

PATIENTS, PRODUCTS, PLANNING and PROCUREMENT

HFA
OCTOBER 2011
Stephanie Gunn

Saving & improving Australian lives through a world-class blood supply

Role of the NBA



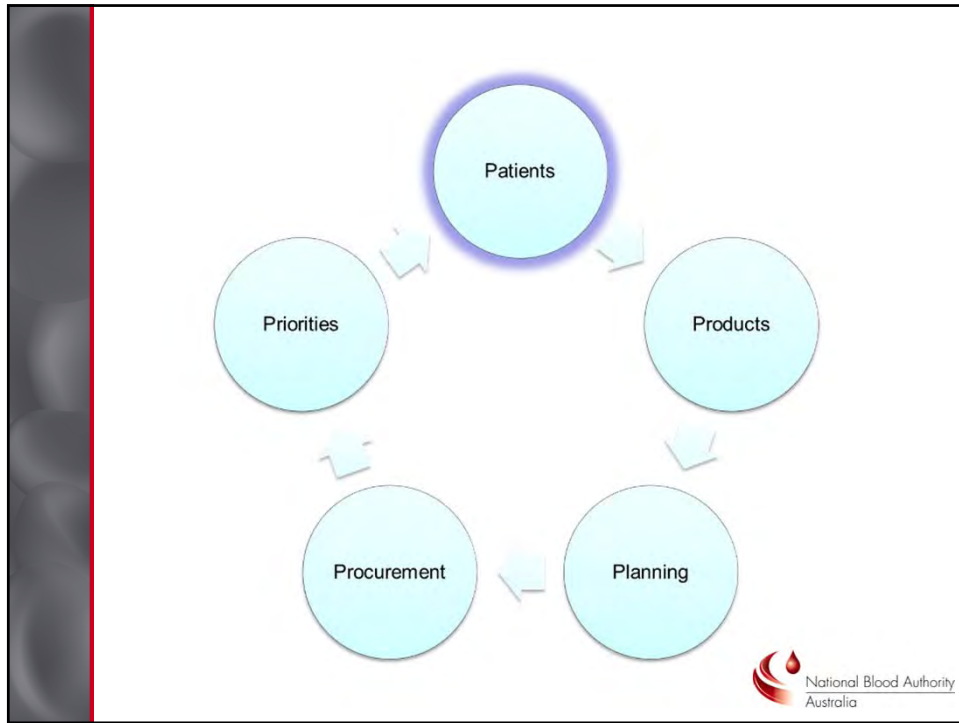
What we are:

- Supply chain management including
 - Coordinator of demand forecasts & Supply planner
 - Contract negotiator & manager
 - Contingency planner & risk manager
- Facilitator of appropriate patient blood management
- Advisor on policy development & implementer of government decisions



What we are not:

- Decision maker on blood policy or funding
- Funding organisation for research
- Responsible for product safety, efficacy and regulation
- Manager of appropriate blood use programs in the jurisdictions



Patient demographics from ABDR

	In register at 30 Jun 2009	Number who received product in 2008-09	In register at 30 Jun 2010	Number who received product in 2009-10
HmA†	1836	690	1927	830
HmB†	443	152	463	185
vWD	1608	100	1748	183
Other Factor Deficiency	208	18	229	18
Platelet Disorder	145	1	154	4
Vascular	4	0	4	0
Miscellaneous	12	2	15	0
Other	23	0	25	0
Not Specified	112	2	115	0
Grand Total	4391	965	4680	1220

How do we compare?

	Severe			Moderate			Mild			Total	
	Inhibitor present	proportion of total with inhibitors	Total Severe	Inhibitor present	proportion of total with inhibitors	Total Moderate	Inhibitor present	proportion of total with inhibitors	Total Mild	proportion of total with inhibitors	Total in Register at 2010
Australia											
HmA (Symp + Asymp)	111	19.0%	584	14	5.6%	248	25	2.6%	980	7.8%	1927
HmB (Symp + Asymp)	6	6.8%	88	0	0.0%	101	0	0.0%	253	1.3%	463
vWD	2	1.7%	119	0	0.0%	225	0	0.0%	1184	0.2%	1748
UK											
HmA (Symp + Asymp)	351	19.3%	1814	43	7.7%	559	62	2.1%	2972	8.5%	5345
HmB (Symp + Asymp)	15	3.8%	396	0	0.0%	244	0	0.0%	482	1.3%	1122
vWD	2	1.6%	125	2	1.2%	164	0	0.0%	8381	0.0%	8670

Incidence of bleeding disorders selected countries 2008 (per 100,000)

