NATIONAL BLOOD AUTHORITY
AUSTRALIA

Secure national supply - the Australian experience

IPFA 3rd Asia Workshop on Plasma Quality and Supply
21-22 March 2018

Michael Stone
Deputy General Manager and General Counsel

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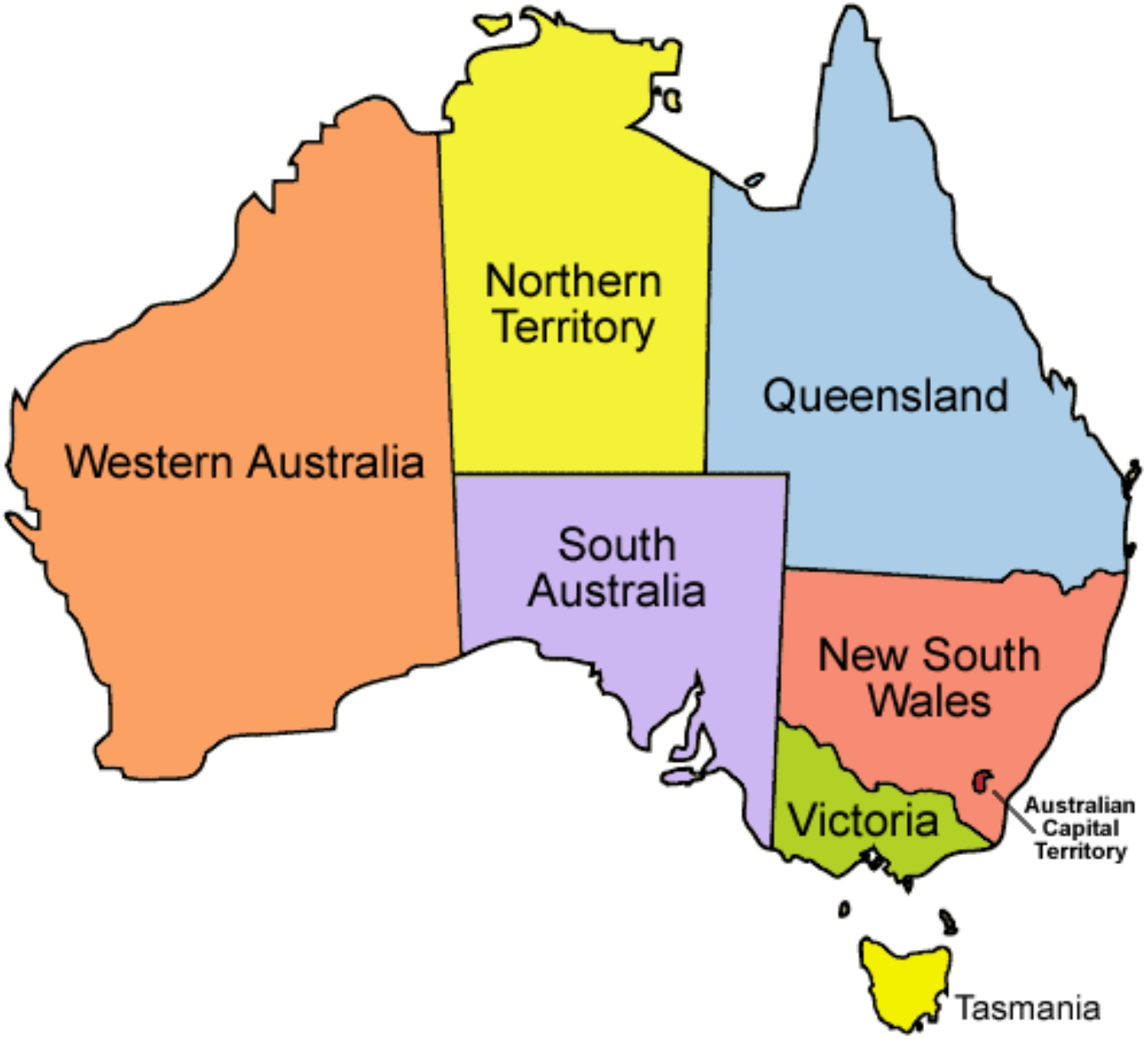
Today's talk

'Saving and improving Australian lives through a world-class blood supply'

Overview of Australian arrangements for blood and plasma products since 2003

Proposition:

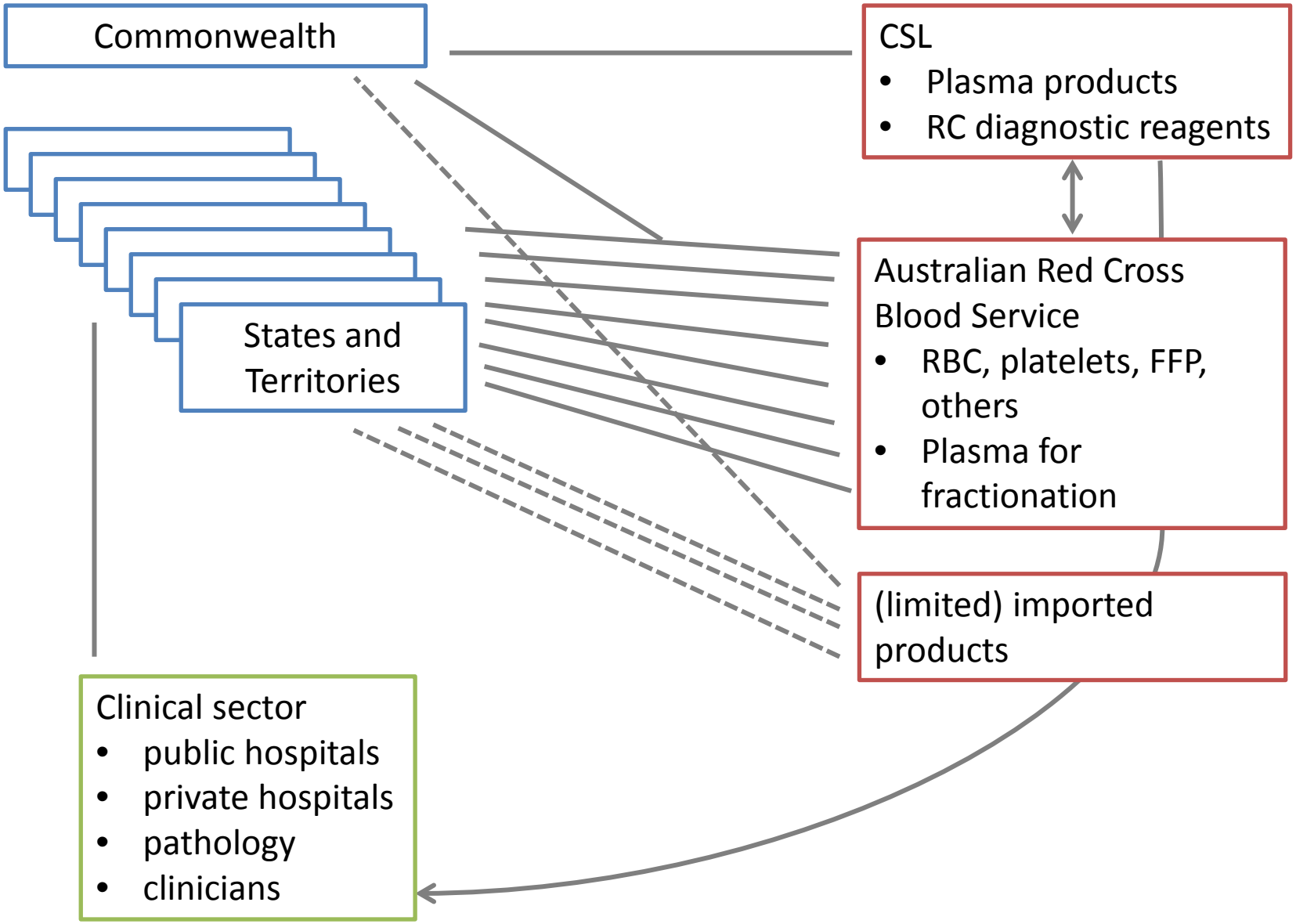
- Important to consider governance, coordination and institutional arrangements as part of 'strategic independence', alongside collection, manufacturing, supply and quality
- Australian arrangements have developed in the specific national context, but may give useful possibilities for other countries to consider


Northern Territory
Queensland
Western Australia
South Australia
New South Wales
Victoria
Australian Capital Territory
Tasmania



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.


Commonwealth
States and Territories
CSL
• Plasma products
• RC diagnostic reagents
Australian Red Cross Blood Service
• RBC, platelets, FFP, others
• Plasma for fractionation
(limited) imported products
Clinical sector
• public hospitals
• private hospitals
• pathology
• clinicians

National Blood Agreement (2003) - objectives

THE PARTIES AGREE AS FOLLOWS -

PART 1 – OBJECTIVES OF GOVERNMENTS FOR THE AUSTRALIAN BLOOD SECTOR

1. The primary policy objectives for the Australian blood sector are:
   (a) to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia; and
   (b) to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

2. In pursuing the primary policy objectives, the Parties will have regard to the following secondary policy aims:

(a) to meet international obligations and standards;

(b) to maintain reliance on voluntary, non-remunerated donations of whole blood and plasma;

(c) to promote national self-sufficiency;

(d) to provide products to patients free of charge and based on clinical need and appropriate clinical practice;

(e) to promote optimal safety and quality in the supply, management and use of products, including through uniform national standards;

(f) to make best use of available resources, and to give financial and performance accountability for the use of resources by all entities involved in the Australian blood sector;

(g) to undertake national information gathering, monitoring of new developments, reporting and research in relation to the Australian blood sector;

(h) to maintain flexibility and capacity to respond in a timely manner to changing circumstances and needs;

(i) to ensure public support and confidence in the Australian blood sector; and

(j) to work towards optimal access to blood products and blood related products across the nation, ensuring that patients continue to access the blood products and blood related products their clinicians determine will best meet their needs so far as practicable in accordance with national best practice based on clinical guidelines. This clause does not preclude States and Territories from altering the range of blood products and blood related products that are prescribed and received in their jurisdiction.

