IPFA Asia Pacific Workshop on Plasma Quality and Supply

An Australasian Perspective on Achieving Strategic Independence in Plasma Product Supply

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Overview

- What is ‘Strategic Independence’?
- Setting the scene for Australasia
- Current demand profile for coagulation factor and immunoglobulins
- The plasma challenge – is there still a place for self-sufficiency in PDMPs?
- Defining the model for ‘Strategic Independence’
- Current and emerging challenges
- Defining the way forward

Strategic Independence

Issues to consider

- Product quality, safety and efficacy
  - How can we ensure that the products are fit for purpose?
- Clinical need and demand
  - How can we ensure the product is used appropriately?
- Product availability
  - How can we ensure that sufficient product is available to meet clinical need?
- Resilience of supply
  - How can we best manage the risk around product recalls and other incidents impacting on supply?
- Financial considerations
  - How can we manage the increasing cost of providing product to patients?

Setting the Scene

New Zealand

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

NZBLOOD
Te Ratonga Toto O Aotearoa

CSL Behring Australia

Australian Government
Department of Health
Therapeutic Goods Administration

CSL Behring
Biotherapies for Life™
Australian Operations

CSL GLOBAL

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Australia

Australian Government
Department of Health
Therapeutic Goods Administration

NATIONAL BLOOD AUTHORITY
AUSTRALIA

Australian Red Cross
BLOOD SERVICE

The Australasian Context

Similarities

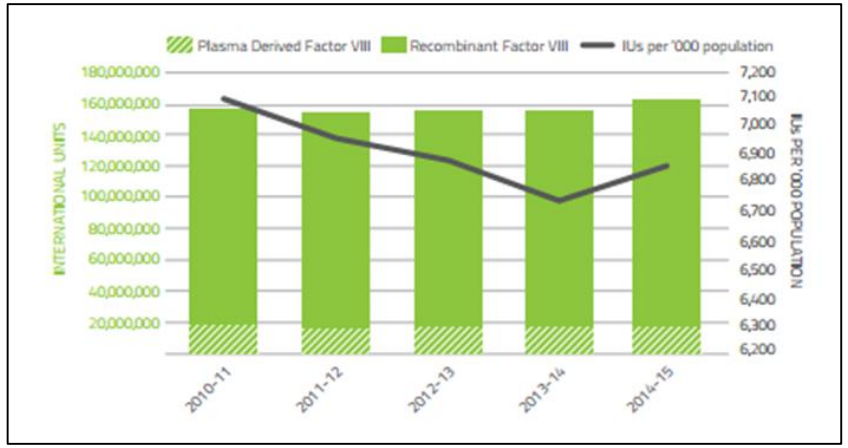
- Australia and New Zealand have:
  - Well-developed public health systems that are mainly free at the point of access to patients
  - Legislation in place to prohibit the sale of blood products to patients
  - Effective medicines regulatory systems
  - National blood services with a commitment to VNRD and self-sufficiency
  - Established links to the EDQM Guide
  - Long history of contract fractionation of plasma by CSL Behring Australia

Differences

- Blood products in Australia are mainly funded by the Federal Government with the process being managed by the National Blood Authority (NBA)
- Blood products in New Zealand are fully costed and provided to hospitals on a 'fee for product' basis
- Both countries are self-sufficient for main plasma products other than immunoglobulin
- Australia have imported immunoglobulin for some years; currently this comprises 33% of total
- New Zealand was self-sufficient in IVIg until late 2015, policy currently under review

