspects of its terms of reference as external oversight of quality assurance in laboratory testing, and made recommendations for broad national quality assurance for the sector.

In submissions to the Review, there were differences in perception of the role and functioning of a 'national quality assurance program'. The purpose of external quality assurance activities in laboratory testing is to ensure safety and quality and to promote public confidence. Some submissions expressed the view that achieving a high level of safety and quality in the supply and production of blood and blood products involves professionally driven commitment and initiatives in addition to legislation and regulation. Respondents referred to the strong tradition of professionally driven internal and external quality assurance activities in the medical laboratory and testing area, while noting the increasing dominance of government regulation in the production and supply of blood and blood products.

External quality assurance activities

There is a range of external quality assurance providers and specialised programs in laboratory testing. Details of the arrangements are outlined in Appendix K.

The *Australian Code of Good Manufacturing Practice: Human Blood and Tissues* (TGA 2000) contains requirements for quality systems in the manufacture of the homologous blood supply. It includes reference to some specific laboratory quality assurance activities (eg participation by licensed facilities in an external quality assurance program including periodic proficiency testing and test kit performance monitoring). For viral

testing, external quality assurance is provided by the NRL. The RCPA provides an external quality assurance program for blood group serology.

Hospital-based and private pathology laboratories collecting autologous and directed donations are not covered by TGA regulatory requirements, but participate in external quality assurance programs for viral testing and blood group serology.

There is currently a strong set of overlapping, generally complementary and effective quality assurance arrangements in place for laboratory testing and processing of Australian blood. However, the arrangements are poorly coordinated and do not extend to, nor influence, sector-wide decisions. The latter is essential to ensure accountability.

Existing external quality assurance arrangements in laboratory testing need to be strengthened through better national coordination, and be complemented by enhancements to quality assurance in the use of blood and blood products.

Should quality assurance be mandatory?

A number of submissions from governments and government agencies, and from a variety of professional bodies, supported the continuation and enhancement of the NRL's established role. The Review supports continuation of the NRL's role in confirmatory testing for viral pathogens and external quality assurance in the blood sector but acknowledges that other laboratories provide similar services.

A related policy question is whether quality assurance programs should be made mandatory for all suppliers of blood and plasma products and, if so, for what testing and by what mechanisms?

Existing regulatory and financial levers to ensure participation in quality assurance and compliance programs are overlapping and indirect. They vary across the sources of supply. Quality assurance systems, and compliance with quality requirements relating to viral safety, are already mandated for much of the sector through the codes of good manufacturing practice (cGMP) administered by the TGA.

It is difficult to justify mandating further quality assurance without investigation of the cost:benefit ratio and the adequacy of data collection, monitoring and reporting under the new governance arrangements proposed for the sector.

There are mechanisms other than legislation and regulation that may be used to ensure participation in and compliance with quality assurance requirements in laboratory testing. They include:

- service delivery and funding agreements between funders and service providers; and
- the memorandum of understanding between the Commonwealth, the States and Territories and the ARCBS to establish a National Managed Fund to cover liability claims against the ARCBS. The memorandum of understanding requires the ARCBS to identify areas of potential risk to the independent funds manager and to operate in a nationally uniform and consistent manner.

These may be used to require reporting of defined information relating to laboratory performance.

It is important that aggregate data on test results from external quality assurance programs are provided to the National Blood Authority in administering service delivery and funding agreements with providers, to the TGA in regulating the safety and quality of supply and to other appropriate bodies. Results will also assist in monitoring and reporting on the performance of the sector.

Future needs for quality assurance including laboratory testing should be examined as part of assessments of future safety improvements as discussed in Section 5.4.

Recommendations

- **Arrangements for external oversight of quality assurance in laboratory testing should ensure that:**
  - **national service delivery and funding agreements with providers of blood products and services require participation in, and compliance with, external quality assurance and proficiency programs;**
  - **external quality assurance programs are conducted independently of service delivery;**
  - **aggregate data on testing results are provided to the National Blood Authority, the Therapeutic Goods Administration and other appropriate authorities for monitoring and reporting; and**
  - **evidence-based assessments of proposed safety and quality improvements in the production and supply of blood products consider quality assurance requirements.**
- **The Commonwealth should establish a mechanism to coordinate nationally activities of external quality assurance providers and specialised programs in laboratory testing.**

6 Enhancing information and research capacity

A recurring Review theme is the need to enhance information and research capacity. This chapter outlines the overall needs for national information management, national coordination of blood information systems, ongoing performance monitoring, links with the wider public health sector, and research. Information and research needs specific to various aspects of the sector are discussed in other chapters of the report.

Responsibility for information management and research rests with a number of bodies within the Australian health system. They include governments, industry and provider groups, the NHMRC, the NPHP and related groups (eg the Communicable Diseases Surveillance Network, Public Health Laboratory Network and others), the ACSQHC, the NICS, universities, professional bodies and consumer groups. The ARCBS and CSL as the two major providers have a significant role to play in information management and research.

6.1 Information management

The Review has encountered a lack of information in the public domain about activities within the multiplicity of arrangements that make up Australia's blood sector. As discussed, there is currently limited capacity to routinely draw together information from a number of sources and build a national picture of activity and performance.

National Blood Management System of the ARCBS

The Review considers that the effectiveness and efficiency of the national blood service and national policy development, monitoring and review would be substantially strengthened by reliable national data and comparable time-series information. This should be a high priority for the ARCBS and governments.

Although the single simple objective of blood banking is to provide blood or blood products to patients in need, many elements and processes are involved to ensure that safe blood components are available where and when needed. Computerised information management systems are needed to track the progress of each donation through each stage of the process. This is essential in donor management, blood typing and pathogen testing, inventory management, and blood ordering and usage monitoring (Kern & Bennett 1996).

The critical need for a national information management system was identified in the McKay Wells review (1995). Submissions to the Review identified problems in donor and inventory information management, along with systems development. The ARCBS advised the Review that, at the time of its formation, there was little commonality between existing State / Territory information management systems.

Despite significant government financial commitment for the development of a national system (of around $13 million in 1998-99), progress towards this goal has been slow. Some early attempts to develop integrated systems between States and Territories or nationally have not proceeded. This may be due to the complexity of the systems involved and the pre-existing variations between States and Territories. Reviews of the development of health care information systems generally have demonstrated a consistently high rate of failure or partial failure in implementation (Heeks et al 1999).

The system currently under development by the ARCBS, known as the National Blood Management System, is expected to be implemented progressively within the service

over the next two and a half years, commencing with the South Australian business unit in February 2002, and finishing with Queensland in July 2003. Early expectations were that the system would be operational by July 2000.

The National Blood Management System is expected to offer significant advantages over current arrangements. It will permit consolidation of national data on donors and provide the ARCBS with a real time, on-line national inventory database to monitor national production, internal product loss and wastage, and internal product transfers. It will facilitate lookback and product recalls, as well as interstate transfers and re-issues. Risk management and efficiency advantages will be offered through enhanced disaster recovery processes and reduced overall operating costs through use of a common system.

The National Blood Management System represents an important development for the national blood service and for the Australian blood supply. Given the slower than expected rate of progress, the extent of government investment, and high risk nature of health information projects generally, the Review believes close monitoring and review of the current project is warranted. Ensuring that the system will meet national service delivery and information needs, and timely implementation are essential.

A related concern is the interface between the ARCBS National Blood Management System, CSL and hospital blood banks, patient identification systems and haemovigilance systems.

Barcode systems already in use in the blood service permit the assignment of a unique identifier to each donation, which can follow every product manufactured from that donation. The International Society of Blood Transfusion (ISBT) has developed an international barcode standard (ISBT-128) that requires the unique identifier to include the country and year of collection, collection site, and a unique chronological identification number linked to the donor base (ISBT 2000). This standard is being implemented by the International Council for Commonality in Blood Banking Automation (ICCBBA). National implementation of this standard within the ARCBS could underpin national production planning and inventory management. Computerised barcode systems have the potential to link the supplier and institutions that use blood. Barcode systems are now available for use at the bedside. In the clinical setting, they can provide positive identification of each transfusion recipient, match identification data at the time of transfusion, monitor vital signs during the transfusion process, and provide electronic charting information, among other things. Such systems have the capacity to reduce errors in the administration of blood. They may have been implemented in an unknown number of Australian hospitals.

The integration of barcode identification systems between the national blood service, CSL and hospitals would facilitate the operation of a national haemovigilance scheme. The Review is not aware of any work being done in this area.

National information management and reporting plan for the blood supply

The ARCBS National Blood Information Management System is one of the national information systems which are essential for the future management and planning of Australia's blood supply. The current lack of national information on activities and outcomes makes it difficult to assess supply and demand for products and to monitor the impact of supply policies and initiatives. Lack of information on service delivery costs makes it difficult to assess the cost effectiveness of resource usage.

One of the proposed functions of the National Blood Authority is to identify information needs and priorities for the sector and provide a national focus for reporting. A national information management and reporting plan is an important first step. It should address matters such as:

- information requirements;
- information priorities;
- the sources and methods of information collection;
- the respective roles and responsibilities of various organisations;
- programs and timetables for development;
- analysis and reporting requirements; and
- monitoring and review arrangements.

Recommendations

- **The National Blood Authority, as part of its national supply planning role, should monitor the implementation of the ARCBS National Blood Management System for national inventory management, with a view to early introduction.**
- **The National Blood Authority should develop a national information management and reporting plan for the Australian blood sector.**

6.2 Performance indicators

An agreed set of performance indicators against which trends in safety, quality, availability and adequacy as well as use can be monitored, and mechanisms to draw together information from a range of sources, are essential prerequisites for sustainable improvements.

Performance indicators should cover key elements of the homologous supply chain — relating to the source population, donors, collection, testing, processing, product storage, pre-market evaluation and post-market surveillance activities (see Appendix I) as well as issue and use. Some monitoring and performance information is already collected in these areas by different groups. Examples of these are:

- source population (eg incidence and prevalence of specific blood-borne infections as measures of the effectiveness of public health disease prevention efforts);
- donor recruitment, selection and retention (eg proportions of new and repeat donors; prevalence of markers for hepatitis C, HIV and hepatitis B in first time and repeat donations — as indicators of the effectiveness of population health strategies and donor selection processes);
- collection (eg adverse reactions in blood donors as an indicator of the quality of collection practices);
- testing (eg test kit failures or recalls — as indicators of the effectiveness of quality control in manufacturing); and
- overall sector indicators (eg availability of products in the right place at the right time; transfusion-acquired infection rates for specific conditions — indicators that will be influenced to some degree by many of the overlapping safety measures, including public health education, donor selection and donation testing, and viral inactivation strategies).

The Review acknowledges that developing appropriate performance indicators for monitoring the safety and quality of the supply and of the sector overall has its difficulties. Appropriate indicators for different components of supply may be difficult to define and quantify. There are inherent measurement problems that make quantification of some quality indicators difficult. Also, the collection and reporting of some indicators (eg transfusion-acquired disease rates) may not be possible without enhancements to current public health communicable disease surveillance. The current lack of a system for monitoring adverse patient outcomes and 'near misses' is widely perceived to be a significant impediment to further improving the safety and quality of the Australian blood supply, as discussed in Part D. However, such problems are not unique to the blood sector and should not deter effort in this area.

One of the roles of the National Blood Authority should be to monitor and report on performance of the blood sector and to develop a set of performance indicators in liaison with and drawing on the expertise and experience of relevant groups.

Performance indicators in agreements

Increasingly, output measures and performance indicators are being used in Commonwealth-State funding agreements and in service delivery agreements between governments and service providers to promote national policy goals.

The Review has highlighted the need for regular performance reporting and recommended that service delivery and funding agreements should be used as a major mechanism for ensuring this. It is important that a comprehensive, sensitive and appropriate range of indicators is selected to assess progress and achievements.

Extensive work has been done by the National Health Ministers' Benchmarking Working Group (1999) in developing performance indicators for hospitals (also discussed in Part D). Valuable experience and information was published by this group over its five years of operation which could assist in developing a framework and performance indicators for the Australian blood sector. The National Health Ministers' Benchmarking Working Group has been replaced by the National Health Performance Committee. The latter's brief extends to population health and other areas in addition to hospitals. In keeping with the principles of the Review, the development of performance indicators should be linked with these broader initiatives.

6.3 Links with public health communicable disease prevention and surveillance

The emergence of new communicable diseases, with potential implications for public health and the blood supply, dictate the need for an effective and timely communicable disease surveillance capacity. Developments in information technology provide opportunities and the potential to link better existing public health laboratory and other systems (including ARCBS laboratories) across States / Territories to collect, analyse and report on communicable disease occurrences and test results.

A number of submissions called for a closer and more structured relationship between the blood sector and the broader public health sector, to bring mutual advantages in terms of safety, quality and effectiveness. The Review supports these suggestions.

A mechanism for linking activities in the national blood service with wider public health initiatives exists in the form of the NPHP. The Partnership is a multilateral group established in 1996 by Australian Health Ministers. It aims to improve service delivery

outcomes by strengthening public health infrastructure in the areas of workforce development, information systems, legislation review and harmonisation, coordination and monitoring of public health interventions and strategies.

Several strategies coordinated under the aegis of the NPHP are linked directly to the ongoing safety of Australia's blood supply including the National HIV / AIDS Strategy, the National Hepatitis C Strategy, and the National Communicable Diseases Surveillance Strategy (NCDSS) (Steering Committee, NCDSS & DHFS 1999).

The NCDSS provides a national framework to monitor communicable diseases and aims to improve the nation's capability in collection, analysis and reporting of selected communicable diseases, including HIV and hepatitis C. In particular, it seeks to maximise capacity to monitor disease trends, produce reliable health intelligence and respond to new and emerging diseases, and involves better integration of laboratory science and epidemiology.

A National Notifiable Disease Surveillance System (NNDSS) operates within this framework under the auspices of the Communicable Diseases Network of Australia and New Zealand (CDNANZ). These public health initiatives complement viral testing and inactivation in assuring safety and quality. Maintenance and strengthening of these surveillance activities are essential to the effective and safe operation of the national blood service.

6.4 Improving research capacity

Research needs

Research is needed to inform innovation (to ensure that products, processes and practices keep pace with developments) and to improve the evidence base for transfusion practice. This can occur through both basic research and strategic, priority driven and applied research.

It is important to identify current knowledge gaps and key research questions. The Review has identified a number of areas where further research is warranted, which are raised in subsequent chapters. A related concern is whether resources should be committed to local research in these areas, or whether support should be given to international collaborative efforts. Australia is well placed to contribute to and benefit from international research. In the face of competing research priorities, it is important that Australian research builds on and does not duplicate research overseas.

Further research will require the cooperation and collaboration of: governments (as principal funders of the blood system but not necessarily of research); key industry groups and providers (including the ARCBS and CSL); interested professional bodies; and academic groups with an interest in biomedical research, systematic reviews and health services research. It is important that collaborative projects are encouraged and that processes for peer review of research proposals are in place.

Research funding and partnerships

A recent review of health and medical research (Health and Medical Research Strategic Review Committee 1999, the Wills Review) noted that investigator-initiated, peer-reviewed research is the foundation of Australia's success in research endeavours and should remain so. Nevertheless, it supported the need for development of funding from both Commonwealth and State governments for priority-driven health and medical

research and a strengthening of the NHMRC's role as Australia's peak body for health and medical research.

Effective research partnerships between researchers, governments and industry have the potential to be mutually reinforcing. The Wills Review noted that the full benefit of the government's commitment to fundamental research can only be achieved with a research culture that can effectively partner with industry (or vice versa) and, where private capital investment is used, to bring ideas to fruition.

Both the ARCBS and CSL occupy critical positions in the sector. They are well placed to carry out basic and applied research relevant to their roles, and to capture the value of specific basic research discoveries once made. Both organisations have considerable capacity to attract research and development funding from multiple sources, including industry and the NHMRC. The ARCBS also has potential to draw research and development funding through charitable donations from philanthropic organisations or as in-kind contributions from commercial suppliers.

The ARCBS currently conducts a research program that is broad in scope. The move to a national organisation has provided the ARCBS with a significant opportunity to undertake strategic applied research, and it has already established collaborative external research relationships with universities and research institutes, commercial suppliers and pharmaceutical companies, the American Red Cross and others. The Review supports the ARCBS' initiative in taking a strategic, national approach to its research and development activities.

CSL also has a research and development program to improve its existing products and develop new products. CSL receives funding through investment programs run by the Commonwealth Government to foster and support a pharmaceutical industry in Australia. Under the current program — the Pharmaceutical Industry Investment Program (PIIP) which was announced by the Commonwealth Government in July 1999 (Minister for Industry, Science and Resources 1999) — CSL is expected to receive $60 million over the five years 1999-00 to 2003-04 to support a range of research and development projects. CSL's purchase of ZLB and the consequent expansion of its research and development base, has potential benefits in providing access to the latest product developments and innovations. Innovation is an important national objective that should be specified in future plasma fractionation agreements.

Next steps

As a first step, it is necessary to identify, promote and coordinate priority areas for research and innovation relevant to Australia's needs. One of the proposed functions of the National Blood Authority is to assist in identifying research needs and priorities, together with the NHMRC, key industry providers (the ARCBS and CSL), the ACSQHC, NICS, blood user groups, and relevant professional groups (including the Australasian Society of Blood Transfusion [ASBT] and Haematology Society of Australia and New Zealand [HSANZ]). A national research agenda needs to be established. A strategic approach to future research needs is required to ensure the best value for research and innovation investment.

Recommendation

- **The National Blood Authority should work with the National Health and Medical Research Council and with other interested parties to identify priorities and develop a research program to strengthen the evidence base for transfusion practice in Australia.**

Part C — Ensuring a safe and adequate supply

Term of reference 4

Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.

Term of reference 5

Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.

7 Australia's blood donors

The Review acknowledges the contribution made by volunteer donors to Australian society. Submissions and consultations also acknowledged the pivotal role that donors play and the importance of donor management strategies. The belief that there has been a significant decline in the number of blood donors and, hence, a 'crisis' in Australia's blood supplies, was expressed in some submissions.

This chapter provides an overview of blood donors in Australia and overseas, discusses the need for a national approach to donor management and presents some principles for future monitoring and research to improve donor management practice. It draws on information about Australian donors provided by the ARCBS, including results of two national donor surveys. The aim is to give an appreciation of the relevant 'human factors' and to support future effort by the ARCBS.

7.1 The current donor pool

ARCBS information indicates that around 460,000 Australians donate blood each year (Appendix J, Table 1). The proportion of the age-eligible population (16-70 years) that donates blood and plasma each year has been steady at around 3.5 per cent and the collection (or donation) rate has been stable at around 48-50 donations per 1,000 population in the four-year period 1996-97 to 1999-00 (Appendix J, Tables 1 and 2). However, there are marked variations in these figures between States and Territories (Appendix J, Tables 1 and 2). These recent data are not indicative of a national 'crisis' in donor numbers but may support other evidence of local shortages in some blood products.

Donor characteristics

Australia's blood donors are not an homogeneous group. They make different types of donations (eg whole blood, plasma only, platelets or red cells only) depending on local or national priorities and needs and their own preferences.

Results of an ARCBS National Blood Donor Survey[1] conducted in 1999 (ARCBS 1999a) suggest that:

- males and females are almost equally represented among current donors nationally — 51 per cent and 49 per cent respectively;
- three-quarters of Australia's donors are aged 35 years or more; and
- many of them are in employment (76 per cent of males and 24 per cent of females in full-time employment and 7 per cent of males and 26 per cent of females in part-time employment).

Most Australian donors (around 90 per cent) donate only whole blood, while about 10 per cent of donors report they have been an apheresis donor at some stage (ARCBS 1999a).

The ARCBS also selectively recruits to its donor base, or identifies from within it, special groups of donors for the collection of components (eg red cells for boosting programs or diagnostic reagents) or plasma for use in the manufacture of some highly specialised products such as Rh D immunoglobulin. These special donor panels are maintained in

[1] These data may not be fully representative of donors nationally, nor of those within individual States and Territories

some States and may comprise only a small number of individuals (around 10-15 people).

Donor recruitment strategies

Australia's donors give their blood out of altruism, that is, for the general good of the community (Harrison Health Research 1997a; 1997b; McDonald 1999; CM Research 2000). Other motivations for donating include personal experience; being encouraged to donate by friends, work mates, family, or community groups; a supportive workplace (eg for donations during working hours); and (for regular donors) habit, or a sense of duty developed from the process.

Blood collection agencies employ a mixture of recruitment strategies that aim to encourage a sufficient number of low-risk donors to donate, ideally on a continuing basis. Various strategies are used to appeal to the motivations of different groups within the population. Strategies tend to fall into three broad categories (Mayo 1992):

- volunteer recruitment strategies which rely heavily on the internally generated motives of donors — their sense of altruism or community responsibility — and offer no material incentives or rewards for donating;
- incentive-based strategies, which may also use media campaigns stressing the positive feelings derived from donating blood but introduce a variety of small material or similar rewards to serve as further incentives for donating; and
- social persuasion-based strategies, which introduce the encouragement or pressure of peers and colleagues to persuade individuals to donate blood. Mobile blood drives, for instance at work places or schools, fit within this group.

Frequency of donation

People who donate frequently are exposed repeatedly to the donor selection process and donation testing. Hence, their donations are safer than those from first-time donors. This is borne out by data on the prevalence of viral markers for HIV, hepatitis C and hepatitis B in first-time and repeat donations from international and Australian surveys (ECEMA 2000; Muller-Breitkreutz 2000). A survey of 22 European countries undertaken in 1999 showed that the prevalence of HIV in donations from first-time donors was 11 times higher than its prevalence in donations from repeat donors (ECEMA 2000).

Frequency of donation in Australia is regulated by standards promulgated under the *Therapeutic Goods Act 1989*, which are based on Council of Europe guidelines (Council of Europe 2000). Standards specify that four whole blood donations per annum for males, and three donations per annum for females should not ordinarily be exceeded, while plasmapheresis donations should not be made more often than once every two weeks.

Over the past four years, since the creation of the ARCBS, the average number of donations per Australian donor per year has remained steady at around 2.0 (derived from data in Appendix J, Tables 1 and 2). However, there is considerable variation, from 1.7 in Western Australia to 2.4 in Tasmania. This measure is a relatively insensitive indicator for use in donor management and production planning. It was the only indicator available readily to the Review.

Donor retention

As donations from repeat donors are safer than those from first-time donors, it is important to understand the factors that cause people to stop donating or to continue with donation.

Reasons for discontinuing blood donation have been found to include a work / family / lifestyle change; opening hours not being convenient; being too busy; experiencing side effects; a medical condition; and the quality of the donation experience (eg pain; treatment by blood service staff; long waits; alienating hospital / clinical culture; slow bleeding; physical well-being post-donation) (Harrison Health Research 1997b; Thompson et al 1998).

Reviews of research in this area suggest that there are differences in the factors that motivate first-time and repeat donors. External factors such as donating with a friend, incentives, a supportive work environment, or persuasion or pressure to donate are important factors in initial decisions to donate, but become less important with experience. Internal factors, such as a desire to help others, a sense of duty or a desire to help the Red Cross, become more important over time (Piliavin 1990; Royse & Doochin 1995). The time interval between the first two donations has also been found to influence donor return behaviour, with a shorter time interval being associated with continuing commitment to donation (Ownby et al 1999).

7.2 Future donor management

Donor management remains the primary means for securing a safe and adequate supply. It covers the recruitment and retention of donors, and donation and collection arrangements. Efforts in Australia and overseas tend to focus on recruiting new donors (including lapsed donors) and increasing the frequency of donation for existing donors. All donor management strategies have their benefits, risks and costs.

Strategies aim to achieve a balance between the safety of donated blood and the adequacy of supply. The latter, in turn, requires balancing the demand for blood and the well-being and safety of blood donors themselves.

Donor management is a core function of the ARCBS. The national service delivery and funding agreement needs to specify donor management requirements.

A national approach to donor management

A national approach to donor management is a vital aspect of Australia's blood supply planning and management. It needs to be responsive to changing circumstances and needs. It should be based on the best available evidence relevant to ensuring a safe and adequate supply. It needs to include modelling of likely impact on the donor pool, donations, collections, production and product issue / use, and concurrent supply initiatives, and costs. There should be clear objectives and agreed performance indicators. Implementation of agreed donor strategies should be monitored, reviewed and evaluated and results reported. The cost effectiveness of different measures should be examined routinely and reported.

Adoption of a national service delivery and funding agreement provides opportunities for the ARCBS to consolidate donor management efforts and to contribute to international literature on donor management in a time of tightening global supplies.

The Review notes that, with the creation of a national blood service, there have been some important initiatives to increase collaboration between ARCBS business units and to optimise use of resources nationally to achieve efficiency in donor recruitment, monitoring and research initiatives. There are some areas where national activity is required. In others, local initiatives are more appropriate.

Emergency donor panels

In rural and remote areas, the low and intermittent demand for blood makes it impractical to store blood locally. In some remote areas, donor panels are maintained and activated when required to ensure a rapid local response for critical cases where distance makes timely access to a blood bank impossible. The Rural Doctors' Association of Australia and the Australian College of Rural and Remote Medicine have been working with ARCBS Queensland to develop safety guidelines to cater for the special circumstances of isolated communities.

The provision of reliable blood transfusion services is vital to the provision of acute care services in these areas. The McKay Wells review (1995) and several submissions to the Review highlighted the important role of emergency donor panels in meeting the needs and special circumstances of isolated rural communities.

Donor recruitment and retention — research and monitoring

A sustainable and safe donor management strategy for Australia needs to achieve and maintain a high proportion of repeat donors, although some new donors will always be required to replace retiring or deferred donors. An appropriate balance needs to be struck in the proportions of first-time and repeat donations. These proportions should be reported on an ongoing basis as part of the monitoring of future donor management practices.

Potential strategies to increase the donor pool suggested in Review submissions included examination of the factors that determine ongoing commitment to donation, the use of incentives and rewards and greater public acknowledgment for donors. Findings suggest that practical strategies that address identified impediments to an ongoing commitment to, and increased frequency of, donation may go some way toward supporting donors in continued donation.

Many factors are involved in determining whether people become blood donors, whether they continue and whether they cease donating blood. Careful management is required to retain donors over a long period and the quality of the donation experience is a key factor. An understanding of donation behaviour and its determinants, through research, is critical to ensuring a safe and adequate blood supply. Protecting donor and recipient safety is also crucial. While recruiting new donors may increase the donor pool and volume of collections, it may also increase the risk profile of the blood supply.

Community and donor knowledge of and attitudes towards donation have implications for the development of successful donor recruitment and management strategies, as knowledge and attitudes can be expected to influence donation behaviour. Research conducted for the ARCBS reveals that both donors and non-donors have limited knowledge of what goes on behind the scenes at the blood bank and of the fluctuating needs for and supplies of different blood products (CM Research 2000).

As volunteers, Australian blood donors give up their time to help others. They accept the scrutiny of a detailed donor questionnaire, as well as the potential discomfort of the collection process. Planning and conduct of future research with donors should ensure that the burden of further questioning in special surveys is kept to a minimum. Adherence to this principle will require careful attention to research questions, sample sizes and approaches.

Increasing frequency of donation

Increasing the frequency of donations from existing donors would bring increases in blood and plasma supplies. Existing donors are familiar with donation arrangements and procedures. The ARCBS is able to target particular groups of donors with the assistance of its donor information systems. The strategy, therefore, does not have the recruitment costs associated with new donors. Its feasibility, however, depends on the extent to which existing donors have reached their donation frequency limits and attitudes towards more frequent donation. Approaches may need to vary between donors as a plasma-only donor can make more frequent donations than a whole blood donor.

In Australian and overseas research (Piliavin 1990; Harrison Health Research 1997b), convenience of donation has been identified as an important factor affecting the frequency of donation. Convenience factors included access to a collection unit, parking, waiting time, repetitive paperwork and childcare facilities. Many respondents requested extended opening hours including evenings and weekends. These are offered by many ARCBS collection centres.

While more frequent donations from a stable donor base are desirable for reasons of safety and cost, this must be balanced against the need to protect the health and well-being of donors.

Use of donor incentives

A number of submissions to the Review suggested that governments and the ARCBS should consider the use of incentives for donation, such as direct financial or other rewards to donors, or tax deductions for donation. Some proposed that incentives should be used to increase the rate of plasma donations in particular.

Overseas experience indicates that incentives may both encourage and discourage donation behaviour — among potential donors as well as among existing donors (Piliavin 1990). Studies suggest that rewards may only be useful in attracting donations from poorly motivated or first-time donors and that incentives may have a negative effect on those who donate for altruistic reasons by contradicting their self-image (Howden-Chapman et al 1996; Williams 2000). These findings highlight the heterogeneity of donor attitudes towards the question of payment and incentives.

A survey conducted for the ARCBS in South Australia with both donors and non-donors suggested that financial incentives were not seen as major motivating factors, either for attracting more donors or encouraging more frequent donations (Harrison Health Research 1997b). However, this research suggested that other small, non-financial incentives, such as obtaining a basic health check (eg blood pressure reading, haemoglobin count) may motivate some Australians to donate.