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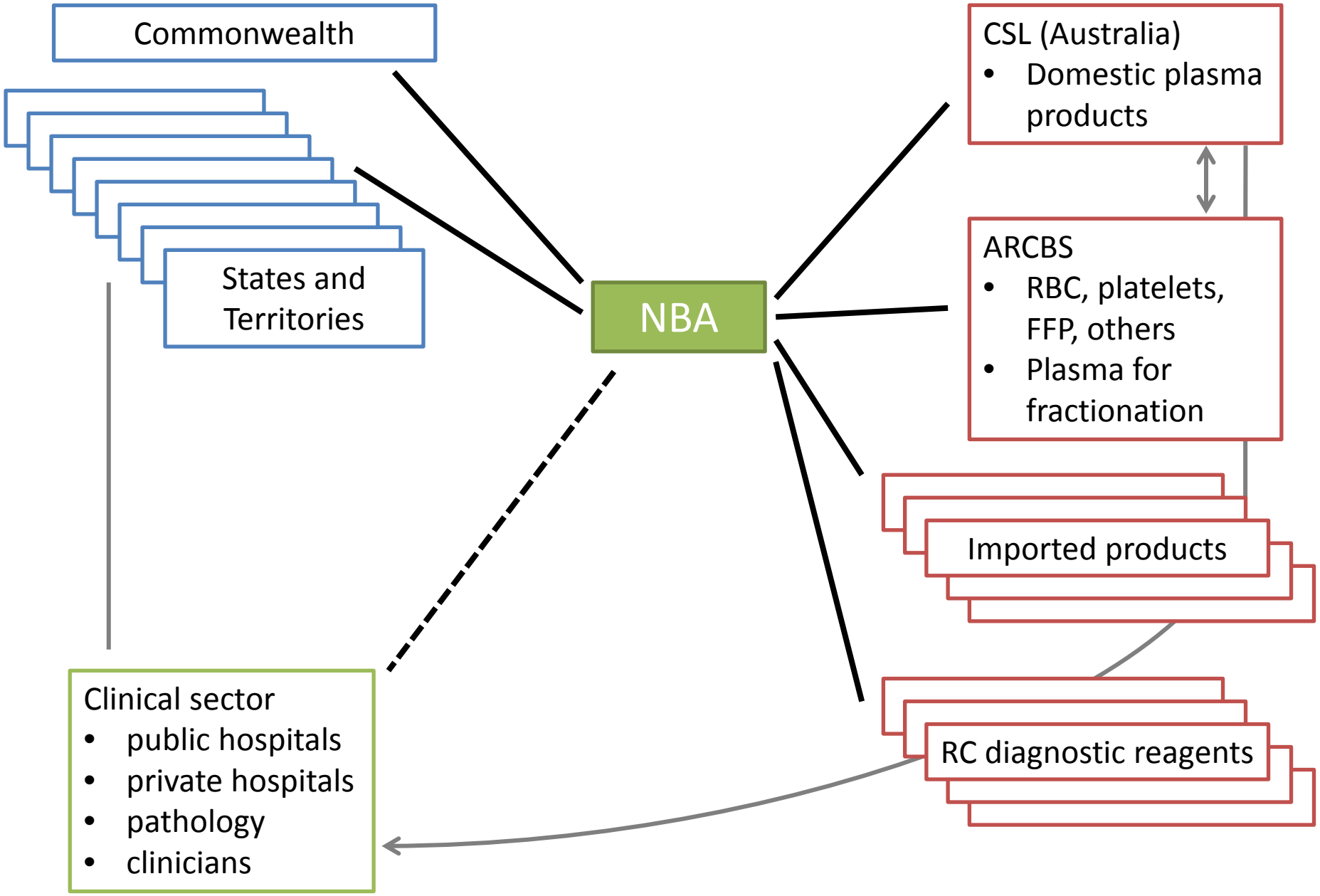
NBA roles

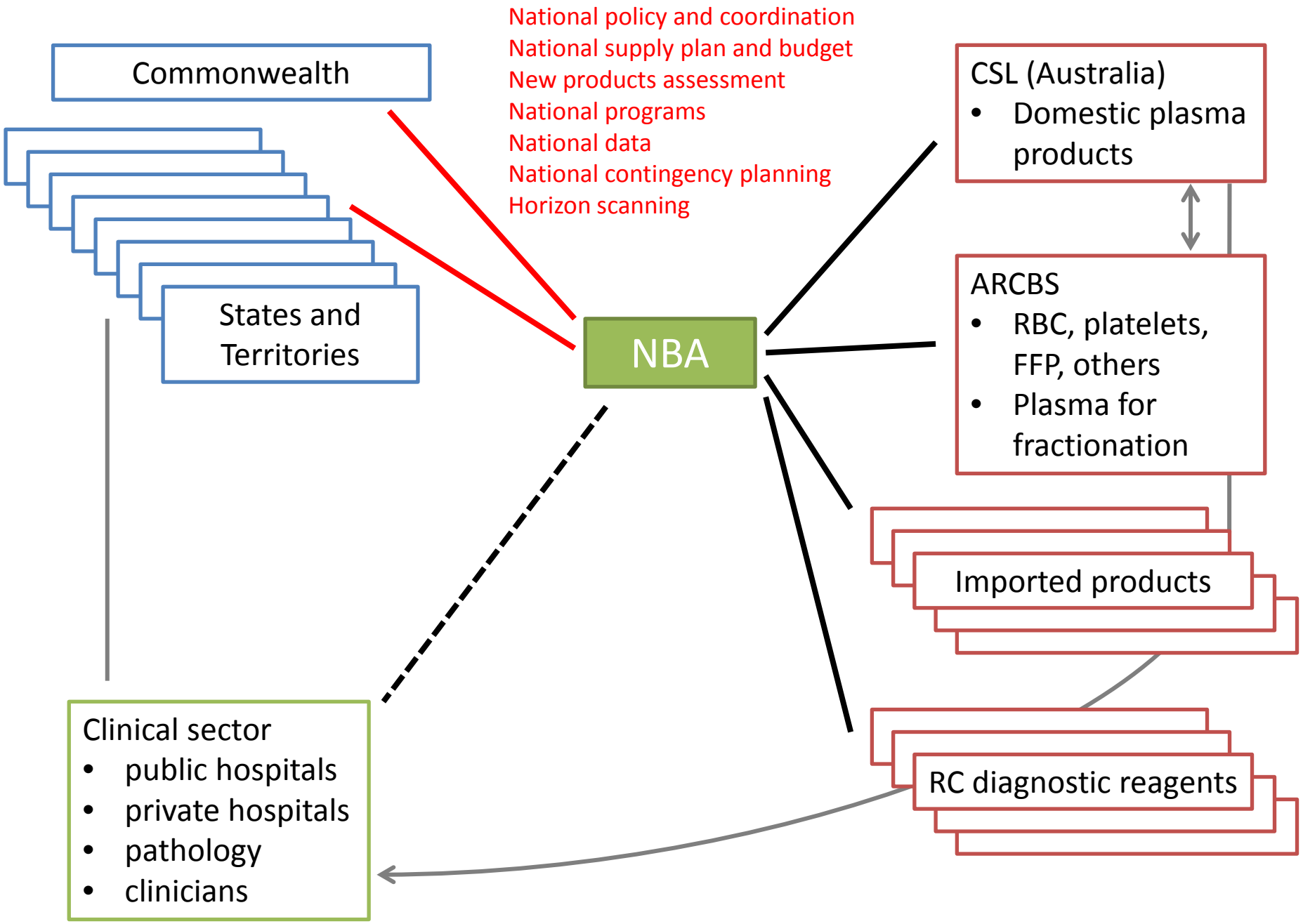
Commonwealth, State, Territory governments

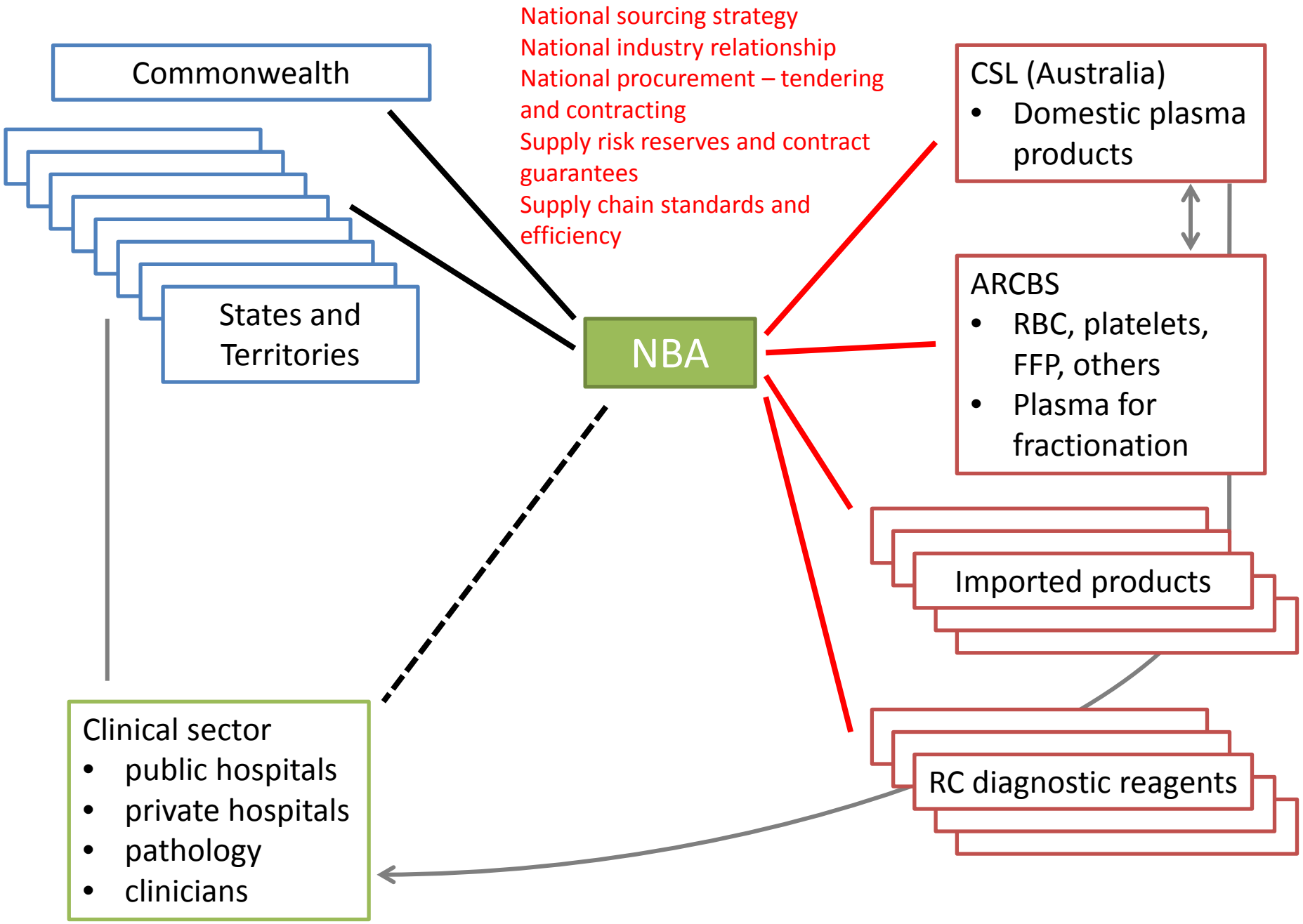
- Policy
- Funding (63:37)
- Health systems