Coagulation Factors

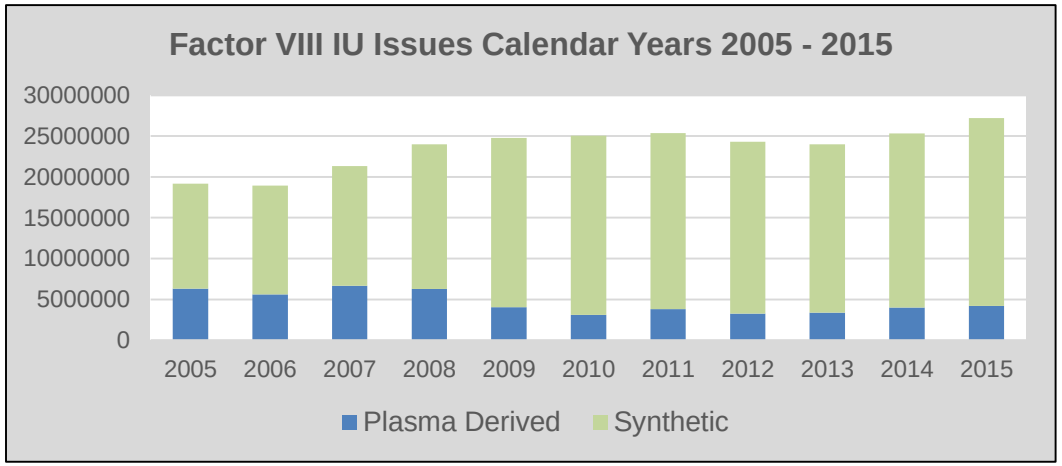
FVIII and FIX use in Australia*





* NBA annual report 2014/15

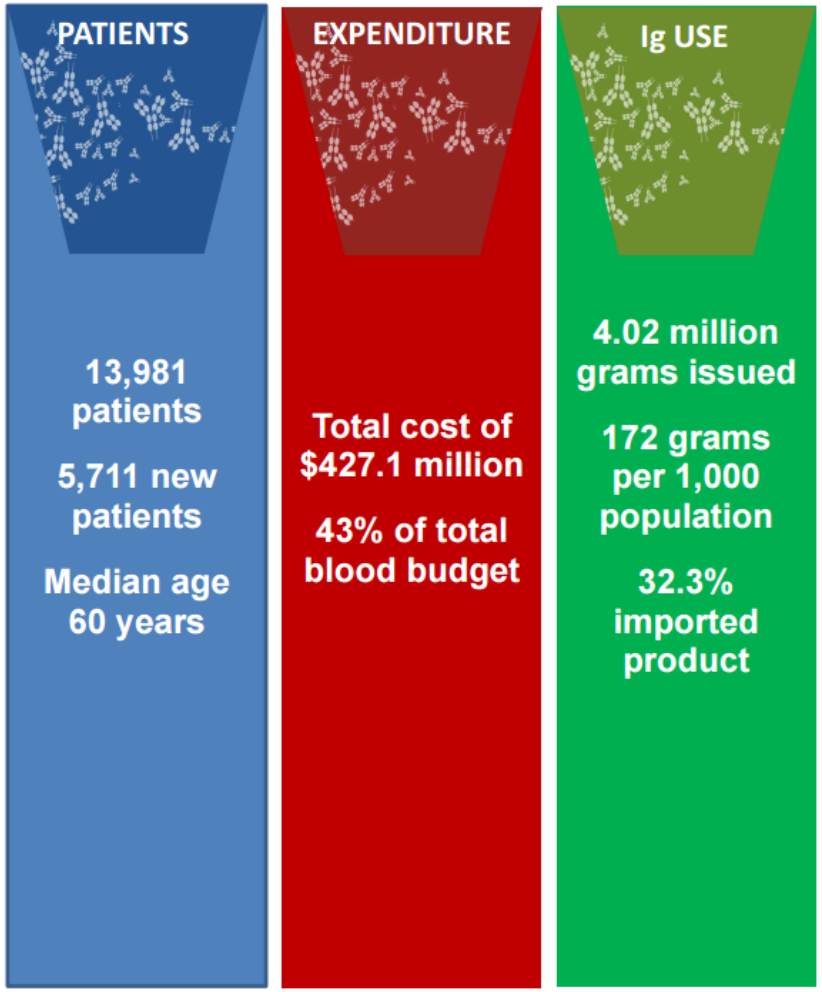
FVIIU use in New Zealand



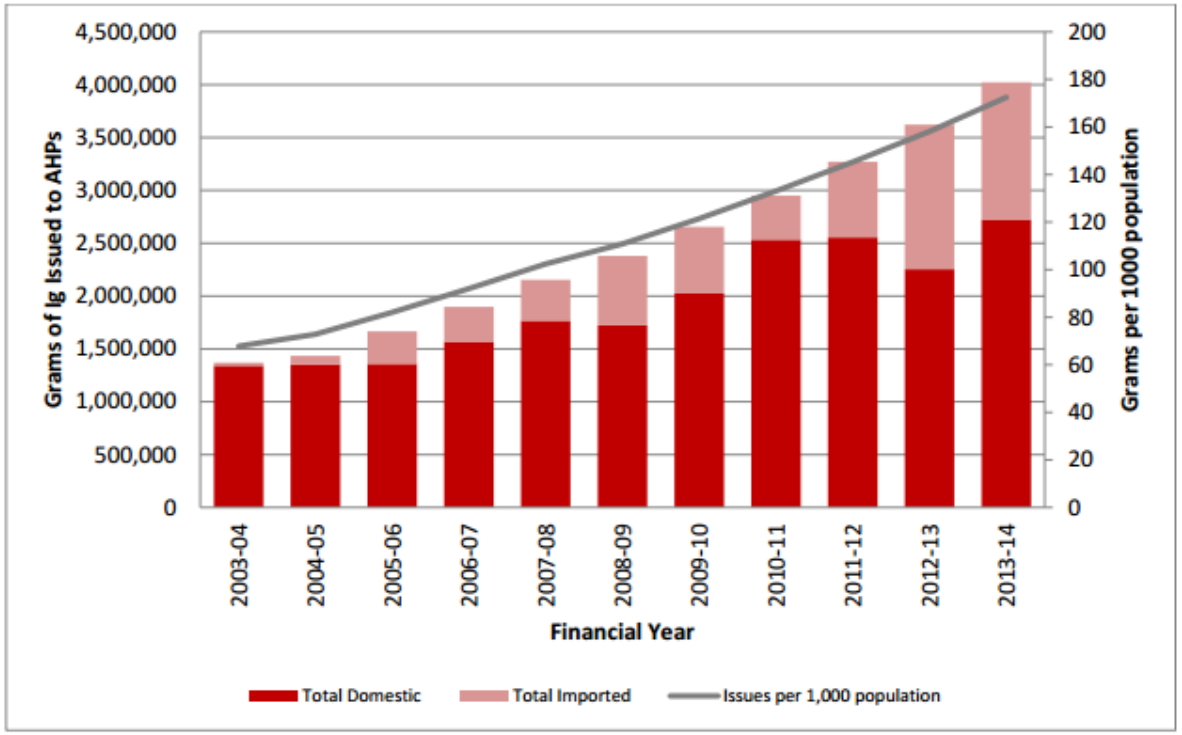
- FVIIU use growing slowly in both countries but this largely involves use of recombinant product
- Significant surplus of plasma derived FVIII now exists in both countries
- Surplus albumin also an increasing problem
  - NZ sells surplus to CSL Behring for on-sale