Overall, existing results suggest that use of incentives or rewards for donation is more complicated than at first appears, and may be counter-productive. Incentives may attract a disproportionate number of donors who are more likely to withdraw after only a few donations, and may interfere with the development of intrinsic motivation and long-standing donation behaviour.

Voluntary, unpaid donation has been a cornerstone of Australia's blood supply situation since its inception and the Review's brief was to take this policy position as given. The available evidence from the international donor research literature and current Australian donation trends give no reason to support a change in this policy at the current time.

Impact of State / Territory and Commonwealth industrial awards and legislation

Comments in submissions suggested there is a perception among some observers that the removal of blood donation provisions (eg time off work to donate) from State / Territory industrial awards and the Commonwealth's Workplace Relations Act 1996 has been responsible for a decline in donor numbers and donation rates.

Recent national and State / Territory data from the ARCBS on donors and collections do not support this general perception. As discussed, ARCBS data for the period 1996-97 to 1999-00 show that the numbers of donors and the collection rate have remained relatively steady. (More detailed data are provided in Appendix J.) This perception may persist from reported sharp declines in the numbers of donors and collection rates in Australia and other countries between the late 1980s and early 1990s, or be driven by knowledge of product shortages and ARCBS blood drives locally.

Under new national enterprise bargaining arrangements, some workers who previously had no blood donation provisions within their awards now have such clauses within their individual workplace agreements. Data on blood donor leave provisions have been retained in a database maintained by the Department of Employment, Workplace Relations and Small Business since 1 January 2000. Among the 6,847 federal workplace agreements certified by the Australian Industrial Relations Commission between 1 January and 31 December 2000, 4.7 per cent provided for blood donor leave. Agreements with this provision related to approximately 117,246 employees (16.7 per cent) covered by agreements in this period. Comparable data are not available for earlier periods, so it is unclear whether there has been an overall decrease in donor leave provisions.

The ARCBS is working with community groups and businesses to promote its activities and boost donor recruitment and retention. There may be greater gains from active recruitment efforts targeting employers rather than relying on passive measures such as provisions in industrial legislation or awards of which many employees remain unaware. At the same time, strategies need to be flexible in accommodating the circumstances of individual workplaces.

The ARCBS is addressing such matters through deployment of mobile services, providing opportunities for donation out of normal working hours, on weekdays or weekends, and other strategies. Efforts could be strengthened within existing budgets and within constraints imposed by public health and occupational health regulations to protect the interests of donors, recipients and blood collection staff.

Broader societal trends in volunteering

Some submissions commented upon perceived declining rates of altruism and volunteering in Australian society. Analysis of data from a series of Australian Bureau of Statistics (ABS) surveys on the provision of welfare services by volunteers conducted between 1982 and 1995 supports this perception of a decline in volunteering. Results of these surveys suggested a decline in at least four States over that time period (Lyons & Fabiansson 1998).

Broader trends in volunteering may impact on community commitment to blood donation and have implications for the blood supply in the longer term. ARCBS donor research reveals that many blood donors, especially those in rural areas, are also involved in other voluntary activities (CM Research 2000).

The ARCBS and the National Blood Authority should monitor trends in volunteering in Australia and assess their implications for the blood supply.

Donor deferral

The practice of declining certain individuals as blood donors, either temporarily or permanently, is known as donor deferral. People may be deferred to protect their own health (for example if they have low iron levels or are underweight) or for the protection of blood recipients where, for a variety of reasons, the person's blood should not be transfused. Decisions about whether a person should be deferred are made after review of responses to an approved form of donor questionnaire and / or the results of testing of donated blood. As knowledge of blood-borne diseases grows and new infectious agents emerge, donor deferral may become a more common measure to ensure the safety and quality of the blood supply.

An understanding of the impact of deferral on donors and potential donors is important for policy development and planning. Little has been published in this important area. Studies show that temporary deferrals had a 'very negative' impact on blood donor return rates and subsequent blood donations (Piliavin 1990; Halperin et al 1998; Beal 1999). Results highlight the importance of careful donor management, including provision of counselling and support services and the need for systematic monitoring of donor deferral and retention activity.

The ARCBS is implementing donor management measures to redress the reduction in donations and collections resulting from introduction of a variant CJD donor deferral policy from December 2000. Formal assessment of measures and reporting of results are essential for future national donor management and supply planning. Examination of donor deferral may also help to determine how donors can be induced to resume donation, should testing for CJD become possible.

7.3 Information and donor management

An understanding of Australian donors and the determinants of their behaviour has implications for donor management — the development of strategies for recruiting and retaining sufficient numbers of donors, and for ensuring the safety of donations — into the future. Research in this area is part of the core business of a national blood service. Knowledge of and sensitivity towards donors are essential in policy development and planning. This is all the more important lest the increasing regulation of the blood sector should lead to donors being regarded as mere 'suppliers of raw material' rather than as people with needs and motivations (Westphal 1997).

Reviews of international research on donors (Piliavin 1990; James et al 1999) have stressed widespread concern about the amount, type and quality of information on donors, their attitudes, motivations and behaviours. Although there is a considerable body of literature on donor motivation, much of it is of poor quality. In other areas, there have been few research studies to date.

Much of the research on donors is conducted by commercial research companies for the internal use of providers such as the American Association of Blood Banks or the ARCBS. Many of the studies are not of sufficient quality to be published in peer-reviewed journals, which affects the availability and usefulness of reliable donor research information (James et al 1999).

Data collection

Future supply planning and management requires an understanding of the reasons for variations in donor behaviour and the cost effectiveness of different measures. Variations — both across regions and over time — in aggregate data on donor characteristics and donation trends (eg frequency of donation) provide useful information for policy, planning and operational purposes. Surveillance of geographic and temporal patterns provides useful data for the evaluation of service performance and recruitment strategies.

In Australia, there is little published information about donors as a group — their characteristics and behaviour. While a considerable amount of information on donors is collected through routine administrative databases, it is often not collated and reported, or may not be comparable from one State or Territory to the next due to differing definitions. For example, nationally consistent data on new, repeat and deferred donors will only become available from 2000-01, following national adoption of the ARCBS glossary of definitions. There is a need for summary information on donors and donation trends to be systematically compiled and reported by the ARCBS as part of the national service delivery and funding agreement.

Donor research

Much remains to be learned about donor behaviour. With the move to a national blood service, there is an opportunity for the ARCBS to make a substantial contribution to the international evidence base on donors. A sound understanding of Australian donors — their characteristics, attitudes, motivations and behaviours — and barriers to donation are critical to the provision of a national blood service. 'Human factors' need to be accorded adequate priority in policy development, planning and operations.

Surveillance and research, in different social settings, with different donor populations, is important in better understanding donor motivations and behaviour. Recruitment and retention strategies should be built on evidence from rigorous behavioural research. This requires multidisciplinary approaches and expertise. Formulation of research questions, as well as good research design, methods, analysis and interpretation, requires the knowledge and skills of national blood service staff, behavioural scientists, and epidemiologists. This highlights a need for strategic research partnerships between the ARCBS and academic units with an interest in health promotion and behavioural or related research.

High quality information and research is required to understand better the behaviour of Australian donors and the effectiveness and impact of specific interventions. Areas for further research might include:

- investigation of donors' understanding of key educational messages;
- systematic examination of donors' perceptions of transfusion risks and denial behaviour;
- examination of the factors that determine continuing commitment to donation;
- rigorous studies of the reasons for ongoing commitment to donation and reasons for giving up donating, including evaluation of the impact of deferral on donors, to support the development of practical donor retention strategies;
- examination of the role of incentives that are consistent with Australia's policy of non-remunerated donation;

- evaluation of the reasons for variations in donor participation and collection rates across States and Territories; and
- evaluation of the cost-effectiveness of various recruitment strategies conducted in Australian workplaces.

Some research questions may require special sampling surveys from time to time. Privacy and confidentiality and the need to minimise the burden on the small population of volunteers are important principles to be considered in the planning of future donor surveys and research.

In acknowledging the debt the nation owes to blood donors, the Review also considers there is a need for more systematic exploration of ways to recognise their contribution and to support them in maintaining their commitment to donation.

8 National supply planning

Australia requires a safe, adequate and secure supply of high quality blood and blood products:

- supply refers to the availability of blood and blood products;
- adequate supply refers to the appropriate mix and volume of products to meet current and future needs; and
- secure supply refers to the ongoing availability of the appropriate mix and volume of products to meet changing needs.

To meet these needs, planning and managing the blood supply requires a national strategic approach rather than single product approaches. To inform supply planning, it is critical to understand supply needs, the factors that influence supply, trends in supply and demand, the factors that drive supply and use, and the most appropriate collection methods and systems. A national approach should aim to make available the appropriate range, volume and mix of blood and blood products to meet Australia's needs, based on the following principles:

- voluntary, non-remunerated blood and plasma donation (Chapter 7);
- self-sufficiency (Section 8.4);
- a national blood service (Chapter 9);
- national inventory management (Chapter 6 and Chapter 11);
- assured access to plasma fractionation services (Chapter 10);
- efficient and effective use of available resources (discussed throughout the report);
- appropriate use of a scarce and valuable resource given freely by donors (Chapter 12);
- management of technological change and transfer in ways that benefit patients and that are affordable to the community (Section 10.4); and
- effective contingency planning and managing supply risks (Chapter 11).

Some submissions considered that Australia's supply needs were met best simply through the provision of additional funding. The Review does not support this proposition.

8.1 Factors influencing supply

Supply factors differ across the three product groups — fresh blood, locally made plasma and imported products — and for particular products.

Fresh blood products

Supply of fresh blood products is influenced by the number and types of donors, collections per donor, collection and manufacturing processes, product yields, product shelf life, inventory management systems and practices to reduce avoidable waste, transfusion practices and use of non-blood alternatives. Collection and usage patterns are subject to seasonal variations and day-to-day needs may fluctuate significantly. Predicting clinical need can be difficult.

Changes to many of these factors require regulatory approvals. Donor recruitment and frequency of donation are dependent on a range of human factors, as discussed in Chapter 7, as well as regulatory requirements. Efficiency in collection, production and inventory management relies also on organisation and management and on technological innovations. Technological developments have benefits, risks and costs. For example, the development of a new screening test may increase recipient safety but reduce numbers of eligible donors and donations, product yields and turn-around times.

Locally made plasma products

Supply of locally made plasma products is influenced by the number and type of donors, collections per donor, collection methods, production capacity, manufacturing methods and processes, inventory management, transfusion practices and use of substitute products. Production times are long — for example, a batch of IVIg may take three months to produce. Production capacity depends on fractionation plant capacity, batch sizes and yields. Changes in production processes may require regulatory approval. New plants are expensive, take time to build and require regulatory approval. The time from planning through to licensing can be five to ten years. There is limited scope to change the mix of products made from each litre of plasma as proportions of proteins are relatively fixed. A disruption in production and supply (eg recall of products, reduced production and manufacturing problems) can affect large batches of products.

Predicting clinical need is easier for some types of plasma products than others. Rh D immunoglobulin and anti-haemophilic factors are used by relatively small and well-defined patient populations. There are epidemiological information systems to assist in determining need for some products (eg Bleeding Disorder Register, as discussed in Section 13.3) but not for others.

Imported products

The import market is influenced by national self-sufficiency (see Section 8.4), funding and regulatory policies and other requirements for the entry and marketing of imported products in Australia. External factors include international product markets, the attractiveness of the Australian market relative to others in terms of size, economic return and market security, and prices.

8.2 Trends in supply and demand

The Review attempted to assess trends in supply and demand for various products in Australia and draw comparisons with other developed countries. Assessment of the Australian situation was difficult because of limitations in information available on activities across the sector. There are also problems inherent in distinguishing and quantifying the effects of various initiatives on supply activities.

The following analysis draws on published studies and reports including:

- information for the four years since the ARCBS was formed (1996-97 to 1999-00; the impact on supply of the variant CJD donor deferral policy introduced in December 2000 is therefore excluded from the analysis);
- analysis of the processes through which blood products are made available in 10 countries — Canada, England, France, Italy, Norway, Scotland, Sweden, Switzerland, South Africa and the United States (Rock et al 2000); and

- a working paper that examines blood and plasma collection and compensation policies in a number of nations, including Australia, and internationally (Bayer Advisory Council on Bioethics 2000).

Fresh blood products

For fresh blood products, supply and demand are delicately balanced in some States and Territories. Seasonal and regional fluctuations in collection and usage mean that demand exceeds supply in some States and Territories at some times as reported frequently in ARCBS media appeals. There is some interstate transfer of fresh blood products in times of peaks in local demand. In 1998-99, the ARCBS reported that some 27,000 units of products were transferred within the national service across State and Territory boundaries (ARCBS 1999b). In 1999-00, over 20,000 units of products were transferred (ARCBS 2000).

Plasma products

Supply and demand vary with plasma products. The use of albumin, which is globally the most abundant product of plasma fractionation, has declined in many developed countries, including Australia. While albumin supply exceeds use, there have been disruptions in supplies over the last few years for other plasma products. From 1997, the United States market experienced shortages of plasma products in the order of 20-30 per cent of estimated demand (Epstein & Weinstein 1999). IVIg, which is used for the treatment of a range of immune disorders, was the product most critically affected and clotting factor concentrates were affected to a lesser extent.

A number of factors are considered to have led to the shortages (Epstein & Weinstein 1999):

- increased demand for IVIg, including off-label use (ie use for non-registered indications);
- reduced production, due in part to actions taken by the FDA to address regulatory compliance matters of some plasma fractionators; and
- product recalls, many associated with CJD policies in effect between 1995 and 1998.

IVIg has become the market driving force in many countries. This is a function of two factors — rapid growth in demand as a result of changing medical practice; and plasma supply constraints. Demand for IVIg is growing by 10-15 per cent per annum in both the United States and Canada (Bayer Advisory Council on Bioethics 2000) and by around 10 per cent per annum in European markets (Robert 1999). In Australia, demand is reported to exceed supply for IVIg and for Rh D immunoglobulin.

In response to rising demand for IVIg in Australia, the AHMAC Blood and Blood Products Committee commissioned a national review of the its use and supply (AHMAC 2000a). The review made a number of recommendations and the report was accepted with qualification by AHMAC. Recommendations relating to use, distribution and supply target levels were accepted. Those relating to strategies to increase IVIg, matters of funding and the time to reach recommended targets were not endorsed. AHMAC agreed that they should be considered with other strategic policy and funding priorities for the Australian blood supply as a whole.

In 1996, the NHMRC issued guidelines for the use of Rh D immunoglobulin in obstetrics (NHMRC 1996). The guidelines were accepted generally as representing best practice. However, there was concern that their uniform implementation could have severe

implications for Rh D immunoglobulin supplies. Updated guidelines that balanced best practice in the use of Rh D immunoglobulin with the limited available supply were issued in 1999 (NHMRC 1999).

The matter of balancing product demand and supply is discussed in Section 11.3.

Recombinant products

The development of recombinant technology has changed the market outlook dramatically for some plasma products. Demand for plasma-derived clotting factors has reduced in some countries with the introduction of recombinant products for factors VIII and IX. Recombinant factor VIII represents 70 per cent of the factor VIII market in the United States and 100 per cent in Canada (Rock et al 2000).

There are calls for increased access and funding for certain products (eg recombinant factors VIII, VIIa) in Australia. Recombinant factor VIII accounts for about 25 per cent of the factor VIII market (Appendix J, Tables 12 and 14). Some submissions called for Australia to develop a local industry, however, current technologies are under international patent and intellectual copyright arrangements.

8.3 Collection and issue of blood and blood products

Available information indicates variations in activity and practice across States and Territories in the collection, issue and use of blood and blood products. Although it is difficult to establish the reasons for these variations given available information, many appear to be related to State and Territory based approaches, despite moves towards national supply arrangements and Australia's policy of national self-sufficiency.

Collection across States and Territories

In 1999-00, the whole blood and apheresis collection rate for Australia was 49.5 collections per 1,000 population. Queensland, South Australia, Tasmania and the Australian Capital Territory have been consistently above the national average over the last four years. Western Australia has increased the collection rate from 46.6 collections per 1,000 population in 1996-97 to 55.8 in 1999-00. New South Wales is consistently below the national average at around 45 collections per 1,000 population in 1999-00. Victoria and the Northern Territory are variable, both are below the national average in 1999-00 with rates of 47.1 and 48.2 collections per 1,000 population respectively (Appendix J, Table 2).

Issue of red cells

According to preliminary estimates provided by the ARCBS, there were variations in red cell issue rates across New South Wales, Victoria, Queensland, Western Australia and South Australia for 1999-00, highlighting opportunities for gaining efficiencies through appropriate interventions. Red cell issue rates ranged from 30.7 units per 1,000 population in Western Australia, 34.6 in New South Wales and 35.1 in Victoria to 40.2 in Queensland and 43.2 in South Australia. Similar calculations were not provided for the remaining, smaller State and Territories where the rates of red cell issue may be significantly influenced by geographical and other factors.

Use and supply of IVIg

The review of the use and supply of IVIg in Australia (AHMAC 2000a) reported that information on per capita use of IVIg reveals differences in usage across States and Territories. Usage in New South Wales and the Northern Territory was low at 2.45 and

2.51 kg per 100,000 population in 1996-97. For the remaining States and Territories, usage ranged from 3.10 kg per 100,000 population for Tasmania to 4.22 kg per 100,000 population in Western Australia.

The review explored the reasons for this variation, considering that product availability and allocation arrangements are a major factor in determining IVIg usage. The review concluded that annual allocations of Australian produced IVIg were largely State and Territory based with the quantity of IVIg received by the ARCBS in a particular State and Territory being in approximate proportion to the amount of plasma collected by that State and Territory. Allocations therefore bear little relation to State and Territory clinical needs for IVIg. Product allocation policies should be based on clinical need not production.

8.4 The self-sufficiency principle

The Review was asked to examine the appropriateness and relevance of the self-sufficiency principle. Submissions and consultations highlighted differing perceptions and understandings about the principle's origins, interpretation and evolution.

How has Australia fared?

Australia is virtually self-sufficient in plasma collected from Australian volunteer donors and virtually self-reliant in plasma products. As noted, currently there are reported supply shortfalls in two plasma products (IVIg and Rh D immunoglobulin). These are discussed in Chapter 11. A small imported product market exists for certain niche products. This is consistent with Australia's interpretation of self-sufficiency as far as practicable. Australia enjoys a privileged position among nations in having a domestic plasma fractionation facility and in being self reliant in production and supply of plasma products. This is not the case for other essential health products (eg pharmaceuticals, vaccines, surgical equipment and prostheses), most of which are imported.

In comparison with other nations that were signatories to the 1975 World Health Assembly resolution (WHA 1975), Australia has performed well. According to a recent analysis undertaken in Canada (Bayer Advisory Council on Bioethics 2000), Finland and Norway have achieved plasma self-sufficiency. Finland has a domestic fractionation industry and is self reliant in meeting its plasma product needs. Norway, however, relies on foreign fractionators. Sweden is not self-sufficient in plasma and depends on foreign fractionation services. Germany is self-sufficient in plasma and employs domestic and foreign fractionators. The situation in the United Kingdom has changed with the deferral of plasma donors. England and Wales import all of their plasma, mostly from the United States, while Scotland imports plasma product intermediates from Holland. The plasma is processed into products in the United Kingdom. Canada has a mixed system. It relies on domestic plasma collections as well as plasma from the United States. Plasma is processed outside the country.

Emerging developments

The self-sufficiency focus is shifting again. Adequacy and security of supply have emerged as key concerns for nations. This is in response to a number of factors including:

- the escalating demand and tightening world supply for certain plasma products, particularly IVIg;
- scarcity of high quality plasma;
- the emergence of new infectious threats to supply;

- globalisation and harmonisation of markets;
- the transnational focus of the plasma fractionation industry; and
- economic, safety and regulatory constraints on the plasma fractionation industry's production capacity.

At the same time, the need for blood and blood products will change as a result of:

- demographic changes — population growth and the ageing of the population;
- changing clinical needs and indications for blood transfusion; and
- changes in the illness and disease profile of the population and the emergence of new illnesses and diseases;
- improvements in the diagnosis and treatment of illness and disease;
- development of substitutes to existing blood products and alternative treatments to blood transfusion; and
- changing consumer and community expectations about the range of services provided, their safety and quality, access and costs.

As discussed in Chapter 3, the impact of these factors on blood and blood products needs is uncertain as are estimates of future demand. On the one hand, the need for blood and blood products may increase as the range of treatments requiring blood and blood products expands and some procedures requiring blood are performed more frequently. On the other hand, improved surgical techniques and better understanding of the clinical thresholds that trigger blood transfusion will reduce the need for blood products in some cases. There is also the prospect of substitutes to replace existing blood products.

Future directions

Self-sufficiency has served Australia well in securing an adequate and safe blood supply. Australia has been largely protected from the volatility of world markets. State, Territory and Commonwealth governments have taken a number of measures to minimise exposure to supply risks (eg establishment of the ARCBS, national regulation, National Reserve of Plasma Products, Blood Product Replacement List) and to improve access to certain imported products (as discussed in Chapter 3).

The Review considers that self-sufficiency in products derived from human blood and plasma remains a relevant and appropriate goal for securing Australia's future blood and blood product needs. It is both a national and an international responsibility. By relying on its own national resources and not the resources of others to meet its blood and blood product needs, Australia maintains the national interest and contributes to global self-sufficiency.

It is important, however, that Australia continues to adopt a pragmatic approach to the application of the self-sufficiency principle. Nations face a changing and uncertain environment. Australia must harness the benefits of this changing environment such as new scientific and technological developments and other innovations that improve patient safety and health. Australia must also take measures to minimise the associated risks and costs. It is critical, therefore, that national strategies secure supply, optimise the use of a scarce and valuable resource given freely by donors, ensure available resources are used efficiently and effectively, and manage technological change.

Recommendations

- **Self-sufficiency should remain an important national goal for Australia recognising that it is a national and international obligation and responsibility.**
- **The Commonwealth Government should monitor the goal's appropriateness, relevance and application in light of scientific, technological and other developments in transfusion medicine and patient care.**

9 Strengthening the national blood service

Trends in blood supply and demand, together with variations in collection and issue across States and Territories, suggest that efficiency gains may be realised by adopting a truly national approach and simplifying current supply arrangements. The Review has stressed the importance of a national strategic approach to supply planning and a key element of this is a national blood service.

Other chapters of this report discuss different aspects of the blood service. This chapter gives details of specific mechanisms for strengthening the national blood service and streamlining its administrative and funding arrangements with government.

9.1 The ARCBS — a national blood service

As discussed in Chapter 1, the formation of a national blood service, administered by a single new business-orientated ARCBS, was recommended in the McKay Wells review (1995) to overcome barriers and problems inherent in the State and Territory-based system. Areas identified included:

- need for a common approach to reduce risk exposure;
- need for national policies, systems and procedures;
- need to optimise the use of resources nationally;
- need for national statistical indicators and uniform procedures;
- need to improve standards and modify traditional practices to comply with TGA codes of good manufacturing practice; and
- need to enable blood and blood products to move across State and Territory boundaries as a national resource for use by all Australians.

As indicated in Chapter 3, some significant developments have occurred since the establishment of the ARCBS in 1996. Although progress has been slow, some of the necessary external reforms have now been completed. National standards, national regulation and a national indemnification arrangement (the National Managed Fund) for the ARCBS took effect from July 2000. Other important reforms — national uniform statutory defence and new financing arrangements — remain under development.

Since its formation, the ARCBS has embarked on a number of national project initiatives. They are aimed at developing a national framework for the delivery of blood services, national production planning, national information systems along with an integrated national computer system, national purchasing initiatives, the development of alliances and partnerships, and national inventory management. Some of the resulting developments include:

- the first National Donor Satisfaction Survey, conducted in 1999, and the first National Blood Donor Survey, implemented in 1999;
- a national donor information telephone line for national media campaigns;
- group purchasing for various supplies, replacing the previous individual arrangements;
- a National Blood Management System to support donor marketing, collection, processing and screening, and product distribution and inventory management (see Chapter 6);

- arrangements to coordinate national production planning and to monitor blood and blood product inventories; and
- research partnerships, for example in the Cooperative Research Centre for Vaccine Technologies.

9.2 Barriers and impediments

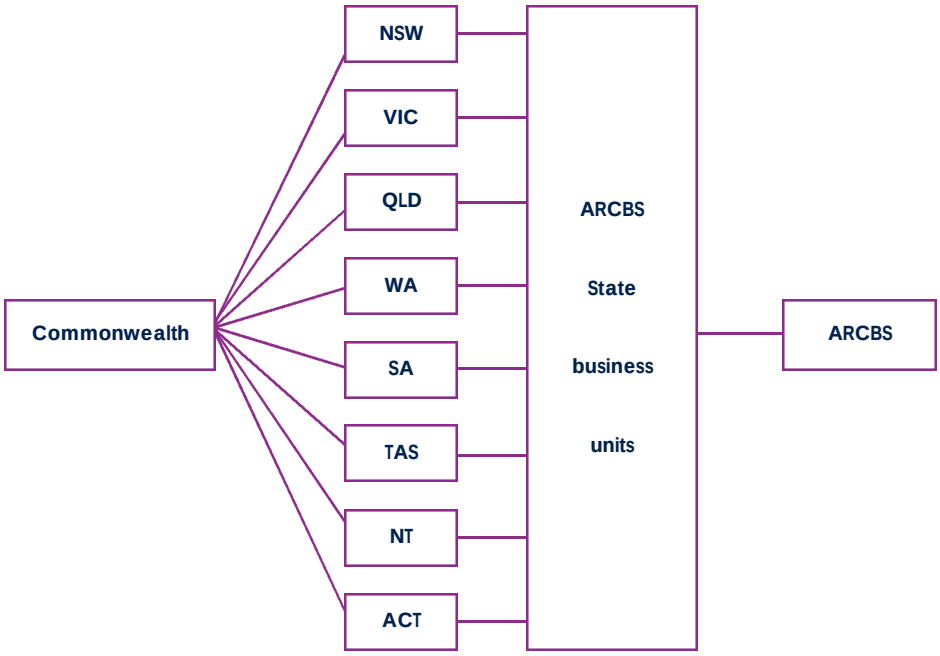
One of the Review's central themes has been to consider structural and other impediments to achieving a national blood service and national approach to blood and blood product matters. The importance of a national blood service in securing a safe and adequate supply for Australia was acknowledged widely in submissions and consultations. However, many Review respondents felt that a national blood service has not yet been achieved. A common concern was that funding, management, organisational and planning arrangements for the ARCBS remain largely unchanged and represent a major barrier to achieving a national blood service. The service still operates largely on State and Territory bases, with the addition of an extra administrative layer.

The effectiveness of the ARCBS national project approach was questioned as being undertaken on top of existing staff activities and responsibilities. While the AHMAC Blood and Blood Products Committee has provided a forum for national policy advice and coordination, the Committee's timeliness and national responsiveness in developing funding, legislative and other infrastructure necessary to support a national service were questioned. Current financing arrangements and policy advice structures are seen as major barriers to the realisation of a truly national blood service. The ARCBS highlighted the need for new and streamlined service delivery and financing arrangements that support a national blood service and national policy advice and implementation structures.

Service delivery and funding arrangements

As discussed in Chapter 4, the current service delivery and funding arrangements of the ARCBS are based on a set of agreements between governments and the ARCBS. Each State and Territory government negotiates an agreement with the local ARCBS business unit. There are agreements between each State and Territory government and the Commonwealth. The ARCBS has to negotiate with nine governments. Agreements are generally annual. Arrangements are illustrated at Figure 9.1.

Figure 9.1 ARCBS service delivery and funding agreements



The establishment of the ARCBS was intended to rationalise and streamline the functions of the individual State and Territory based blood transfusion services, to develop a national supply with free transfer of product across boundaries, and to enable centralisation of testing in one or two sites (McKay & Wells 1995; AHMAC 1998). These objectives have been realised only to some degree. This is for a number of reasons. The government reform program was ambitious. It underestimated the effort, resources and time involved in achieving national agreement to the regulatory, management and financing reforms required for the new organisation. It also underestimated what was involved in integrating the separate State and Territory based blood transfusion services into a national organisation. The ARCBS is a relatively new national organisation.

The service delivery and funding model did not change with the move from State and Territory based blood transfusion services to a national service. It remains inconsistent with the needs of a national blood service and in securing national supply, in national responsiveness and in national efficiency and effectiveness. This is for a number of reasons:

- the model encourages a State and Territory rather than a national approach to supply planning, to service delivery and to performance reporting;
- it hinders the optimal allocation of available resources nationally;
- it does not facilitate the development of economies of scale;
- it does not support the development of areas of specialisation nationally;
- negotiation requirements are inefficient (they are resource intensive, take time and are costly) and do not facilitate timely outcomes and responses;
- the annual nature of most agreements makes service delivery, supply planning and financial budgeting difficult for all parties and for sector nationally;
- the model does not facilitate the development of national priorities; and

- it does not provide the ARCBS with the flexibility to mix and match needs and resources nationally and achieve the best value for the available resources.