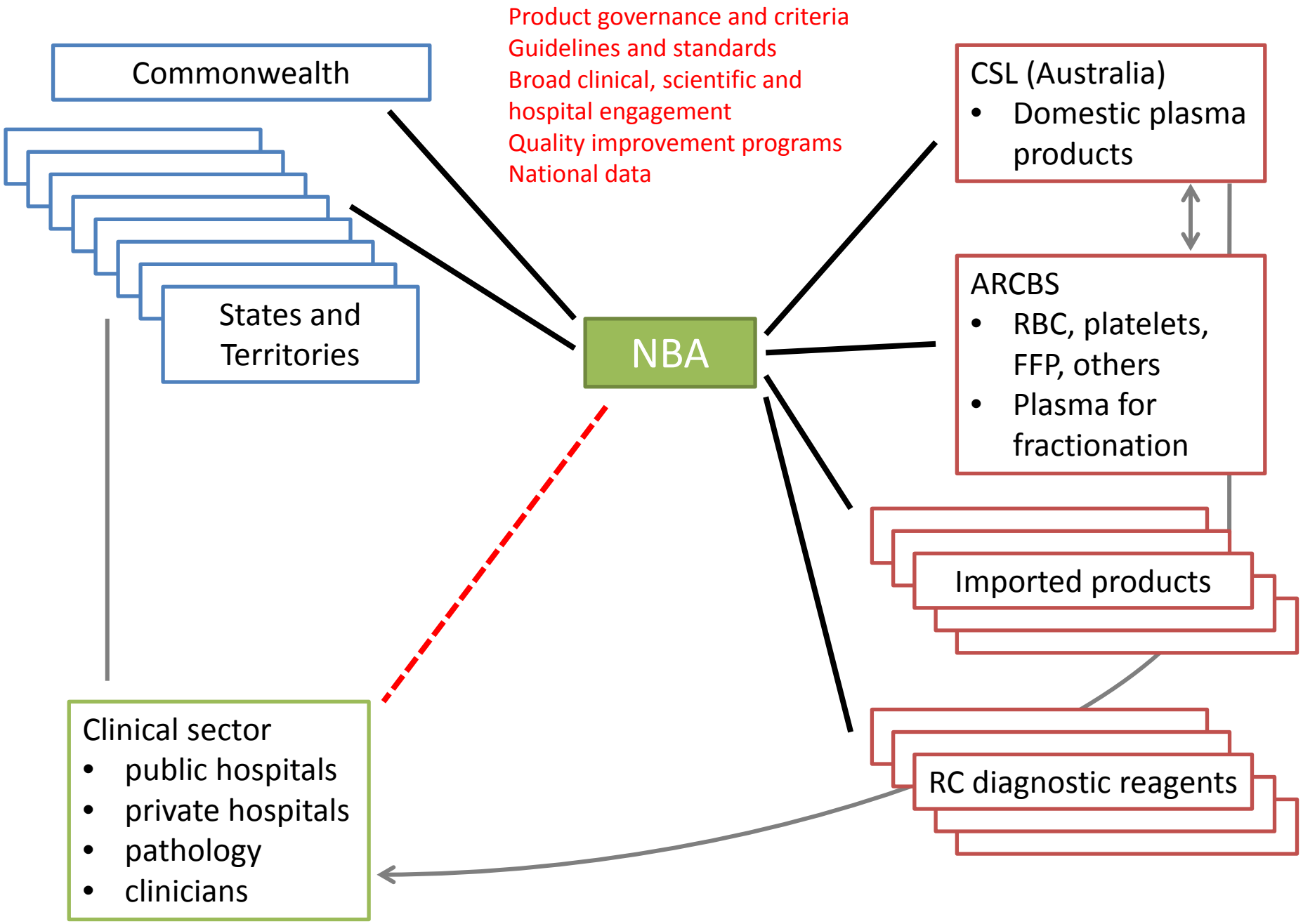
National Blood Authority

- National demand forecasting and supply planning
- National tendering and contracting for product supply
- Governance, appropriate use and management of products
- Blood sector systems, supply chain efficiency
- Evaluation process for new or changed products
- Reporting and analysis


Commonwealth
States and Territories
NBA
CSL (Australia)
• Domestic plasma products
ARCBS
• RBC, platelets, FFP, others
• Plasma for fractionation
Imported products
RC diagnostic reagents
Clinical sector
• public hospitals
• private hospitals
• pathology
• clinicians


National policy and coordination
National supply plan and budget
New products assessment
National programs
National data
National contingency planning
Horizon scanning
Commonwealth
States and Territories
NBA
CSL (Australia)
• Domestic plasma products
ARCBS
• RBC, platelets, FFP, others
• Plasma for fractionation
Imported products
RC diagnostic reagents
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• public hospitals
• private hospitals
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• clinicians


National sourcing strategy
National industry relationship
National procurement – tendering and contracting
Supply risk reserves and contract guarantees
Supply chain standards and efficiency
Commonwealth
States and Territories
NBA
CSL (Australia)
• Domestic plasma products
ARCBS
• RBC, platelets, FFP, others
• Plasma for fractionation
Imported products
RC diagnostic reagents
Clinical sector
• public hospitals
• private hospitals
• pathology
• clinicians


Product governance and criteria
Guidelines and standards
Broad clinical, scientific and hospital engagement
Quality improvement programs
National data
Commonwealth
States and Territories
NBA
CSL (Australia)
• Domestic plasma products
ARCBS
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Domestic and imported products

Domestic

- IVIg
- Albumin
- pd FVIII and FIX
- PCC
- Thrombotrol
- Rh(D) Ig
- Hyperimmunes

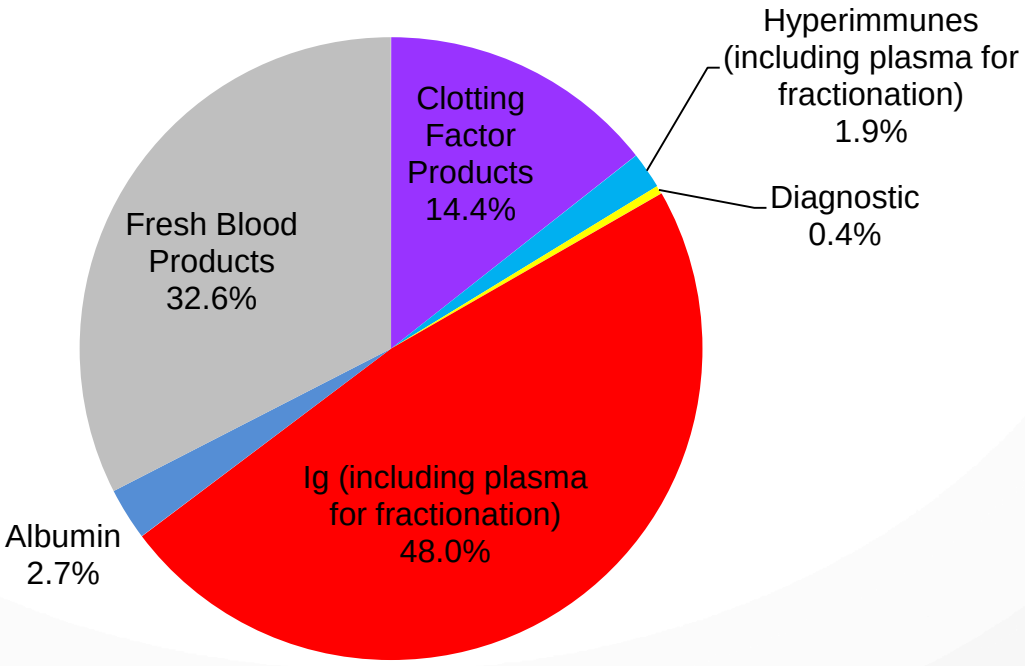
Imported

- rFVIII and rFIX
- FEIBA, rFVIIa
- Rh(D) Ig (IV)
- FXI and XIII
- Protein C

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2016-17 expenditure

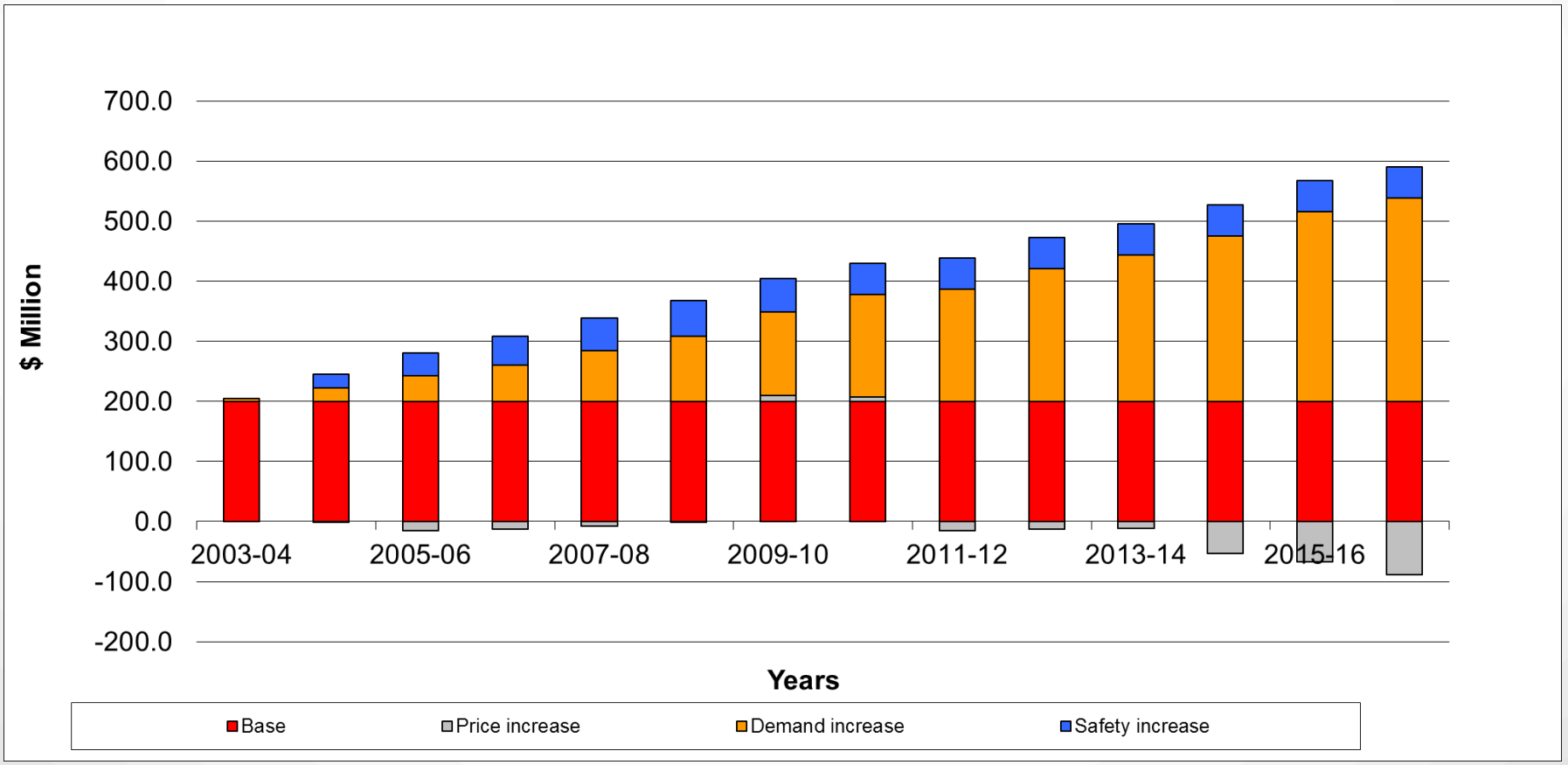
- Governments spent around $1.15 billion in 2016-17 for the supply and management of blood and blood products and services