IVIg Use In Australia

2013/14 Financial year

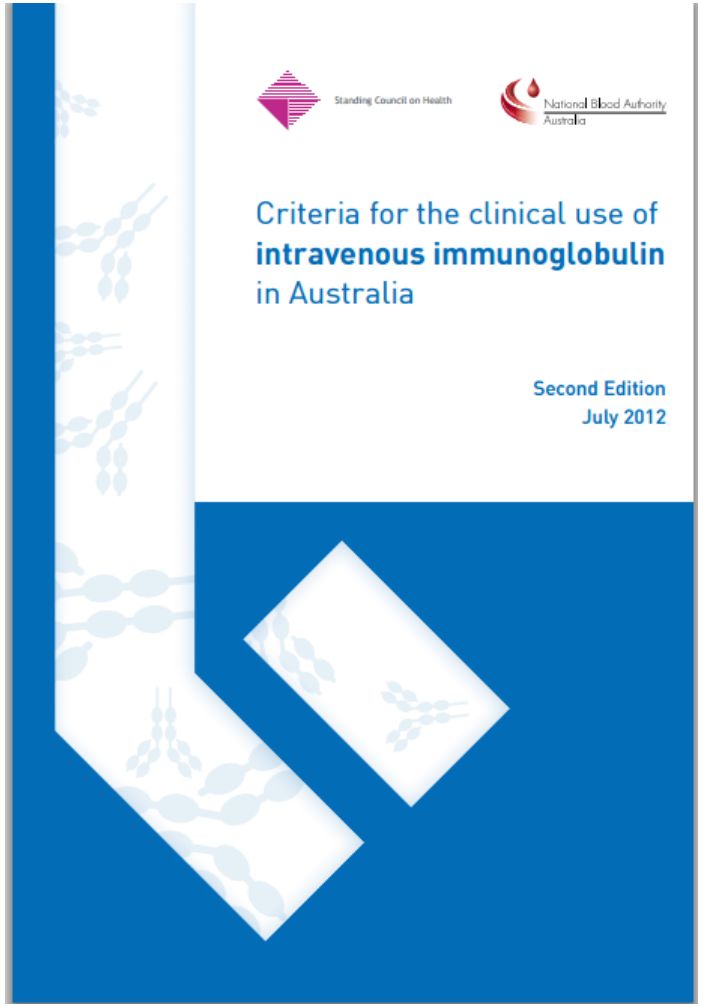


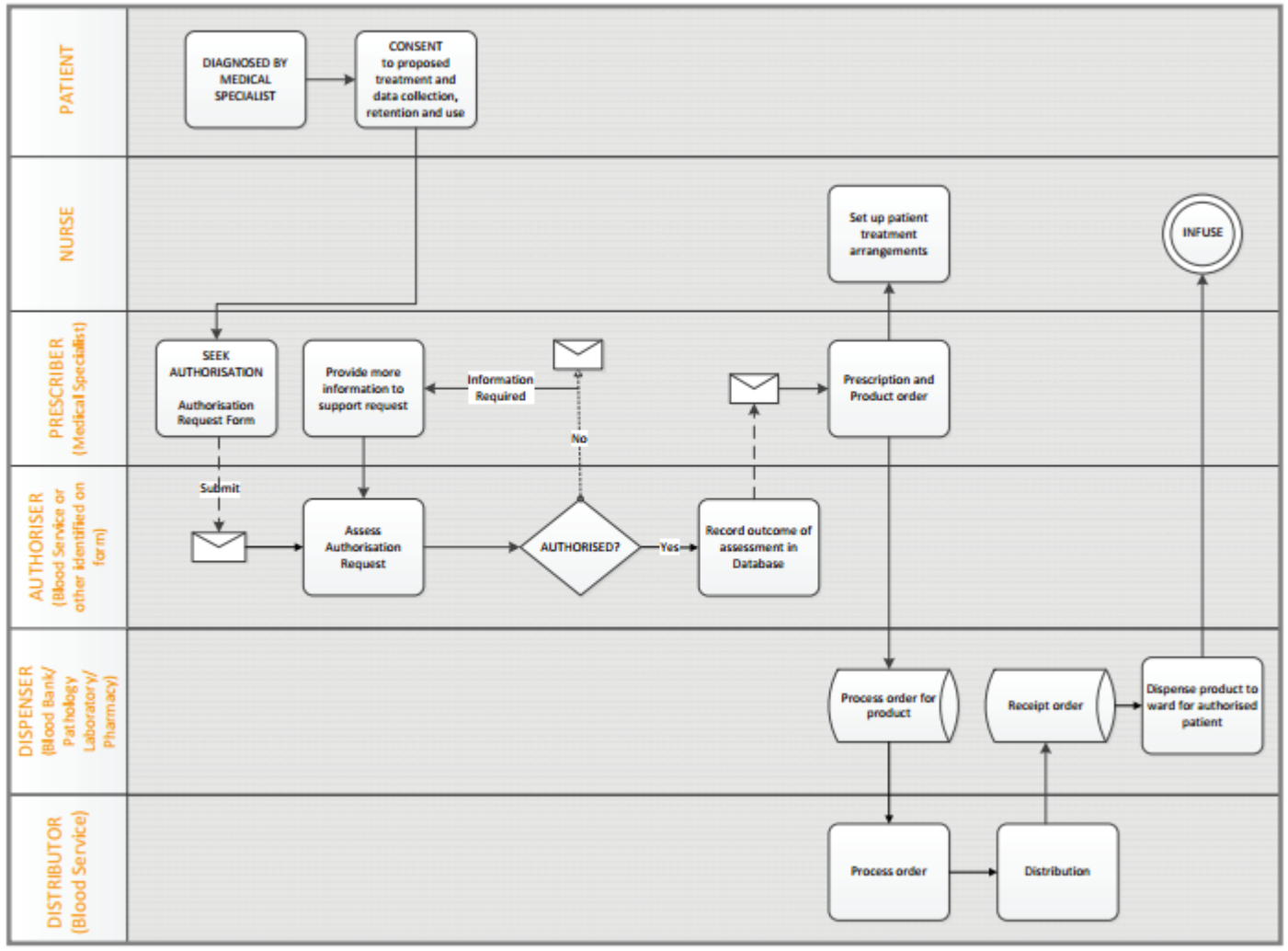
10 year trend of IVIg use



- Annual growth in demand of 10-12% each year for last 5 years
- Use per 1000 population reached 172g by June 2014