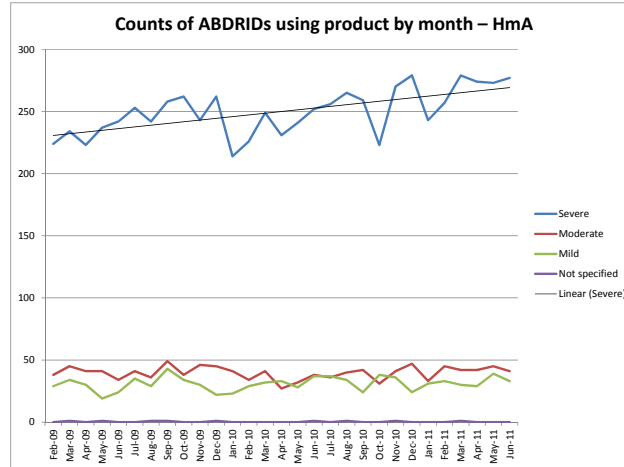
Country	Population	B1. Number of PWH (HmA or HmB)	B2. Number of people with vWD	B3. Number of people with OBD	Number of PWH per 100,000	Number of people with vWD per 100,000	Number of people with OBD per 100,000
Australia	21,262,641	1,760	1,308	629	8.3	6.2	3.0
France	64,057,792	4,779	272	215	7.5	0.4	0.3
Germany	82,329,758	4,000	745		4.9	0.9	0.0
Netherlands	16,715,999	1,452	263	64	8.7	1.6	0.4
Spain	40,525,002	1,932	690	199	4.8	1.7	0.5
Sweden	9,059,651	1,017	1,523		11.2	16.8	0.0
United Kingdom	61,113,205	6,061	7,852	4,999	9.9	12.8	8.2
United States	307,212,123	16,243	11,852	1,616	5.3	3.9	0.5

^[1] PWH means people with haemophilia.
^[2] OBD means other bleeding disorders.

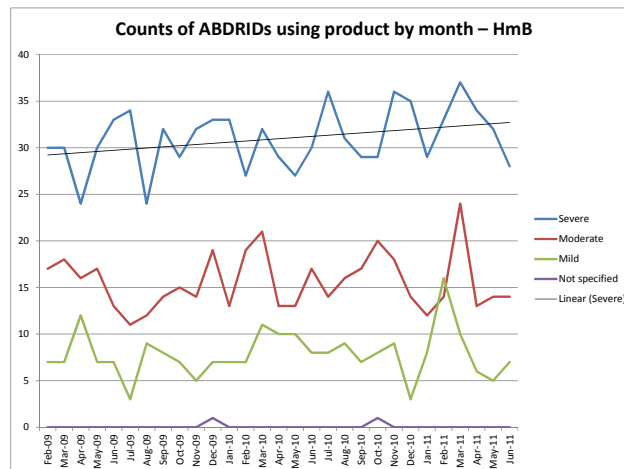
Source: World Federation Hemophilia Report on the annual global survey 2008