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Long term savings

PLASMA DERIVED AND OVERSEAS PRODUCT EXPENDITURE: CUMULATIVE INCREASES ON 2003-04 BASE YEAR



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New products - HTA

Completed

- rFVIII and rFIX (2004)
- Domestic product enhancements
- SCIg – domestic and imported
- Fibrinogen concentrate (congenital deficiency)
- C1-INH
- rFXIII

Underway

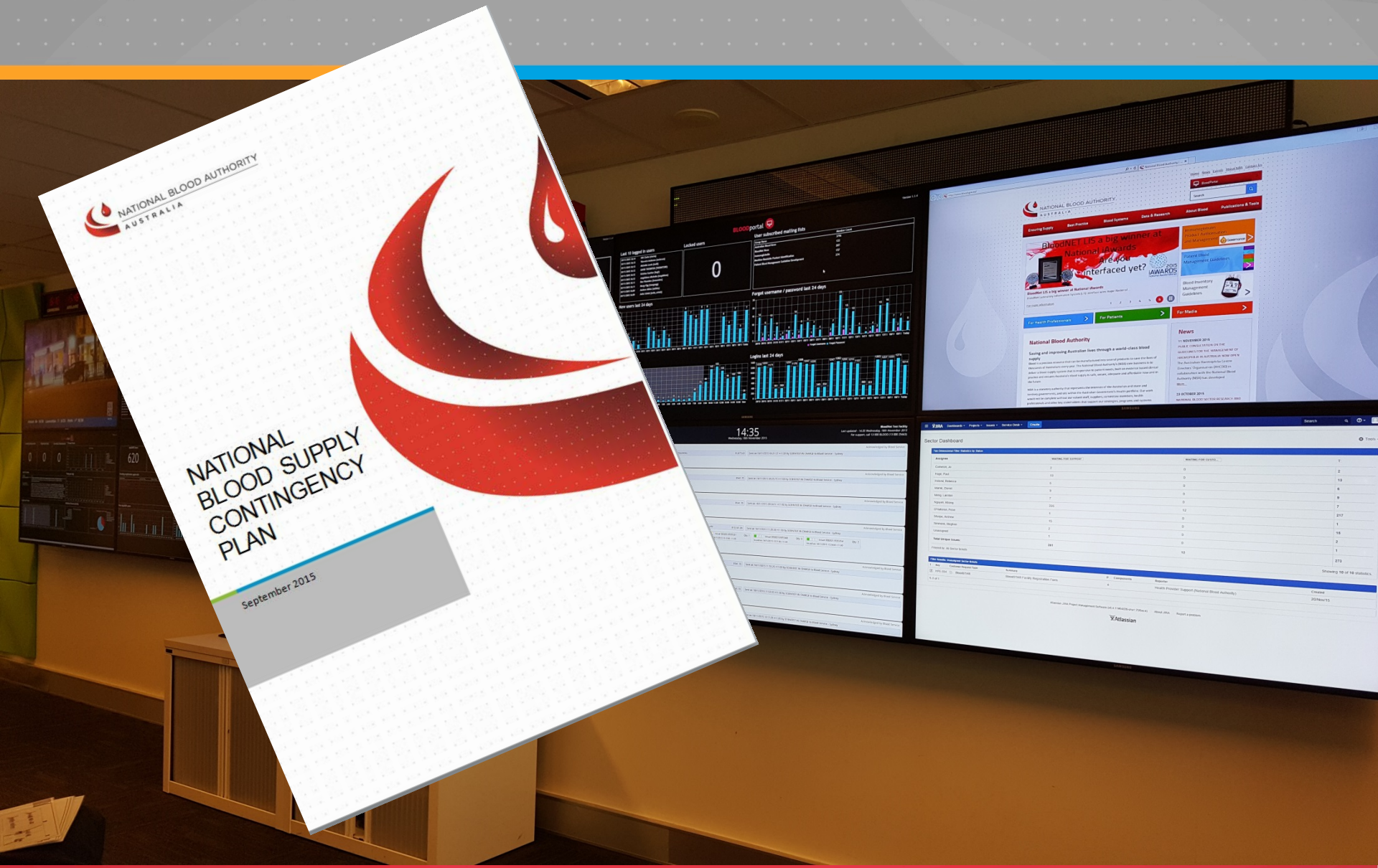
- EHL clotting factors
- Emicizumab
- A1-PI

Still to come?

- SCIg part II
- Fibrinogen concentrate for massive bleeding
- Ig indications
- CSL 112?
- Further haemophilia monoclonals?
- Genetic therapy?

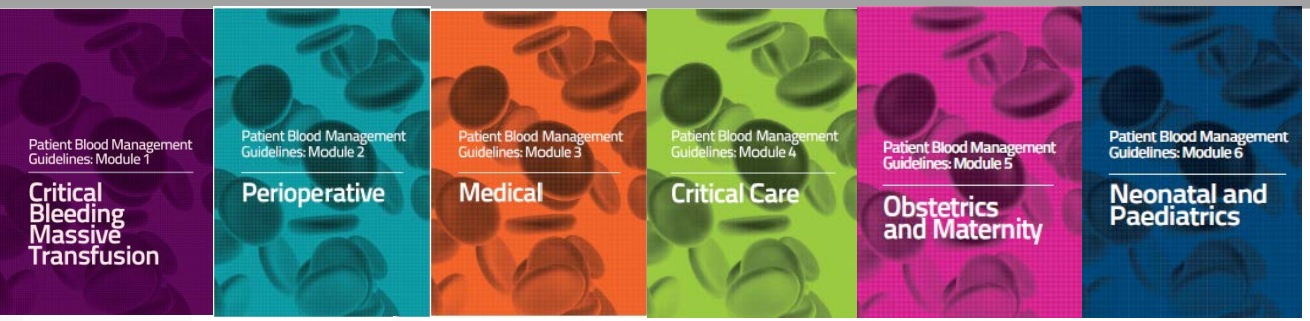
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Supply risk management



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Patient Blood Management

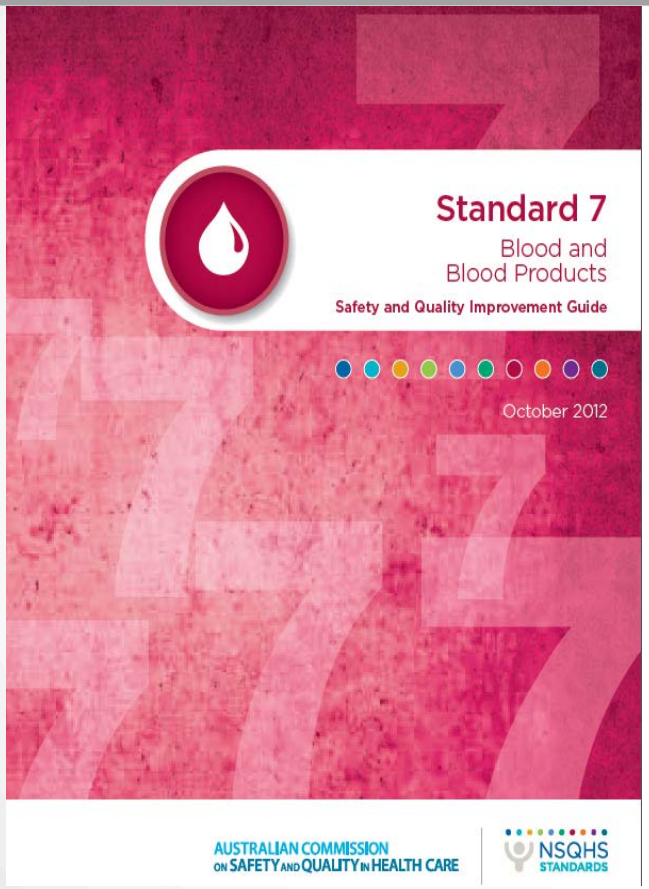




- Guidelines
- Tools and resources
- Conferences
- Education and Training
- Promotion and Communication

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Healthcare Quality Standard



National Patient Blood Management Collaborative



Standard 7
Blood Management

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Publications

SUPPLEMENT ARTICLE

Patient blood management: the global view

Aryeh Shander,[1,2] James Isbister,[3] and Hans Gombotz[4]

TRANSFUSION 2016;56;S94–S102

Contents lists available at ScienceDirect
Transfusion Medicine Reviews
journal homepage: www.tmreviews.com

Patient Blood Management Bundles to Facilitate Implementation

Patrick Meybohm [a,*], Toby Richards [b], James Isbister [c], Axel Hofmann [d], Aryeh Shander [e], Lawrence Tim Goodnough [f], Manuel Muñoz [g], Hans Gombotz [h], Christian Friedrich Weber [a], Suma Choorapoikayil [a], Donat R. Spahn [i], Kai Zacharowski [a]

Transfus Med Rev. 2017 Jan;31(1):62-71

ORIGINAL RESEARCH

Improved outcomes and reduced costs associated with a health-system–wide patient blood management program: a retrospective observational study in four major adult tertiary-care hospitals

Michael F. Leahy,[1,2,3] Axel Hofmann,[4,5,6] Simon Towler,[7] Kevin M. Trentino,[8] Sally A. Burrows,[1] Stuart G. Swain,[8] Jeffrey Hamdorf,[9,10] Trudi Gallagher,[11,12] Audrey Koay,[11] Gary C. Geelhoed,[11,13] and Shannon L. Farmer[9,14]

DOI 10.1111/trf.14006

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Education



CRITICAL BLEEDING

Introduction | Course Details | Endorsement & CPD | Assessment | Development Team

ACCESS COURSE

Introduction

The content for this Critical Bleeding course is based on the national *Patient Blood Management Guidelines: Module 1 Critical Bleeding/Massive Transfusion*. It is designed for medical practitioners, nurses and midwives, transfusion laboratory technicians, and other healthcare workers involved in critical bleeding situations.