- Proportion of commercial product continues to increase despite significant increase in domestic plasma collection

Ensuring Appropriate Use – The Australian System

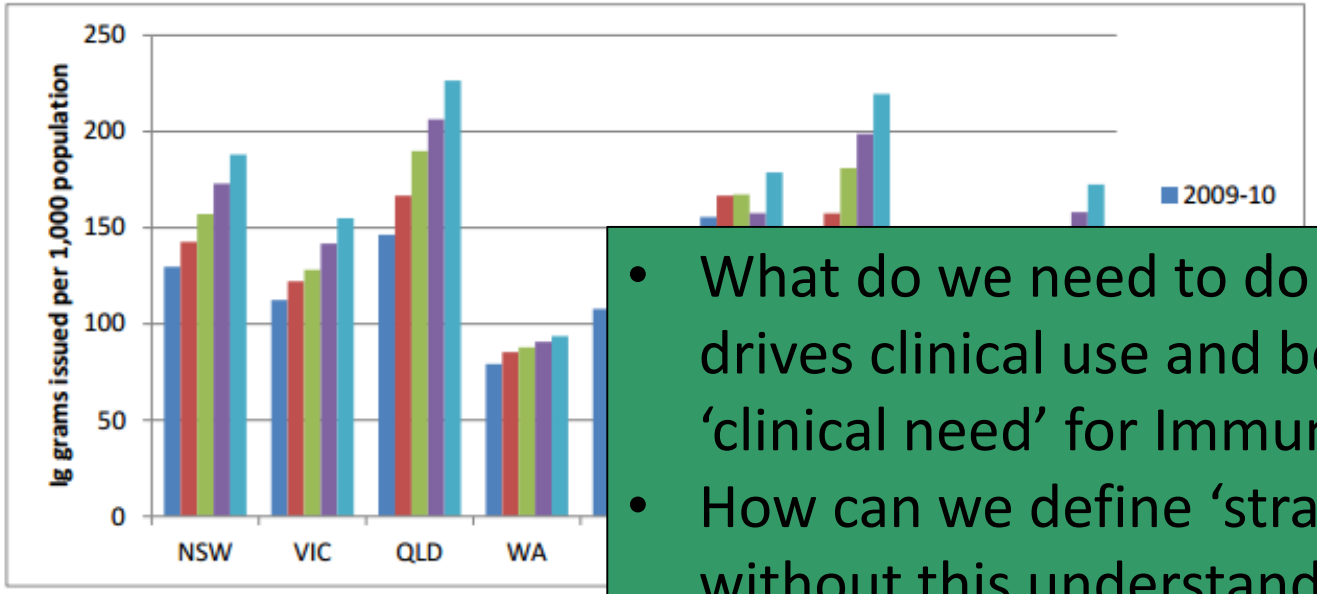




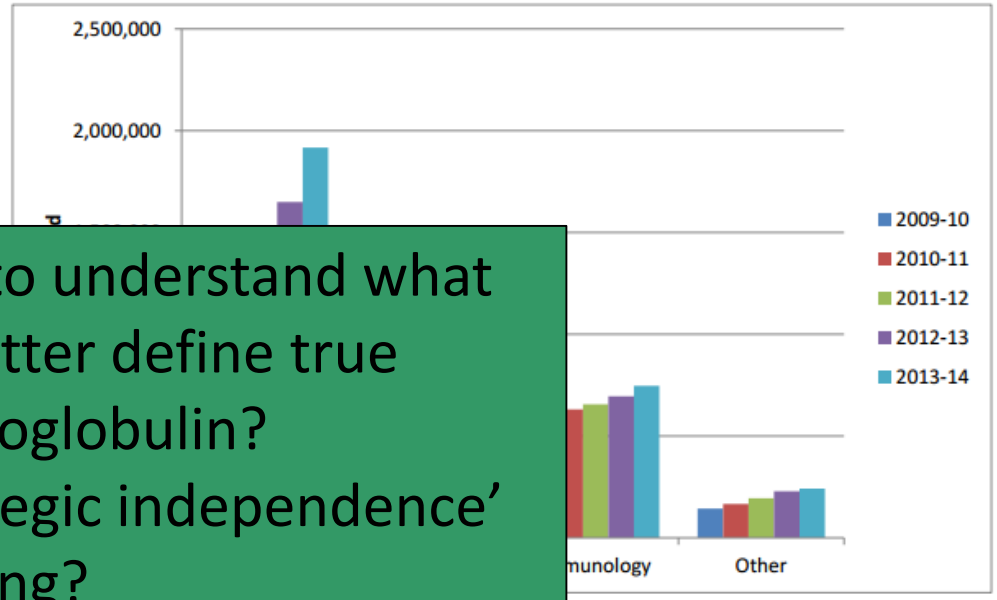
Initial access and supply of government funded immunoglobulin products.