9.3 Future directions

The Review has stressed the importance of single national service delivery agreements with providers of blood and blood product services in national supply planning and management. A national approach has been adopted for the National Managed Fund for the ARCBS. A single national service delivery agreement for the ARCBS is consistent with and supports this measure. Arrangements must ensure clear lines of government responsibility and accountability.

Establishment and management of the agreement must include setting out the obligations, responsibilities and accountabilities of the parties, specifying core service requirements and establishing clear performance reporting, monitoring and review. Principles are set out in Section 4.3. Specific aspects have been addressed in subsequent chapters — Chapter 5 discusses safety and quality standards and requirements, Chapter 6 outlines information and research needs and Chapter 7 examines donor management and information. Subsequent chapters address the need for information on the costs of the ARCBS national blood service (Chapter 10), future supply needs, contingency planning and inventory management (Chapter 11) and monitoring safety and quality in the supply and use of blood and blood products (Chapter 13).

Underpinning the national service delivery and funding agreement, there needs to be a clear and formal agreement between governments on supply needs, service requirements and priorities for the national blood service to be provided by the ARCBS. This is essential for national planning and management, service responsiveness and financial accountability. To facilitate financial planning and resource allocation decisions, budgeting for the ARCBS blood service should be on a triennial basis.

The National Blood Authority should be responsible for administration of the agreement. It should report regularly to Australian Health Ministers on progress with the administration of the agreements and outcomes.

The ARCBS also has a responsibility to maintain and operate a risk-management strategy to minimise adverse outcomes from its blood service activities. This is a requirement of the memorandum of understanding for the National Managed Fund between States and Territories, the Commonwealth and the ARCBS, established to cover liability claims against the ARCBS.

The service delivery and funding agreement with the ARCBS for the national blood service should be consistent with National Managed Fund obligations and requirements. They should be specified in the agreement and reported as part of reporting requirements.

Recommendations

- **A single service delivery and funding agreement should be entered into between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and the ARCBS for the provision by the ARCBS of the national blood service, operational from 2002-03.**
- **Budgeting for the ARCBS should move to a triennial basis.**

- **There should be an agreement between the Commonwealth and States and Territories regarding supply needs, service requirements and priorities for the national blood service.**
- **The National Blood Authority should administer the Agreement with the ARCBS.**
- **The National Blood Authority should report regularly to Australian Health Ministers on progress with the administration of the agreement with the ARCBS and outcomes.**
- **The national service delivery and funding agreement with the ARCBS for the provision of the national blood service should be consistent with, and require compliance with, the obligations of the memorandum of understanding for the National Managed Fund.**

10 The Australian plasma fractionation industry

Australia has had a plasma fractionation industry since 1953 when CSL began processing plasma collected by the Australian Red Cross from volunteer, unpaid donors into plasma products for the Australian population. This chapter examines the role of the plasma fractionation industry in Australia in the context of international and national developments. Future arrangements for plasma fractionation and the diagnostic products area are considered.

The Review's assessment draws on information from a number of sources. The Review commissioned an analysis of the economic characteristics of the Australian and global plasma fractionation industry, based on:

- Review submissions and consultations;
- a benchmarking study provided by CSL comparing the prices of Australian plasma products with national European and commercial suppliers;
- the results of recently published international studies and surveys (Bayer Advisory Council on Bioethics 2000; Marketing Research Bureau Inc 2000; Rock et al 2000); and
- other published sources.

Generally, Term of Reference 5 was not covered well in Review submissions and consultations. This was not unexpected given the specialised nature of plasma fractionation, the commercial orientation of the industry and the commercial in-confidence service delivery and funding agreements between the Commonwealth Government and CSL. There is a tension between the public interest and commercial interests. These matters are discussed in this chapter.

10.1 Developments and trends in the plasma fractionation industry

As highlighted in Chapter 1, plasma fractionation represents one of the most important developments in transfusion medicine. The plasma fractionation industry developed rapidly after World War II. By the early 1980s, the industry comprised two groupings: commercial manufacturers, located mainly in Europe and North America; and public health service or non-profit plasma fractionation plants, established often as adjuncts of blood services, with activities directed towards national self-sufficiency rather than the international market (examples include England, Scotland, France, Germany, the Netherlands, Switzerland, Canada, South Africa and Australia).

Assessing the economic and productive capacity of the Australian plasma fractionation industry is difficult because of the lack of information in the public domain on these matters. The capacity of the industry is determined by a number of domestic and international variables, including the world market for plasma products, productive capacity, regulatory requirements and production costs and product prices. There are few published studies of the international and Australian plasma fractionation industry from a consumption, production and cost perspective.

Developments in the plasma fractionation industry internationally over the last two decades are surveyed in Chapter 3. Significant changes in the structure of the industry have resulted. The following summary of key industry characteristics and trends draws on surveys of international plasma fractionators conducted by The Marketing Research

Bureau Inc every three years since 1984. Unless otherwise stated, figures refer to statistics from 1999.

World plasma product market

The international market for plasma and plasma products may be characterised in terms of the sourcing of plasma and plasma products.

The United States market is the dominant consumer, manufacturer and supplier of plasma and plasma products. Around 60 per cent of the world supply comes from the United States (Bayer Advisory Council on Bioethics 2000). There are several reasons for this. Plasma fractionation was developed in the United States and much of the industry's fractionation capacity is located there. Suppliers have been successful in recruiting large numbers of donors from outside as well as within the United States, and in collecting large volumes of plasma (the volume collected per donor per annum is higher than in other countries). Over 85 per cent of plasma is collected from paid donors in a commercial setting with the remaining 15 per cent collected from volunteer donors (US General Accounting Office 1999). Many countries depend on the United States for plasma products and plasma obtained from donations from paid donors.

There are various national markets characterised by plasma self-sufficiency with domestic consumption met largely or completely from domestic plasma sources and either domestic fractionation plants or contract fractionators in other countries. France, Finland, the Netherlands, Norway and Australia are examples of this type of market. There is trade (imports and exports) in plasma and products in some countries. Generally, these countries use voluntary unpaid donations; however, in some, donors may receive a sum of money or equivalent in recognition of the cost of making a donation (eg Sweden, the Netherlands).

There are mixed markets that rely partially or completely on imports of products or plasma and plasma intermediates, often sourced from paid United States donations. Canada, for example, collects sufficient plasma to meet around 50 per cent of overall need for albumin and IVIg with the plasma fractionated in the United States. It relies on contracts with the United States and others to supply products to cover the shortfall (Rock et al 2000).

A subsidiary 'second world' market exists for surplus fractionation products, principally albumin, from the United States and Europe.

There is little information available on the value of the world plasma and plasma product market. Rock et al (2000) reported that the worldwide plasma fraction market exceeded US$4 billion in 1996. CSL (2000a) reports that the global plasma products market was valued at US$5 billion in 1998 with the market growing by an average of 4.5 per cent per annum and the United States and Europe accounting for more than 70 per cent of the market. CSL has advised the Review that Australia represents less than 1 per cent of the international plasma fractionation market.

Industry trends

The number of plants worldwide has fallen from 95 in 1984 to 86 in 1999, with the number of plants in North America falling from 13 to 10 and that in Europe falling from 58 to 33. Traditionally, most plants have been located in Europe and the United States but there has been significant recent expansion in Asia (from 7 plants in 1984 to 26 in 1999).

There has been increasing commercialisation of the industry with commercial fractionators operating less than 40 per cent of plants in 1984 and 53 per cent of all plants in 1999. There has also been industry consolidation through mergers and acquisitions. The top eight commercial fractionators now account for over 51 per cent of worldwide capacity.

Capacity

Most of the world's plasma fractionation capacity is located in Europe (38 per cent), North America (32 per cent) and Asia (24 per cent). While North America has only 12 per cent of all plants, the average plant size is large at approximately 1.1 million litres per year. Commercial fractionators account for most of the industry's production capacity (71 per cent), with commercial fractionators in Europe and North America accounting for the majority of world supply (57 per cent).

Plasma fractionation capacity has expanded significantly over the last 20 years. The volume of plasma processed worldwide has increased from 12 million litres in 1984 to 26.1 million litres in 1999; growing by 17 per cent between 1996 and 1999 (Marketing Research Bureau Inc 2000). A total of 26.1 million litres of worldwide capacity (77 per cent) was utilised in 1999, leaving about 7 million litres of excess capacity worldwide.

Over two-thirds of plasma used for fractionation is collected by plasmapheresis (Marketing Research Bureau Inc 2000). Commercial fractionators make greater use of plasma from plasmapheresis (81.5 per cent of plasma processed) while the proportion for the non-profit sector is 34 per cent (Marketing Research Bureau Inc 2000).

Global fractionation capacity is expected to continue to increase (Marketing Research Bureau Inc 2000). New facilities are expected to begin operations in the United States and Taiwan; new fractionation projects are under consideration in Greece and Turkey and others; and plant expansions are likely to continue in order to meet demand for IVIg.

Future prospects

The world plasma product market will continue to change in response to scientific, technological, economic and other factors. It is difficult to predict. There are differing views about future directions. This section surveys possible trends and draws on the views of various commentators (Robert 1999; Bayer Advisory Council on Bioethics 2000; CSL 2000a).

IVIg is expected to continue to be the predominant product in many developed countries with projected market growth of 9 per cent per annum over the next five years (CSL 2000a). There are no recombinant substitutes for IVIg, and none are expected within the next five years. The albumin market is expected to continue to decline. The market for plasma derived clotting factors is expected to decline in many developed countries but growth in the developing regions of the world is likely (Robert 1999; CSL 2000a). More products made from non-plasma sources (recombinant factor VIII, non plasma-based colloids, and monoclonal antibodies) are likely to be developed and become competitive. The respective contributions of albumin and factor VIII concentrate to revenues are expected to decline (Robert 1999; CSL 2000a). Price increases in other products are likely to counter the trend. The fractionation industry is expected to develop a more restricted product portfolio than in the past. Niche products such as protein C, antithrombin and alpha-1-antitrypsin are likely to become available from some manufacturers.

10.2 CSL — a national fractionator

The need for a national fractionator to safeguard the national interest has been a dominant theme in the development of Australia's blood sector. Australia has relied on CSL to provide plasma fractionation services to the Australian community since 1953, both as a government business enterprise and, since 1994, as a listed public company.

Most Review submissions and consultations supported continuation of CSL playing this role, emphasising that meeting domestic needs must take priority over export aspirations. There was some concern that, with CSL's international expansion, domestic needs may become a secondary interest. Some submissions, especially from industry, raised concerns about the market position of CSL and its impact on activities, prices and value for public funds to government and taxpayers. Few, however, suggested alternative approaches. CSL has stressed to the Review that providing effective, safe and cost-effective plasma products to the Australian community is a priority but that, to provide world class plasma products for Australia at competitive prices, CSL must participate in the global fractionation industry.

Roles and regulation of CSL

The sale of CSL was part of a broader government micro-economic reform agenda. Sale objectives, as outlined in the Second Reading Speech for the CSL Sale Bill 1993 (Australian Parliament 1993) included:

- promoting the internationalisation of CSL and the future development of the Australian pharmaceutical industry through greater financial and managerial flexibility in securing capital;
- releasing the Commonwealth from the incongruous position of company owner, customer and regulator;
- ensuring continuing CSL independence under Australian control; and
- ensuring continued supply of blood products to the Australian community.

Provisions in the CSL Sale Act 1993 were designed so that CSL remains an independent, Australian controlled company providing blood and related products to the Australian community (see Appendix G). Continuity and security in the supply of blood products was achieved through two long-term contracts between CSL and the Commonwealth Government — the Plasma Fractionation Agreement and the Diagnostic Products Agreement. Provisions to ensure performance of blood product contracts are contained in the CSL Sale Act.

CSL plays a number of important roles in the Australian blood banking and plasma product sector. It is Australia's sole domestic plasma fractionator and sole supplier of plasma fractionation services to the Australian community. It produces, supplies and distributes a range of diagnostic products, made from human blood supplied by the ARCBS (see Section 10.5). CSL also sponsors imported plasma products and related products for use in Australia, assisting in their sourcing and provision (see Section 10.4).

In addition to its roles in the domestic market, CSL provides contract fractionation services to a number of countries. CSL advised the Review that, in 1999-00, it fractionated just over 240 tonnes of plasma for the Australian market and around 90 tonnes of plasma for contract and commercial fractionation. CSL further advised that the current capacity of its fractionation facility at Broadmeadows is approximately

400 tonnes. CSL anticipates that the facility will provide capacity substantially greater than domestic production into the foreseeable future.

Using imported plasma from FDA-accredited United States suppliers, CSL manufactures a range of products for export to overseas customers. CSL earned some $140 million in domestic and international sales of bioplasma products, representing around 31 per cent of total sales revenue ($451 million) and the second largest area of CSL activity after the pharmaceutical division (CSL 2000b).

With its purchase of ZLB in 2000, CSL is now one of the five largest plasma fractionators worldwide. ZLB's Swiss plant is a United States-FDA licensed plasma fractionation facility. Its main products are IVIg, albumin and Rh D immunoglobulin and its major markets are in the United States and Europe (CSL 2000a). The combined CSL / ZLB operations make it the largest fractionator of recovered plasma in the world and a major producer of IVIg products (CSL 2000b).

CSL anticipates that it will increase the Broadmeadows plant capacity to about 500 tonnes per annum in 2001-02 through optimisation of manufacturing processes and proposed increases in batch size. This expansion will ensure more than adequate throughput to meet projected Australian production.

CSL has advised the Review that with the purchase of ZLB it is integrating its fractionation operations. With an estimated capacity of 2 million litres of plasma per annum, the ZLB facility will provide for future requirements for contract and commercial fractionation.

Export potential

The Review was asked to consider Australia's future domestic needs against export opportunities for Australia's plasma fractionation industry. The Review notes the recent international expansion of CSL has made this aspect of the terms of reference less relevant.

International expansion of CSL has been a government objective for a number of years. Between 1980 and 1985, key legislative changes were made to allow CSL to use excess manufacturing capacity for commercial profit, to form subsidiaries, joint ventures and partnerships, and to increase exports. Fractionation capacity was extended significantly with the commissioning of the Broadmeadows facility. One of the aims of privatisation was internationalisation of CSL. It was recognised that, to survive and continue to deliver safe, high quality and cost-effective plasma products for the Australian market, CSL must participate in the global fractionation industry and the global pharmaceutical industry. The Australian market for plasma products is small in size and a national fractionator that serves only a domestic market would face difficulties in supporting the development of innovative, high technology products and manufacturing scale efficiencies.

The Review's primary concern is ensuring an adequate, safe and secure supply of plasma products to the Australian community at an affordable cost. The national imperative is that Australia's needs for plasma products are met and that CSL's use of the Broadmeadows facility to fractionate both domestic and foreign plasma does not pose any significant risks to the safety and quality of domestic products and to product recipients.

The Review notes that the Australian National Audit Office (ANAO) (ANAO 1996; 2000) has made a number of recommendations relating to the regulation of processing of

foreign-sourced plasma. They have led to a number of changes by the TGA to regulatory requirements. These regulatory requirements need to be monitored and reviewed by the TGA in light of changing circumstances and needs and as part of its ongoing standards development work.

Production costs and prices

Production costs and prices are indicators of economic and productive capacity. There is little information in the public domain about industry production costs in Australia or internationally. International prices may be used as an indicator of costs, however, market prices also reflect the supply and demand for products.

The CSL benchmarking study provided to the Review concluded that Australian prices for plasma products average 75 per cent of prices in major European markets and 64 per cent of the prices available from commercial sources (ANAO 2000). The Review found it difficult to draw policy conclusions from this study. Prices exclude plasma collection and associated costs. Collection systems and methods vary across nations. They are an important consideration in comparative cost and price assessments. Benchmarking studies are inherently difficult to conduct given organisational, funding, social, cultural and other differences across countries.

Existing arrangements

CSL has a unique and special position in the Australian blood banking and plasma product sector. It has assured access to the Australian market under the Plasma Fractionation Agreement that secures Australia's needs for plasma products and services. Australian demand for plasma products is met almost solely by CSL. The Commonwealth Government meets the costs of production and supply while the States, Territories and Commonwealth meet the costs of plasma collection, initial processing and distribution undertaken by the ARCBS. In 1999-00, government funding to the ARCBS and CSL was $290.8 million. Entry into the Australian market, manufacturing and production, product registration and overseas trade are regulated, mainly by the TGA. The level of regulation is similar to that in comparable countries.

CSL activities are governed in part by the Plasma Fractionation Agreement. The contract, struck at the time of privatisation, is that CSL agrees to fractionate plasma to meet Australian needs and the Commonwealth agrees to cover CSL's costs including a return on capital. Each year, CSL must seek the Commonwealth's approval on the product range, mix and quantity of each product to be funded in the following year. The CSL Sale Act provides a statutory mechanism to ensure CSL meets its obligations under the Agreement. Payments for CSL products are based on a fixed price for each unit of production using a two-tier pricing structure. First tier prices are paid on a threshold level of production for each product. The threshold is based on CSL's 1993-94 production levels. A second tier, lower price is paid on all production above the threshold level for each product. The maximum volume, second tier prices aim to recover variable costs. The specified range of products can be added to or varied by agreement between the parties. The risks that CSL faces in supplying the Australian market are low compared with those it faces in commercial fractionation and its other activities.

The Commonwealth also provides certain indemnities to CSL for product liability claims that may result from the use of particular CSL products manufactured before the CSL sale. None of the indemnities applies in the case of claims resulting from CSL's culpable negligence.

Alternatives to current arrangements

Alternatives to the current arrangements with CSL do exist. They include seeking tenders for fractionation services from overseas fractionators; or the Commonwealth sponsoring a competing fractionation service provider. The Review does not support either option for a number of social and economic policy reasons.

The economic and social benefits of a tendering system for fractionation services are unclear and uncertain. Tendering may provide a discipline on prices. There are high costs associated with contract fractionation such as regulation and approval. The availability of appropriate and sufficient plasma fractionation capacity in the international market place is uncertain, and may place Australia in a vulnerable position. CSL has surplus capacity that is directly regulated by the TGA. A national plasma fractionation facility has been a major driving force in the development of Australia's blood sector and blood supply. It affords Australia a high level of control of the safety, quality and adequacy of future supplies provided that national policy and strong regulatory oversight are maintained.

Sponsored or facilitated entry of a second fractionator is likely to be inefficient and costly. The Australian market is small. The costs of entry are high in terms of both capital costs and regulatory approvals. While high costs may be sustainable to a new entrant given potential revenues under a Plasma Fractionation Agreement or by sales in the United States market, CSL has surplus capacity and the costs of expansion of existing plant are less than those relating to a new plant. There is no credible prospect of entry by a competing fractionator into the Australian market.

Australia's needs for plasma products must be of prime importance. CSL operates a national facility for servicing those needs. The Review considers that Australia's future plasma fractionation needs are best met through that national facility. Some form of regulation is necessary to ensure access to the CSL facility and the achievement of national social and economic policy objectives. This is best managed through some form of contract similar to the Plasma Fractionation Agreement.

10.3 A new Plasma Fractionation Agreement

The Review supports the establishment of a new, shorter-term plasma fractionation agreement, rather than an extension of the current one. This is for several reasons. The first agreement was an historical, foundation agreement struck in 1993 at the time of the CSL sale with a specific cost structure. It was a long-term agreement covering ten and a half years. The broader environment in which blood programs and governments operate has changed over that period and further changes are likely. Other chapters have explored their implications for Australia. Service delivery and funding agreements and contractual arrangements must keep pace with and be responsive to changing circumstances and needs.

Parties to the Agreement

The current Plasma Fractionation Agreement is between the Commonwealth and CSL. An alternative approach is for the ARCBS to be the contracting party with CSL. The latter proposition is based on the view that the ARCBS is the customer of CSL, receiving product to store and distribute to hospitals and clinicians and well placed to manage demand because of its understanding of domestic demand and needs.

The Review does not support this approach. There is a mutual dependence between the ARCBS as the national blood service, including the supplier of plasma, and CSL as the

national fractionator that uses the plasma that the ARCBS supplies to manufacture plasma products. Increased production is linked to increased plasma collection and potentially increased funding. Both the ARCBS and CSL are government funded, as is the rest of the blood supply. Safer alternative products and treatments are likely to emerge that may alter the need for plasma and plasma products. Such a contractual arrangement has potential to pose conflicts of interest and to further complicate an already complex system.

The Review considers that the Agreement should remain one between the Commonwealth and CSL. The Agreement should be managed as part of national oversight of the Australian blood supply. The National Blood Authority should administer service delivery and funding agreements with providers including the Plasma Fractionation Agreement with CSL as part of its national supply management role.

Clear lines of responsibility and accountability

Clear lines of responsibility and accountability are essential. Establishment and management of the Agreement must include setting out the obligations, responsibilities and accountabilities of the parties, specifying core service requirements and establishing clear performance monitoring, reporting and review.

The National Blood Authority should report regularly to Australian Health Ministers on progress with the administration of the Plasma Fractionation Agreement and outcomes.

Ensuring safety and quality

Reliance on a single provider presents some risks in relation to delivery of a safe, adequate and secure supply of plasma products in the event of disruptions in national collection, production and supply systems and national emergencies.

Ensuring a safe and high quality supply of plasma products is an important national objective of a Plasma Fractionation Agreement. Compliance with national safety and quality standards and requirements for the provision of products and services are essential requirements for all service delivery and funding agreements including a Plasma Fractionation Agreement. Strong national regulatory oversight by the TGA and regular performance reporting are important in maintaining public support and confidence and protecting public health and safety.

CSL also has a responsibility to maintain and operate a risk-management strategy to minimise adverse outcomes from its plasma fractionation activities. This should be specified in and reported on through the Plasma Fractionation Agreement. Reporting should include the number and type of accidents and errors in relation to risk-management procedures, breaches of quality standards notified to them by the TGA or other appropriate authorities, and advice on potential avenues for risk reduction and steps taken to reduce risks

Reliance on a single supplier may affect the national regulator's ability to always ensure compliance with and maintenance of requirements and standards. There is a tension between the regulator and the regulated concerning balancing the adequacy of supplies with high levels of safety and quality and reasonable costs. The Review has recommended that new initiatives to improve the safety and quality of the blood supply, including proposed changes to national safety and quality standards, be developed in light of national needs and circumstances. This should occur through formal evidence-based assessments and public consultation, and in context of national public health and risk management (see Section 5.4). The Review has also recommended that effective

lines of communication and advice be established between the National Blood Authority in managing and planning Australia's blood supply and the TGA in regulating its safety and quality. The two recommendations are important aspects of managing risks including those associated with reliance on a single supplier. Others are discussed in Chapter 11.

Ensuring efficiency in supply of plasma products

Efficiency in resource use is an important national objective. The Review found it difficult to assess efficiency in plasma product supply arrangements. There is a lack of data on ARCBS and CSL costs. The former is being addressed by AHMAC through an output based costing study (see Section 4.3). As discussed in Section 8.3, available information suggests that efficiency gains may be realised through changes in collection and distribution arrangements. Lack of national cost data, and lack of performance measures concerning the Australian plasma product supply, affects establishing payments and efficiency gains under a Plasma Fractionation Agreement. The AHMAC costing study will help fill this gap. It is important that the study is completed and results published.

Payments to CSL represent a major component of government funding of the Australian blood supply. The Commonwealth needs to be assured that CSL is operating efficiently, that the prices it charges are fair and the payments it receives represent value for public funds. To meet public accountability responsibilities, the Commonwealth requires information on CSL costs.

CSL is both a domestic fractionator and contract fractionator for overseas markets. It also undertakes other pharmaceutical activities. In establishing a new plasma fractionation agreement, information is required to enable assessment of joint and common costs for CSL's domestic and contracted fractionation activities and between fractionation and non-fractionation activities. This is necessary for establishing appropriate payment schedules that reflect the risks CSL faces in domestic plasma fractionation activities for the Commonwealth Government. At present, the Commonwealth lacks sufficient information on these matters.

Recommendations

- **The Commonwealth Government should enter into a second Plasma Fractionation Agreement with CSL at the expiry of the first ten and a half years of the present agreement (at 30 June 2004) to ensure Australia's future needs for plasma products are met.**
- **The Agreement should be for a shorter term than the current one.**
- **The National Blood Authority should administer the Plasma Fractionation Agreement as part of national supply planning.**
- **The National Blood Authority should report regularly to Australian Health Ministers on progress with the administration of the Agreement and outcomes.**
- **As a matter of priority, AHMAC should complete and report on the results of the study examining the costs of the national blood service provided by the ARCBS.**

10.4 Product developments and innovation

Submissions and consultations expressed concerns about CSL's market position as a sole provider and the risks that this poses for product developments and innovation for the Australian market. A single plasma fractionator with an assured market through the

Plasma Fractionation Agreement has little or no incentive to invest in product development and innovation. Review respondents also considered that the current policy for imported plasma products (Appendix 19 of the *Australian Guidelines for the Registration of Drugs* and the requirement for demonstrable clinical superiority), and the small size of the Australian market, may impede access to product developments and innovations from overseas.

Current situation for imported plasma products

To date, two imported plasma products have been approved by the TGA for marketing in Australia on the basis of clinical superiority to the locally made product. An IVIg product, Sandoglobulin, was approved in 1987. The other was in 2001 — an Rh D immunoglobulin product, WinRho. CSL has registered locally sourced and manufactured IVIg products during that time. It should be noted that a registered imported product is not subsequently de-registered in the event that a locally made product matches the import's clinical efficacy.

As discussed in Chapter 3, a Blood Product Replacement List was introduced in 1997. Sponsors were invited to enter the names of their products on the List to assist State, Territory and Commonwealth governments in choosing available alternative products which could be supplied readily under special regulatory arrangements. No foreign-sourced products have as yet been listed.

Recent developments

The clinical superiority requirement was put in place some years ago. There have been developments since that time. They include the emergence of substitutes for plasma products, such recombinant products, and the establishment of the Orphan Drug Program, administered by the TGA (TGA 1998). The latter provides an avenue for sponsors to achieve registration of products for clinical conditions with a low prevalence. It encourages sponsors to market orphan drugs (products used to treat, prevent or diagnose rare diseases which may not otherwise be commercially viable in Australia) by reducing costs through waiving registration fees. Some imported products have been registered through the program.

The Commonwealth Department of Health and Aged Care advised the Review that it is developing a strategy to harmonise processes for evaluating and pricing new blood products (plasma products made by CSL, other plasma products, and substitutes for plasma products such as recombinants) with the Pharmaceutical Benefits Scheme arrangements for other drugs.

The lack of expert based assessment arrangements for new blood products was commented on widely in submissions and consultations. Expert advice structures and processes are in place in other areas of health care to ensure patient health and safety and to assist resource allocation decisions of governments — for example, through the PBAC and PBPA arrangements for pharmaceuticals and through MSAC for diagnostic tests, procedures and other medical interventions.

The Review has sought to build on these developments by establishing principles for guiding the evaluation of the role and place of product developments and innovations in national supply planning and management.

Some Review respondents advocated that 'parallel' or 'separate' processes should be applied to blood products. Reasons included the special features of blood products; decisions affecting the safety of the blood supply involve broader matters of public

confidence and government accountability than other therapeutic goods; the cost of risk-reduction strategies introduced for the supply would exceed benchmark figures that apply in other areas; and lack of clinical trial data given small patient numbers for some products would mean these products are never funded.

The Review does not support these propositions. Matters of public confidence and government accountability apply to other areas of health care. Evaluation is comparative, not absolute, where alternatives that aim to achieve the same outcome are assessed. Similar methodological concerns apply to other therapeutic products and other areas of health care.

Guiding principles for the future

The Review has stressed the importance of Australia continuing to adopt a pragmatic approach to the application of the self-sufficiency principle in order to respond to changing needs and circumstances and to harness benefits of the changing environment (Section 8.4).

Benefits include improved patient care through product developments and innovations such as new plasma products, substitute products and new clinical indications for existing products. Developments may come from within Australia or overseas.

The Review considers that future arrangements should enable systematic consideration of the role, place and impact of new product developments and innovations in patient care to aid decisions about their adoption in the Australian health system within a policy framework of national self-sufficiency.

Plasma products, and substitutes for plasma products, should be considered in the same way as other therapeutic goods marketed in Australia. They should be registered by the TGA in order to ensure public health and safety. They should meet the same registration requirements for safety, efficacy and quality as other pharmaceutical products with the sponsor providing the necessary evidence. The TGA is responsible for these matters.

Australian governments should seek expert advice on the potential place and costs of plasma products, and substitutes for plasma products, in the Australian supply. Advice should be drawn from existing health system structures and arrangements. The PBAC and PBPA should be used to provide the necessary expert advice.