If your role involves prescribing a transfusion, administering blood and monitoring patients during and after a transfusion, it is recommended that you complete the Clinical Transfusion Practice course.

Learning modules

1. Understanding Critical Bleeding
2. Identifying and Stopping Critical Bleeding
3. Fluid Resuscitation and Pharmacotherapy
4. Massive Transfusion Protocol

BloodSafe eLearning Australia
https://bloodsafelearning.org.au



Education and Training - Case Studies



KAPUNDA HOSPITAL, SA

Perioperative blood orde

Liverpool Hospital NSW – RFID tags

– extended life plasma protocol



s Hospital Brisbane

Perioperative

Management

POC testing - Prince Ch

War Memorial Hospital

Royal Children's Hospita



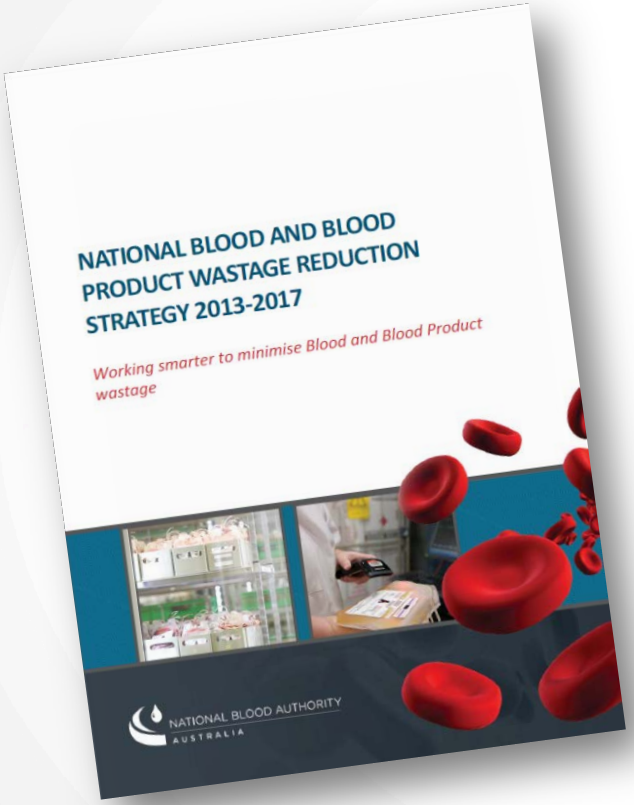
SYDNEY ADVENTIST HOSPITAL, NSW



JOHN HUNTER HOSPITAL, NSW

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Wastage strategy





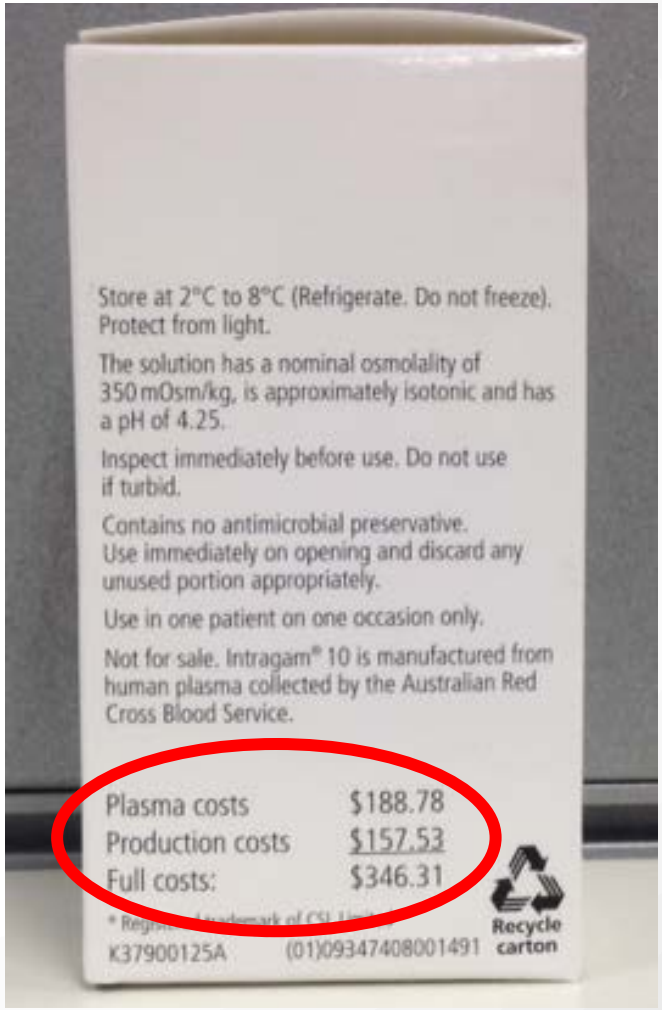




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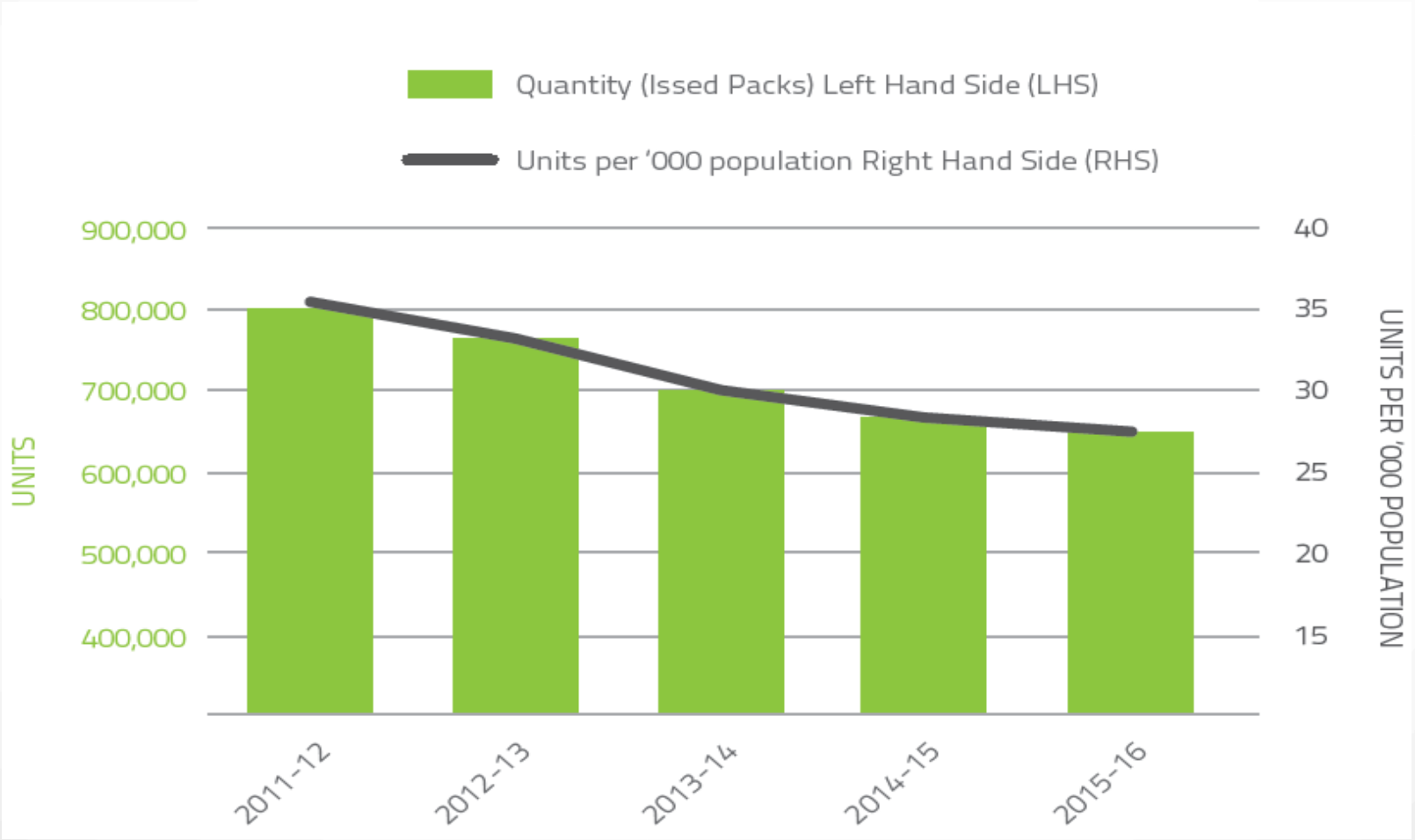
Price signals





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Red Blood Cell Demand



Plasma rationed as demand soars

PLASMA is being rationed to hospital patients because demand is outstripping supply.

The Australian Red Cross Blood Service has been forced to restrict its dwindling supply of a widely used plasma product called Intragam P.

Patients with life-threatening conditions have been guaranteed supply, but others are likely to miss out.