How is Immunoglobulin used in Australia?

Use by state and territory



Use by clinical condition



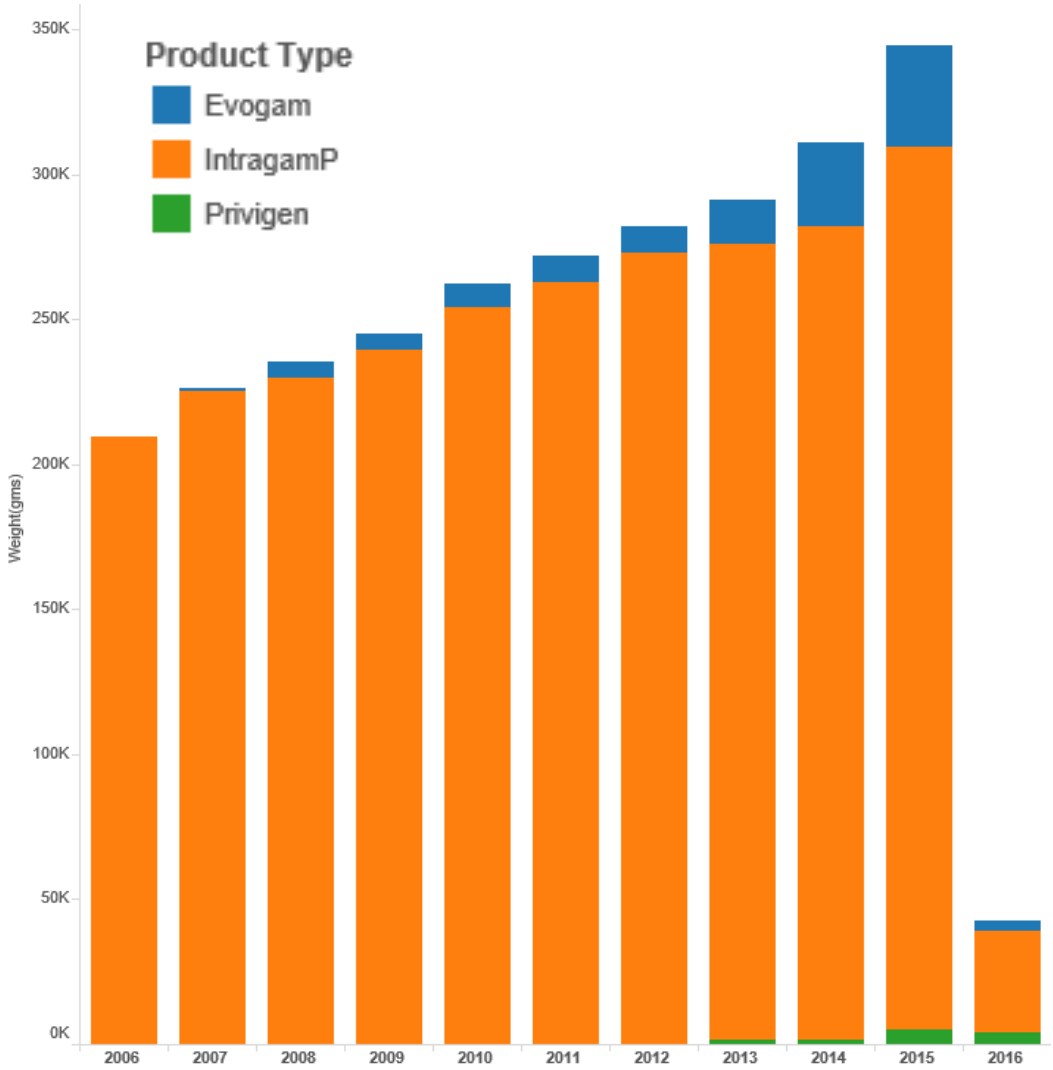
- What do we need to do to understand what drives clinical use and better define true 'clinical need' for Immunoglobulin?
- How can we define 'strategic independence' without this understanding?