As discussed, the Blood Product Replacement List has had no effect in encouraging suppliers to list products. The Review recommends that it be discontinued. At Section 11.3, the Review recommends that national intelligence gathering on product markets, suppliers and prices be established by the National Blood Authority to assist national supply planning.

The Commonwealth should put in place the necessary legislative and regulatory changes to bring these arrangements into effect. *The Australian Guidelines for the Registration of Drugs* should be amended accordingly. The impact of the new arrangements should be monitored by the National Blood Authority and reported to Australian Health Ministers.

This new approach has implications for the Plasma Fractionation Agreement, which are discussed below, and access and provision arrangements for imported products, which are discussed at Section 11.1.

Arrangements for the Agreement

The Plasma Fractionation Agreement must be responsive to new products from CSL, and other suppliers, and new clinical indications for existing products.

CSL has domestic expertise in biotechnological manufacturing and research and development. With the purchase of ZLB, CSL expands its research and development base. Research and development is one of the major factors driving the future of all pharmaceutical businesses. Expansion of CSL's research and development base has potential benefits to Australia — providing access to the latest product developments and innovations; and providing evidence of safety, clinical efficacy and cost effectiveness required by regulatory bodies for product registration and by government for product reimbursement decisions.

The Plasma Fractionation Agreement needs to include arrangements and provisions for:

- establishing an agreed product list and pricing schedule;
- reviewing new products and new clinical indications for existing products for which government funding is sought with expert advice provided by the PBAC criteria and with the supplier providing supporting evidence on clinical effectiveness and cost effectiveness;
- establishing product prices based on PBPA arrangements and criteria to enable consideration of financial consequences to governments, the Plasma Fractionation Agreements and other agreements; and
- maintaining an agreed product list with a mechanism that allows products to be added where they are proven to be safe, effective and cost effective, and deleted where they are of little or no clinical value or are replaced by product substitutes.

Product prices should foster innovation and not reward developments of little or no clinical relevance. Consideration, therefore, should be given to a two-tiered approach to product pricing that comprises:

- a basic set of products for which an agreed price will be paid; and
- an appropriate payment for new products based on PBAC / PBPA advice.

Sponsorship arrangements

Under TGA requirements, an Australian sponsor of an overseas therapeutic good is required to seek its registration before availability and use in the Australian market. Sponsorship involves a set of duties, obligations and responsibilities both at the time of seeking registration and during post market surveillance. CSL is a sponsor of imported plasma products and other blood-related products for use in the Australian market. Concerns have been raised about whether CSL should both be the exclusive Australian producer of plasma products and also the major sponsor of imported products. These concerns centre on the strong market position this gives CSL and the potentially conflicting objectives to which it may give rise.

Market position concerns have also been raised in light of CSL's purchase of ZLB. With the ZLB purchase, CSL becomes the producer of the only registered imported IVIg in Australia — Sandoglobulin, a ZLB product — as well as the local producer of IVIg. Once ZLB's distribution arrangement with the present importer of Sandoglobulin (Novartis Pharmaceuticals Pty Ltd) expires, CSL will control directly the production and marketing of all IVIg supplies in the Australian market. A conflict may arise between CSL improving and increasing IVIg production at Broadmeadows and its import aspirations.

Australian sponsorship is a requirement for all therapeutic goods registered for use on the Australian market. There may be sound reasons why CSL should act as a product

sponsor. It is familiar with Australian regulatory requirements and processes and the needs of the market. It is well placed to identify products that would meet an Australian niche, to facilitate registration and to help manage product liability matters. The purchase of ZLB provides CSL with increased international market networks. However, there is concern that this increases CSL's market power and reduces incentives to be efficient and innovative as long as CSL can profit from the importation of its own overseas product.

One option that has been proposed is a review of the appropriateness and relevance of current sponsorship arrangements for blood products and alternative products through an independent audit. The Review has recommended changes to registration and assessment arrangements for plasma products and substitute products aimed at altering current market access and product access incentives within a framework of national self-sufficiency in plasma collection and national self reliance in production (see Section 10.4). The Review considers that a review of product sponsorship arrangements is not warranted at this time. New arrangements should be monitored and product sponsorship arrangements kept under review by the National Blood Authority.

Recommendations

- **A Plasma Fractionation Agreement should include provisions for:**
  - **— establishing an agreed product list and pricing schedule;**
  - **— reviewing new products and new clinical indications for existing products for which government funding is sought with expert advice provided by PBAC and with the supplier providing supporting evidence on clinical effectiveness and cost effectiveness;**
  - **— establishing product prices, based on the PBPA arrangements, to enable consideration of financial consequences to governments, the Plasma Fractionation Agreement and other agreements; and**
  - **— addition and deletion of products in light of evidence about safety, effectiveness and cost effectiveness.**
- **Consideration should be given to a two-tiered approach to product pricing that comprises:**
  - **— a basic set of products for which an agreed price will be paid; and**
  - **— appropriate payment for new products based on PBAC / PBPA criteria and advice.**

10.5 The Diagnostic Products Agreement

Under the Diagnostic Products Agreement, the Commonwealth pays CSL to manufacture and supply a range of diagnostic products to approved blood banks and pathology laboratories across Australia.

Reagent red cells comprise the majority of products manufactured under the Agreement, accounting for 99 percent ($5.9 million) of Agreement funding in 1999-00. Reagant red cells are used to perform a range of immunohaematological tests — for example, to identify antibodies in potential blood transfusion recipients that could adversely impact on the success of transfusion; and to identify antibodies to assist in the selection of compatible blood. Reagent red cells are used in both manual and automated testing procedures. Other products include blood grouping sera for testing of blood groups.

CSL manufactures the products from red cells provided by the ARCBS from special donor panels in New South Wales and Victoria. CSL pays the ARCBS a fee to cover the additional costs associated with the collection of red cells. Products have a short shelf life

(three to five weeks) and specialised storage requirements. An efficient and reliable product distribution and storage system is required. Blood banks and pathology laboratories pay CSL's freight costs.

Changing environment

The Diagnostic Products Agreement was established in 1993, at the time of CSL's privatisation. Its aim was to ensure continuing access to a safe, adequate and secure supply of diagnostic products. Since then, there have been a number of changes in the Australian market for these diagnostic products including the emergence of another potential supplier of domestically made diagnostic products.

There has been a move from manual to automated processing systems for diagnostic blood testing, blood typing and compatibility testing. Automated testing systems and associated gel card technology are imported for use in Australia. There are several equipment suppliers. Suppliers provide reagent red cells for use in the equipment. Reagent red cells may come from two sources: products derived from red cells provided by volunteer Australian donors and made in Australia by CSL; and imports. Changes in the Australian regulatory environment for these and other diagnostic products and therapeutic devices are likely over the next 12-18 months.

Therapeutic devices are regulated by the TGA for inclusion in the Australian Register of Therapeutic Goods (ARTG) for marketing and use in Australia. They are subject to pre-market assessment and post-market surveillance. A two-tier assessment system applies with the level of assessment required depending on the risk implications of the device. *Registered devices* are evaluated for safety, quality and efficacy while *listed devices* are assessed only for safety and quality. Diagnostic products are listed devices so they are not evaluated for efficacy.

In June 2000, European regulatory requirements for diagnostic products were altered with blood grouping reagents required to conform to the highest level of regulation. This is the same as that applying to diagnostic kits for detecting HIV and hepatitis C. The TGA is proposing to harmonise with European practice. Consideration is being given to whether Australia should adopt the European system in total or adapt it to the Australian environment, circumstances and needs. Whether blood grouping reagents require this level of regulation in Australia is still to be determined.

Future directions

The Review considers that the national objective is to ensure a continuing, adequate and secure supply of safe, high quality diagnostic products at an affordable price and that represents value for public funds. The Review, however, found it difficult to assess the likely impact of the various changes on the Australian market. The available evidence supports a retention of the current arrangements for a period, pending any market adjustments that may occur should the potential second domestic supplier enter the market. The period should be sufficient to enable resolution of the following outstanding matters:

- availability of Australian red cells from the ARCBS to the supplier;
- TGA approval of manufacturing plant and production processes;
- demonstrated capacity to supply reagent red cells to a significant proportion of the market on an ongoing basis;
- TGA approval of products for marketing and use in Australia; and
- the impact of proposed regulatory changes on the industry.

At the same time, the Government needs to undertake further policy development relating to establishing future needs.

Recommendation

- **The Commonwealth Government, in establishing future supply and delivery arrangements for blood banking related diagnostic products, should consider:**
  - **the range of products and services required to meet future needs;**
  - **the costs (direct and indirect) of current agreement arrangements and their cost effectiveness;**
  - **the ability of suppliers to meet domestic needs;**
  - **approaches for assessing product cost effectiveness and determining product prices; and**
  - **information and performance reporting requirements.**

11 Meeting Australia's future supply needs

Despite Australia's near self-sufficiency, supply and demand vary with plasma products. The adequacy and security of the plasma product supply are emerging as key concerns worldwide, as the impact of donor deferral and other policies on the supplies of products in individual countries take effect. There is escalating demand for certain products, particularly IVIg, and decreasing use of other products such as albumin. The Review was asked under its fourth term of reference to consider and report on strategies to ensure a continuing, balanced and cost-effective supply of safe, high quality plasma products.

11.1 Arrangements for imported products

Existing arrangements for imported blood products and related products operate on a State and Territory basis. There are two sets of cost-shared arrangements, relating to recombinant factor VIII and to imported blood products and related products for rare coagulation disorders.

There are concerns about existing arrangements for procuring recombinant factor VIII. Submissions considered that there were cost inefficiencies resulting from State and Territory based procurement arrangements and called for access to be expanded. Products are registered with the TGA and purchased in bulk by States and Territories. Some States are moving to joint purchasing arrangements.

For the imported blood products and related products for rare coagulation disorders, concerns centre on administrative and cost inefficiencies of State and Territory based arrangements as well as differences between States and Territories in access to products. Products covered under these arrangements include factor VII, factor IX, factor XI, factor XIII, FEIBA, recombinant factor VIIa and porcine factor VIII. Product purchasing decisions are made by State and Territory health authorities on an individual patient basis against an approved product list and funding criteria. However, administrative differences between States and Territories mean that access varies across the country. A number of Review submissions and consultations highlighted the inequities that result.

The Review also notes that, while the new scheme for imported blood products and related products was agreed between the Commonwealth, States and Territories in 1997, the agreements required to underpin the scheme have not yet been finalised.

The Review considers that the current State and Territory based approaches should be replaced by a national arrangement for imported blood products and related products. A national supply and access arrangement must be put in place as part of a national blood supply to achieve equity in access and efficiency in purchasing and administration. It should be based on the following:

- evidence-based agreed product lists and associated clinical indications, with expert advice provided by the PBAC and PBPA;
- purchasing through national service delivery and funding agreements between the Commonwealth, on behalf of itself and States and Territories, and product suppliers;
- national administration;
- information systems to monitor product issue and use; and

- regular review of products and associated clinical indications in light of evidence.

Arrangements for imported blood products and related products should be administered by the National Blood Authority as part of its national supply planning and management role. The Authority should report regularly to Australian Health Ministers on the administration of the arrangements and outcomes.

Recommendations

- **The States, Territories and Commonwealth should establish a national arrangement to replace the existing State and Territory based approaches for the provision of imported blood products and related products.**
- **The national arrangement should provide for:**
  - **evidence-based product lists and associated clinical indications, with expert advice provided by PBAC / PBPA;**
  - **purchasing through national service delivery and funding agreements between the Commonwealth, on behalf of State, Territory and Commonwealth governments, and suppliers;**
  - **national administration;**
  - **information systems to monitor product issue and use; and**
  - **regular review of products and associated clinical indications.**
- **The National Blood Authority should administer the arrangement and report to Australian Health Ministers.**

11.2 Future supply options

The Review has recommended that self-sufficiency remains a relevant and appropriate national policy goal for securing Australia's future blood and blood product needs (see Section 8.4). At the same time, it is recognised that national blood programs are facing a changing and uncertain environment.

The Review considers that national objectives must be an integration of social and economic objectives — namely, ensuring a continuing, adequate and secure supply of safe, high quality plasma products at an affordable price that represents value for public funds. Subsequent sections examine these objectives and future requirements. While mindful of the need to consider directions beyond the period of the Plasma Fractionation Agreement, the Review has also sought to identify areas that may be improved more immediately.

Increasing plasma collection through plasmapheresis

Plasmapheresis enables more plasma to be collected than in a whole blood donation and also permits more frequent donations, since the limiting factor for blood donations is the time period required for the body to regenerate red cells. A number of submissions proposed increasing the supply of plasma though more extensive and systematic use of plasmapheresis.

The Australian sector, like that of a number of other countries, is geared to collecting homologous whole blood donations. The Review has used the number of apheresis collections (which include collections of plasma, platelets and red cells or any combination of these) as an indicator of the use of plasmapheresis in Australia. Separate data for each type of collection is not compiled routinely. For 1999-00, the ARCBS reported some 111,400 apheresis collections representing around 12 per cent of

homologous whole blood and apheresis collections (Appendix J, Tables 2 and 4). The proportion has increased over the last four years from 8.6 per cent in 1996-97. Use of apheresis collections varies across States and Territories. In 1999-00, over 25 per cent of collections were by apheresis in Western Australia; followed by 13.8 per cent in Queensland and 11.6 per cent in New South Wales. Collection arrangements vary across ARCBS business units. As at 1999-00, no apheresis collections were reported for the Northern Territory and the Australian Capital Territory.

The ARCBS participated in a trial of a particular collection system (TRIMA) in 1998-99, the results of which have led to the adoption of plasmapheresis in some areas. The ARCBS indicated to the Review that the unit costs of production of plasma from a whole blood collection are below those of plasmapheresis. Preliminary cost analyses undertaken for AHMAC support this view with costs varying across States and Territories (AHMAC 1999). The apparently high costs of plasmapheresis in Australia may reflect a number of factors including the fragmented nature of collection arrangements; historical investments in collection and processing arrangements; and differences in regulatory requirements, collection frequency and volumes across countries (eg United States regulations allow more frequent donations in a year than do Australian regulations). Future supply planning requires a sound understanding of these matters.

Plasmapheresis programs have been established in some countries as part of strategies for supplying long-term needs. Some involve volunteer unpaid donors while others are on a paid basis. The benefits, risks and costs of more extensive use of plasmapheresis as part of Australia's supply planning warrants critical assessment. Plasmapheresis has implications for donors (in terms of safety and acceptability), providers (the ARCBS and CSL), governments and resource allocation. It also requires a clear understanding of supply needs, factors that drive supply and most appropriate collection methods and systems. For example, reliance on whole blood collections when plasma is the market driving force may result in unused fresh blood components (red cells and platelets), product wastage and associated ethical concerns.

The Review considers that future supply planning in this area requires firstly a sound understanding of Australia's experience in the use of plasmapheresis in meeting plasma supply needs. Information on current patterns of use and costs of plasmapheresis in Australia versus other methods, initiatives undertaken to date and their outcomes, planned initiatives and their expected outcomes, and reasons for the adoption of plasmapheresis in some parts of the country and not in others is required. The ARCBS is best placed to advise on these matters. The resulting analysis and advice should be used to determine further assessment requirements in this area.

Increasing plasma pool sizes

Increased pool size has been one method used by the plasma fractionation industry to increase productive capacity. Plasma products are manufactured from large pools or batches of plasma made up of donations from numerous donors. The optimal pool size is the subject of considerable debate between regulators and the plasma fractionation industry. Pooling is acknowledged to have both advantages and disadvantages. Advantages include economies of scale, product consistency, and increased yield of plasma product. Disadvantages include increased possibility of including an infectious donation in the plasma pool, increased exposure of product recipients to the risks of infections because larger pools have more potentially infectious units, and the impact on product supply if a plasma batch is lost during production or has to be destroyed.

Limiting the size of plasma pools has been used in some countries to reduce the risks of viral transmission. Modelling data suggest that smaller plasma pool sizes will reduce the likelihood of transmission of viral agents to infrequent users of plasma products but will not have a major effect on those who are frequent recipients of such products (Lynch et al 1996). It is important to note that risk of exposure does not always equate with risk of infection.

The optimal pool size appropriate to a particular country will depend on a variety of factors. Factors include population size; patterns of use of plasma products; manufacturing efficiency; the number of suppliers on which the country relies (single, a handful or multiple); safety, adequacy and security of supply considerations; and the risk exposure of the target groups.

In the United States, following congressional inquiry, the FDA entered into negotiations with the plasma products industry to reduce the risk of infections that occurs in fractionation. A limit of 60,000 donors has been established for each individual plasma product (US General Accounting Office 1999). Pool sizes in the United States industry approached 400,000 in the mid-1990s.

In Australia, as part of requirements for product registration, the TGA has set limits on the pool sizes used by CSL. The TGA's risk-assessment approach limits pool sizes according to type of use (acute or chronic). The maximum pool size is 60,000 donations for plasma products intended for chronic, long-term uses and 15,000 donations per pool for products used by patients with acute conditions requiring only a single treatment, where possible within the constraints of good manufacturing practice.

It is important that the TGA monitors and reviews the situation for Australia in light of new developments and changing national needs and circumstances. Assessments should follow the principles and approaches for decisions about blood matters recommended in Section 4.5 and may become particularly important in view of CSL's stated desire to increase batch sizes.

Importing plasma for local production and use

Importing foreign-sourced plasma for CSL to fractionate into products for use in Australia is another potential strategy for increasing the supply of plasma products. As noted in Section 8.4, many countries are not self-sufficient in plasma donations and rely on foreign-sourced plasma. Australia has not imported foreign-sourced plasma to meet domestic needs; instead certain products have been imported to meet supply shortages or needs for products not made in Australia.

There was widespread support in Review submissions that Australia's needs should be met as far as practicable by locally sourced and made plasma products, with measures to minimise risks associated with reliance on a single supplier and to improve product choice and access in certain areas (plasma-derived and alternatives). Among the overseas sourcing options, the use of imported products was preferred over imported plasma, there being little support for the latter. Concerns about use of imported plasma centred on national self-sufficiency, safety, public support and confidence, and cost.

The use of imported plasma would have implications for Australia's self-sufficiency and its national and international responsibilities. Concern was expressed about the consequences for the country from which plasma is sourced (eg whether plasma is being diverted to exports rather than being used to meet that country's needs). Other considerations were the availability of high quality plasma internationally; the security

of the international plasma supply; and the potentially vulnerable position in which this placed Australia in terms of international markets and costs.

Safety considerations were linked closely to public perceptions that plasma collected from paid donors has higher viral safety risks than plasma collected from donations given by unpaid donors. There was concern about the source of plasma (including whether it is from unpaid or paid donors), the characteristics of the source donor base, donor selection, testing and blood processing regimes in the countries from which plasma is imported, and conformance with Australian standards and TGA regulatory requirements.

Advocates of the use of imported plasma to complement Australian supplies argued that stringent regulatory policies implemented in many countries over the last few decades have reduced considerably viral hazards. It was also argued that Australian patients have access to registered foreign-sourced plasma products; and that, by relying on foreign-sourced plasma, Australia would have greater control over the safety and quality of the resulting products.

The Review considers Australia's efforts and priorities should be directed towards improving the efficiency and effectiveness of the domestic supply within the existing framework of voluntary unpaid donations. This is an important part of Australia's supply risk-management strategy.

Autologous collection services

Use of pre-operative autologous donation (PAD) has been advocated strongly in some quarters as a strategy to reduce demands on the homologous blood supply. PAD is an intervention by which a patient scheduled for major surgery (ie total hip replacement or coronary bypass surgery) donates his or her own blood for storage, which is used during or after surgery if clinically indicated.

The role and place of PAD in the blood supply was examined recently by the AHMAC Blood and Blood Products Committee. The resulting report concluded that, on the basis of available evidence, PAD should not be promoted as its safety as an alternative to homologous blood has not been established (AHMAC 2000b). While PAD reduces the need for homologous blood, the chance of receiving a blood transfusion is increased significantly when autologous blood is available. It is difficult, therefore, to determine whether the benefits of PAD (reductions in homologous blood use) outweigh the risk of excessive transfusion. The AHMAC review recommended that 'autologous donation should be available to those who wish to use it as a matter of personal choice, but not if resources are diverted from other interventions in order to make it available' (AHMAC 2000b).

This examination of alternatives to homologous blood donation is an example of the use of evidence-based assessments that the Review is recommending to inform decisions about the adoption of interventions and the allocation of resources in the Australian health system, and to assist informed consumer choice. Developments in alternatives to homologous donation should continue to be monitored and reviewed as part of expert advice arrangements for the sector. The Review notes that AHMAC accepted the recommendations regarding use of PAD and that some States and ARCBS business units have subsequently introduced patient charges for autologous collection services provided by the ARCBS. The Review supports these measures. As a general principle, public funding for interventions should be based on evidence of cost effectiveness.

Recommendations

- **The ARCBS should provide the National Blood Authority with an assessment of Australia's experience in developing, implementing and reviewing the role, place and cost effectiveness of plasmapheresis in meeting current and future plasma supply needs.**

11.3 Addressing supply risks

Preparing for chance events, emergencies and uncertainties that may affect supply or place unexpected demands on supply is an important part of supply planning.

Managing supply risks — contingency planning

Contingency planning is part of risk management. It needs to cover domestic and external events. Domestic events may include national diasters and emergencies and disruptions in collection, production and supply systems. External events may include the overseas peacekeeping activities of the Australian Defence Force, and crises in neighbouring countries and emergency calls for blood products. Contingency planning should cover both supply shortfalls and domestic surpluses.

As discussed in Chapter 3, recent initiatives in contingency planning for the Australian blood supply include the National Reserve of Plasma Products, the Blood Product Replacement List, national crisis management guidelines developed by the ARCBS and a contingency plan in the event that a case of variant CJD is reported in Australia. There is a need for these and other activities to be drawn together into a national contingency plan.

National Reserve of Plasma Products

The National Reserve is a key initiative in addressing supply risks in Australia. It is Australia's first systematic attempt to build a reserve to provide short-term security in the supply of plasma products in the event of natural disasters and failures in blood and plasma collection systems or the plasma fractionation process. The concept of establishing a Reserve has been around for some years. There have been previous attempts to set aside amounts of products to begin to build up a national reserve. Short-term emergencies hindered these attempts.

Maintaining an effective and responsive National Reserve is an important part of contingency planning for Australia's blood supply. Key policy and logistical matters are that:

- the Reserve must be considered part of Australia's blood supply, not separate from it;
- reserve product holdings must be consistent with current Australian standards;
- reserve holdings must balance current urgent clinical needs against possible future need;
- reserve holdings must be compatible with the changing product use profile in the Australian community;
- reserve products must be able to be tracked as part of national inventory management systems and turned over to ensure use by date of expiry;
- reserve holdings must achieve a balance of domestic and imported products;
- reserve holdings must balance risks associated with reliance on single imported supply sources and multiple sources.

A reserve requires active and close management to ensure it is responsive to changing needs and circumstances.

Monitoring and assessing developments

One of the recommended functions of the National Blood Authority is to monitor and assess local and international markets and developments in the sector. The Review considers that supply planning should include maintaining up-to-date intelligence on product markets, product supplies and prices. The Blood Product Replacement List in effect sought to provide such intelligence. However, for the reasons discussed in Section 10.4, the Review has recommended that it be discontinued and that the *Australian Guidelines for the Registration of Drugs* be amended accordingly. The Review considers that the National Blood Authority is best placed to undertake national intelligence gathering on product market, suppliers and prices.

Supply agreements with other countries

The development of cooperative product exchange with other countries was raised in a few submissions as a strategy for managing product shortfalls and other supply risks. The proposal involves Australia establishing bilateral agreements to enable exchange of products in times when either country may have shortfalls or surpluses. The notion is that for countries like Australia, with small international markets, cooperation between nations is a way of managing supply risks associated with national self-sufficiency and exposure to the volatility of international markets. For example, Australia may have a shortage of Rh D immunoglobulin while the other country has surplus product. The agreement would enable the exchange of product. Alternatively, a country with which Australia has a bilateral agreement may have a shortfall of factor VIII, while Australia has some surplus product. The agreement would enable the exchange of product. A bilateral agreement was proposed with New Zealand.

A number of factors need to be considered in assessing the benefits, risks, costs, appropriateness and feasibility of this strategy. They include consideration of safety, product availability, national and international policy, legislation and regulation requirements, agreement arrangements and operational requirements. The appropriateness, relevance and feasibility of bilateral agreements with appropriate countries for the supply of blood products should be examined by the Commonwealth Government.

Balancing product demand and supply

Review submissions reported chronic shortages in two products — IVIg and Rh D immunoglobulin — and an emerging product surplus in albumin. The Review has examined the recent reviews of IVIg and Rh D immunoglobulin in order to understand the factors that influence product supply and demand and to develop principles to guide future national supply management and planning (see Chapter 8).

While Review respondents agreed that there is a chronic shortage of Rh D immunoglobulin, different views were expressed about the demand and supply of IVIg in Australia. Some questioned whether there was a national shortage, arguing that problems in supply were the result of a number of factors including: the rising number of new clinical indications for IVIg use, some evidence based while others are not; inappropriate use; and State and Territory based plasma production-related allocation policies, rather than national clinical needs. They highlight the problems involved in

determining whether a real shortage exists or whether there are other systemic factors at work.

The Review therefore considers that national management of product supply and demand requires:

- evidence-based clinical indications for product use (the new assessment arrangements for products and clinical guidelines development discussed in Section 10.4 and Section 12.4 will assure this);
- capacity to model the impact of the above on product supply;
- national product allocation and distribution policies that support evidence based use;
- national inventory management systems to enable product supply and use to be monitored and reviewed; and
- national arrangements for managing surplus products and shortages.

The Review has noted the action being taken by the Commonwealth with the ARCBS and others to redress the chronic shortage of Rh D immunoglobulin. This is an important initiative. It should be integrated into the national supply planning and management approach recommended by the Review.

Surplus

The potential for surplus in the supply of particular plasma products raises important social and ethical concerns. They include implications for national self-sufficiency policies, product needs, donors' views and perceptions, and product payment and associated matters. Together they highlight the need to examine carefully any product surplus on a case by case basis.

Australia's international obligations include providing humanitarian aid to countries in need. At the same time, the national self-sufficiency principle encourages countries to use their own resources to meet their human blood and plasma needs rather than depend on other countries for supplies.

Recent market research commissioned by the ARCBS indicates that donors and potential donors support the provision of surplus product on humanitarian grounds, with product provided on a cost-recovery basis. Some concern was expressed, however, where product based on voluntary, non-remunerated donations was provided on a commercial basis to overseas markets. Donors' perceptions need to be explored further.

Other concerns centred on the product involved. Ethical matters of supplying a product no longer used in Australia, because of the availability of a safer substitute or alternative treatment, were raised by some. For others, however, giving access to clinically relevant products where no products were available was paramount.

The National Blood Authority should play a key role in ensuring that national arrangements for managing surplus products are put in place.

National inventory management

National inventory management is an important component of national supply planning and risk management. It concerns the logistical management of stocks of blood and blood products. It involves the tracking of products from point of manufacture to point of issue. The aim is to maximise appropriate use of a scarce and valuable resource by minimising product waste and expiry. Inventory management systems also provide a mechanism for

the acquittal of payments to ensure products and services funded under an agreement are delivered.

National inventory management should enable ready identification of the stocks of blood products by type of product, location, expiry date and issue, and facilitate product transfers and national supply planning. It is also important for tracking products as part of product recalls and other risk-management strategies.

Stocks of blood and plasma products are held by the ARCBS, CSL and hospitals. Systems are required to track product within and between organisations. The ARCBS indicated to the Review that significant efficiencies can be achieved through better national inventory management. The ARCBS has implemented some initiatives to improve inventory management within business units and with hospitals. The ARCBS highlighted the mix of arrangements that exist in this area. Improved national inventory management systems have the potential to improve information on product usage in the Australian blood supply. Performance requirements of inventory systems should be incorporated in service delivery and funding agreements with providers.

As discussed in Section 6.1, the National Blood Management System currently under development by the ARCBS is expected to offer significant advantages over current arrangements.

Recommendations

- **The National Blood Authority should develop a contingency planning strategy for Australia's blood supply. The strategy should draw on Australian and overseas expertise and experience in crisis management and contingency planning, and include monitoring of product markets and developments nationally and internationally. The strategy should be reviewed regularly.**
- **In the context of national contingency planning:**
  - **— the importation of foreign-sourced plasma is not recommended as a strategy for meeting Australia's plasma product shortfalls. The National Blood Authority should keep this approach under review.**
  - **— the National Blood Authority should manage the National Reserve of Plasma Products, established to provide short-term security in national supply. The Reserve should be continually monitored and reviewed in light of experience and changing national needs and circumstances.**
  - **— the Commonwealth Government should examine the appropriateness, relevance and feasibility of bilateral agreements with appropriate countries for the supply of blood products.**

Part D — Ensuring quality in the use of blood and related products

Term of reference 1

Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best-practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.