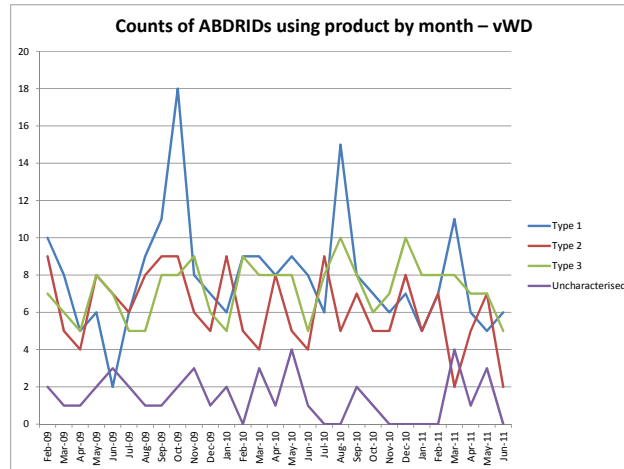
Haemophilia A numbers treated trends



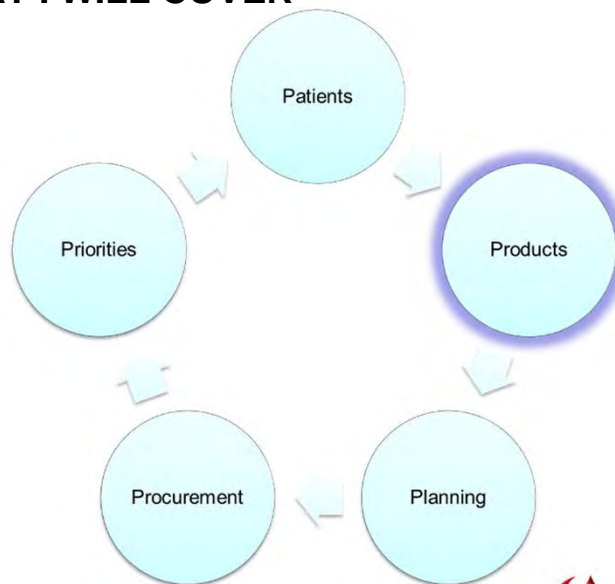
Haemophilia B numbers treated trends



von Willebrand Disease numbers treated trends

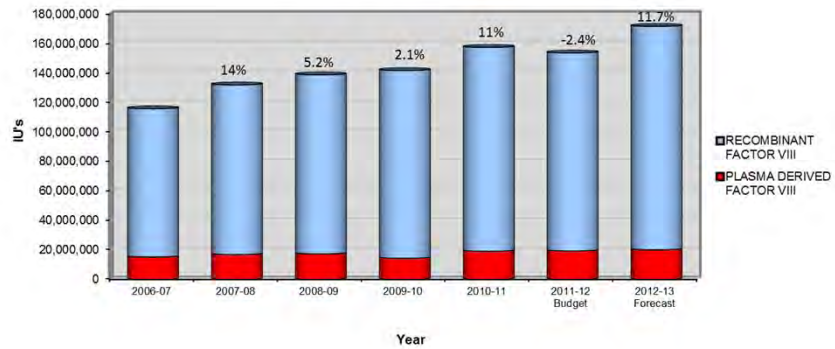


WHAT I WILL COVER



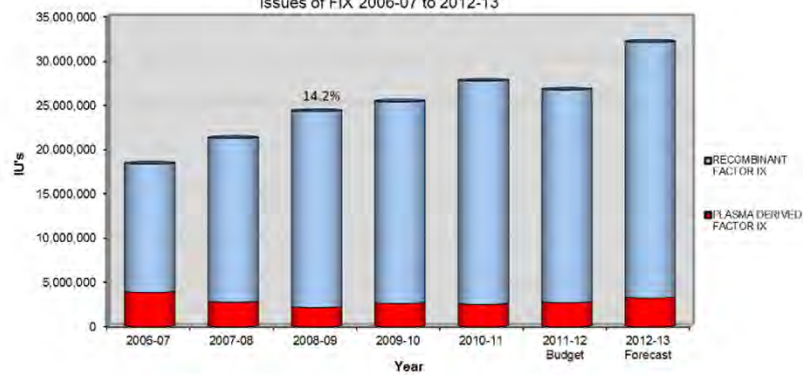
Issues of FVIII