- Significant variation in use by state and territory despite use of common access criteria and approval mechanisms
- Progressive increase in use in all states and territories

- Good data on how product is used
- Main increase in use in neurology conditions and acquired hypogammaglobulinaemia in haematology conditions

http://www.blood.gov.au/system/files/documents/report-on-the-issues-and-use-of-ivig-2013-14-finalv2_0.pdf

Immunoglobulin Use in New Zealand



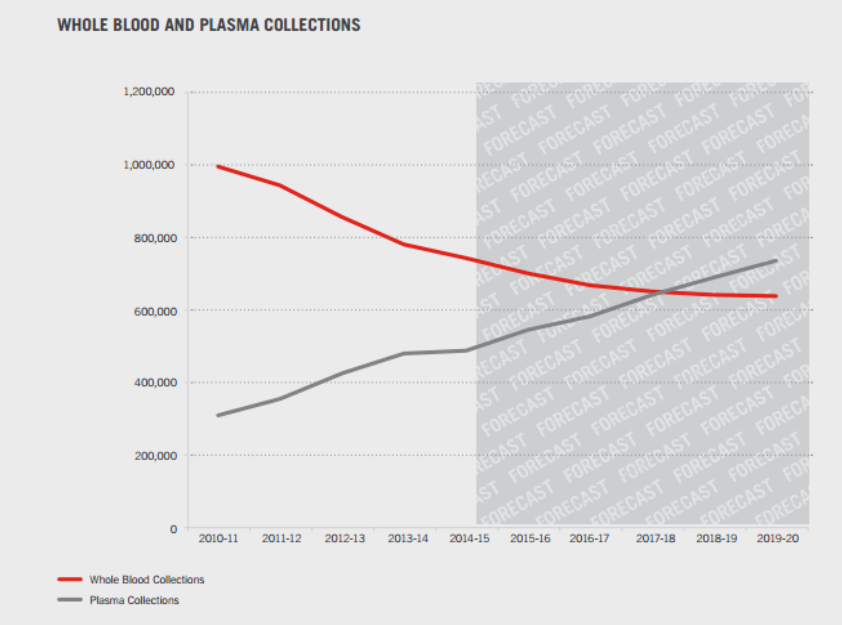
YEAR	POPULATION	Grams IgG Issued	Grams/1000 POPN
2010	4,353,000	252199	57.9
2011	4,386,300	271737	62.0
2012	4,410,700	282268	64.0
2013	4,446,700	291494	65.6
201			.9
201			.9

- Why is demand in New Zealand significantly lower in NZ despite the use of the same clinical criteria for use?

YEA		pp'n
2011	7.7	6.9
2012	3.9	3.3
2013	3.3	2.4
2014	6.7	5.1
2015	10.8	8.7

Blood and Plasma Collected by ARCBS

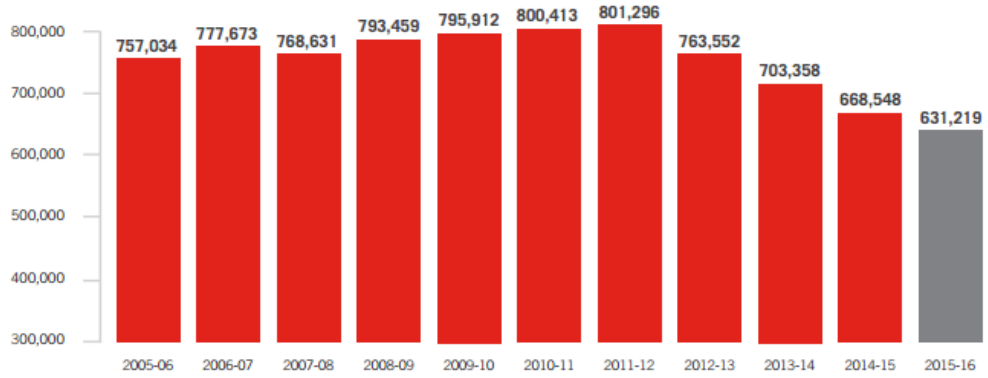
ARCBS Collection overview**



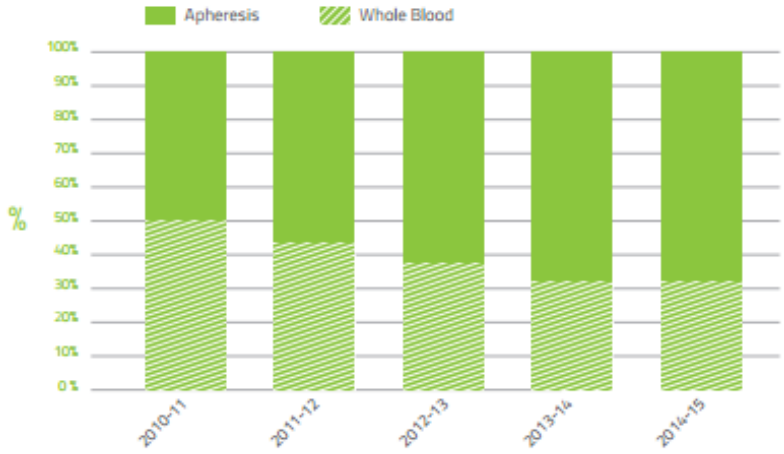
** ARCBS annual report 2014/15

- Progressive decline in whole blood collection with increasing emphasis on apheresis plasma
- Plasma growth running at 5% per annum versus 10-12% for IVIg