12 Improving transfusion outcomes

Quality in the clinical use of blood products involves administering the right quantity of the right blood product in the right way at the right time to the right patient, and appropriate documentation of both the process and the outcome (European Commission 2000b).

Blood transfusion should be prescribed only when necessary, as there are hazards associated with transfusion — both homologous and autologous. Sources of risk associated with blood products include infectious agents (such as bacterial or viral contaminants) and non-infectious immune system complications. The administration of blood and blood products may also involve human error (eg use of the wrong blood or use of a blood product when it is not clinically indicated).

Strategies to promote appropriate use of blood and blood products are essential to ensure the health and safety of recipients, to meet ethical and moral obligations to Australia's volunteer blood donors and to counter pressures on supply.

Work directed towards more appropriate use of blood and blood products in Australia has been undertaken at a time of heightened recognition locally and internationally of the need to strengthen the safety and quality of health care generally (eg Institute of Medicine 1999; National Expert Advisory Group on Safety and Quality in Australian Health Care 1999; Quality Interagency Coordination Taskforce 2000).

The ACSQHC should help to promote the development of systems and infrastructure to increase the safety and quality of health care, while the NICS will focus on developing and evaluating strategies to improve clinical practice for application at the institution level. Further initiatives to improve the use of blood products and their alternatives should be considered within the context of, and linked with, broader health system reforms.

12.1 Principles for appropriate use of blood and related products

There has been significant investment in ensuring a safe, high-quality supply of blood and blood products in Australia and other countries over the past two decades. While scope remains for improvement, this may result in relatively marginal health gains (AuBuchon et al 1997). The Review considers that ensuring public health and safety through the more appropriate use of blood and blood products and alternatives is part of a national quality assurance strategy for Australia's blood sector.

Recent developments in Australia

Greater emphasis is being placed on the appropriate use of blood and blood products and quality management systems to facilitate this. Most recently, the NHMRC Health Advisory Committee, together with the Australasian Society of Blood Transfusion and other professional bodies, initiated a process to develop clinical practice guidelines on the appropriate use of blood and blood products. Guidelines on appropriate use of red cells are being developed first, followed by guidelines on appropriate use of fresh frozen plasma, platelets and cryoprecipitate.

Other initiatives to improve the use of blood products and their alternatives have been undertaken by the Blood and Blood Products Committee of AHMAC, the ARCBS, a variety of professional and blood user groups (including the Australasian Society of Blood Transfusion, the Haematology Society of Australia and New Zealand and the

Australian New Zealand Intensive Care Society) and academic groups with a research interest in evidence-based health care. Some of the studies or reviews undertaken by these groups include:

- a review of the supply and use of factor VIII and recombinant alternatives to improve the standard of treatment in Australia for people with haemophilia (AHMAC 1995);
- a review of the supply and use of blood products for patients with haemophilia or other coagulation disorders (AHMAC 1997);
- a study of the suitability of casemix classification of diagnosis-related groups to quantify blood use for potential direct output funding of hospitals (Whyte & Brook 1998);
- surveys of the use of blood products or alternatives to homologous blood in hospitals in Western Australia and nationally (eg Finn et al 1998; Henry et al 2000);
- a systematic review of the evidence for appropriate use of red cells and for the effectiveness of strategies to improve transfusion practice (Hill et al for the Newcastle Systematic Review Group 1999);
- guidelines for the use of Rh D immunoglobulin (anti-D) first approved by the NHMRC in 1996 (NHMRC 1996; 1999);
- consensus guidelines for the use of IVIg developed in 1992 under the auspices of the ASBT (Keller et al 1993);
- a review of the use and supply of IVIg in Australia (AHMAC 2000a);
- a systematic review of the effectiveness of techniques to minimise the use of homologous blood, including PAD, acute normovolaemic dilution, and pharmacological agents (AHMAC 2000b); and
- a survey of infrastructure and practices for monitoring blood transfusion in New South Wales hospitals (Dean & Vincent 2000).

The above list indicates the range and types of themes pertinent to better use. Most of the studies have dealt with single matters rather than with systemic structures that contribute to less than optimal practice. The Review received information about other work currently in progress that addresses these themes during a series of site visits and face-to-face consultations around Australia (see Appendices D and E).

Evidence provided to the Review indicated some of the above reports have led to improvements in patient care, for patients with haemophilia in particular. In other cases, it is too early to evaluate their impact.

There have been numerous smaller studies reporting on practice improvement and other initiatives to promote better use of blood products in individual Australian institutions (eg Metz et al 1995; Tuckfield et al 1997; Hodgkinson et al 1999). All these studies represent an important and welcome development.

Quality assurance

In developing principles and recommendations for future action, the Review has sought to accelerate and strengthen the reach and impact of other initiatives in quality assurance.

Ultimately, clinicians determine the day-to-day care that patients receive. The following principles are essential to secure sustainable clinical practice improvement in transfusion:

- clinicians should lead and actively collaborate in practice improvement initiatives within institutions to ensure ownership and support;
- strategies to support quality assurance in the use of blood products and their alternatives must be simple, and easily integrated into everyday practice;
- strategies should extend and strengthen work already commenced;
- strategies should be coordinated with other safety and quality initiatives in the health system; and
- strategies should be considered part of national quality assurance.

12.2 Identifying problem areas

Many factors influence the use of blood and related products and patient health and safety. Key concerns identified in submissions and in local and international research include inappropriate use and errors and adverse events in administration.

Variation in use

Significant variations in the use of blood and blood products in comparable clinical situations between countries and within countries suggest some level of inappropriate use — the misuse, over- or under-use of these products. Such variability has been noted in reports from the European Safe and Good Use of Blood in Surgery (SANGUIS) initiative involving 43 hospitals in 10 countries (Sirchia et al 1994), a survey of three major hospitals in West Scotland (Garrioch et al 2000), and a survey involving 86 hospitals in Western Australia (Finn et al 1998) among others.

Variation also extends to the level of adoption of alternatives designed to minimise the use of homologous blood for peri-operative blood loss, including PAD, cell salvage, acute normovolaemic dilution and a variety of drugs (Laupacis & Fergusson 1997; Forgie et al 1998; Henry et al 2000).

Inappropriate use of blood and related products in Australia

There have been relatively few published studies of transfusion practice in Australian hospitals and little evaluation of interventions designed to improve the ordering and use of blood products.

An audit of transfusion practice at a large Melbourne teaching hospital during 1993-94 indicated relatively high rates of inappropriate use as assessed against criteria developed by the hospital's blood transfusion committee (Metz et al 1995). Overall, red cells were used inappropriately in 16 per cent of procedures and levels of inappropriate use of platelets and fresh frozen plasma were 13 per cent and 24 per cent, respectively.

Submissions received by the Review, commenting on more recent research, suggested that up to 30 per cent of current red cell usage in some regions may be inappropriate.

Some data on the appropriateness of usage of IVIg have also been collected in Australia under the auspices of AHMAC. Sampling audits were conducted by the ARCBS in some States during 1997 and 1998 to determine the indications for which IVIg was issued nationally. Results suggest that, despite perceived national and local shortages of IVIg, around 12 per cent of IVIg may have been used inappropriately in Australia at the time

of the study (AHMAC 2000a). This assessment was based on clinical indication criteria developed in 1992 by the ASBT. New criteria for the use of IVIg, reflecting later evidence, have been proposed and were adopted by AHMAC in June 2000 (AHMAC 2000a).

Errors and adverse events in the administration of blood products

Public perceptions of transfusion risks tend to focus on viral transmission through the supply. However, overseas data show that human error or system failures in the clinical transfusion process are considerably more common and sometimes result in a fatal outcome (Sazama 1990; Linden et al 1992; Mummert & Touralt 1993; Linden 1999; SHOT Steering Group 2000). Patients may be given the wrong blood (responsible for around half of all serious or fatal errors) or there may be mishandling of blood products and / or related equipment. Inadequate observation of patients for signs of a transfusion reaction or lack of attention to equipment functioning before or during administration are examples of errors which fall within the latter category.

Alternatives to homologous transfusion

A study of the extent of use of alternatives to homologous (allogeneic) blood showed that these interventions are widely used in Australian hospitals, with the notable exception of the various pharmacological agents available (Henry et al 2000). The results showed many respondents believed alternatives to homologous blood should be used more often. Perceptions that these technologies are cost effective and have few side effects were common, as were concerns about the safety of the blood supply and possible legal action (Henry et al 2000). Some of these perceptions are at odds with other evidence on the effectiveness and efficiency of PAD (Forgie et al 1998).

A meta-analysis of available studies of PAD (all undertaken overseas) suggests that patients who pre-donate autologous blood are less likely to receive homologous blood than those who do not, but they are more likely to undergo any transfusion with autologous and / or homologous blood (Forgie et al 1998). This is a concern given that non-infectious hazards (eg wrong blood, fluid overload) also occur in recipients of autologous blood. PAD may not only increase the risk of receiving any transfusion, but it is also less efficient than homologous donation. Forgie et al (1998) report that a high proportion of collected autologous units (25-46 per cent) are not used.

12.3 Opportunities for improvement

There are common underlying factors that influence patterns of use of blood and related products and procedures, as well as the occurrence of errors and adverse outcomes. They operate at the systemic, organisational / institutional and individual levels (European Commission 2000b) and include:

- government policies on what is funded and how it is funded, which may act as incentives or disincentives to good clinical practice;
- the availability of evidence to guide practice (eg on appropriate 'triggers' or indications for red cell and platelet transfusion or on the comparative safety and effectiveness of autologous and homologous transfusion);
- the extent of dissemination of available evidence into everyday practice (eg through educational and related interventions, or decision-support systems in the clinical setting);

- the availability of supporting infrastructure such as hospital transfusion committees to coordinate safety and quality initiatives (eg standard operating procedures or audit) within institutions; and
- relevant documentation and data collection to trace products, ensure accountability and evaluate the outcomes of transfusion.

Clinician and patient preferences also influence the care provided. Prescribing behaviour may be influenced by individuals' awareness and knowledge of relevant risks and by their personal perceptions of or aversion to particular types of risk.

Sustainable change in the use of blood and related products requires action across all levels. While governments can play a role in creating the right environment through a variety of structural and organisational arrangements, further improvements require commitment and effort within institutions.

Hospital infrastructure to support best practice

Many Review submissions advocated more widespread establishment of hospital transfusion committees and audit within Australian hospitals to promote quality use of blood and related products. A number of submissions also commented on the need to have specialist haematological expertise available to support clinicians in the transfusion setting. Arguments in submissions as well as in the research literature suggested that such expertise would be more effective if brought closer to the clinical user.

Hospital transfusion committees (or differently named equivalents) have been widely advocated in the international literature as a means to provide oversight of clinical transfusion practice to improve the quality of care to patients (Calder & Woodfield 1991; Pink et al 1994; Stehling et al 1994; NHS Executive 1998; Popovsky 1998; Krempel & Jarosz 1999; Dean &Vincent 2000). Such committees may take on a variety of roles:

- overseeing and ensuring good inventory management practices in the hospital;
- maintaining information systems on usage of blood products;
- developing and implementing policies on blood ordering and use (eg Maximum Blood Ordering Schedules);
- developing and implementing standard operating procedures and local transfusion protocols to promote safety and quality in use;
- conducting audits and other monitoring activities to review compliance with locally agreed protocols;
- examining areas where there is potential for error or waste;
- querying events or incidents at variance with accepted protocols or norms;
- developing and monitoring locally agreed indicators of performance (such as the cross-match / transfusion ratio and other indicators of wastage);
- providing continuing education in transfusion medicine within the hospital; and
- developing patient education tools.

Hospital transfusion committees can ensure that good data collection, analysis and reporting processes are in place, and provide timely and relevant feedback to the clinicians who provide the data. They can also play a role in the ongoing education of the clinical workforce in hospitals.

The international literature suggests that, to be effective, the hospital transfusion committee should meet regularly and should establish and maintain collaborative, inclusive relationships with significant clinical departments of the hospital, the hospital laboratory / blood bank and with the local blood service.

Audits of blood utilisation practices have been reported as effective in reducing unnecessary transfusion and blood wastage (Clark & Ayoub 1989; Calder & Woodfield 1991; Pink et al 1994; Krempel & Jarosz 1999), although there have been few rigorous evaluations of various approaches to audit (Kanter 1998).

Given some evidence that transfusion committees and audit can be effective in promoting better practice, it is of concern that a recent Australian study indicated relatively low levels of establishment of such committees and related infrastructure (Dean & Vincent 2000).

The Review considers quality management systems are required within hospitals to promote better use of blood and blood products and to minimise waste. On the basis of evidence provided to it, the Review believes that hospital transfusion committees could effectively fulfil this role.

Transfusion committees and accreditation requirements

The use of incentives for hospitals to establish transfusion committees was raised in some submissions. Hospital accreditation requirements have been used as a mechanism to promote quality assurance and to encourage adoption of particular practices in other areas and, the Review notes that many hospitals have already established hospital transfusion committees.

The Australian Council for Healthcare Standards develops and maintains criteria and procedures for accrediting Australian health care institutions, including hospitals. Some of the matters discussed above should form the basis of standards to be met by hospitals involved in blood transfusion.

Informed consent and information disclosure

As a general principle, insistence upon informed consent must be supported. While there are practical difficulties (eg in emergency situations or some paediatric settings), they should not deter adherence to the principles of informed consent.

Medical practitioners have a legal duty to provide patients with information about proposed medical interventions. The NHMRC *General Guidelines for Medical Practitioners on Providing Information to Patients* (NHMRC 1993) outline principles for providing information to patients. Patients are entitled to make their own decisions about medical treatments or procedures and should be given adequate information on which to base those decisions.

Information about blood transfusion provided to a patient should include sufficient detail of the risks and benefits of the transfusion and discussion of any alternatives being used to minimise homologous blood use. Hospital transfusion committees should play a role in developing appropriate information for patients.

Accounting for blood product usage

The need for accountability of hospitals and clinicians for blood product use was a common theme across Review submissions. Ensuring wise and appropriate use of a valuable resource is a key national objective, and effective and efficient strategies to

achieve this objective should be supported. With the tightening in national and global supplies, it is important that governments expedite examination of these matters.

Market research commissioned by the ARCBS found that donors and potential donors have a low awareness of current accountability for blood product usage (CM Research 1998). However, they have an expectation that the ARCBS and hospitals are already accountable including reporting blood product unit usage and costs.

Available evidence on the role of financial and other incentives in reducing waste and promoting appropriate use indicates that merely giving clinicians a notional cost of the blood and blood products they use is not sufficient. Price signals to clinicians have been introduced in other similar countries, including England, without undermining donor participation and support (Whyte & Brook 1998).

Examination and analysis of these matters is required to inform public discussion and debate. A discussion paper on promoting appropriate and efficient use of Australia's national blood supply should be commissioned by Australian Health Ministers. The discussion paper should analyse available research and information, including donors' views and perceptions and overseas experiences, and recommend areas for further development work.

Recommendations

- **All hospitals regularly performing blood transfusion should have an appropriately supported group to implement and oversee quality assurance. At a minimum, the group should be responsible for:**
  - **disseminating national or local guidelines within the institution;**
  - **developing local policies and protocols for blood use and collection;**
  - **auditing use and wastage, and developing related performance indicators;**
  - **risk management, including monitoring adverse or unexpected events and potential errors, analysing underlying system failures, providing timely feedback and advice to management and staff, and overseeing action taken;**
  - **staff and patient education; and**
  - **communication with internal and external bodies (including State Blood User Groups) about quality assurance matters.**
- **These functions should be performed by a dedicated hospital transfusion committee or be incorporated within the role of another appropriate quality assurance or risk-management committee as the situation demands.**
- **Establishment of hospital transfusion committees should be linked to the hospital accreditation requirements of the Australian Council for Healthcare Standards.**
- **Australian Health Ministers should commission a discussion paper on promoting appropriate and efficient use of Australia's national blood supply.**

12.4 Improving the evidence base for transfusion

Submissions argued for the need to strengthen the evidence base for policy and practice in transfusion medicine. Several commented on the paucity and generally poor quality of studies relating to transfusion of fresh blood products.

Defining appropriate use

Expert groups in a number of countries have attempted to define appropriate use. They have also developed national practice guidelines governing use of some blood products

(eg red cells) and techniques to avoid or minimise the use of homologous blood. Guidelines have been implemented with mixed success (eg British Committee for Standards in Haematology 1992; Canadian Medical Association Expert Working Group 1997; European Commission 2000b).

The appropriateness of transfusion involving specific components remains a contentious area. There is a lack of consensus among clinicians about what constitutes 'appropriate' transfusion (eg Hasley et al 1994; Metz et al 1995), with much of the disagreement stemming from the lack of reliable evidence (Allain & Williamson 1997; European Commission 2000b).

Evidence is scant or lacking in a number of areas, for example on the comparative safety of autologous and homologous transfusion, the appropriate triggers for red cell and platelet transfusion and the quality of red cells (Manner et al 1998; Corwin 1999; Goodnough et al 1999; Hébert et al 1999). While there is no scientific basis for many of the uses of fresh frozen plasma, it is still widely used in many countries (Cohen 1993; European Commission 2000b). There is little consensus about the clinical criteria for use of albumin (European Commission 2000b). In 1998, the Cochrane Injury Group published results of a systematic review showing an increase in mortality among patients treated with albumin (Cochrane Injuries Group Albumin Reviewers 1998). There has been considerable debate about the methods and materials of this study. It has served to highlight the potential hazards of blood products as well as the relative lack of clinical trials data to support their efficacy. An Australian study to address some of the questions raised by the Cochrane review is being developed by the Australian and New Zealand Intensive Care Society with funding support from Australian governments, the NHMRC, CSL and others.

Escalating demand in many developed countries for IVIg (see Chapter 10) has drawn attention to 'off-label' use. A number of submissions referred to off-label use and it has been examined in several recent reports (AHMAC 2000a; Bayer Advisory Council on Bioethics 2000). There is a need for more clinical trials to determine the efficacy of novel and off-label uses of IVIg within the ethical and logistical constraints of conducting such trials (Bayer Advisory Council on Bioethics 2000).

Once a pharmaceutical or plasma product has been approved for registration for marketing in Australia, 'off-label' uses will arise, as new knowledge and evidence accumulates from basic research and clinical trials. Some of these new uses will be for legitimate, evidence-based indications while others may be of doubtful or little value. This problem is not unique to the blood supply.

Responding to technological advances

The Review acknowledges that the need for and use of blood and blood products will change inevitably as a result of technological advances and the accumulation of new medical knowledge. It is important that new products and treatments, and new indications for existing products and treatments, are assessed in terms of their benefits, risks and costs and that their role in health care is determined. Public funding for interventions should be based on evidence-based assessments. This requires systematic approaches to monitoring and assessing developments on the horizon, with expert advice sought through existing structures.

The Review has recommended that the NHMRC regularly monitors and reports on developments on the horizon (see Section 4.5) and that PBAC provides expert advice about new products as long as they meet TGA registration requirements (see

Section 10.4). A common concern in submissions was the variation in availability across States and Territories of particular interventions that may reduce the need for or replace blood transfusion. The role of these types of developments needs to be considered and assessed as part of a national response to managing technological change in blood transfusion. Advice on the benefits, risks and costs of medical interventions that may reduce the need for or replace blood transfusion should be sought from MSAC.

Research needs

There is a need to clearly identify current information gaps, and key research questions and priorities to assist in strengthening the evidence base for transfusion practice. As discussed in Section 6.4, further research in this area will require the cooperation and collaboration of governments, industry groups and providers, professional bodies, and academic groups.

12.5 Translating evidence into practice

The gap between evidence and practice has been well documented across the spectrum of health care (Haines & Donald 1998). The care provided to patients is influenced by the quality of the available evidence and the effectiveness of its dissemination.

Reliance on the passive diffusion of information to keep health professionals up to date is not feasible given the high volume of medical publications. Used alone, conventional continuing education interventions, such as conferences and courses, which focus largely on the transfer of knowledge, are thought to have little impact on the behaviour of health professionals. The dissemination of evidence-based guidelines is more likely to have an effect on clinical practice if it occurs as part of a well-planned implementation strategy involving other interventions at the local practice level (Grimshaw & Russell 1994; Haines & Donald 1998).

A wide spectrum of approaches and interventions has been used in health and in transfusion medicine to facilitate behaviour change among clinicians. Systematic reviews of overseas studies designed to evaluate the effectiveness of interventions to promote professional behavioural change have identified modest improvements in performance. Some interventions have been demonstrated to be consistently effective in a range of settings, while others have had mixed effects, or little or no effect in changing practice (Bero et al 1998).

Consistently effective interventions have included:

- educational outreach;
- reminder systems (eg computer generated reminders of appropriate prescribing);
- interactive educational meetings and workshops; and
- combinations of two or more of: audit and feedback, reminders, local consensus process, marketing.

Interventions that showed *mixed effects* when used alone included:

- audit and feedback activities;
- use of local opinion leaders; and
- local consensus process.

Interventions that showed *little or no effect* (used alone) included:

- distribution of educational materials; and
- didactic educational meetings / lectures.

Several published studies have reported success with some of the above kinds of interventions in changing clinical transfusion practice in Australian hospitals. For example, audit and feedback mechanisms and local consensus processes have been reported as effective (Tuckfield et al 1997; Hodgkinson et al 1999). Other publications have advocated the development of local protocols and guidelines, educational outreach, reminder systems (such as Maximum Blood Ordering Schedules) and audit in Australian hospitals (Dean & Vincent 2000; Street & Cole-Sinclair 2000).

Guidelines development

A number of countries have developed national guidelines for some aspects of transfusion, although as noted above, guidelines used alone have not been shown to be particularly effective in changing clinician behaviour. Used in conjunction with other strategies, however, guidelines may be a valuable tool for conveying current knowledge and encouraging more uniform transfusion standards, provided there are mechanisms in place to ensure they are kept up to date.

As discussed, the NHMRC together with the ASBT and other professional bodies has embarked on the development of clinical guidelines for the appropriate use of blood and blood products. This important collaborative work should continue, along with further development of effective implementation strategies.

State Blood User Groups have been established in most jurisdictions representing the interests of the ARCBS, hospitals, clinicians and others. These groups, along with the ASBT and other professional bodies (eg the Royal Australasian College of Surgeons, the Haematology Society of Australia and New Zealand), the ACSQHC, NICS, and others should play an active role in the dissemination and implementation of any national guidelines developed under the auspices of NHMRC. They could also play a prominent role in adapting national guidelines for hospital use, or in the development of specific protocols to guide appropriate transfusion practice at the hospital level.

For clinical guidelines to be valuable in promoting best practice, a mechanism is required to ensure they are kept up to date and reflect current evidence.

Evaluation of strategies to improve practice

The number of Australian hospitals that have established infrastructure and processes to promote the better use of blood is unknown. A recent survey of hospitals in New South Wales suggests that a number of public and private institutions in that State have already adopted quality assurance systems to monitor and improve transfusion practice, but did not evaluate the effectiveness of these interventions (Dean & Vincent 2000).

The NICS can play a pivotal role in supporting initiatives by disseminating evidence from primary research as well as experience and evidence from applied practice research. To be effective at the hospital level, interventions need to be integrated easily into day-to-day practice, and the Institute can assist in identifying strategies that have proven effective across a range of settings and procedures. Its activities in this area should be assisted by the infrastructure and capacity building initiatives of the ACSQHC. The NICS also has a role to play in fostering interventions to improve clinical practice and related evaluation research.

Recommendations

- **The Health Advisory Committee of the National Health and Medical Research Council should lead the development and implementation of evidence-based guidelines to promote appropriate use of blood and blood products in liaison with the Australasian Society of Blood Transfusion, the Haematology Society of Australia and New Zealand and other professional colleges and societies.**
- **The Australian Council for Safety and Quality in Health Care and the National Institute of Clinical Studies should promote initiatives to support better transfusion practice in Australian hospitals including:**
  - **— the adoption of interventions (eg guidelines, audit approaches, transfusion committees);**
  - **— their formal evaluation; and**
  - **— dissemination of results of successful interventions.**

12.6 Documentation, data collection and monitoring

As discussed in Section 6.1, there is a need for the ARCBS to be able to monitor the progress of each blood donation — both for monitoring use and wastage and for health and safety reasons (eg product recalls, or instances of infectious disease transmission). To fulfil this need, data collection and monitoring should occur at different levels. Data collected by the ARCBS allows national monitoring of production and issue of blood and blood products. Data collection in hospitals complements the national picture by giving more detailed information on reasons for using blood, amounts of blood used and outcomes. Complementary mechanisms for monitoring performance will also be needed nationally and in hospitals.

Better information on blood product resource usage

A significant development in hospital information systems in Australia has been the introduction of the Diagnostic Related Group (DRG) patient classification system, that orders patients' conditions into similar clinical categories with similar costs. Associated with each DRG are resource weights that reflect the relative costs of nursing, pathology, radiology, pharmacy and allied health components. Unfortunately, at the time the Australian DRG system was being developed, it was decided to exclude information on blood product usage.

The DRG classification system provides a ready means for obtaining information on blood product usage for Australia. A major theme for the Review has been consideration of ways in which information needs for the ongoing management and review of Australia's blood supply may be integrated into existing hospital systems.

Blood use and wastage

Currently, systematically collected data on national trends in use of blood and blood products and their alternatives are limited. Issue data from the ARCBS may serve as proxy measures for usage, although the level of wastage following issue is unknown. There is no requirement for blood transfusion or pathology services to document usage and wastage rates for blood and blood products (Street & Cole-Sinclair 2000).

The National Blood Management System (see Section 6.1) will provide national information on issue of blood products. However, hospitals need more detailed information on their own usage patterns over time. Within hospitals, transfusion committees can implement the monitoring of use of blood and blood products and

wastage can be assessed through inventory management. A study of inventory management practices in Sydney public hospitals examined the factors correlated with the outdating of donated blood units. By providing information on effective inventory management practices (eg effective stock rotation and cross-matching procedures), combined with monthly feedback on individual hospital outdating performance, this intervention was able to achieve a significant reduction in the overall outdating of product which was sustained for a further 12 months (Pink et al 1994).

Documentation of the reasons for transfusion

The specific indications for transfusion, when documented on the blood order request, form an important part of the patient management record and can serve as a useful tool for audit and monitoring of patient outcomes. The European SANGUIS study showed poor rates (<30 per cent) of documentation of the reasons for transfusion irrespective of the procedure or product used (Sirchia et al 1994).

Better documentation of everyday transfusion practice would be useful as a means for obtaining information on the use of blood and blood products. Simple approaches will be required if this is to be readily integrated into busy clinical schedules. Documentation should include reasons or indications for requesting blood, amounts of blood used and expired, outcomes of transfusion and related procedures (including errors or potential errors).

Incident, accident and near miss reporting

Accident and incident reports are already widely used in a variety of ways in Australian hospitals and with varying success to monitor potentially hazardous incidents and adverse events. An unknown number of hospitals would also be participating in more formal quality assurance activities and incident / adverse event reporting projects, such as those of the Australian Patient Safety Foundation.

Incidents or errors involving the administration of blood or use of an alternative need to be placed within the wider context of efforts to improve the safety and quality of care provided in hospitals, as well as being related to data collection and reporting activities for supply (eg communicable disease surveillance mechanisms). These matters are discussed further in Chapter 13.

Organisations such as the ACSQHC and NICS, as well as the hospital / health care accreditation agency the Australian Council for Healthcare Standards, are well placed to strengthen the culture of safety in hospitals in conjunction with other professional groups. Central to this is the promotion of better reporting of safety incidents and errors, including those involving blood transfusion or related procedures.

Hospital transfusion committees have a role in facilitating better reporting by clinicians of transfusion-related incidents and analysing and reporting on data from their institution, providing feedback to those within the institution, as well as passing on agreed data to national authorities.

Performance indicators for monitoring practice improvement

While the National Blood Authority will develop a set of performance indicators as part of its role in national supply planning and management (Chapter 6), measuring performance in the use of blood will occur in hospitals. At present, there is little capacity to monitor and evaluate transfusion practice within and across institutions (eg blood use, patient outcomes, practice improvement initiatives).

Over the past five years, the National Health Ministers' Benchmarking Working Group has examined performance measurement and related tools and indicators for hospitals (National Health Ministers' Benchmarking Working Group 1999).

The Group has developed a framework for performance measurement and a number of specific performance indicators, relating to the effectiveness, efficiency, quality, appropriateness and accessibility of care for public acute care hospitals. Specific indicators of performance include variations in intervention rates, hospital-acquired infection rates, and percentage of facilities accredited by the Australian Council for Healthcare Standards.

As discussed in Section 6.2, the National Health Ministers' Benchmarking Group has been replaced by the National Health Performance Committee.

Appropriate performance indicators for monitoring hospital transfusion practice are required. Their development should be linked with these broader initiatives.