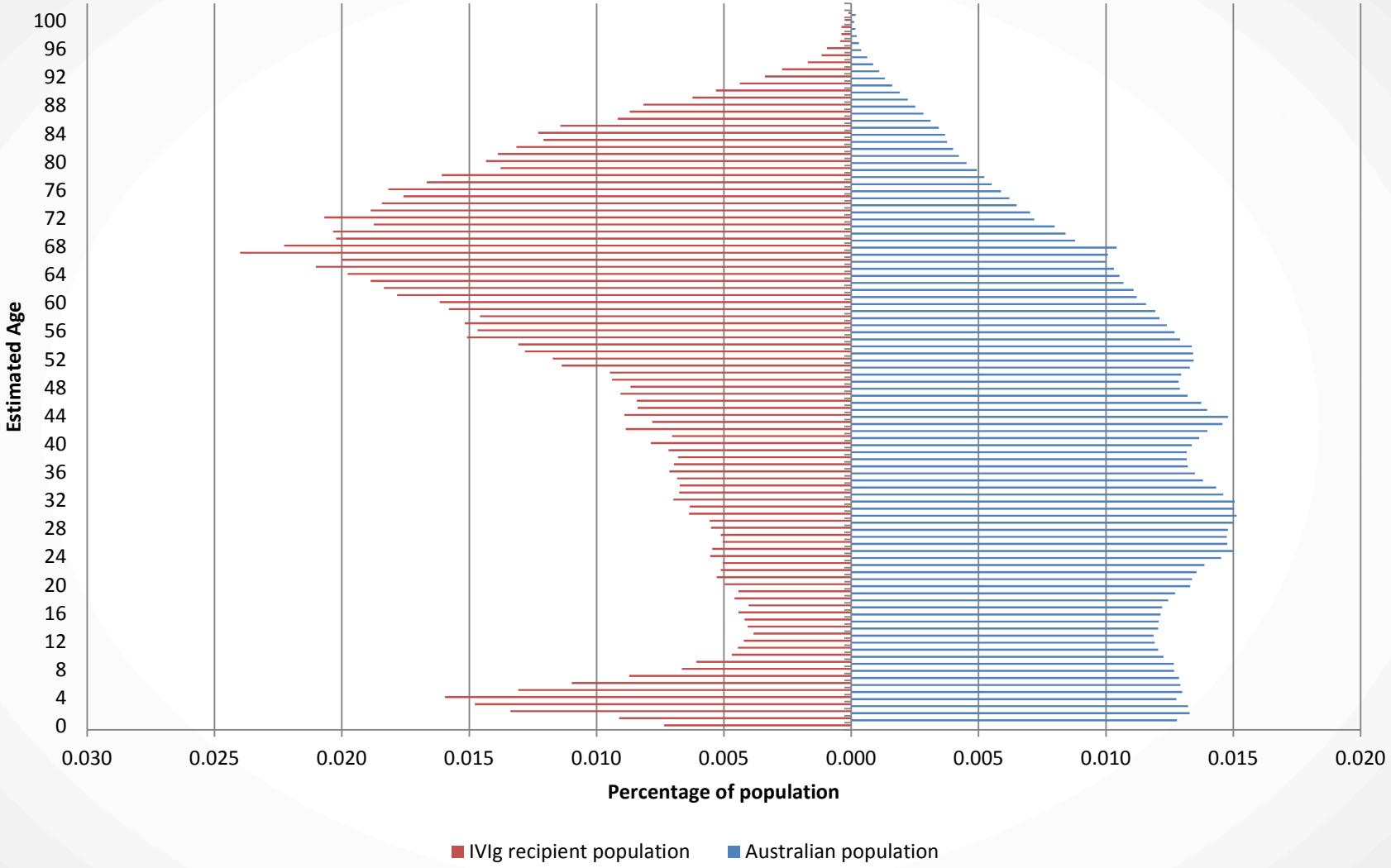
Thousands of Australians a year need Intragam P, which strengthens the immune system and is used to treat more than 50 conditions.

An alternative to the blood service's cost-free plasma product is available, but hospitals must dig into shrinking cash reserves to pay for it.

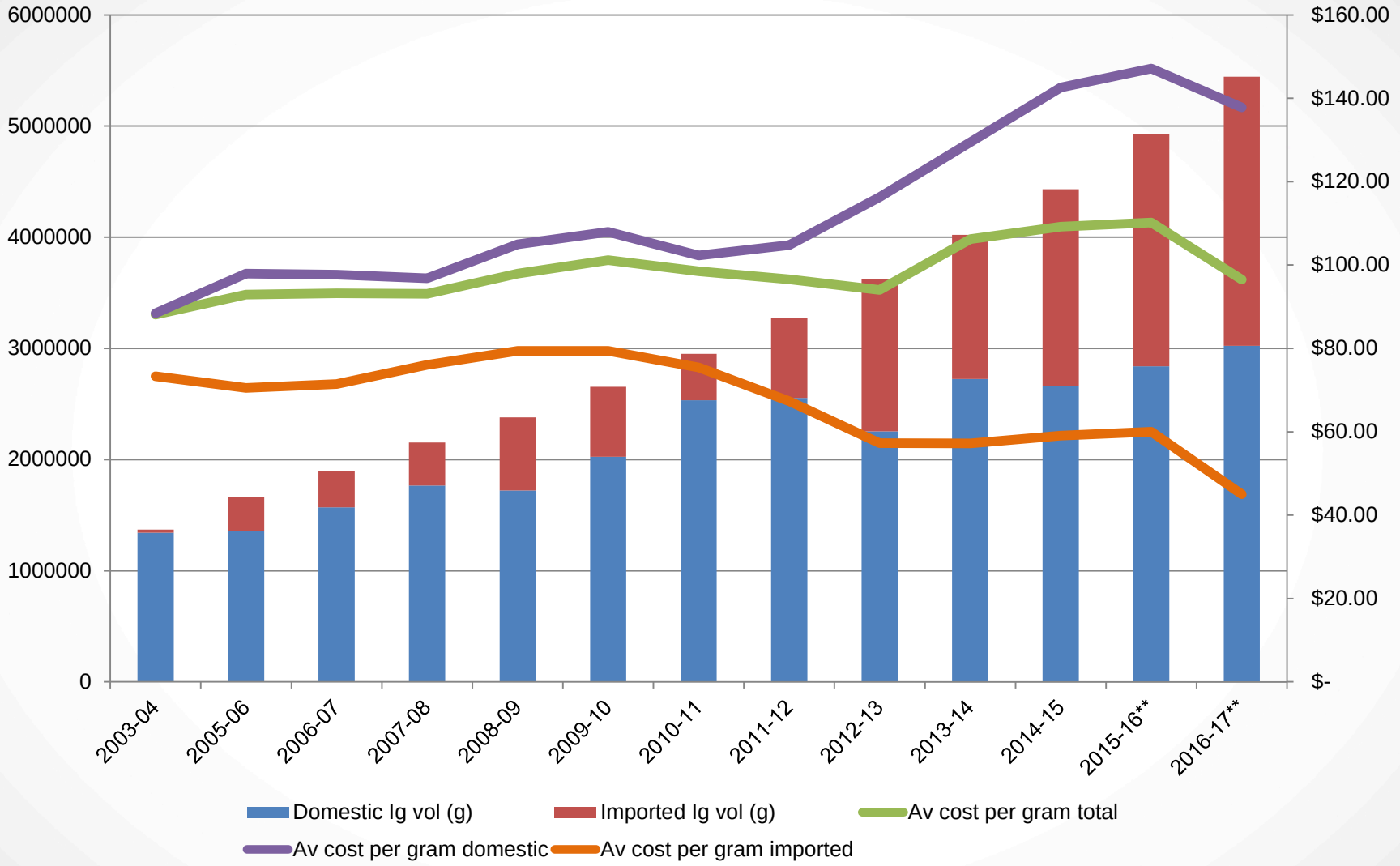
Australian Red Cross Blood Service blood products manager Brenton Wylie said people who needed Intragam P for life-threatening conditions would not miss out.

"Where people may have a need for it outside that, there is an alternative product, another form of intravenous immunoglobulin called Sandoglobulin, which is commercially available," he said.

Herald Sun 18 March 2004



http://www.blood.gov.au/data-analysis-reporting


6000000
5000000
4000000
3000000
2000000
1000000
0
$160.00
$140.00
$120.00
$100.00
$80.00
$60.00
$40.00
$20.00
$-
2003-04
2005-06
2006-07
2007-08
2008-09
2009-10
2010-11
2011-12
2012-13
2013-14
2014-15
2015-16**
2016-17**
Domestic Ig vol (g)
Imported Ig vol (g)
Av cost per gram total
Av cost per gram domestic
Av cost per gram imported

Ig Governance is not new



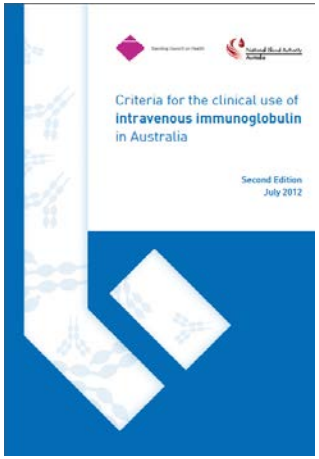




2004 National supply sufficiency through imported IVIg

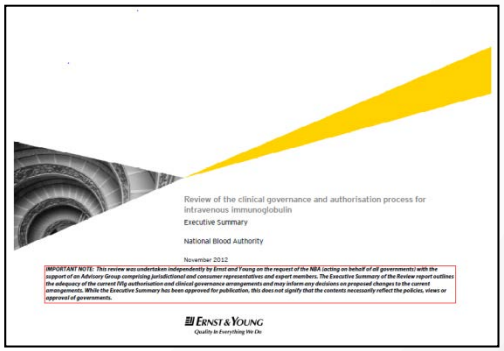
2008 Criteria for Use (Ed 1)