Issues of FVIII 2006-07 to 2012-13

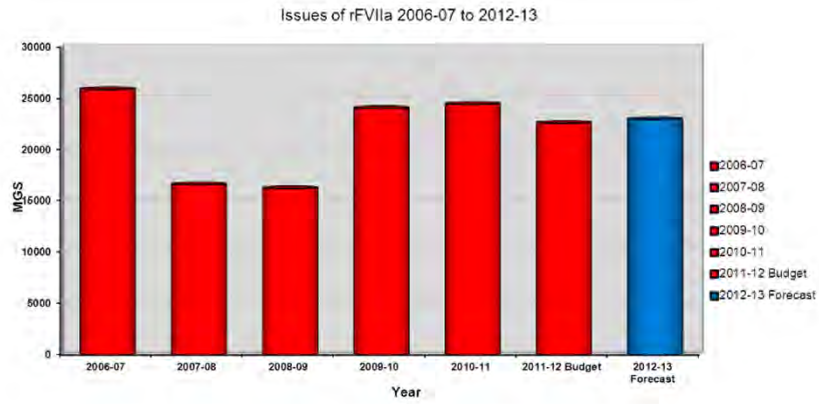


Issues of FIX

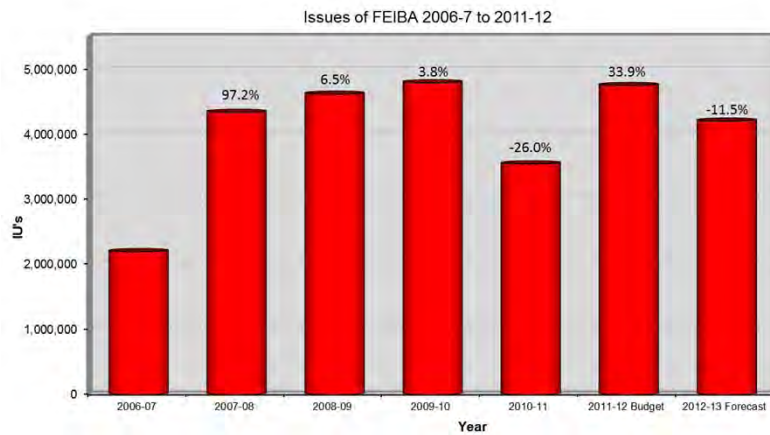
Issues of FIX 2006-07 to 2012-13



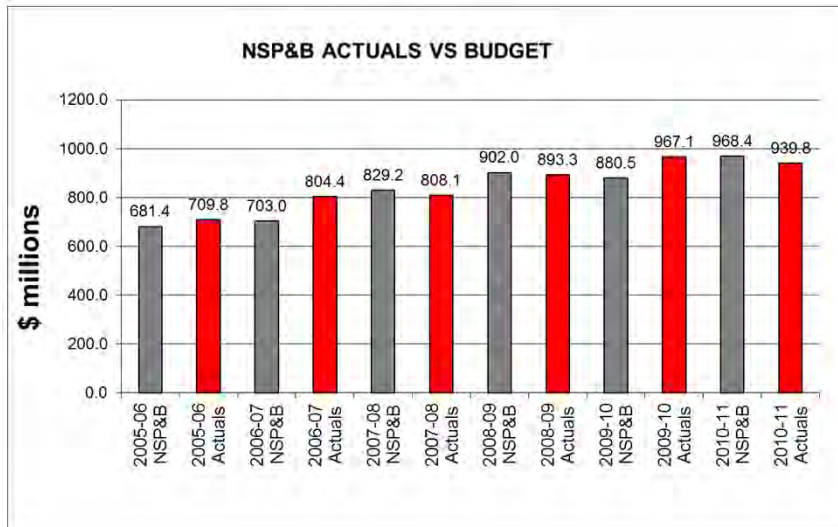
Issues of rFVIIa



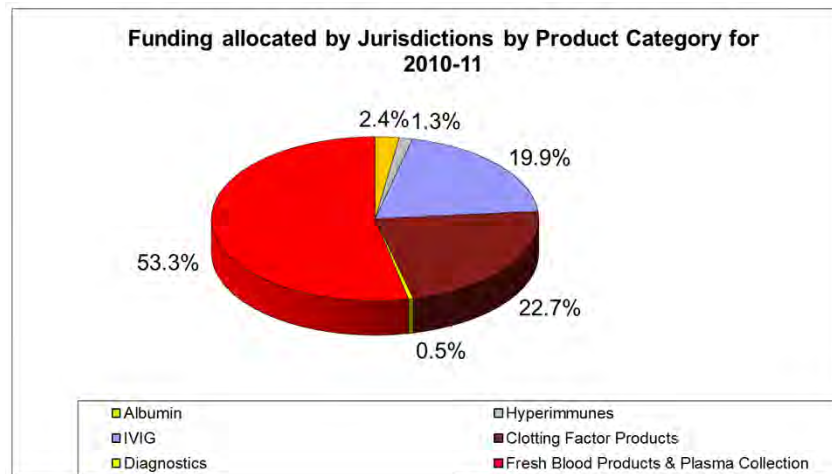
Issues of FEIBA



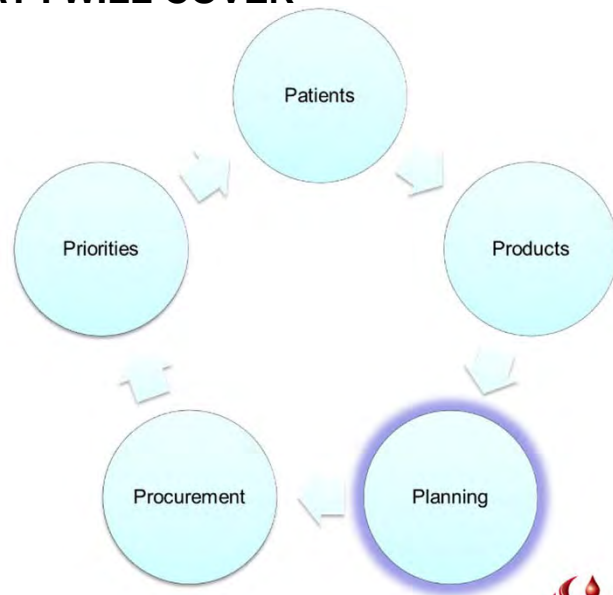