Recommendations

- **Collection and analysis of data related to the reasons for transfusion of blood products should be integrated into relevant hospital information and documentation systems. Hospital transfusion committees (or their equivalent) should take the lead in such developments.**
- **The National Health Performance Committee should initiate the development of performance indicators for monitoring hospital transfusion practice in liaison with the Australasian Society of Blood Transfusion, the Haematology Society of Australia and New Zealand, the Australian Council for Healthcare Standards and other relevant groups.**

13 Assuring high quality use of blood and blood products — the role of haemovigilance

Review submissions overwhelmingly supported the establishment of a national system for haemovigilance in Australia. The term 'haemovigilance' had a variety of meanings among Review respondents. Different views were held about the purposes and scope of such a system. Some submissions favoured a regulatory, whole of system approach that detected, gathered and analysed information on all untoward and unexpected effects associated with the supply of blood and blood products and their use in clinical practice. Others supported a more limited scheme.

The term 'haemovigilance' was originally coined in Europe. Haemovigilance can serve a number of objectives, depending on a nation's specific needs. Increasingly, haemovigilance is being promoted in underpinning blood safety and quality (Council of Europe 2000).

There are numerous agencies and schemes that monitor aspects of the safety and quality of Australia's blood supply. However, information on adverse events associated with the use of blood products is limited.

The Review considers that the major focus of an Australian haemovigilance scheme should be to monitor untoward transfusion events and outcomes in hospitals. Efforts in this area will complement quality assurance in production and supply. They should be seen as a component of adverse events monitoring in Australian hospitals and part of a national approach to improving patient safety being led by the ACSQHC.

Information from existing schemes, and the proposed haemovigilance scheme, should be drawn together to provide regular national reports on safety and quality in the supply and use of blood and blood products. Such reports will assist in informing clinicians and the public about the relative frequency of different hazards, thus placing the risks of blood transfusion in perspective.

13.1 Haemovigilance developments in other countries

Most developed countries, including Australia, have established pharmacovigilance programs as part of their regulation of pharmaceuticals and plasma products. Programs generally mandate reporting of product recalls and adverse events by the manufacturer and permit voluntary reporting of adverse events by clinicians and consumers. A cluster of adverse events around particular products or batches of product can then serve as a warning.

A number of countries have established or are establishing national haemovigilance systems. Different approaches have been adopted, from voluntary, confidential reporting to mandatory identified hospital and patient data. Some are system-wide and comprehensive in scope, while others are limited in their coverage, for instance reporting only serious or fatal outcomes, or data collected only for a sample of all transfusion.

United States

The United States relies on a network of surveillance programs and cooperative, multifaceted arrangements to ensure blood safety. There is no single program of centralised blood safety monitoring, in keeping with the overall pluralistic nature of the system. There is a national scheme of voluntary reporting by clinicians and patients of adverse reactions linked to blood products under the FDA's MedWatch program. The

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has a policy for encouraging reporting of sentinel events, including ABO- or Rh- incompatible transfusion, on a voluntary basis. JCAHO requires a thorough 'root cause' analysis and corrective action on all reported events (Menitove 1999). Blood product manufacturers are required by FDA to report unexpected deaths within seven days and serious adverse reactions within fifteen days. FDA also requires manufacturers of plasma products to report infectious disease transmissions (Busch et al 1999).

France

The French haemovigilance system was mandated by the Blood Transfusion Safety Act of 1993. It covers all transfusion and requires reporting of all adverse transfusion events, through a haemovigilance network that links around 2,000 physicians and other health workers in blood centres and hospitals throughout France (Debeir et al 1999). A government agency, the Agence Francaise du Sang (AFS), was initially entrusted with the task of implementing the system in 1994. The Establissement Francais du Sang (EFS) replaced this in December 1999. As well as monitoring and reporting on transfusion incidents at a national level, the EFS initiates and funds haemovigilance research through academic institutions. Data analysis occurs centrally in the EFS, with input from specialists in transfusion medicine, public health, epidemiology and statistics.

United Kingdom

In 1996, the United Kingdom launched a voluntary and confidential reporting scheme called Serious Hazards of Transfusion (SHOT) (McClelland et al 1998). Its objectives are to:

- improve standards of hospital transfusion practice;
- inform policy within transfusion services;
- aid production of clinical guidelines for the use of blood components; and
- educate users on transfusion hazards and their prevention.

SHOT is managed by a Steering Group with wide representation from relevant professional groups, representing medical, nursing and laboratory staff. Funding is derived from the transfusion services of the United Kingdom and Ireland, supplemented by grants from professional bodies.

As its name suggests, SHOT focuses only on serious or fatal transfusion events. It does not cover complications associated with the use of fractionated plasma products, as these are monitored separately through another voluntary ('yellow card') scheme, as licensed medicinal products. There is no over-arching mechanism to collate adverse events involving the two product lines.

13.2 Lessons from existing haemovigilance systems

Available evidence indicates that ABO incompatibility (giving the wrong blood to a patient) is the largest category of serious adverse transfusion event (Noel et al 1998; Linden 1999; SHOT Steering Group 2000).

Data for the first three years of reporting from the United Kingdom SHOT scheme indicate that the most important single cause of mistransfusion was failure of some aspect of the bedside checking procedure immediately before transfusion. Causes included remote checking (eg at the nurses' station) rather than at the bedside, checking a component against the accompanying paperwork rather than the patient, and failure

to note discrepancies between labels. There was evidence that interruption during critical checking steps is responsible for some of these errors. Simple things, such as a patient getting into the wrong bed, can lead to disastrous results in the absence of a systems approach to safety. Several studies report the occurrence of compound errors, where the opportunity to detect and correct the primary error is missed through a second error (eg Linden 1999).

The overriding message from haemovigilance in the United Kingdom and from related studies in the United States is that around half of serious or fatal incidents are potentially preventable (Mummert & Touralt 1993; Linden 1999; SHOT Steering Group 2000). Haemovigilance can aid identification and analysis of contributory factors and has the capacity to deliver improvements in clinical care and patient safety, as well as lead to better use of available resources. Accumulated experience with the SHOT program suggests that it is most likely to achieve this and the full support of clinicians if it is seen as a tool for future clinical improvement rather than as a regulatory or punitive exercise.

Some selected data on transfusion errors and adverse patient events, derived from haemovigilance efforts in the United States, France and the United Kingdom, are presented in Table 13.1. As discussed in Chapter 12, available data suggest that many untoward or adverse events in transfusion are preventable.

Table 13.1 Selected data on adverse events reported for the United States, France and the United Kingdom

Type of adverse event	Frequency (%)	Comments	Source
United States, 1976-1985			
ABO incompatibility	51	Data relate to transfusion-related fatalities only	Sazama 1990
Pulmonary oedema / fluid overload	15		
Bacterial contamination of product	10		
Delayed haemolysis	10		
United Kingdom, 1998-1999			
Wrong blood to patient [a]	57	Scheme covers serious and fatal events only. Around 2.4 million red cells and 259,000 platelets issued in survey period.	SHOT Steering Group 2000
Transfusion-transmissible infections [b]		(a) Causing 1 definite, 2 probably deaths; (b) resulting in 2 deaths	
France, 1996-1999			
Transfusion incident rate of 1.5 per 1,000 delivered blood products			Noel et al 1998
Described as 'minor'	70-80	Severity scale does not take account of pre-transfusion state, so outcome may not be due to transfusion.	l'Agence Francaise de Securite Sanitaire des Produits de Sante 2000.
Long-term consequences to patients	13-25		
Vital threat	3-4		
Fatal	<1	In 1999, 30 incidents involving ABO incompatibility were reported among a total of 4,395 immediate reactions, 3 of them fatal and 9 posing a serious threat to the patient.	

Note: Time periods and study populations differ between countries

13.3 Australian developments

In Australia, a number of initiatives, directly or indirectly related to haemovigilance, are in place or are in train.

Blood sector and haemovigilance initiatives

In January 1997, a working group of the AHMAC Blood and Blood Products Committee recommended development of a nationally integrated, comprehensive database on haemophilia patients and their treatment (AHMAC 1997). The intended primary focus of this system was to assist with the monitoring and planning of supplies of plasma and recombinant products. The Bleeding Disorder Registry includes demographic information and data on diagnosis, severity and treatment, in addition to inhibitor, hepatitis C and HIV status (HFA 2000). It could serve as a useful tool for monitoring adverse outcomes. Ownership resides with the Australian Haemophilia Directors Inc (formerly the Medical Advisory Panel of the Haemophilia Foundation Australia). At present, New South Wales does not contribute data to the Registry.

The ARCBS, in conjunction with CSL, the Australasian Society of Blood Transfusion, and the National Centre for Epidemiology and Population Health at the Australian National University, has undertaken preliminary work on the haemovigilance concept and approaches that might be adopted in Australia. The work was progressed through an ARCBS Haemovigilance Working Party with a brief to 'advise on the development and implementation of a National Haemovigilance Policy for monitoring and recording side-effects to transfusion …'. The Working Party has set up pilot studies in the first instance in Sydney and Adelaide to collect information about adverse transfusion reactions and to test a surveillance reporting system for the Australian situation.

Other initiatives in adverse events monitoring and clinical improvement

The TGA's regulatory responsibilities include post-market surveillance of plasma products but it does not regulate clinical practice. Responsibility for hospitals lies with the States and Territories, which has implications for future haemovigilance development.

Within the health system, there are other initiatives that should be linked directly or indirectly to further development of the haemovigilance concept. These include the Australian Patient Safety Foundation, communicable disease surveillance schemes, the ACSQHC and NICS. In planning for haemovigilance in Australia, the experiences or resources of these groups should be drawn upon as appropriate.

13.4 Haemovigilance in Australia

The Review urges the establishment of a national haemovigilance scheme to monitor untoward transfusion-related events and outcomes in hospitals. This is the area where information and effort are currently lacking. It is important that a national haemovigilance scheme is developed within an agreed policy framework, as part of an overall strategic quality assurance plan for the sector. Details of any such scheme also need to be considered as part of broader developments in patient safety in hospitals.

Some valuable pioneering work has already been done, which will form a useful foundation for aspects of implementation. Options for funding, ownership, objectives and operational aspects of the scheme need to be developed. It is essential that funding mechanisms are agreed before an Australian model for haemovigilance or detailed

operational matters become entrenched. The scope and coverage of any scheme, as well as its effectiveness, will depend on the resources made available to support it.

Purpose and objectives

Haemovigilance may serve a number of objectives. The Review considers the primary purpose of haemovigilance should be to improve patient safety, through feedback and education to enable system improvement.

As a subsidiary purpose, haemovigilance data can be used to place the risks of transfusion in perspective for providers and the public, to inform policy, and to show that action is being taken to minimise risk. It provides a valuable tool to maintain public confidence.

While all hospitals should accumulate their own haemovigilance data (under the auspices of the hospital transfusion or quality assurance committee), a system for collating this information nationally will be required. This will permit meaningful analysis and identification of trends and patterns which can be fed back into practice.

Scope

Decisions about the scope and comprehensiveness of haemovigilance have significant resource implications and may affect the scheme's overall effectiveness and sustainability. A comprehensive scheme, while having the potential to facilitate detailed epidemiological monitoring and research, is costly and may not achieve the desired goal of complete and accurate coverage.

After some years of operation, the comprehensive French scheme is described as being 'fragile' (Debeir et al 1999). Reasons given include the system's inability to capture data on recipients and actual blood usage, variable data standards and quality, and the lack of dedicated funding for remote staff in the network. A substantial proportion of resources are used for reporting minor events in such a scheme. A more restricted scheme can be run at a relatively lower cost (McClelland et al 1998).

Consideration might be given to including 'near misses' or potential errors in addition to adverse events, as is done in aviation and other high-risk industries. The same patterns of causes of failure precede both types of event (Barach & Small 2000). There is evidence that the true incidence of errors relating to transfusion is at least four times the level of actual mistransfusion events detected (Ibojie & Urbaniak 2000).

There is a perception that the safety gap is widening between homologous and autologous transfusion, given greater regulation and oversight of homologous transfusion and overseas data indicating the application of more liberal transfusion policies for autologous blood use. Consideration should be given to the inclusion of autologous and directed transfusion within a national haemovigilance scheme.

The Review considers that the United Kingdom SHOT scheme provides an affordable, cost-effective approach that is compatible with local needs and clinical traditions. It forms a useful starting point for developing an Australian haemovigilance system. However, it will need to be adapted to circumstances, for example, to account for the lower volume of activity in the Australian blood sector.

Proposal for an Australian haemovigilance scheme

A first priority is the development of a detailed proposal for a national haemovigilance scheme that builds on the principles identified by the Review. The Review considers that the ACSQHC, in conjunction with the National Blood Authority, should lead the

development of a proposal and implementation plan for consideration by Australian Health Ministers. They should liaise and consult with relevant bodies on these matters. The ACSQHC was established by Health Ministers to lead national efforts to improve the safety and quality of health care. It is important that a national haemovigilance scheme is developed as part of these efforts to improve patient safety.

The proposal should cover such aspects as purpose and objectives, scope, implementation plan, timetable, budget and associated funding arrangements. Implementation matters should address operational linkages between hospitals, the ARCBS and national authorities, which were identified by the Council of Europe (2000) as important for an effective haemovigilance system. The plan should address responsibility for and details of the management and operation of the national scheme for monitoring untoward transfusion events and outcomes in hospitals. It is important that the body is at arm's length from service delivery, has the confidence of clinicians and the necessary expertise.

It is vital that clinicians and technical personnel within institutions that use blood play a lead role in the planning, implementation and ongoing operation of haemovigilance. Information management and epidemiological skills will also be essential to ensure timely, reliable and useful reporting.

Confidential reporting

Available evidence suggests that medical mishaps are more likely to be reported and acted upon where reporting is both voluntary and confidential. Australia and the United Kingdom have a tradition of voluntary, confidential reporting (eg maternal, peri-operative and anaesthetic deaths). Such reporting acknowledges that there are powerful disincentives to reporting adverse events in a culture of blame, where disciplinary action, the media and the medicolegal climate may all work together to discourage honest, open discussion (Institute of Medicine 1999; Barach & Small 2000). Mandatory reporting of medical errors and adverse events may drive evidence of mistakes underground.

Voluntary, confidential reporting does, however, have disadvantages. It cannot be used for epidemiological monitoring and research, as the true risk of any event covered by the scheme cannot be calculated (Williamson 1999). A guarantee of confidentiality means that institutions that are careless in reporting or that seek to conceal adverse events cannot be identified.

These disadvantages may be offset by an increased preparedness to report adverse events, especially errors, in a confidential scheme. Evidence from SHOT provides indications of increased reporting of adverse events in which human error plays a part over the three years of reporting, whereas other adverse events have remained relatively static (SHOT Steering Group 2000).

Fear of litigation has been a recurring theme in quality assurance activities in medical care (Review of Professional Indemnity Arrangements for Health Care Professionals 1995). Commonwealth quality assurance confidentiality legislation (Part VC of the *Health Insurance Act 1973* and subsequent amendments) was introduced in December 1992 and is intended to encourage national activities that will improve the quality of health care. The Act provides protection from subpoena, and confidentiality for information that becomes known through declared *national* quality assurance activities. The public interest in providing this confidentiality is balanced with the competing public interest in openness by requiring publication of non-identifying information about the activity.

The Professional Indemnity Review report (1995) concluded that the best way to minimise the human and financial costs of adverse patient outcomes is to implement effective quality assurance and risk-management strategies at all levels in the health system.

Recommendations

- **A national scheme for monitoring untoward transfusion events and outcomes in hospitals (a haemovigilance scheme) should be established as a priority for the purposes of:**
  - **identifying contributory factors;**
  - **providing feedback to enable clinical practice and product improvements; and**
  - **providing data to place Australian transfusion risks in perspective.**
- **The haemovigilance scheme should be developed as part of the national approach to improving patient safety being led by the Australian Council for Safety and Quality in Health Care.**
- **The Australian Council for Safety and Quality in Health Care, in collaboration with the National Blood Authority, should provide Australian Health Ministers with a detailed implementation plan, timetable, budget and associated funding arrangements for the scheme. The proposal should be developed in liaison with relevant bodies.**
- **A voluntary, confidential approach should be adopted for reporting adverse transfusion events in hospitals with appropriate legislative protections.**

13.5 Monitoring safety and quality

There are numerous agencies and schemes that monitor aspects of the safety and quality of Australia's blood supply. Schemes and criteria for monitoring performance have been developed often on an agency basis, reflecting specific responsibilities in the sector. In some cases, information is published routinely, in other cases it is not. Collated information from these schemes would provide valuable information for use in quality assurance, service improvement and policy development and review.

The TGA and its committees play an important role in such areas as product recalls, adverse drug reactions, test kit failures and other device failures (eg blood bags). The ARCBS and CSL as major providers of blood and blood product services are required to maintain reporting systems. The NRL and other agencies involved in external quality assurance of laboratory testing are also a valuable source of relevant information. A number of bodies support or are involved in collating information on the incidence and prevalence of specific blood-borne diseases and markers for these diseases. They include the National Centre for Disease Control and related surveillance and notification schemes, the National Centre for HIV Epidemiology and Clinical Research and the National CJD Registry among others.

There is no ready mechanism that draws together information from these various schemes and arrangements to provide a national picture of the safety and quality of Australia's blood supply. The national haemovigilance scheme discussed above will be an important addition in monitoring the safety of blood transfusion.

There is a need for collection and analysis of information from these schemes to provide a national overview of safety and quality performance. This function should be established at arm's length from service delivery. It should be linked with the performance reporting role of the National Blood Authority and associated performance indicator development. It should also be linked to and draw on the experience of the

ACSQHC in the development of a national framework for health service performance measurement and reporting.

Recommendation

- **The National Blood Authority, in collaboration with the Australian Council for Safety and Quality in Health Care, should establish a mechanism for collating and analysing information from existing monitoring and surveillance schemes, and the proposed haemovigilance scheme. It should draw together expertise from these schemes to provide regular national reports on safety and quality in the supply and use of blood and blood products.**

Part E — Conclusions

14 Conclusions of the Review

The Review has involved a comprehensive examination of the blood banking and plasma sector, that part of the health system responsible for meeting Australia's blood and blood product needs. The Review's five terms of reference were wide-ranging. Its primary aim has been to ensure that Australia is equipped to meet emerging and future challenges, to provide an adequate and secure supply of safe, high quality blood and blood products and to promote appropriate clinical use. This chapter presents the major conclusions and recommendations of the Review, phrased against the terms of reference.

The Review's recommendations fall into two broad categories. The first category relates to new governance arrangements that build a strong national management and decision-making capacity, streamline service delivery and funding arrangements, and redirect effort and resources to align better demand and supply.

The remaining recommendations cover a wide range of activities, providing the basis for a work program to guide activities over coming years.

The recommendations represent an integrated package which includes several mechanisms for ongoing monitoring and review. These are essential given the need for Australian governments to respond to the changing national and international environment.

Term of reference 1

Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.

Blood banking is a service where a focus on donors and recipients as well as on manufacturing processes and supply is crucial. There has been significant investment in assuring a safe, high quality blood supply, but there is still scope for improvement. Opportunities for significant public health and safety gains lie in the better use of blood and blood products and alternatives. Future sustainable improvements in safety and quality of blood transfusion will require quality assurance approaches that cover the spectrum from donors to recipients and that strike a balance between regulatory and other approaches.

Term of reference 2

Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.

Australia requires a national approach to the supply of blood and blood products that delivers efficient and effective services, responds to new and emerging developments and develops responsible and responsive policies. Governance arrangements must be strengthened in order to provide the national approach to blood matters required to meet Australia's current and future needs. This will require moving from the remnants of State and Territory based approaches and division of responsibilities between States, Territories and the Commonwealth. A national approach that recognises the roles and responsibilities of States, Territories and the Commonwealth in a contemporary governance framework is vital.

A National Blood Authority should be established as a priority to provide national management and oversight of the Australian blood supply. The National Blood Authority should be a statutory body, with a Board comprising an independent chairman and nominees of State, Territory and Commonwealth governments drawn from the public and private sectors.

New governance and financing arrangements should be simpler, with single lines of accountability and clear, consultative relationships established between governments and key organisations.

Term of reference 3

Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time. Among other things, the advice should cover:

- *the need for and financial impact of new testing procedures and new products;*
- *legal and ethical issues where access to products may have to be based on clinical priorities;*
- *cost effectiveness of proposed safety improvements;*
- *the role of an expert reference laboratory in setting and maintaining a national quality assurance program;*
- *the impact of change on public confidence in the blood supply.*

The Review has sought to provide principles and approaches to guide decisions. Australia's needs for expert advice on blood matters across a range of areas should be drawn from the National Blood Authority and from existing health system structures and arrangements. Advice on blood matters should be developed in the context of national public health and risk management applicable to Australia's circumstances. Evidence-based assessments should be adopted where possible for the provision of advice on the benefits, risks and costs of proposed blood policies and for public information and dissemination. Emerging technological, scientific and other developments should be monitored.

Term of reference 4

Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing of additional product from overseas suppliers.

Self-sufficiency should remain an important national goal for Australia. It is a national and international obligation and responsibility. To plan and manage Australia's blood supply needs, a national strategic approach rather than single product approaches is required. To inform supply planning, it is critical to understand supply needs, the factors that influence supply, trends in supply and demand, the factors that drive supply and use, and the most appropriate collection methods and systems.

The blood and plasma given by Australia's donors are sources for many therapeutic products. Reliance on whole blood collections when plasma is the market driving force may result in unused fresh blood components (such as red cells or platelets), product wastage and associated ethical concerns. Similarly, plasma is a source of several

therapeutic products that are extracted simultaneously. Increased production in one product generally results in a similar production increase in others.

A national approach should aim to make available the appropriate range, volume and mix of blood and blood products to meet Australia's needs, based on the principles of: appropriate use of a scarce and valuable resource given freely by donors; a national blood service (the ARCBS); national inventory management to monitor use; assured access to plasma fractionation services; efficient and effective use of available resources; management of technological change in ways that benefit patients and the community; a national access and supply arrangement for imported blood products and related products; and effective contingency planning and supply risk management.

Term of reference 5

Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.

Australia's future plasma fractionation needs are best met through the national facility operated by CSL. This should be managed through some form of contract similar to the Plasma Fractionation Agreement.

The national imperative is that Australia's needs for plasma products are met and that CSL's use of the Broadmeadow's facility to fractionate foreign plasma does not pose any significant risks to the safety and quality of domestic products and to product recipients. Clear lines of responsibility and accountability, and performance monitoring, reporting and review, should be incorporated into the Plasma Fractionation Agreement.

The Review has developed principles to guide future arrangements for the manufacture and supply of a range of diagnostic products for blood testing, typing and cross-matching made by CSL from human blood supplied by the ARCBS.

The Review was asked to consider Australia's future domestic needs against export opportunities for Australia's plasma fractionation industry. The Review notes the recent international expansion of CSL has made this aspect of the terms of reference less relevant.

Recommendations of the Review listed against the terms of reference

Term of reference	Recommendations
1 Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best practice standards, recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.	**6** National safety and quality standards of blood and related products (see pages 48 and 51) **7** External oversight and coordination of the quality of laboratory testing (see page 53) **8** Assuring safe and quality use of blood and blood products (see pages 114, 118 and 120) **9** Reducing untoward and unexpected effects of blood transfusion (see pages 127 and 128) **16** Information (see pages 56 and 91) **17** Research (see page 59)
2 Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.	**1** A National Blood Authority (see page 35) **2** Establishing effective relationships (see page 36) **3** New financing arrangements (see page 40) **5** Intergovernmental agreements (see page 40)
3 Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time.	**4** Expert advice on blood matters (see page 42)
4 Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.	**10** National self-sufficiency (see page 77) **11** The ARCBS — the national blood service (see pages 56, 81 and 103) **13** National supply and access arrangements for imported blood products and related products (see page 99) **14** Managing supply risks — contingency planning (see page 106)
5 Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.	**12** Plasma fractionation (see pages 91 and 95) **15** Diagnostic products — Diagnostic Products Agreement (see page 97)

Appendices

Appendix A

The Review Committee and Secretariat

The Review Committee

Sir Ninian Stephen (Chairman)

Dame Margaret Guilfoyle DBE

Professor Judith A Whitworth

Professor Robert Beal AM

The Secretariat

Ms Penny Rogers

Dr Margaret Dorsch

Ms Elizabeth Scroope (Committee Secretary, part-time)

Ms Jodi Wood (Office Manager)

Dr Alex Proudfoot and Dr Elaine Walker provided medical and scientific advice to the Review.

Research assistance was provided at various times during the Review by Mr Ian Bidmeade, Ms Fiona Brooke, Ms Julie Cutts, Ms Kirryn Holloway, Ms Cindy Kemp, Ms Asimina Peristeri and Ms Pippa Robinson.

Other contributors

The following individuals and groups provided consultancy support to the Review.

Australian Government Solicitor

Dr Peter Brennan , MA International Pty Ltd — general

Dr Thierry Burnouf — plasma fractionation

Elizabeth Hall, Ampersand Editorial and Design — report editing

Kay McNiece, McNiece Communications Pty Ltd — media liaison

Monash Institute of Public Health, Monash University — survey of current and emerging technologies

Network Economic Consulting Group (NECG) — industry and market analyses of plasma fractionation and of relevant diagnostic products

Jennifer Zangger, Ampersand Editorial and Design — report editing

Appendix B

Media release announcing the Review of the Australian Blood Banking and Plasma Product Sector

The Commonwealth Minister for Health and Aged Care, Dr Michael Wooldridge, announced today that he had established a review of the Australian blood banking and plasma product sector to ensure the highest standards of blood supply continue to be met in Australia.

The review will cover blood collection and banking activities as well the processing and distribution of blood and blood products.

The review, which will be headed by former Governor General, Sir Ninian Stephen, will investigate the capacity of the blood system to maintain the quality and safety of the blood supply into the future and consider ways to increase the supply of essential blood products.

'The Australian blood supply is one of the safest in the world, thanks in large measure to our voluntary donor system,' Dr Wooldridge said. 'At the same time we have very effective screening, testing and processing measures in place that minimise risk to patient safety.'

'However, the demand for blood and blood products is increasing faster than supply. This imbalance sometimes puts undue pressure on the system and I am worried that quality controls might slip in order to meet demand.'

The Minister said that the recent announcement by the Canadian Blood Service that it is considering whether it has to defer donors who have visited the United Kingdom because of the potential risk of new variant CJD is an example of the sort of pressures that blood banks worldwide face.

'One of the aims of the Review is to ensure Australia has the capacity to assess such situations in a timely and effective manner so that the blood supply remains as safe as possible and public confidence can be retained. Should it be necessary, this particular issue will be referred to the Review committee for early consideration.' the Minister said.

'The international trend is for increasingly stringent testing of blood that yield marginal gains in safety but often at a high cost. I am concerned that because of the currently split of roles and responsibilities between the Commonwealth and the States, these improvements might not be implemented, or worse implemented in a piecemeal manner across jurisdictions, the Minister said. 'I want to ensure we have a system that can react in a uniform, effective manner to these safety requirements so that Australia continues to have a safe, high quality blood supply.'

'I am also concerned that the demand for some processed blood products exceeds supply to the extent that effective treatment of some patients is being compromised. Also the emergence of new synthetic substitutes can increase supply and reduce risk. Patient advocacy groups such as Haemophilia Foundation Australia and the Inflammatory Neuropathy Group are calling for a solution to these problems. I propose that the review examine the supply situation and recommend strategies to overcome the shortages.'

The Minister emphasised that the review would not seek to change the fundamentals of the voluntary donor system or the provision of blood and blood products free of charge to patients.

The Minister said that the review would complement and extend the various review activities currently being conducted by the Australian Health Ministers'Advisory Council.

'My Department is an active participant in these activities and will continue to be so but I think we need a broader process for pulling it all together. An independent review seems the ideal way to achieve this outcome.'

The other members of the Committee are Dame Margaret Guilfoyle, Professor Robert Beal and Professor Judith Whitworth.

'I am confident that a Committee comprised of such eminent Australians will have the trust and confidence of the general public and the key agencies and consumer groups associated with the blood system,' the Minister said. 'Between them they have a lot of experience and expertise.'

The review is expected to run for about a year.

Dr Michael Wooldridge

MW 50 / 99
10 May 1999

Appendix C

Submissions to the Review

The individuals and organisations that provided submissions to the Review are listed below. Some submissions or parts thereof were provided on a confidential basis. The Review has sought permission from all those individuals and organisations to be listed here. The Review also received correspondence and materials relating to its work. The Review thanks all correspondents.

Abbott Diagnostics Division

ACT Department of Health and Community Care

Alison Hunter Memorial Foundation

Alliance Health Pty Ltd

Australasian Society of Blood Transfusion Inc.

The Australia Institute

Australian and New Zealand College of Anaesthetists

Australian Association of Pathology Practices Inc.

Australian Cancer Society (through the Clinical Oncological Society of Australia Inc.)