2007 – 2009 NIMS project



2012 Criteria for Use (Ed 2)

2011 – 2012 Review of clinical governance and authorisation



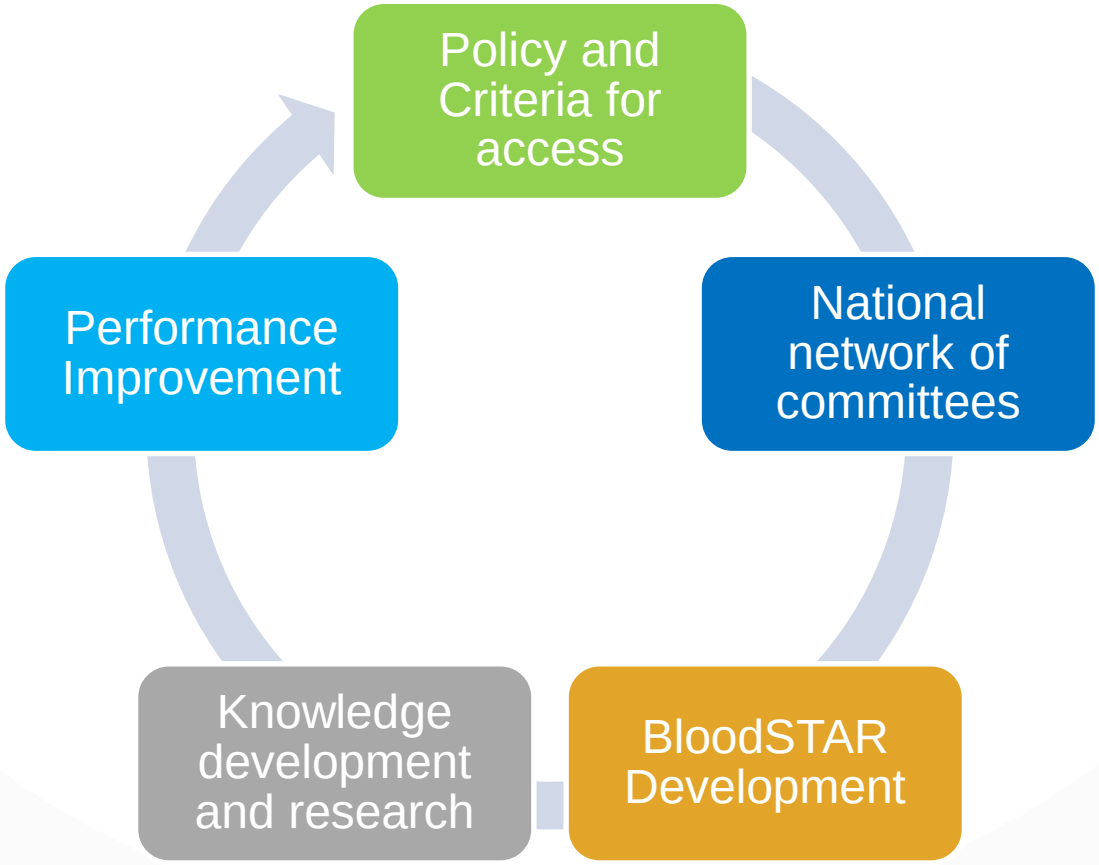
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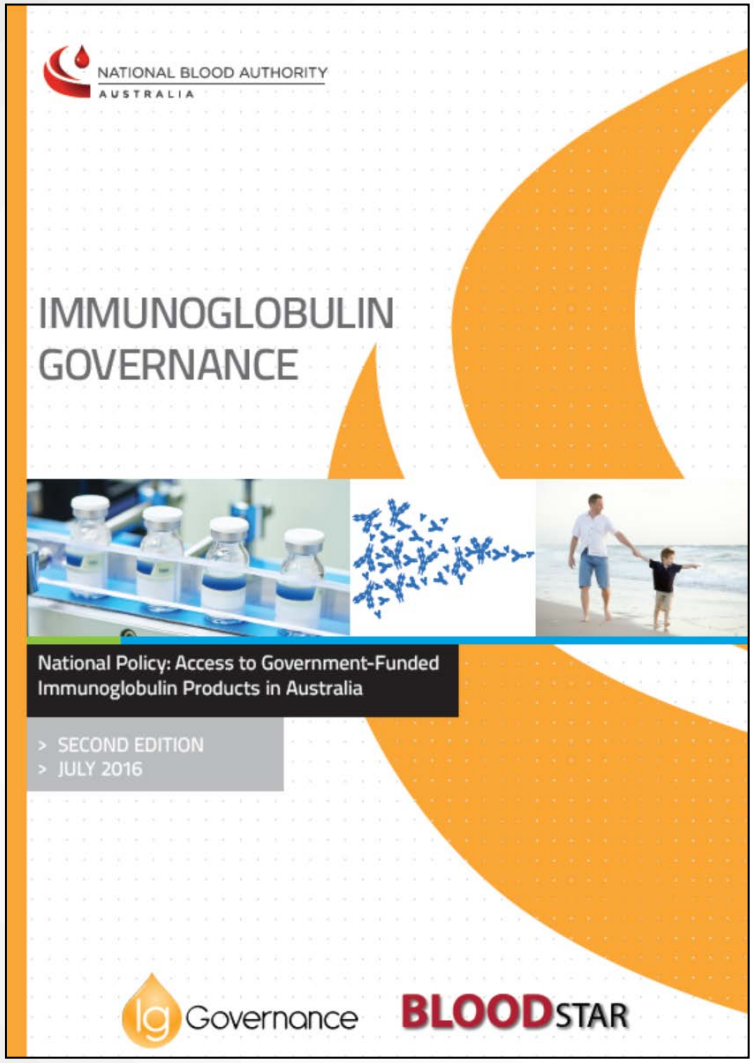
Ig Governance

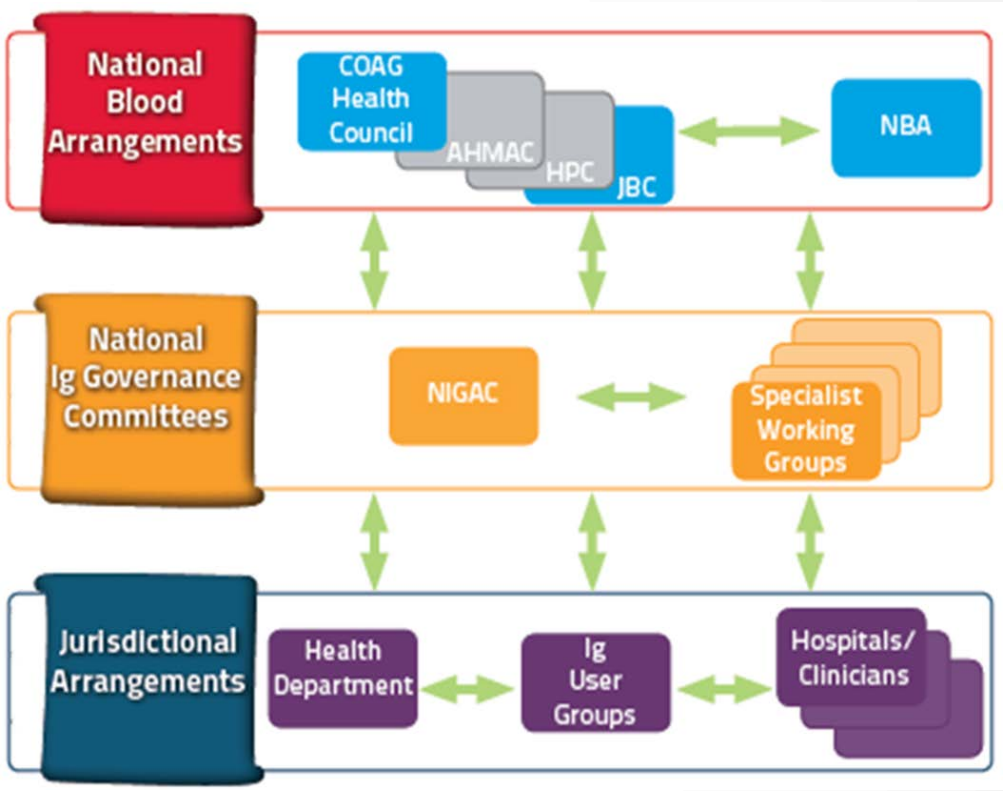
BLOODSTAR

Australian Red Cross BLOOD SERVICE

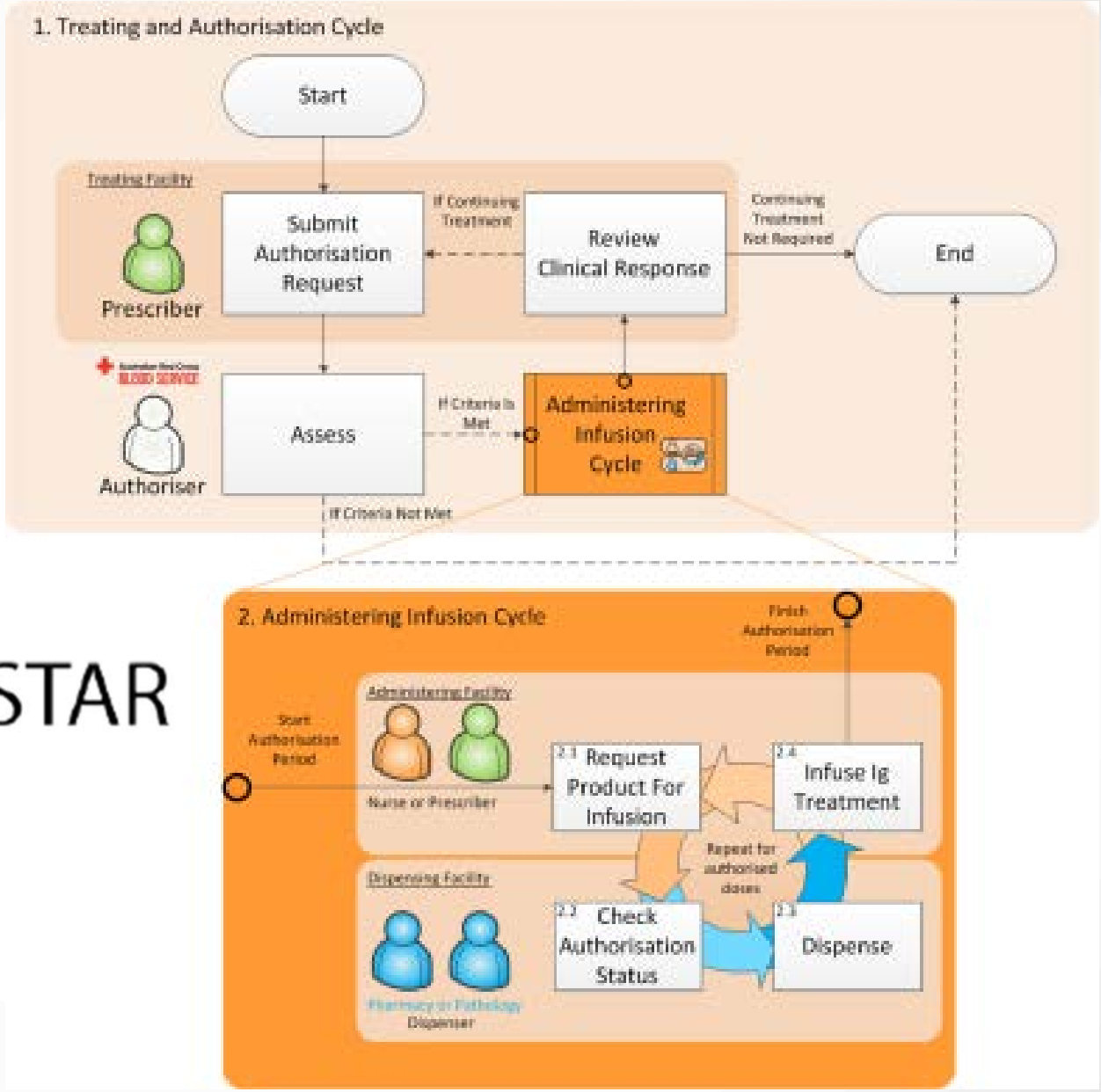
Ig Governance Program




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IMMUNOGLOBULIN GOVERNANCE
National Policy: Access to Government-Funded Immunoglobulin Products in Australia
> SECOND EDITION
> JULY 2016
Governance
BLOODSTAR