Demand growth continues



2010-11 Demand

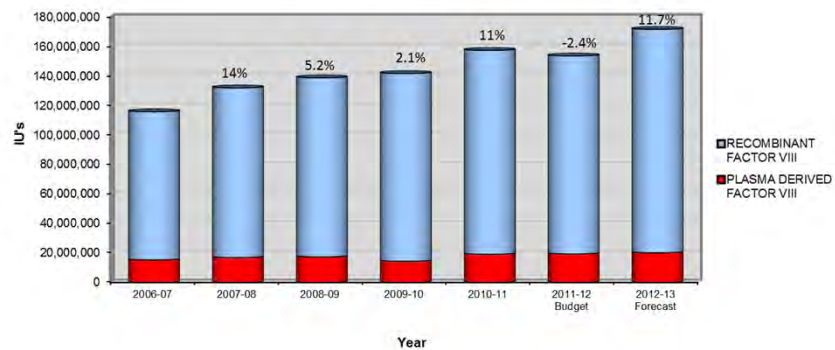


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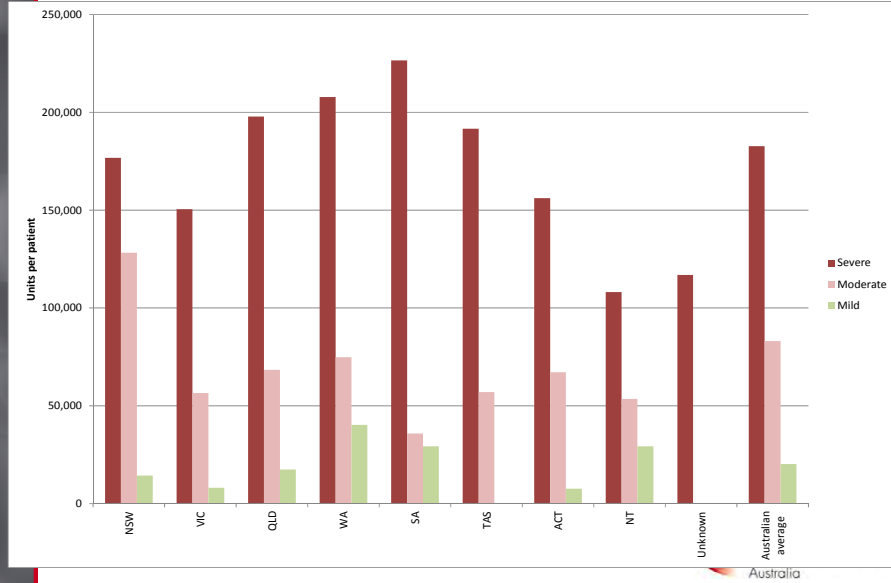


Issues of FVIII

Issues of FVIII 2006-07 to 2012-13



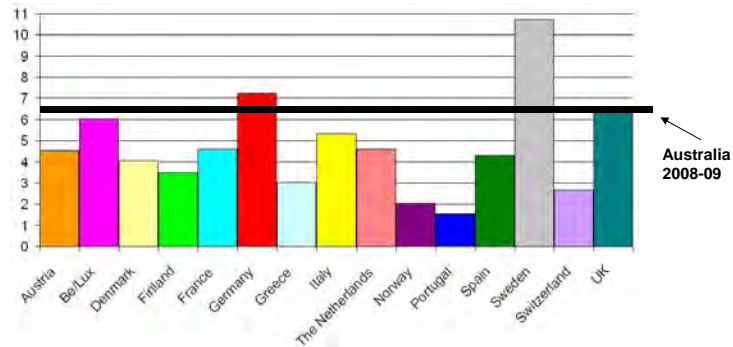
What causes demand to be different by state ?