Australian Defence Force, Department of Defence, Australian Capital Territory

Australian Health Ministers'Advisory Council Blood and Blood Products Committee

Australian Institute of Medical Scientists

Australian Medical Association Limited

Australian New Zealand Intensive Care Society

Australian Red Cross Blood Service — National

Australian Red Cross Blood Service — (South Australian Division) User Group

Bates, Mr Ian R

Baxter Healthcare Pty Limited

Blood, Mr Alan

Cabrini Pathology

Catholic Health Australia

CJD Support Group Network Inc.

COBE Laboratories Pty Ltd

Commonwealth Department of Health and Aged Care

Consortium for Plasma Science, LLC, United States

Consumers' Health Forum of Australia

Cooperative Research Centre for Vaccine Technology

The Council of GBS / CIDP Support Groups of Australia

CSL Limited

Department of Health and Human Services, Tasmania

Department of Human Services, South Australia

Department of Human Services, Victoria

DiaMed Australia Pty Limited

Endeavour Forum Inc.

Gradipore Ltd

Guillain-Barré Syndrome Association of New South Wales Inc.

Haematology Society of Australia and New Zealand

Haemophilia Foundation Australia

Health Department of Western Australia

The Inflammatory Neuropathy Support Group of Victoria Inc.

Inner and Eastern Health Care Network, Victoria

Intergovernmental Committee on AIDS and Related Diseases

International Study of Perioperative Transfusion (ISPOT), School of Population Health Services (University of Newcastle) and the Australian Centre for Effective Health Care (University of Sydney)

Isbister, Professor James

KIDS Foundation New Zealand and KIDS Foundation Australia

Lyell, Mr Peter

Managers of Blood Banks at Sydney Metropolitan Hospitals

Masters, Professor Colin L

MDA Pharma (Medical Dynamics Australia)

Medical Advisory Panel for Haemophilia

Medical Industry Association of Australia

Medtel Pty Limited (on behalf of Haemonetics Corporation, United States)

Moschioni, Mrs Marjory

National Association of Testing Authorities, Australia

National Centre in HIV Epidemiology and Clinical Research

National Pituitary Hormones Advisory Council

National Public Health Partnership Group

National Serology Reference Laboratory, Australia

New South Wales Health Department

Novartis Pharmaceuticals Australia Pty Ltd

Novo Nordisk Pharmaceuticals Pty Ltd

Pathology Services Table Committee

Perfusion Services Pty Ltd

Quality of Surgical Care Project in Western Australia

Queensland Health

Royal Australasian College of Surgeons

The Royal College of Pathologists of Australasia

Rural Doctors Association of Australia and The Australian College of Rural and Remote Medicine

Strugnell, DJ

Territory Health Services, Northern Territory

Therapeutic Device Evaluation Committee

Tiley, Dr Campbell

Western Australian Blood Products User Group

Whyte, Associate Professor Gordon

Williams, Jean R

Appendix D

Consultation program

Abbott Diagnostics Division

Australasian Society of Blood Transfusion Inc.

Australian and New Zealand College of Anaesthetists

Australian Capital Territory Department of Health and Community Care

Australian Council for Safety and Quality in Health Care

Australian Defence Force, Department of Defence, Australian Capital Territory

Australian Health Ministers' Advisory Council Blood and Blood Products Committee

Australian Patient Safety Foundation

Australian Medical Association Limited

Australian Red Cross

Australian Red Cross Blood Service — Donor Recruitment and Public Relations Managers

Australian Red Cross Blood Service — Haemovigilance Working Party

Australian Red Cross Blood Service — National

Australian Red Cross Blood Service — (South Australian Division) User Group

Commonwealth Department of Health and Aged Care

Consortium for Plasma Science, LLC

Consumers' Health Forum of Australia

The Council of GBS / CIDP Support Groups of Australia

CSL Limited

Department of Health and Human Services, Tasmania

Department of Human Services, South Australia

Department of Human Services, Victoria

DiaMed Australia Pty Limited

Guillain-Barré Syndrome Association of New South Wales Inc.

Haematology Society of Australia and New Zealand

Haemophilia Foundation Australia

Health Department of Western Australia

Henry, Professor David, International Study of Perioperative Transfusion (ISPOT), School of Population Health Services (University of Newcastle)

The Inflammatory Neuropathy Support Group of Victoria Inc.

Isbister, Professor James

Masters, Professor Colin L

MDA Pharma (Medical Dynamics Australia)

Medical Advisory Panel for Haemophilia

National Centre in HIV Epidemiology and Clinical Research

National Public Health Partnership Group

National Serology Reference Laboratory, Australia

New South Wales Health Department

New Zealand Blood Service

Novartis Pharmaceuticals Australia Pty Ltd

Novo Nordisk Pharmaceuticals Pty Ltd

Penny, Professor Ron, Chairman of the Working Party to AHMAC Blood and Blood Products Committee on the Use and Supply of Intravenous Immunoglobulins in Australia

Quality of Surgical Care Project in Western Australia

Queensland Health

The Royal College of Pathologists of Australasia

Rubin, Professor George, Australian Centre for Effective Health Care

Western Australian Blood Products User Group

Whyte, Associate Professor Gordon

Williamson, Dr Lorna, Chair, Serious Hazards of Transfusion Working Group

Appendix E

Site visits

The Alfred Hospital, Victoria

Ashford Hospital, South Australia

Australian Red Cross Blood Service — National

Australian Red Cross Blood Service — North East, Southern and North West Regions

CSL Limited, Victoria

National Serology Reference Laboratory, Victoria

Princess Margaret Hospital for Children, Western Australia

Royal Adelaide Hospital, South Australia

Royal Children's Hospital, Victoria

Royal Hobart Hospital, Tasmania

Royal Melbourne Hospital, Victoria

Royal North Shore Hospital, New South Wales

Royal Perth Hospital, Western Australia

Sir Charles Gairdner Hospital, Western Australia

Swan Districts Hospital, Western Australia

Appendix F

AHMAC Blood and Blood Products Committee — terms of reference

The terms of reference of the AHMAC Blood and Blood Products Committee are as follows (AHMAC 1996):

- advise on the production and usage of blood and blood products in Australia and New Zealand;
- advise on the need for and appropriate funding of measures to ensure the safety and efficacy of blood and blood products in Australia;
- advise on the cost and cost benefits of new technology, including new products and new production methods for blood and blood products;
- advise on appropriate mechanisms for funding, including pricing / charging arrangements;
- advise on the need for, and facilitate the development of national guidelines on the usage of blood and blood products;
- provide an annual report on all the above matters to AHMAC; and
- provide such other urgent advice as may be necessary on any of the matters as requested through the Chair of AHMAC.

Appendix G

Summary of legislation relating to the Australian blood supply

A mix of State and Territory and Commonwealth laws deal with the blood supply. This appendix describes them and their role in the sector.

State and Territory Human Tissue Acts

All States and Territories have some form of legislation controlling the collection and use of human tissue including blood. They focus on consent for the removal of blood for transfusion or for therapeutic, medical or scientific purposes. In all States and Territories, except Queensland, statutory defences are in place to protect donors, suppliers or medical practitioners against actions for contraction of certain diseases (eg HIV) from blood transfusion. The number of pieces of legislation and their names vary across States and Territories, as do their provisions.

New South Wales	*Human Tissue Act 1983*
Victoria	*Human Tissue Act 1982*
	Health Act 1958
Queensland	*Transplantation and Anatomy Act 1979*
Western Australia	*Human Tissue and Transplantation Act 1982*
	Blood and Tissue (Transmissible Diseases) Regulations 1985
	Blood Donation (Limitation of Liability) Act 1985
South Australia	*Transplantation and Anatomy Act 1983*
	Blood Contaminants Act 1985
Tasmania	*Human Tissue Act 1985*
	Blood Transfusion (Limitation of Liability) Act 1986
	HIV / AIDS Preventative Measures Act 1993
Northern Territory	*Human Tissue Transplantation Act (1985)*
	Notifiable Diseases Act (1981 as amended 1999)
Australian Capital Territory	*Transplantation and Anatomy Act 1978*
	Blood Donation (Transmittable Diseases) Act 1985

Other State and Territory legislative responsibilities

There is other State and Territory law that relates to the sector. In essence, States and Territories have regulatory controls over the institutions in which blood transfusion services are provided. States and Territories are responsible for the regulation and management of public hospitals and other health services, the licensing of private hospitals and the registration of medical practitioners.

Therapeutic Goods Act 1989

The Therapeutic Goods Act is Commonwealth legislation that provides a national framework for the regulation of therapeutic goods in Australia and that ensures their quality, safety and efficacy for marketing and use in Australia. For the Australian blood banking and plasma product sector, the Act provides national regulatory controls covering the activities of two major domestic providers (the ARCBS and CSL); registered imported blood products and related products; devices used in blood banking such as test kits, blood bags etc; and contract fractionation activities of CSL. The TGA, which is a Division of the Commonwealth Department of Health and Aged Care, is responsible for administering the provisions of the Act. The TGA promulgates and oversees the cGMP.

National Health Act 1953

The National Health Act is Commonwealth legislation that covers the provision and funding of certain medical, pharmaceutical and dental services. The Act provides the basis for Commonwealth funding of plasma fractionation, products and related products.

Health Insurance Act 1973

The Health Insurance Act is Commonwealth legislation that covers the major elements of the Australian Medicare program providing access to medical and hospital services and Commonwealth funding for services. The Act covers Commonwealth funding for hospital and professional services associated with provision of blood transfusion. It includes requirements to be met for payment of Medicare benefits for autologous collections services and therapeutic collections including accreditation of public and private pathology services under the RCPA / NATA program against NPAAC standards.

CSL Sale Act 1993

The CSL Sale Act is Commonwealth legislation that provided the legislative framework for the sale of CSL process. The Act gives certain powers to the Commonwealth to protect the national interest in relation to the activities of CSL. Provisions include a mechanism to enforce blood fractionation contracts, restrictions on the disposal or encumbrance of CSL's Broadmeadows plasma fractionation facility without the approval of the Commonwealth and maintaining CSL independence under Australian control. The Act also preserves certain employee entitlements and repeals or makes technical amendments to provisions of the CSL Act 1961.

Customs Act 1901

The Customs Act is Commonwealth legislation that empowers the making of regulations that prohibit the import or export of goods into and out of Australia. There are no customs restrictions on the importation of blood or blood products to Australia. The export of human body fluids and substances from human blood requires the granting of permission by the Commonwealth Department of Health and Aged Care and the production of the permission to the Collector of Customs. The Commonwealth is responsible for quarantine laws.

Corporations Law (Commonwealth and State / Territory)

There is State / Territory and Commonwealth law that regulates the business management of Australian companies incorporated under that legislation, as opposed to bodies incorporated under cooperative legislation, associations legislation and bodies set under dedicated statutes.

The Trade Practices Act 1974 (Commonwealth) provides protection to consumers against unconscionable conduct, false representations, misleading or deceptive conduct and other 'unfair practices' in connection with the supply of goods, services and land. It provides remedies in the event of defective goods or inadequate services being supplied to consumers and regulates restrictive trade practices. In the context of the provision of blood products, the Federal Court held that the ARCBS, the New South Wales Division of the ARCBS and the Royal Prince Alfred Hospital are all trading corporations within the meaning of Section 4 of the Trade Practices Act. All States and Territories have similar legislation.

Appendix H

Australian Guidelines for the Registration of Drugs — Appendix 19

Australia's pursuit of national self-sufficiency in blood and blood products as far as practicable is given effect through Appendix 19 of the *Australian Guidelines for the Registration of Drugs* (TGA 1994). This was amended in 1997 (TGA 1997) to cover the establishment of the Blood Product Replacement List.

The policy is as follows:

> Intending sponsors of products derived from human blood or plasma should note that Australia favours national self-sufficiency in products derived from human blood or plasma, believing that a policy of not being reliant on donors in other countries is not only in the national interest but an international responsibility.
>
> Blood products sourced from foreign countries will be registered only if the foreign product has a demonstrably significant clinical advantage over the local product. Intending sponsors of foreign-sourced blood products should discuss their prospects of satisfying this criterion before lodging an application for registration.
>
> From time to time, locally produced blood products are subject to short-term supply and / or quality problems. To cover such contingencies, the Commonwealth wishes to establish a short list of suitable foreign-sourced products which would be imported when the need arose. Sponsors are invited to express interest in having appropriate foreign blood-derived products entered on this 'Blood Product Replacement List'.
>
> In case of shortage of registered blood products of adequate quality, the Blood Product Replacement List would assist Australian Governments in choosing between available alternatives which could be supplied under special regulatory arrangements (eg s19A of the Therapeutic Goods Act).

Appendix I

Strategies to ensure safe, high quality blood products

Chapter 5 examined the capacity of existing arrangements to ensure safety and quality in the production and supply of blood and blood products and ways that improvements to these arrangements could be made. This appendix provides background material on strategies in place to ensure a safe, high quality supply.

Australia's supply of blood and blood products comes from four sources — domestic homologous donations (the vast majority of reported domestic collections), autologous collections, directed donations, and imported blood products and related products.

Domestic homologous supply

The vast majority of activity relates to domestic homologous supply. Strategies to ensure safety and quality involve screening of the donor, then collection, testing, and processing through to post-market surveillance.

The following chart summarises quality objectives for each element of the homologous supply and current related quality assurance measures. Many of the measures are regulatory, with the trend towards national regulation administered by the TGA. In 1991, Commonwealth regulatory controls for plasma collection and production were introduced. In 2000, they were extended to the manufacture of fresh blood products by agencies licensed for that purpose, including the ARCBS. This is a significant step in improving the quality of the Australian supply.

Regulatory controls recognise inherent differences between fresh blood products and plasma products. Regulation of fresh blood products focuses on the assurance of good manufacturing practice, while plasma products are also subject to pre-market assessment and evaluation and registration on the ARTG. The ARTG contains information about therapeutic goods for human use approved for supply in, or export from, Australia.

The TGA is supported by a number of advisory committees. Key committees of relevance to the blood product area are as follows.

The *Therapeutic Goods Committee* (TGC) advises the Commonwealth Minister for Health and Aged Care on standards for therapeutic goods including labelling and packaging and principles to be observed in their manufacture for use in humans.

The *Australian Drug Evaluation Committee* (ADEC) advises the Commonwealth Minister for Health and Aged Care or the Secretary of the Commonwealth Department of Health and Aged Care on medical and scientific evaluations of drugs and on the timely availability of new therapeutic advances in Australia.

One of ADEC's subcommittees, the *Adverse Drug Reactions Advisory Committee* (ADRAC), reports on matters relating to adverse drug reactions. Reporting is mandatory for manufacturers and voluntary for treating clinicians and others who suspect adverse reactions.

The *Therapeutic Device Evaluation Committee* (TDEC) advises the Commonwealth Minister for Health and Aged Care or the Secretary of the Commonwealth Department of Health and Aged Care on the safety, quality, efficacy, use and availability of

therapeutic devices and their import into, export from, and production and distribution within Australia;

The *National Coordinating Committee on Therapeutic Goods* (NCCTG) is a Commonwealth, State and Territory Committee that provides recommendations on the coordination of administrative and regulatory controls on therapeutic goods and poisons. It makes recommendations to AHMAC as necessary.

Safety and quality objectives and strategies for Australia's domestic homologous supply

Key element	Safety and quality objectives and strategies
Source population	Public health strategies for reducing the incidence and prevalence of blood-borne infections (eg hepatitis C, HIV) play a critical but often forgotten role. The safety profile of donors will reflect the underlying prevalence of risk factors in the wider Australian population, but the prevalence will always be lower because of donor selection practices.
Donor recruitment, education, retention, eligibility and screening / selection	A sufficient number of healthy, safe donors is critical to the safety and quality of the supply. Objectives are to attract donors at low risk of transmitting disease in sufficient numbers to ensure an adequate supply, to retain donors as repeat donations tend to be safer, and to protect the safety of donors and recipients. Donor selection is the chief means available to prevent transmission of 'non-testable' potential infections or to offset false-negative tests. Multi-tiered screening strategies are in place including population-based disease control initiatives, donor registration and identification systems, donor interviews, donor declarations, donor deferral policies and donor education.
Collection	Objectives in collection and processing of blood and plasma are to ensure the safety and well-being of donors and to ensure safety and quality of products. Strategies include licensing of collection sites and adherence to processes and practices that comply with the relevant cGMP. Collection sites and procedures are inspected and audited by the TGA to ensure compliance.
Testing of donated blood and plasma	Important steps include typing (eg for ABO and Rh blood groups) and testing of donated blood or plasma for infectious disease markers. Objectives are to protect public health and safety by ensuring that the right blood type is transfused and minimising the possibility of infectious agents passing into the blood supply. National regulations specify infectious disease testing requirements, including licensing of testing sites by the TGA and use of TGA-approved test kits. The NRL plays a role in pre-market evaluation and post-market monitoring of viral test kits, in confirmatory testing and proficiency testing / external quality assurance of viral testing methods. Different agencies (eg RCPA) are involved in external quality assurance programs for other testing methods. Sites and procedures are inspected and audited by the TGA to ensure compliance with national standards.
Processing	This covers processing in blood banks (eg separation of whole blood into components) or at the plasma fractionation facility (including viral inactivation procedures). Product safety and quality are covered by a cGMP, licensing requirements and quality assurance requirements. Processes, practices and systems are inspected and audited to ensure compliance.
Storage of products	The cGMP specifies storage, handling and labelling requirements. Processes, practices and systems are inspected and audited to ensure compliance.
Pre-market evaluation and registration	Plasma products are subject to pre-market evaluation of animal toxicity and clinical trials data, and process validation for manufacturing methods, to ensure product safety and efficacy prior to registration.
Post-market surveillance	Objectives are to protect donors, recipients and public health and safety by tracking problems that may only become evident with widespread use rather than in clinical trials. Activities cover reporting and investigation of problems, monitoring of adverse reactions, laboratory testing of products on the market, evaluation of changes to manufacturing processes, a uniform recall scheme for the recovery of substandard product, and good manufacturing practice inspection. Manufacturers are obliged to monitor and investigate errors and accidents in their procedures, to audit systems and to correct deficiencies.

Autologous collections

There is no single safety and quality regulatory regime for autologous fresh blood. A mix of arrangements and strategies apply depending on where autologous collections are performed and how they are funded.

The ARCBS and pathology services in both the public and private sectors provide autologous collection services. Pathology services are subject to general laboratory standards set by NPAAC and laboratory accreditation and inspection under a program run jointly by NATA and the RCPA. There are also requirements in State and Territory legislation relating to blood and other human tissue.

Directed donations

Directed donations involve the collection of blood that is designated for use by a particular patient. Safety and quality assurance arrangements for directed donations are similar to those applying to autologous fresh blood products. The ARCBS has developed national policy guidelines for directed donations. These are to be considered by AHMAC.

Imported products

Australia imports certain plasma-derived, recombinant and other related products. The TGA is responsible for registration of imported blood products and related products. Two sets of arrangements are particularly relevant for registration of imported blood or recombinant products:

- Products may be registered under Appendix 19 of the *Australian Guidelines for the Registration of Drugs*. Registration is restricted to plasma products that have a demonstrable clinical superiority over the local product. Products require an Australian sponsor and undergo pre-market assessment and evaluation (in terms of quality, safety and efficacy) and post-market surveillance. To date, two imported plasma products (an IVIg product, Sandoglobulin and an Rh D immunoglobulin product, WinRho) have been approved by the TGA for marketing in Australia on the basis of clinical superiority to locally made products under Appendix 19 arrangements. Once approved for marketing in Australia, products are included in the ARTG as 'registered' products.
- Products may be registered under the *Orphan Drug Program*. The program encourages sponsors to market orphan drugs (products used to treat, prevent or diagnose rare diseases) that may not be commercially viable in Australia by reducing costs through waiving registration fees (TGA 1998). Some imported blood related products have been registered through the program (eg recombinant factors VIII and IX). Products require an Australian sponsor.

Special Access Scheme arrangements allow individuals with serious conditions access to certain drugs, including imported blood products not registered for marketing in Australia. Products provided under the scheme do not undergo TGA evaluation. Products include factor VII for a small number of patients and several products derived from human or animal plasma, including factors VIII, IX, XI and XIII for people with inhibitors to domestic products or on the basis of clinical preference.

Contracted plasma fractionation services

Plasma products manufactured by CSL from foreign-sourced plasma and destined for export are subject to different regulation and standards from those applied to plasma products destined for the domestic market. These contract fractionation products cannot be distributed in Australia. CSL is required to demonstrate that the fractionation of

overseas-sourced plasma does not affect the safety of products registered for the Australian market.

Firstly, quarantine approval is required for the movement of plasma into Australia. Secondly, processing plasma from an overseas source cannot proceed without TGA inspections, audits and approval to ensure safety and quality requirements have been met. All overseas collection centres for which CSL provides contract fractionation must provide documentation (Plasma Master Files) on donor selection, viral prevalence and test methods in the format of guidelines laid down by the European CPMP (1994). Documentation is evaluated by the TGA to ensure the plasma does not exceed the viral loads against which CSL's plant and quarantine and decontamination processes have been validated (eg relating to donor selection and testing arrangements).

The finished products must be listed on the ARTG and have an export permit.

Appendix J

Australian blood supply — statistical overview of activity and expenditure

This appendix provides statistical information on activity and expenditure in the Australian blood banking and plasma product sector. It covers statistics on donors, collections, production and product issue as well as some supply expenditure statistics.

Information has been drawn from a number of published and unpublished sources. Information on aspects of the sector's activities is reported under various State and Territory and Commonwealth service delivery and funding agreements, however, it is not drawn together routinely and systematically to provide a national picture. Broad level information is published by the ARCBS on the activities of the national blood service. For other aspects of the sector, little information is available in the public domain. The Review has sought to redress this situation. National statistics and some State and Territory statistics are presented.

Information sources

The ARCBS provided data relating to its activities. The data covered blood donors; homologous whole blood and plasma collections; autologous and therapeutic collections and directed donations; production of fresh blood products; plasma collected and sent to CSL for fractionation; and issue of blood products and plasma products.

CSL provided information on the production of plasma products.

The Commonwealth Department of Health and Aged Care provided information on autologous blood collections funded by the Medicare Benefits Scheme; imported plasma products and substitute products; and supply expenditure.

Australian Bureau of Statistics (ABS) population statistics were used to calculate various rates (eg donor participation rates, collection rates).

The information contained in this appendix has been verified with each organisation.

Time series

The Review confined its analysis of activity in the sector to the four years, 1996–97 to 1999–00, since the formation of the ARCBS. Reasons for this included limitations in the availability of consistent time-series information on the sector nationally; and the Review's focus on recent and future developments and directions. The impact on supply activities of the variant CJD donor deferral policy introduced in December 2000 is therefore excluded from the analysis. Information on supply expenditure is provided either for the last ten years (1990–91 to 1999–00) or the last six years (1994–95 to 1999–00).

Notes and interpretation

The formation of the ARCBS highlighted the importance of a national approach to statistical collection and reporting. The McKay Wells review (1995) commented on the lack of uniformity in statistical indicators and collection procedures across the State and Territory based blood transfusion services. While progress has been made, there remains a lack of uniformity in data collection, definitions and reporting processes across ARCBS

business units. For example, agreed nationally consistent information on new, repeat and deferred donors who present to the ARCBS took effect from July 2000. Also, some business units collect information on expiry of products (eg red cells and platelets) while others do not.

Expenditure (Tables 15 to 19) refers to direct expenditure of State, Territory and Commonwealth governments on supply of blood and blood products and Australian Red Cross contributions to the operating costs of the national blood service.

Where figures have been rounded, there may be discrepancies between the sums of the component items and the totals. A dash indicates either nil or that the number was rounded to zero.

Structure

Statistics are provided in a series of parts:

A — Australia's blood donors
B — Collections of blood
C — Plasma (normal and hyperimmune) sent to CSL for fractionation
D — Selected fresh blood products
E — Plasma products — locally sourced and made
F — Imported blood products and related products
G — Expenditure on Australia's supply of blood and blood products

A Australia's blood donors

Table 1 Australian blood donors, States and Territories, 1996–97 to 1999–00

	NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Aust
Number of donors ('000)[a]									
1996–97	121.0	113.1	69.7	61.2	49.2	10.8	9.5	4.4	439.0
1997–98	128.1	117.1	81.5	66.0	48.7	11.0	9.6	4.4	466.4
1998–99	130.1	114.7	84.4	66.0	48.8	11.1	9.4	4.4	468.9
1999–00	127.8	112.6	79.5	66.1	49.4	10.9	9.8	6.6	462.7
Donors as a proportion of age-eligible population (%)[b]									
1996–97	2.8	3.5	3.0	4.9	4.8	3.4	4.3	3.4	3.4
1997–98	2.9	3.6	3.4	5.2	4.7	3.4	4.3	3.3	3.6
1998–99	2.9	3.5	3.5	5.1	4.7	3.4	4.2	3.2	3.6
1999–00	2.8	3.4	3.2	5.0	4.8	3.4	4.4	4.8	3.5

(a) Includes people who made homologous donations (whole blood or apheresis), autologous collections, directed donations and therapeutic collections to the ARCBS.
(b) The Review has used 'donors as a proportion of age-eligible population' to give an indication of the donor participation rate. Often the indicator 'donors per 1,000 total population' is used. Such a measure does not take account of differences in the age distribution of populations in different regions. The generally acceptable age range for blood donors in Australia has been 16–70 years, subject to meeting additional criteria and gaining parental consent in those States / Territories permitting blood donation for people aged 16–17 years.
Note: Rates were calculated using Australian estimated resident population statistics at 31 December for 1996, 1997, 1998 and 1999 from the ABS.
Sources: ARCBS, ABS.

B Collections of blood

Table 2 Combined homologous whole blood and apheresis collections,[a] States and Territories,[b] 1996–97 to 1999–00

NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Aust	
Number of collections ('000)									
1996–97	278.1	228.2	176.0	82.6	81.2	24.0	18.3	9.3	897.8
1997–98	285.0	231.5	180.3	84.9	84.9	24.8	18.4	10.1	919.9
1998–99	296.1	226.8	185.1	97.0	87.1	25.6	19.2	8.8	945.8
1999–00	290.2	223.5	185.0	104.5	86.7	25.4	19.4	9.4	944.0
Collection rate (number per 1,000 population)									
1996–97	44.6	49.8	52.2	46.4	55.0	50.6	59.3	50.5	48.7
1997–98	45.2	50.0	52.6	46.9	57.3	52.4	59.9	53.7	49.4
1998–99	46.4	48.4	53.2	52.6	58.5	54.3	62.4	46.3	50.2
1999–00	45.0	47.1	52.3	55.8	58.0	54.0	62.3	48.2	49.5

(a) Includes collections of plasma, platelets and red cells or any combination of these. Where a donor has given blood more than once in a year, each collection episode is included.
(b) No apheresis collections were made in the Northern Territory or the Australian Capital Territory during the period covered.
Note: Rates were calculated using estimated resident population figures for December in each of the years 1996 to 1999 (ABS 1999).
Sources: ARCBS, ABS.

Table 3 Homologous whole blood collections, States and Territories, 1996–97 to 1999–00

	NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Aust
Number of collections ('000)									
1996–97	251.9	212.0	160.8	67.6	77.4	23.0	18.3	9.3	820.3
1997–98	258.8	213.8	160.9	68.5	80.0	24.2	18.4	10.1	834.7
1998–99	259.0	209.3	162.8	72.0	80.2	25.0	19.2	8.8	836.6
1999–00	256.5	206.1	159.5	77.4	79.3	24.9	19.4	9.4	832.6
Collection rate (number per 1,000 population)									
1996–97	40.4	46.3	47.7	37.9	52.4	48.5	59.3	50.5	44.5
1997–98	41.1	46.2	47.0	37.8	54.0	51.2	59.9	53.7	44.8
1998–99	40.6	44.7	46.8	39.0	53.9	53.1	62.4	46.3	44.4
1999–00	39.8	43.5	45.1	41.3	53.0	52.9	62.3	48.2	43.6

Notes: Where a donor has given blood more than once in a year, each collection episode is included. Rates were calculated using estimated resident population figures for December in each of the years 1996 to 1999 (ABS 1999).
Sources: ARCBS, ABS.

Table 4 Apheresis collections,[(a)] States and Territories,[(b)] 1996–97 to 1999–00

	NSW	Vic	Qld	WA	SA	Tas	Aust
Number of apheresis collections ('000)							
1996–97	26.2	16.2	15.2	15.1	3.8	1.0	77.5
1997–98	26.3	17.7	19.4	16.4	4.9	0.6	85.2
1998–99	37.1	17.5	22.3	25.0	6.9	0.5	109.2
1999–00	33.7	17.4	25.5	27.1	7.3	0.5	111.4
Collection rate (number per 1,000 total population)							
1996–97	4.2	3.5	4.5	8.5	2.6	2.1	4.2
1997–98	4.2	3.8	5.7	9.0	3.3	1.2	4.6
1998–99	5.8	3.7	6.4	13.5	4.6	1.2	5.8
1999–00	5.2	3.7	7.2	14.5	4.9	1.0	5.8

(a) Includes collections of plasma, platelets and red cells or any combination of these. Where a donor has given blood more than once in a year, each collection episode is included.
(b) No apheresis collections were made in the Northern Territory or the Australian Capital Territory during the period covered.
Note: Rates were calculated using estimated resident population figures for December in each of the years 1996 to 1999 (ABS 1999).
Sources: ARCBS, ABS.