Whole blood collections by ARCBS**

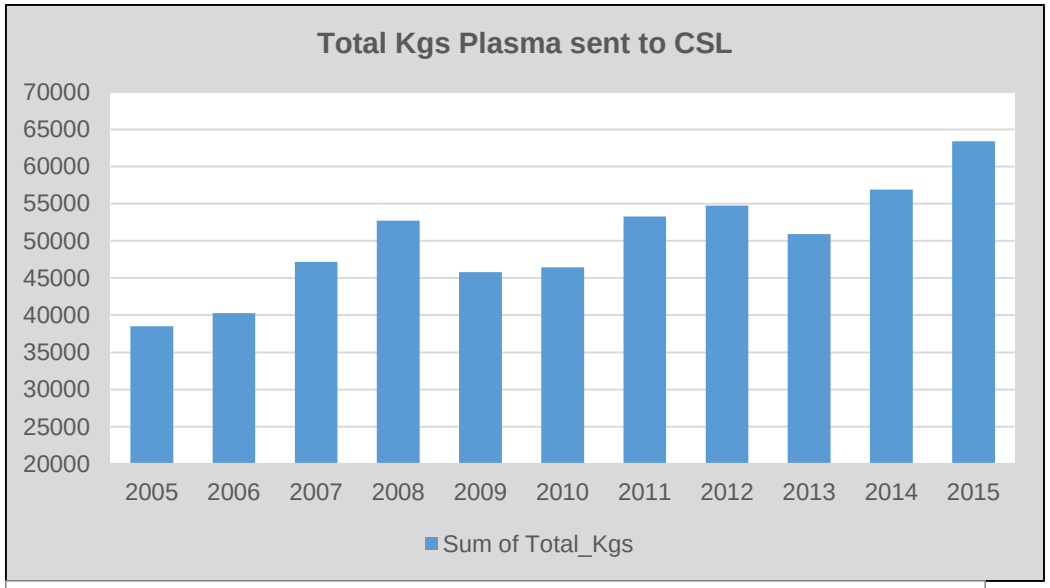


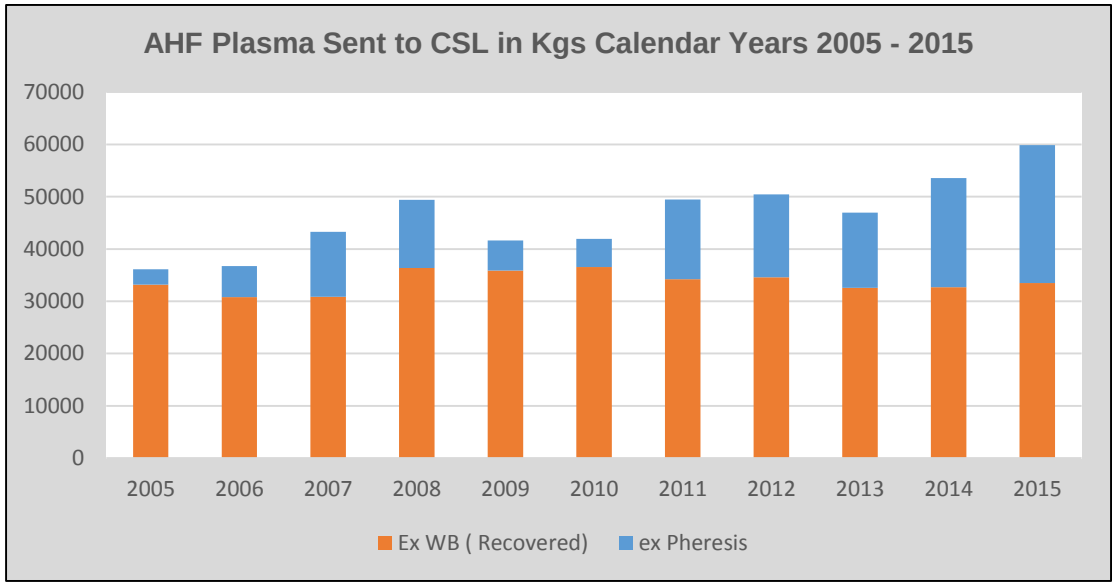
Plasma collected by ARCBS*

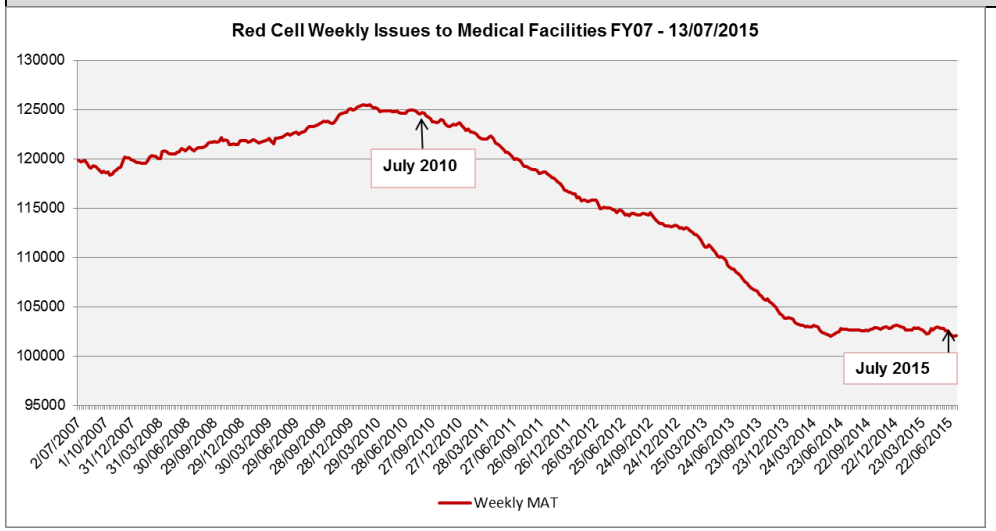


* NBA annual report 2014/15

Blood and Plasma Collected by NZBS







- Plasma sent to CSL for fractionation increasing year on year
- Amount of plasma recovered from whole blood falling in real terms and as a percentage
- Increasing concern at cost per kg apheresis plasma