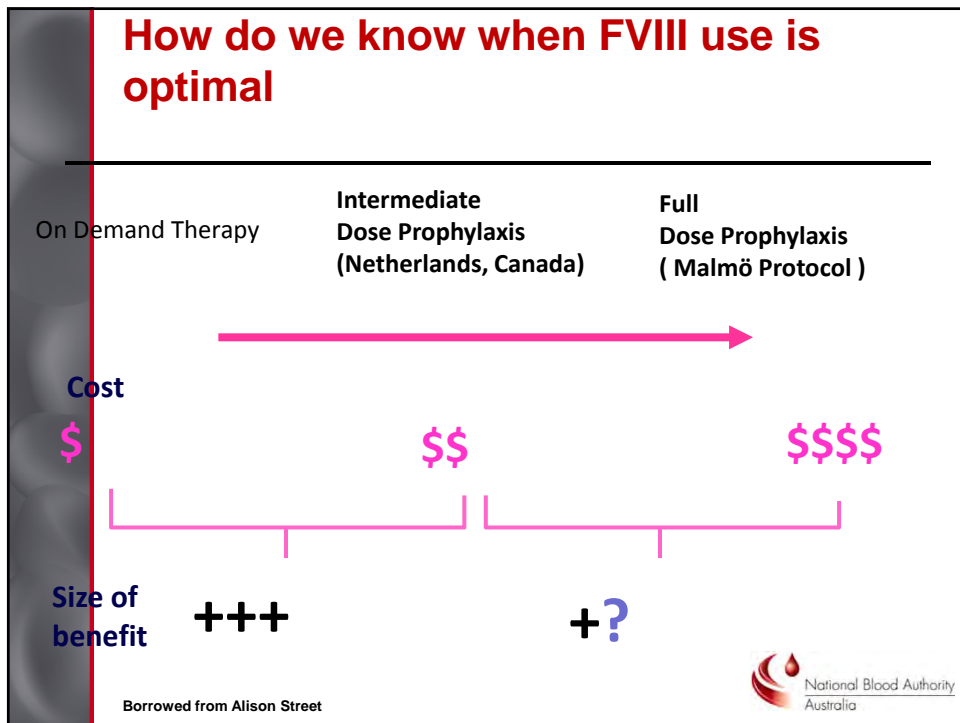
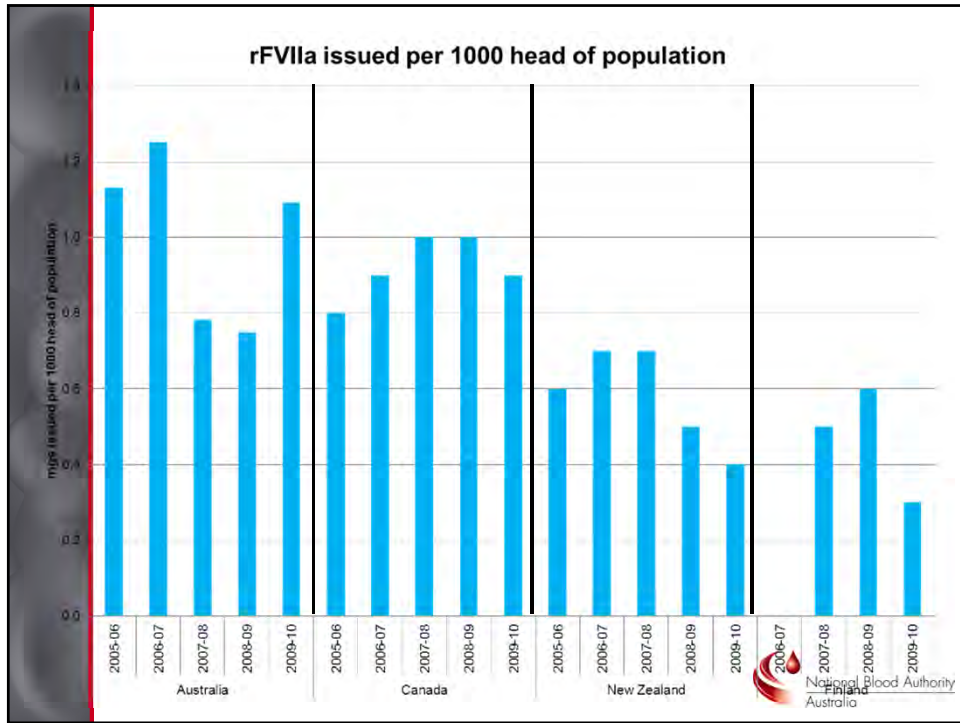
Treatment Usage Trends

Usage by population throughout the world*

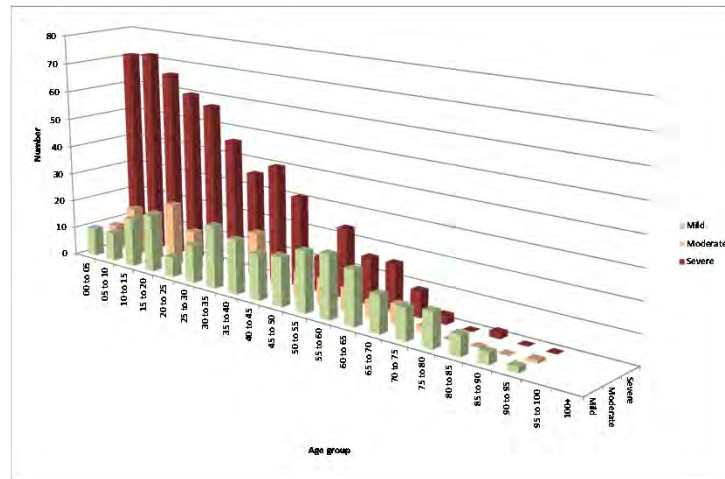
Total Factor VIII: IU ('000) per 1000 capita



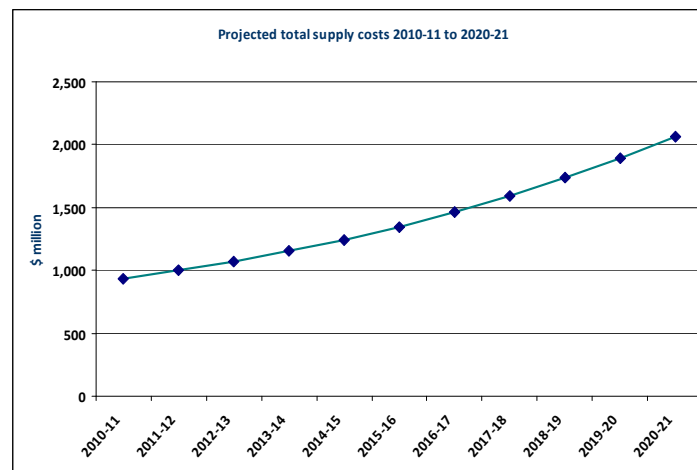
* Presentation to the NBA by Jan M. Bult President PPTA, Canberra, Nov 10 2008