Table 5 Autologous collections and directed donations, States and Territories, 1996-97 to 1999-00

	NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Aust
Number of collections ('000)									
1996–97									
ARCBS[(a)]	9.8	2.5	2.0	2.9	–	0.4	0.3	0.1	18.1
MBS[(b)]	8.8	4.5	4.2	0.4	6.1	0.7	–	–	24.8
Total	**18.7**	**7.0**	**6.2**	**3.3**	**6.1**	**1.0**	**0.4**	**0.1**	**42.9**
1997–98									
ARCBS[(a)]	8.0	2.2	1.8	2.3	0.1	0.4	0.3	0.1	15.0
MBS(b)	8.1	4.4	4.0	0.9	5.8	0.6	0.1	–	23.9
Total	**16.1**	**6.6**	**5.8**	**3.2**	**5.9**	**0.9**	**0.4**	**0.1**	**39.0**
1998–99									
ARCBS[(a)]	6.6	2.1	1.4	2.3	0.1	0.2	0.3	0.1	13.1
MBS(b)	7.3	4.5	4.4	1.4	5.9	0.4	0.1	–	24.1
Total	**13.9**	**6.5**	**5.9**	**3.7**	**6.0**	**0.7**	**0.4**	**0.1**	**37.1**
1999–00									
ARCBS[(a)]	5.5	2.1	1.1	2.2	0.1	0.4	0.3	0.1	11.8
MBS[(b)]	6.6	5.4	4.4	1.6	5.8	0.4	–	–	24.2
Total	**12.1**	**7.5**	**5.5**	**3.8**	**5.9**	**0.8**	**0.3**	**0.1**	**36.0**

(a) Numbers of autologous collections and directed donations provided by the ARCBS.
(b) Number of autologous collection services provided under the Medicare Benefits Scheme (MBS). The Medicare item numbers do not identify separately autologous collections from other services such as therapeutic collections. Therefore it is an overestimate.
Sources: ARCBS, Commonwealth Department of Health and Aged Care.

C Plasma (normal and hyperimmune) sent to CSL for fractionation

Table 6 Plasma sent to CSL, Australia, 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
kg ('000)				
Normal plasma for fractionation	194.7	201.8	215.9	221.3
Hyperimmune plasma				
Rh D immunoglobulin	1.9	1.7	1.6	1.5
Other (hepatitis B, CMV, Tetanus, Zoster)	8.2	10.7	13.3	15.9
Total hyperimmune	10.1	12.4	14.9	17.4
Total plasma to CSL	**204.8**	**214.2**	**230.9**	**238.7**

Source: ARCBS.

Table 7 Plasma sent to CSL for fractionation, States and Territories, 1996–97 to 1999–00

	NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Aust
Rh D immunoglobulin (kg per 100,000 population)									
1996–97	15	7	5	16	6	3	4	3	10
1997–98	13	7	6	13	5	3	5	–	9
1998–99	13	6	5	10	7	1	5	–	9
1999–00	11	7	2	17	6	1	4	2	8
Other (hepatitis B, cytomegalovirus, tetanus, zoster) (kg per 100,000 population)									
1996–97	54	42	41	32	62	–	20	–	45
1997–98	75	56	38	42	86	–	10	–	58
1998–99	95	67	55	40	99	–	6	–	71
1999–00	82	71	143	65	63	–	9	–	83
Total hyperimmune plasma (kg per 100,000 population)									
1996–97	69	49	46	48	68	3	24	3	55
1997–98	88	63	44	55	92	3	15	–	67
1998–99	108	73	60	50	107	1	11	–	79
1999–00	93	78	145	82	69	1	13	2	91
Plasma for fractionation (kg per 100,000 population)									
1996–97	870	1,093	1,099	1,274	1,232	1,278	1,313	1,248	1,057
1997–98	841	1,112	1,204	1,243	1,427	1,302	1,379	1,089	1,084
1998–99	979	1,078	1,232	1,375	1,448	1,463	1,422	1,000	1,145
1999–00	897	1,122	1,192	1,626	1,584	1,504	1,480	1,151	1,160
Total plasma to CSL rate (kg per 100,000 population)									
1996–97	939	1,142	1,145	1,322	1,300	1,281	1,337	1,251	1,111
1997–98	929	1,175	1,248	1,297	1,518	1,304	1,394	1,089	1,150
1998–99	1,087	1,151	1,291	1,425	1,555	1,464	1,433	1,000	1,225
1999–00	990	1,200	1,338	1,708	1,652	1,505	1,493	1,152	1,251

Source: ARCBS. ABS.

D Major fresh blood products

Table 8 Production and issue of red cell concentrates, Australia, 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
Production[(a)]	673,983	686,988	693,071	707,435
Issue[(b)]	635,366	657,481	655,497	700,220

(a) Some product is produced in a State or Territory and later issued in another State or Territory. Product transported across State / Territory boundaries is counted only once.

(b) Product issued does not necessarily equal product used (eg some product may have expired after issue).

Source: ARCBS.

Table 9 Production[a] and issue[b] of platelets, Australia, 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
Random platelets				
Production	335,968	334,963	331,965	331,135
Issue	273,436	281,769	280,384	215,359
Buffy coat platelet pools[c]				
Production		2,263	2,362	19,355
Issue		2,106	2,080	15,528
Apheresis platelets				
Production	3,878	4,062	7,703	10,386
Issue	3,536	3,688	7,119[d]	9,213

(a) Some product is produced in a State or Territory and later issued in another State or Territory. Product transported across State / Territory boundaries is counted only once.

(b) Product issued does not necessarily equal product used (eg some product may have expired after issue).

(c) Traditionally, random platelets have been prepared from single whole blood donations. A recent development has been the production of pooled buffy coat platelets prepared from the whole blood of about five donors. Table counts each single donation used in platelet production as one unit of platelets. Each pooled buffy coat platelet is counted as one unit issued. Production of pooled buffy coat platelets commenced in Tasmania in 1997–98 and in Victoria and South Australia in 1999–00.

(d) Figure includes about 200 buffy coat platelet pools from Victoria

Source: ARCBS.

E Major plasma products — locally sourced and made by CSL for the Australian market

Table 10 Albumin production[a] and issue,[b] Australia, 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
Production (kg)	4,197	4,510	4,843	5,067
Issue (kg)	3,569	3,828	3,752	3,754
Allocation to National Reserve (kg)	–	–	85	1,922

(a) Some product is produced in a State or Territory and later issued in another State or Territory. Product transported across State / Territory boundaries is counted only once.

(b) Product issued does not necessarily equal product used (eg some product may have expired after issue).

Sources: CSL, ARCBS.

Table 11 IVIg production[a] and issue,[b] Australia, 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
Production (kg)	602	668	664	946
Issue (kg)	638	623	674	731
Allocation to National Reserve (kg)	–	–	17	110

(a) Some product is produced in a State or Territory and later issued in another State or Territory. Product transported across State / Territory boundaries is counted only once.

(b) Product issued does not necessarily equal product used (eg some product may have expired after issue).

Sources: CSL, ARCBS.

Table 12 Coagulation factors production[a] and issue,[b] Australia, 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
Production (million IU)				
Factor VIII	34.7	38.6	42.6	47.1
Factor IX	11.0	11.7	12.5	15.7
Issue (million IU)				
Factor VIII	33.3	37.0	36.9	43.1
Factor IX	9.5	10.0	11.5	14.2
Allocation to National Reserve (million IU)				
Factor VIII	–	–	0.9	3.2

(a) Some product is produced in a State or Territory and later issued in another State or Territory. Product transported across State / Territory boundaries is counted only once.

(b) Product issued does not necessarily equal product used (eg some product may have expired after issue).

Sources: CSL, ARCBS.

Table 13 Rh D immunoglobulin (Anti D) production[a] and issue,[b] 1996–97 to 1999–00

	1996–97	1997–98	1998–99	1999–00
Production (million IU)	15.3	15.2	44.5	26.0
Issue (million IU)	15.3	25.9	34.5	34.8

(a) Some product is produced in a State or Territory and later issued in another State or Territory. Product transported across State / Territory boundaries is counted only once.

(b) Product issued does not necessarily equal product used (eg some product may have expired after issue).

Sources: CSL, ARCBS.

F Imported blood products and related products

Table 14 Imported blood products and related products, 1996–97 to 1999–00

Product (million IU)	1996–97	1997–98	1998–99	1999–00
Recombinant factor VIII[a]	5.84	8.32	10.70	13.66
Antithrombin concentrate[b]	0.02	–	0.03	–
Factor VII concentrate[b]	0.06	0.04	0.07	0.27
Recombinant factor VIIa[b]	0.63	1.68	1.15	5.90
Porcine factor VIII[b]	0.29	–	0.15	0.27
Factor IX[b]	0.57	1.07	0.68	–
Factor XI concentrate[b]	–	0.01	–	0.02
Factor XIII[b]	–	–	0.03	0.03
FEIBA[b]	0.04	0.18	–	0.01

(a) Covers product purchased by State and Territory health authorities with the Commonwealth reimbursing 50 per cent of the costs.

(b) Funded jointly by States / Territories and Commonwealth under a 50:50 cost-sharing arrangement.

Source: Commonwealth Department of Health and Aged Care.

G Expenditure on Australia's supply of blood and blood products

Table 15 Australian blood sector expenditure, by source of funds, 1990–91 to 1999–00 ($million)

	Government sector		Non-government [a]	Total
Year	Commonwealth	State / Territory		
1990–91	63.1	43.4	0.8	107.3
1991–92	67.1	46.3	0.9	114.3
1992–93	70.9	54.4	1.0	126.3
1993–94	111.0	68.3	1.0	180.3
1994–95	128.6	68.6	1.0	198.1
1995–96	143.7	73.6	1.0	218.3
1996–97	148.5	80.4	1.0	229.9
1997–98	172.5	85.7	1.0	259.3
1998–99	187.3	98.2	1.0	286.6
1999–00	224.1	107.7	1.0	332.7
Average annual growth rates (%)				
1990–91 to 1999–00	14.9	11.0	2.5	13.4
1995–96 to 1999–00	11.4	10.8	–	11.2

(a) Australian Red Cross Society contribution.

Source: Commonwealth Department of Health and Aged Care.

Table 16 Commonwealth funding to CSL, 1990–91 to 1999–00 ($million)

	Plasma	Diagnostic	
Year	fractionation[a]	Products[b]	Total
1990–91	33.7	na	33.7
1991–92	35.6	na	35.6
1992–93	32.8	3.2	36.0
1993–94	62.5	3.4	65.9
1994–95	72.7	5.1	77.8
1995–96	83.3	5.5	88.8
1996–97	84.3	5.2	89.5
1997–98	101.7	5.8	107.5
1998–99	109.5	5.7	115.2
1999–00	119.4	6.2	125.6

(a) Plasma Fractionation Agreement commenced 1 January 1994.

(b) Diagnostic Products Agreement commenced 1 January 1994.

na not available to the Review.

Source: Commonwealth Department of Health and Aged Care.

Table 17 Funding to the ARCBS, by source of funds, 1990–91 to 1999–00 ($million)

	Government sector[a]		Non-government[b]	
Year	Commonwealth	State / Territory		Total
1990–91	29.1	43.4	0.8	73.3
1991–92	30.8	46.3	0.9	78.1
1992–93	37.1	54.4	1.0	92.4
1993–94	47.2	68.3	1.0	116.5
1994–95	47.2	68.0	1.0	116.3
1995–96	47.0	69.9	1.0	117.9
1996–97	50.4	74.7	1.0	126.1
1997–98	55.4	80.3	1.0	136.7
1998–99	62.4	89.9	1.0	153.3
1999–00	67.2	98.0	1.0	166.2

(a) Includes funding for both capital and operating costs.

(b) Australian Red Cross Society contribution.

Source: Commonwealth Department of Health and Aged Care.

Table 18 Expenditure on imported blood-related and alternative products, 1994–95 to 1999–00 ($million)

	Imported blood-related and alternative products[a]			Recombinant factor VIII[b]		
Year	Commonwealth	State / Territory	Total	Commonwealth	State / Territory	Total
1994–95	1.6	0.5	2.1	–	–	–
1995–96	3.3	1.5	4.8	2.2	2.2	4.5
1996–97	2.6	2.2	4.8	3.5	3.5	6.9
1997–98	2.7	0.9	3.7	4.5	4.5	9.0
1998–99	1.5	2.5	4.0	5.9	5.9	11.7
1999–00	4.2	2.7	6.9	7.0	7.0	13.9

(a) There is an agreement between the Commonwealth and States and Territories to cost share (50:50) the purchase of approved blood-related and alternative products.

(b) There is an agreement between the Commonwealth and States and Territories to cost share (50:50) funding for the annual purchase of recombinant factor VIII.

Source: Commonwealth Department of Health and Aged Care.

Table 19 Australian blood supply expenditure, by area of expenditure, 1990–91 to 1999–00 ($million)

Area of expenditure	1994–95	1995–96	1996–97	1997–98	1998–99	1999–00
ARCBS	116.3	117.9	126.1	136.7	153.3	166.2
CSL	77.8	88.8	89.5	107.5	115.2	125.6
National Reserve	–	–	–	–	–	17.7
Imported products (a)	2.1	9.3	11.7	12.7	15.7	20.8
Other (b)	2.0	2.3	2.5	2.4	2.4	2.4
Total outlays	198.1	218.3	229.8	259.3	286.6	332.7
			Percentage of annual outlays			
ARCBS	58.7	54.0	54.9	52.7	53.5	50.0
CSL	39.3	40.7	38.9	41.5	40.2	37.8
National Reserve	–	–	–	–	–	5.3
Imported products	1.1	4.3	5.1	4.9	5.5	6.2
Other	1.0	1.1	1.1	0.9	0.8	0.7
Total	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**	**100.00**

(a) Includes funding for recombinant factor VIII from 1995–96.

(b) Includes funding for autologous collections.

Source: Commonwealth Department of Health and Aged Care.

Appendix K
Quality assurance in laboratory testing

This appendix provides details of quality assurance arrangements in laboratory testing. It complements the discussion in Chapter 5 about the need for 'mandatory compliance with a national quality assurance program' and the potential 'role of an expert reference laboratory in setting and maintaining' such a program. The purpose of internal and external quality assurance activity in laboratory testing is to ensure safety and quality and to promote public confidence.

A range of quality assurance programs is needed to cover both production and use of blood and blood products and to assist decisions. Requirements for production are specified in TGA standards and codes of good manufacturing practice. Current arrangements for assuring quality in laboratory testing in the blood sector are described below, including the role of expert reference laboratories (such as the NRL).

Principles of quality assurance in laboratory testing

Ideally, a test should be reliable and reproducible, with no interpretive errors, rapid and inexpensive. This ideal is rarely met in practice. Performance and predictive value of tests depend on technical characteristics of the test, environmental factors (including facilities, equipment and materials used) and the skills and experience of personnel conducting and interpreting the test. In viral testing of donated blood, an initial reactive test must be followed up with supplementary or confirmatory tests to confirm its status.

In medical laboratory testing, quality assurance involves all measures taken to ensure the reliability of investigations, from test selection and performance, through appropriate interpretation, documentation and reporting.

Quality assurance is important for maintaining professional standards of service and improving patient outcomes, as well as maintaining public confidence. It can also play a role in containing costs by reducing error and product wastage.

The term *external quality assurance* is used to describe external proficiency testing programs. These involve periodic assessments of laboratories' performance in carrying out specified tests and procedures. They are well-established in laboratory medicine generally, for benchmarking and as a means of facilitating greater accuracy and consistency in testing and reporting. Their underlying philosophy is generally one of continuous improvement.

External quality assurance programs complement the day-to-day internal quality control procedures of individual laboratories. They provide an independent, arm's length safety and quality check.

Quality assurance in blood testing

Proficiency testing programs in production primarily cover the two key areas of viral testing and blood grouping serology (eg for red cell ABO- and Rh D surface antigens). Both are important for safety and quality.

Viral testing

Guidelines such as those of the Council of Europe (2000) provide detailed descriptions of quality assurance programs for viral testing. These state that 'only validated tests that have been licensed or authorised by the responsible health authority may be used.

Special emphasis must be placed on staff training and competencies, equipment calibration and maintenance, storage of test materials and documentation. National protocols should be developed to enable uniform resolution of problems associated with discordant or unconfirmed results, and data on results of screening for infectious markers and other epidemiological data should be collected as part of haemovigilance'.

Council of Europe recommendations divide the necessary measures into four categories:

- internal day-to-day quality control of reagents and techniques by individual laboratories;
- occasional internal quality assurance exercises with a panel of control sera (for which results are known);
- external quality checks for new tests and reagents with confirmation of positive and negative results by an appropriate microbiological reference laboratory; and
- external proficiency exercises including testing of a panel of sera circulated by an appropriate reference institution.

Blood grouping serology

The Council of Europe recommendations for quality assurance programs are similar in nature to, but less detailed than, those for viral testing.

Specific Australian requirements

There is a range of quality assurance activities and arrangements currently in place. These are summarised below.

Codes of good manufacturing practice

The ARCBS is subject to the *Australian Code of Good Manufacturing Practice: Human Blood and Tissues* (TGA 2000). CSL is subject to both the cGMP for human blood and tissues (TGA 2000) and the cGMP for medicinal products (TGA 1999). Requirements for quality systems, personnel, facilities, documentation, control of materiel, donor selection and testing, process control and storage of product are specified in the relevant codes. The cGMP for human blood and tissues (TGA 2000) requires licensed facilities to monitor test kit performance and to undertake 'periodic quality assessment' for comparison of performance.

National Managed Fund arrangements affecting the ARCBS

The memorandum of understanding relating to the National Managed Fund requires the ARCBS to identify areas of potential risk exposure to the independent funds manager and to operate its activities (which would include screening tests / quality assurance processes) in a nationally uniform and consistent manner. There are also explicit requirements to report on quality assurance arrangements.

Provision of test kit monitoring data to NRL

Conditions of registration for viral test kits for hepatitis C and HIV set restrictions on the distribution of different kits to a series of accredited laboratories and mandate the provision of test results to the NRL.

Council of Europe viral testing framework

Testing laboratories in the blood sector can be divided broadly into three tiers on the basis of the testing they perform and the elements of quality assurance they perform within the viral testing framework, as follows.

1. ARCBS, CSL and some hospital laboratories (screening and confirmatory testing):

- performance of viral and serology tests together with daily internal quality control;
- periodic internal quality control exercises;
- participation in external quality assessment (proficiency testing) programs; and
- reporting of incidence of viral markers in blood donors to NRL.

The ARCBS has indicated to the Review that it uses a mix of arrangements for supplementary testing to confirm an initially reactive donor sample. For example, six of the eight States and Territories use NRL for confirmatory testing for HTLV-1 / 2, while supplementary testing for hepatitis C is currently done in-house by most ARCBS laboratories.

2. State reference laboratories (confirmatory testing):

- supplementary / confirmatory viral tests for the ARCBS and pathology laboratories; and
- specialist advice (eg Victorian Infectious Diseases Reference Laboratory).

3. National Serology Reference Laboratory:

- evaluation of new hepatitis C and HIV test kits and reagents under contract to the TGA;
- some confirmatory testing as part of national algorithms for problem resolution; and
- provision of external proficiency exercises for hepatitis C and HIV testing and collation of results.

The function of NRL relates predominantly to testing for hepatitis C and HIV and is funded under national population health programs. At present, other kits used in testing blood donations undergo no pre-market evaluation and only limited national monitoring. In 2000, Europe moved to strengthen regulation of in vitro diagnostic tests to include all tests used in testing blood donations. Given Australia's mutual recognition agreement arrangements with Europe, the inclusion of other test kits in the most stringent risk assessment category is now being considered by the TGA.

In addition to NRL, several ARCBS and other State-based laboratories maintain reference materials and perform external quality assurance and test validation activities.

NPAAC and NATA arrangements

Pathology laboratories (collecting autologous blood) and hospital blood banks are not regulated by the TGA but may seek accreditation under the NATA / RCPA arrangements against NPAAC standards. Some ARCBS laboratories participate voluntarily in this accreditation program. The number has fallen since the implementation of TGA regulatory processes, mainly to reduce duplication of effort.

Private and public pathology laboratories must be accredited by the NATA / RCPA system to be eligible for Medicare benefits. One accreditation requirement is that laboratories must participate satisfactorily in an appropriate external quality assurance program.

Other — blood group serology

The RCPA and the Australian Institute of Medical Scientists have both developed external quality assurance programs in blood group serology. NATA also recognises a number of other such programs.

In line with European practice, quality assurance programs for blood group serology are not afforded the same degree of national support as hepatitis C and HIV testing in Australia. For instance, there is no nationally recognised and supported blood-grouping reference laboratory. Many of the serious and fatal adverse events in blood transfusion relate to transfusion of the incorrect blood component. While most result from clerical and bedside errors, rather than laboratory problems, there are still opportunities for improvement through quality assurance programs (Linden 1999; SHOT Steering Group 2000).

Acronyms and abbreviations

ABS	Australian Bureau of Statistics
ACHS	Australian Council for Healthcare Standards
ACSQHC	Australian Council for Safety and Quality in Health Care
ADEC	Australian Drug Evaluation Committee
ADRAC	Adverse Drug Reactions Advisory Committee
AHMAC	Australian Health Ministers'Advisory Council
AIDS	Acquired Immunodeficiency Syndrome
ANAO	Australian National Audit Office
ANCAHRD	Australian National Council on AIDS, Hepatitis C and Related Diseases
AQIS	Australian Quarantine and Inspection Service
ARCBS	Australian Red Cross Blood Service
ARTG	Australian Register of Therapeutic Goods
ASBT	Australasian Society of Blood Transfusion Inc.
BSE	bovine spongiform encephalopathy
CDNANZ	Communicable Diseases Network of Australia and New Zealand
cGMP	code of good manufacturing practice
CJD	Creutzfeldt Jakob Disease
CPMP	Committee for Proprietary Medicinal Products (EU)
CSL	CSL Limited
DHFS	Commonwealth Department of Health and Family Services
DRG	Diagnostic Related Group
ECEMA	European Centre for Epidemiological Monitoring of AIDS
EFS	Establissement Francais du Sang (France)
EMEA	Evaluation Agency of the European Union
EU	European Union
FDA	Food and Drug Administration (US)
FEIBA	factor eight (VIII) inhibitor bypass agent
Health	Commonwealth Department of Health and Aged Care
HFA	Haemophilia Foundation Australia
HIV	human immunodeficiency virus
HSANZ	Haematology Society of Australia and New Zealand
HTLV	human T-lymphotropic virus
ICCBBA	International Council for Commonality in Blood Banking Automation
IGCARD	Intergovernmental Committee on AIDS and Related Diseases
IMIg	intramuscular immunoglobulin

ISBT	International Society for Blood Transfusion
ISO	International Standards Organisation
ISPOT	International Study of Perioperative Transfusion
IU	international unit
IVIg	intravenous immunoglobulin
JCAHO	Joint Commission on Accreditation of Healthcare Organizations (United States)
MBS	Medicare Benefits Scheme
MSAC	Medicare Services Advisory Committee
NATA	National Association of Testing Authorities
NCCTG	National Coordinating Committee on Therapeutic Goods
NCDSS	National Communicable Diseases Surveillance Strategy
NHMRC	National Health and Medical Research Council
NICS	National Institute of Clinical Studies
NNDSS	National Notifiable Disease Surveillance System
NPAAC	National Pathology Accreditation Advisory Council
NPHP	National Public Health Partnership
NRL	National Serology Reference Laboratory
PAD	pre-operative autologous donation
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PIIP	Pharmaceutical Industry Investment Program
RCPA	Royal College of Pathologists of Australasia
RNA	ribonucleic acid
SAA	Standards Association of Australia
SANGUIS	Safe and Good Use of Blood in Surgery
SHOT	Serious Hazards of Transfusion (UK)
SRK	Schweizerische Rotkreuzstiftung (Swiss Red Cross)
TDEC	Therapeutic Device Evaluation Committee
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee
TSE	transmissible spongiform encephalopathy
WHA	World Health Assembly
ZLB	Zentrallaboratorium Blutspendedienst

Glossary of terms

Acute normovolaemic haemodilution	The process by which a patient is deliberately bled for the purpose of collecting autologous red cells for subsequent transfusion, for the preparation of autologous blood products (eg platelets, plasma) or to obtain specific benefits from the effect of reducing the viscosity of blood.
Albumin	The major protein in plasma that is important in maintaining blood volume.
Allogeneic blood transfusion	The term allogeneic blood transfusion has exactly the same meaning as homologous blood transfusion.
Anti-(Rh) D antibody	Antibody against the Rhesus D-antigen.
Antibody	A protein usually produced by the immune system (an immunoglobulin) and found in the blood in response to the presence of antigens.
Antigen	A substance that causes the formation of an antibody.
Apheresis	A procedure in which blood is temporarily withdrawn, one or more components are selectively removed, and the remainder of the blood is reinfused into the donor.
Autologous collection	Blood donation for the donor's own use.
Blood group	Complex chemical substances found on or in the surface of red cells which distinguish each blood group. The two more important blood group systems in transfusion work are the ABO (blood types A, B O and AB) and Rh D (positive or negative) systems.
Bovine spongiform encephalopathy	An infection of the nervous system in cows. Also known as 'mad cow disease'.
Cell salvage	A procedure where a person's own red cells lost at the time of surgery are retrieved, machine washed and used for reinfusion for the conservation of autologous red cells.
Code of good manufacturing practice	A set of standards that provide assurance that a manufacturer has a quality system in place that meets the requirements for the product being made.
Creutzfeldt-Jakob Disease	A central nervous system disease that causes presenile dementia, myoclonus, and distinctive electroencephalographic changes caused by a prion.
Cross-match	A term used when testing the patient's serum against the donor's red cells.
Cryoprecipitate	A clotting factor preparation derived from plasma. It includes factor VIII and is used in the treatment of massive bleeding and occasionally for the treatment of haemophilia A.
Cytomegalovirus	A common virus which causes an illness similar to glandular fever.

Directed donation	Donations of blood from relatives or friends of a recipient that are specifically requested to be given to that recipient.
Donor	A person who gives blood, tissues or an organ to be used in another person.
Encephalopathy	A non-specific disease of the brain.
Erythropoietin	A hormone which regulates red cell production by the bone marrow. A genetically engineered version is available for therapeutic use.
Factor IX	Used to treat haemophilia B (also known as Christmas Disease).
Factor VIII	Used to treat certain types of haemophilia.
Fibrinogen	A protein in blood plasma that is involved in the clotting mechanism.
Fractionation	The separation of a substance into its basic constituents.
Haemolysis	The breakdown of red cells with the release of haemoglobin. Normally occurs at the end of the life span of a red cell. Haemolysis may occur in antigen / antibody reactions.
Haemolytic disease of the newborn	A disease that can arise when there is incompatibility between the red cells of a foetus and those of the mother.
Haemophilia	An hereditary deficiency of clotting factors in blood.
Haemovigilance	Monitoring of untoward transfusion events and outcomes in hospitals.
Hepatitis B	Viral disease of the liver caused by the Hepatitis B virus.
Hepatitis C	Viral disease of the liver caused by the Hepatitis C virus. Now the most commonly reported notifiable disease in Australia.
Homologous blood	Blood donation given for transfusion for an unknown recipient.
Human T-cell lymphotropic virus type 1	A virus associated with adult T-cell leukemia
Hyperimmune globulins	Immunoglobulin products prepared from the plasma of donors with high concentrations of specific antibodies.
Immunoglobulins	Proteins that combat infection.
Intramuscular immunoglobulin	An immunoglobulin preparation designed for intra-muscular rather than intravenous use.
Intravenous immunoglobulin	An immunoglobulin designed for intravenous use.
Leucodepletion	Removal of white cells from blood.
Meta-analysis	Statistical methods used to combine the results of different studies.

Nucleic acid amplification testing	Highly sensitive methods for detecting and identifying minute amounts of genetic material.
Pathogen	Disease-causing agent.
Plasma	Liquid portion of blood that contains proteins.
Plasmapheresis	Automated procedure for removing whole blood from the donor, separating out the plasma and returning remaining components to the donor.
Platelets	One of the cellular components of blood that contribute to blood clotting.
Recombinant product	Recombinant products are produced by inserting a human gene into an organism (eg bacterium) that then produces the required human protein (eg factor VIII).
Transmissible spongiform encephalopathy	A group of transmissible infections of the nervous system caused by a prion, including CJD.
Variant CJD	A form of Creutzfeldt-Jakob Disease, thought to be caused by eating beef infected with Bovine Spongiform Encephalopathy (BSE) or mad cow disease.

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