Emerging Challenges for New Zealand

- Uncertain future growth pattern for IgG products
- Increasing cost of producing domestic IgG
  - On-going reduction in availability of recovered plasma
  - Increasing dependency on apheresis source plasma
  - Demand for IgG significantly higher than for other products derived from pool
- Increasing cost-efficiency of apheresis plasma collection
  - Maximising utilisation of current donor centres
  - Optimising volume of plasma collected per procedure (EDQM)
  - Reducing unnecessary testing of apheresis plasma donations
- Growing size of plasma panels with a reducing need for whole blood collection
- Managing the impact of the globalisation of CSL Behring

Maintaining Resilience in Supply of Plasma Products

DOMESTIC PRODUCT

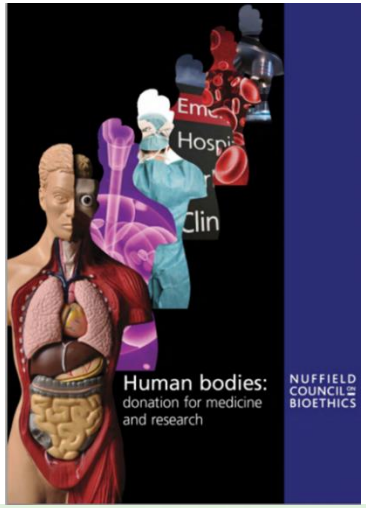
- Maintain minimum stock levels of product
  - 4 months finished product
  - 3 months product with 5 months WIP
- Strategic plasma reserve
- Preferentially used in patients with long term dependency
  - Primary Immunodeficiency
  - CIDP

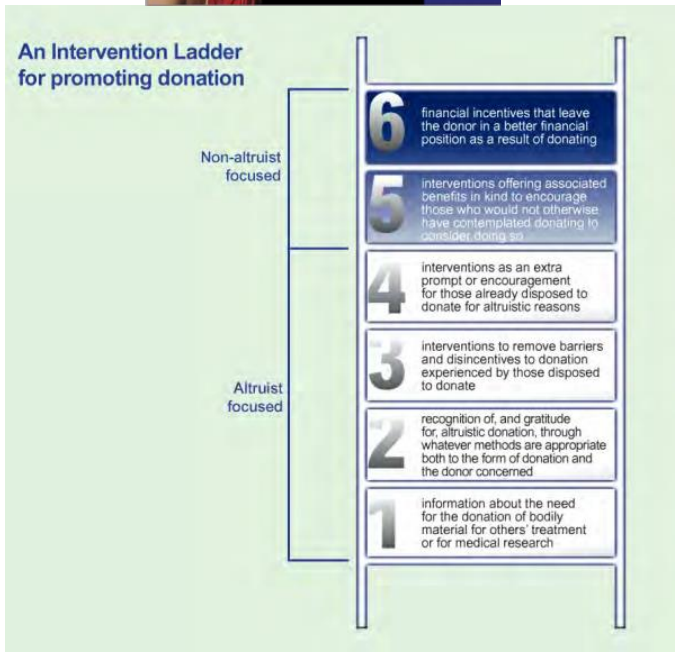
IMPORTED COMMERCIAL PRODUCT

- Products must be registered by national medicines regulatory agency
- Long term contracts with ‘preferential supplier’ status
- Product used mainly in patients receiving short term or intermittent treatment with IgG

What is the optimal mix of domestic and imported commercial product?

Wither Self-Sufficiency?





- WHO continues to promote self-sufficiency in PDMPs based on VNRD as a goal for national blood services (WHA 63.12 on the Availability, safety and quality of blood products)
- Increasing use of 'donor incentives' by VNRD Blood Services blurs the difference between VNRD and compensated or paid donors
- Nuffield Council on Bioethics intervention ladder distinguishes between incentives that increase the ability for altruistic donation from those that encourage donation for other reasons.

Nuffield Bioethics on Altruism

‘**It must, of course, be repeated that individuals who are paid, or otherwise rewarded, for their services can also be altruists.**

We accept that non-altruist-focused interventions will sometimes make altruists even keener to act on their altruistic motivation.

***But such interventions also give individuals who are not concerned with the welfare of others a motivation to do*nate**’.

‘While some of the claims made about altruism may be overblown, the notion of altruism as underpinning important communal values expresses something very significant about the kind of society in which we wish to live.

Understood in this way, altruism has much in common with solidarity: an altruistic basis for donation helps underpin ***a communal, and collective, approach to the provision of bodily material for others' needs, where generosity and compassion are valued***’.

Concluding Remarks

- Australia and New Zealand have effective systems to maintain ‘strategic independence’ for supply of plasma products
- On-going growth in clinical use of IgG products is putting increasing pressure on the ability of blood services to collect more apheresis plasma
- High cost of producing apheresis plasma from VNRD is a challenge
- Increasing dependency on commercial products will potentially diminish future certainty of ‘strategic independence’
- Important to find the ‘sweet spot’ balance between domestic and commercial product to support future strategic planning
- **Is a Self-Sufficiency model still sustainable and desirable?**