National Blood Arrangements
COAG Health Council
AHMAC
HPC
JBC
NBA
National Ig Governance Committees
NIGAC
Specialist Working Groups
Jurisdictional Arrangements
Health Department
Ig User Groups
Hospitals/ Clinicians

BLOODSTAR


1. Treating and Authorisation Cycle
Start
Treating Facility
Prescriber
Submit Authorisation Request
If Continuing Treatment
Review Clinical Response
Continuing Treatment Not Required
End
Authoriser
Assess
If Criteria is Met
Administering Infusion Cycle
If Criteria Not Met
2. Administering Infusion Cycle
Finish Authorisation Period
Administering Facility
Start Authorisation Period
Nurse or Prescriber
2.1 Request Product For Infusion
2.4 Infuse Ig Treatment
Repeat for authorised doses
Dispensing Facility
2.2 Check Authorisation Status
2.3 Dispense
Dispenser

Governance

Criteria for Clinical Use of Immunoglobulin in Australia

Reference Number

Browse the Criteria for Use | Check Eligibility | Dose Calculator

Browse the Criteria for Use

Established Therapeutic Role | Emerging Therapeutic Role | Exceptional Circumstances Only | Not Supported

Conditions for which IVIg has an established therapeutic role.

- Acquired hypogammaglobulinaemia — haematological malignancy and post HSCT
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Guillain–Barré syndrome (GBS)
- Immune thrombocytopenic purpura (ITP) — adult
- Inflammatory myopathies: polymyositis (PM), dermatomyositis (DM) and inclusion body myositis (IBM)
- Kawasaki disease
- Lambert–Eaton myasthenic syndrome (LEMS)
- Multifocal motor neuropathy (MMN)
- Myasthenia gravis (MG)
- Neonatal haemochromatosis (NH)
- Primary immunodeficiency diseases (PID) with antibody deficiency
- Stiff person syndrome

https://www.criteria.blood.gov.au/

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NBA blood sector systems

BLOODNET

ABDR
Australian Bleeding Disorders Registry

MyABDR

BLOODSTAR

BLOODportal

Jurisdictional Reports

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Data reports

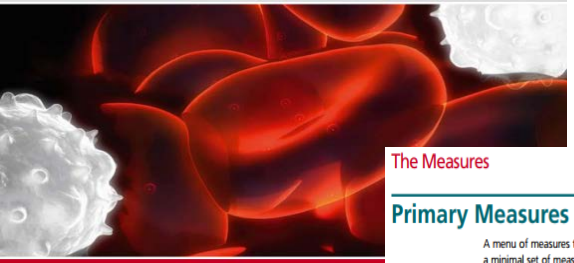


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Blood Measures

National Blood Authority Australia

Australian Red Cross BLOOD SERVICE



Blood Measures

A Guide to the Set of Standard Measu
for the use of Fresh Blood Componen
in Australia

Consultative draft for comment

The Measures

Primary Measures (P)

A menu of measures that are ideally collected in all studies of fresh blood components, containi
a minimal set of measures to collect about the use of fresh blood components in order to provic
meaningful, critical and, wherever possible, epidemiologically sound information. An example o
where these measures could be used would be when you wanted to add some additional questions
about blood components to existing or proposed clinical data collections (e.g. a clinical study or
registry) but had only limited scope in terms of the number of data points you could collect. These
measures could also be used when designing an audit, again where you wish to capture a limited
number of data points but still ensure meaningful information.

Supplementary Measures (S)

This menu of measures could be collected, in addition to the primary measures, where more
information about fresh blood components is needed. This set of measures, together with the
primary measures, would enable a comprehensive picture of the use of fresh blood components.
One example of where these measures could be used would be to provide more information in
a clinical audit by answering the specific questions the auditor is interested in. Another example
would be in a detailed clinical research study investigating the transfusion triggers associated with,
or the efficacy of, fresh blood components. It is anticipated that only the measures relevant to a
specific question or project would be selected.

Epidemiologically sound principles

Wherever possible, epidemiologically sound measures should be used. This will be critical for some studies.

Definition:

An epidemiologically sound measure is something which is readily available and can be measured objectively and in a standard way, anywhere and in any circumstances and which can be collected by non-experts.

Epidemiologically sound means:

Routinely collected
Routinely accessible
Consistent interpretation

No.	Primary measures (P)	Supplementary measures (S)
Reasons for transfusion		
41	Pre-transfusion Hb level	
42		Pre-operative Hb level
Transfusion episode		
43	Number of bags of leucocyte-depleted red blood cells transfused during transfusion episode	
44	Volume of leucocyte-depleted red blood cells transfused during transfusion episode	
45		Type of transfusion (autologous/allogeneic)
Post-transfusion data		
46	Post-transfu	
47		

Reasons for transfusion

Haemoglobin Levels

In relation to collecting Haemoglobin levels, either or both of Pre-operative or Pre-transfusion measures could be used. This choice would be determined by the project purpose and information available.

P

Pre-transfusion Hb level

No.	**P41**
Measure	**Pre-transfusion Hb level**
Format	**Hb g/L**
Definition	**The Hb level obtained closest to the time before the transfusion episode**
Potential source of data	**Pathology reports, patient notes for blood gas analyser or haemocue® results**

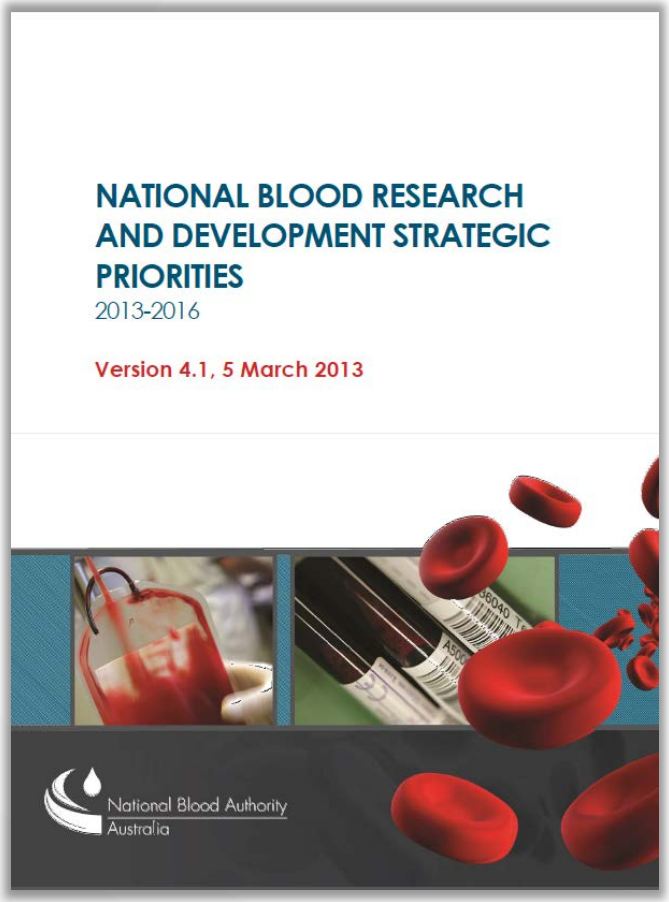
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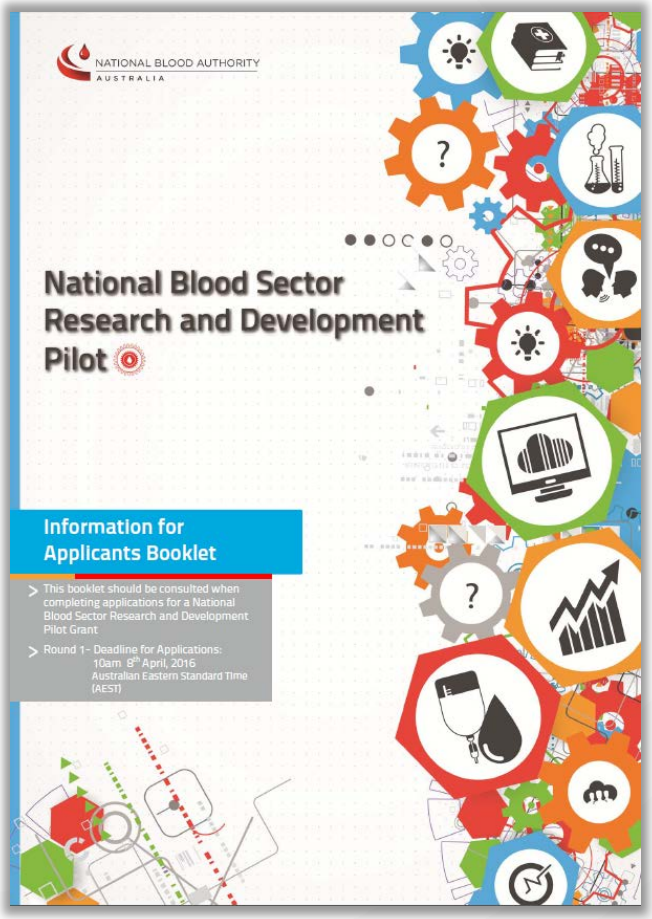
Pre-operative Hb level

No.	**S42**
Measure	**Pre-operative Hb level**
Format	**Hb g/L**
Definition	**The Hb level obtained closest to the time before surgery within 24 hours and before the infusion of fluids**
Potential source of data	**Pathology reports, patient notes for blood gas analyser or haemocue® results**

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Research and Development





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Today's talk

'Saving and improving Australian lives through a world-class blood supply'

Overview of Australian arrangements for blood and plasma products since 2003

Proposition:

- Important to consider governance, coordination and institutional arrangements as part of 'strategic independence', alongside collection, manufacturing, supply and quality
- Australian arrangements have developed in the specific national context, but may give useful possibilities for other countries to consider

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Q&A