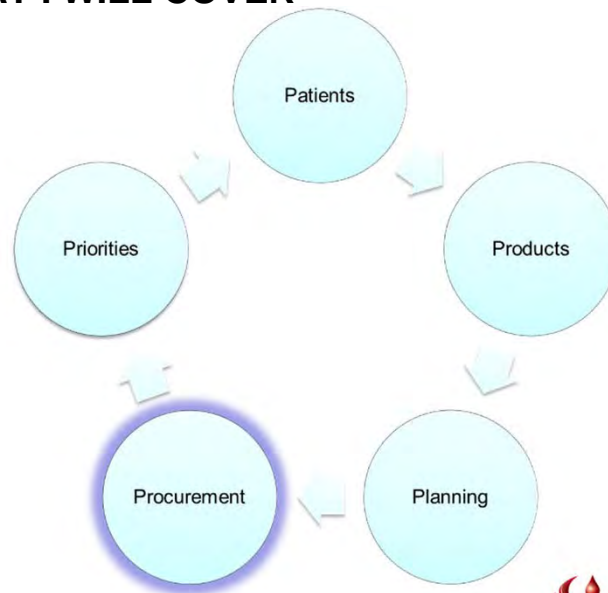
What will the demand be



Projected costs to 2020-21



WHAT I WILL COVER



2011 rFVIII

- 🔥 JBC meeting September 2010:
 - JBC determined a preference for two national suppliers of recombinant Factor VIII
 - provided other procurement goals are able to be met;
- 🔥 Process
 - Request for information
 - Round table
 - Tender release
 - Tender evaluation committee
 - Transition Consultation Group
- 🔥 Outcome announced on 6 June 2011:
 - Choice of two imported rFVIII products
 - Kogenate FS and Xyntha.

Improvements in contracts

In addition to benefits of current contracts:

- 💧 Substantial savings
- 💧 Home delivery standardised against AHCCO/AHNG guidelines
- 💧 Tightened performance requirements (delivery times, DIFOT, minimum shelf-life, reserve holding)
- 💧 Additional supply security through 3 months 'committed global stock'
- 💧 Improved definition of requirements for product support, and better delineation of role of supplier vis a vis clinicians and patients
- 💧 Specific requirements for customer feedback framework
- 💧 Commitment to supply chain and environmental sustainability initiatives
- 💧 Requirements to provide additional needles, pooling vials, etc clarified
- 💧 Specific requirements in the case of a product recall
- 💧 Removal of price confidentiality restrictions



Transition Principles

- 💧 Suppliers to provide detailed information, instruction materials and demonstration kits for these products.
- 💧 No direct contact with patient until authorised by HTC.
- 💧 Transition to occur at earliest convenient opportunity for the patient, clinician and HTC.
 - For most patients – within 6 months from 1 July 2011
 - Baxter product to remain available during this transition
 - No stockpiling
- 💧 Adverse events to be recorded and monitored closely
- 💧 Additional support to be provided to HTC's to assist in patient load – including where required, additional testing



2011/12 – IPRP New Products/Product update

🔴 Bayer:

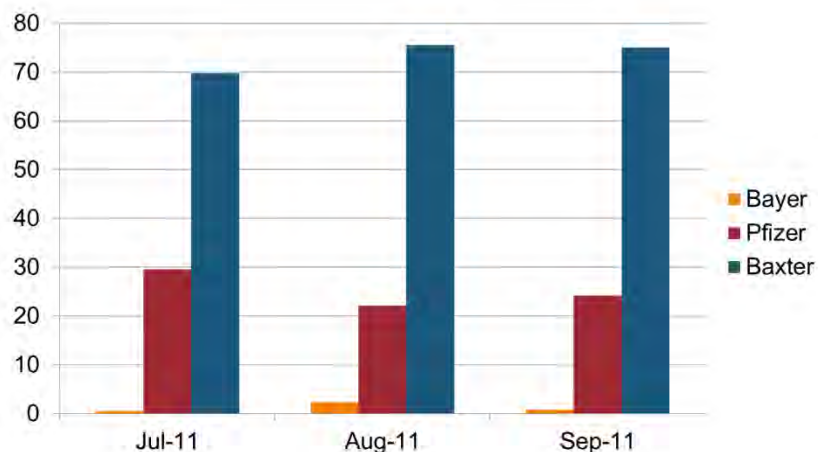
- 3000 IU Kogenate – TGA approval July 2011
- Storage for Kogenate – 6 months at 30 degrees
- “KOTWIST” reconstitution device for Kogenate – expected late in 2012 (submitting to TGA late 2011)

🔴 Pfizer:

- Xyntha “dual chamber” device TGA approval Sept 2011 / Schedule 4 application to be submitted
- iPhone application (launched September 2011)



STATUS 2011/12 rFVIII – Supplier Market Share (%)



🔴 **No evidence (from purchasing data) that transition is actually occurring**



Issues

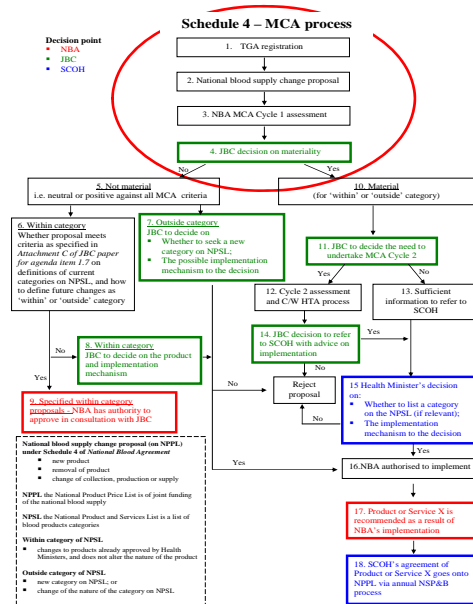
🔥 Aledort paper

- We do not consider this new or substantive evidence
- Outcomes heavily caveated
- Support for monitoring of impact
 - Will raise with governments if facts change

🔥 Baxter Request

- Will NOT be extending contract
- Is inconsistent with procurement policy
- No new evidence that this is justifiable

Flow chart of MCA process

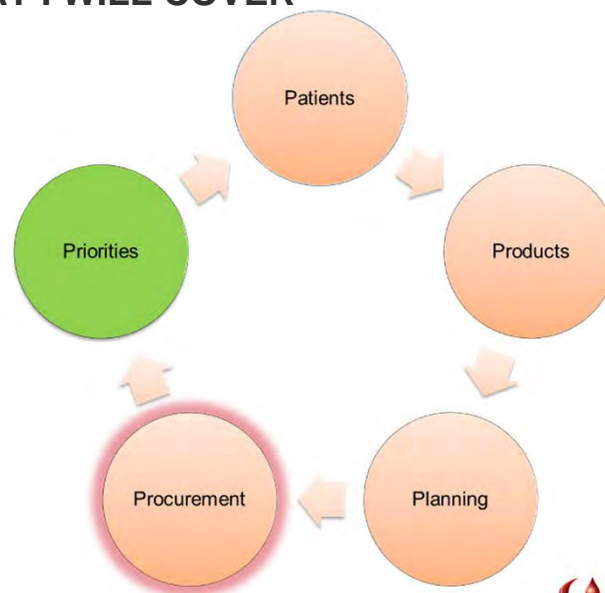


Cycle 1 Assessment Criteria

1. Security of Supply
2. Comparative Health Gain
3. Comparative Safety Gain
4. Comparative Cost-Effectiveness:
5. 5a. Financial Implications for the National Blood Budget
5b. Financial Implications for the Government Health Budgets
6. 6a. Self-Sufficiency – Reliance
6b. Self-Sufficiency – Efficiency of Domestic Production
7. Donations
8. Accessibility and Utility
9. Feasibility
10. Clinical Need
11. International Practice

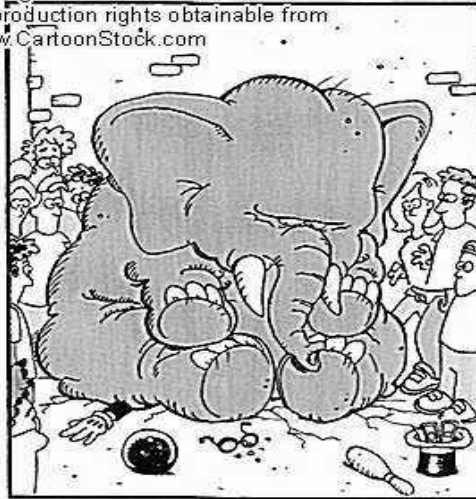


WHAT I WILL COVER



Priority One – Get the juggling act right

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To the horror of the bystanders,
The "Amazing Jimmy" miscalculates as he attempts
to juggle a pin, bowling ball, and an elephant.

 od Authority
Australia

Priority 2 – shared understanding about risks and benefits



 National Blood Authority
Australia

Priority 3 – Thoughts into action

- 🔴 Adverse Events
- 🔴 Genotyping / Immunogenicity
- 🔴 Cost effective prophylactic dose
- 🔴 Comprehensive Care treatment
- 🔴 Patient data recording
- 🔴 Compliance