ISBT KUALA LUMPUR - 2013

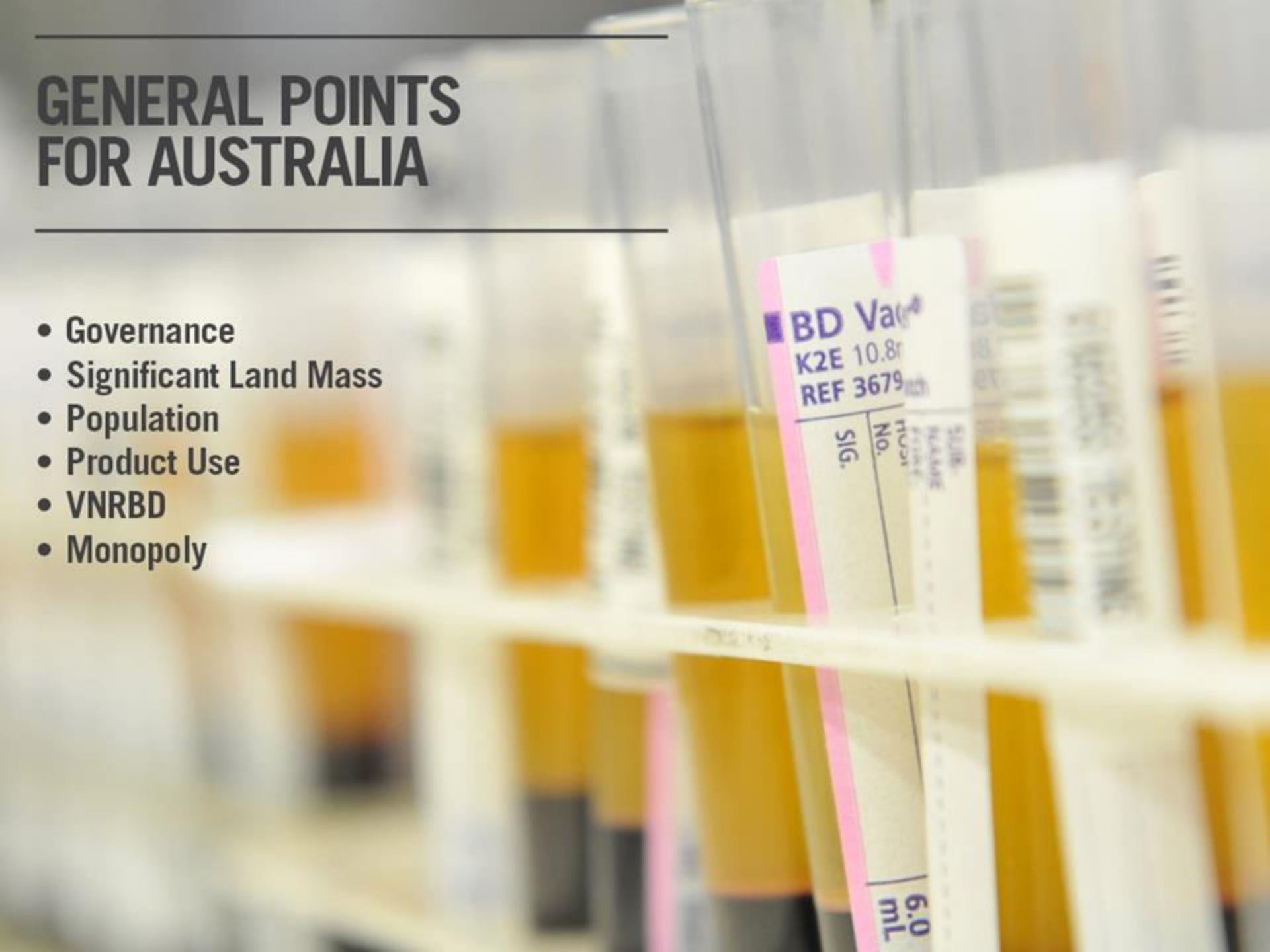
Meeting Clinical Demand - A perspective from Australia

Jacqui Caulfield, Executive Director of Manufacturing
Australian Red Cross Blood Service

Australian Red Cross
BLOOD SERVICE

GENERAL POINTS FOR AUSTRALIA

- Governance
- Significant Land Mass
- Population
- Product Use
- VNRBD
- Monopoly



GOVERNANCE

States and Territories / Commonwealth Governments

Australian Government
Department of Health and Ageing

the power of humanity
AUSTRALIAN RED CROSS

Standing Council on Health (SCoH)

Jurisdictional Blood Committee (JBC)
Membership comprise Commonwealth, State and Territory Ministers with responsibility for health matters

National Blood Authority (NBA)

NATIONAL BLOOD AUTHORITY AUSTRALIA

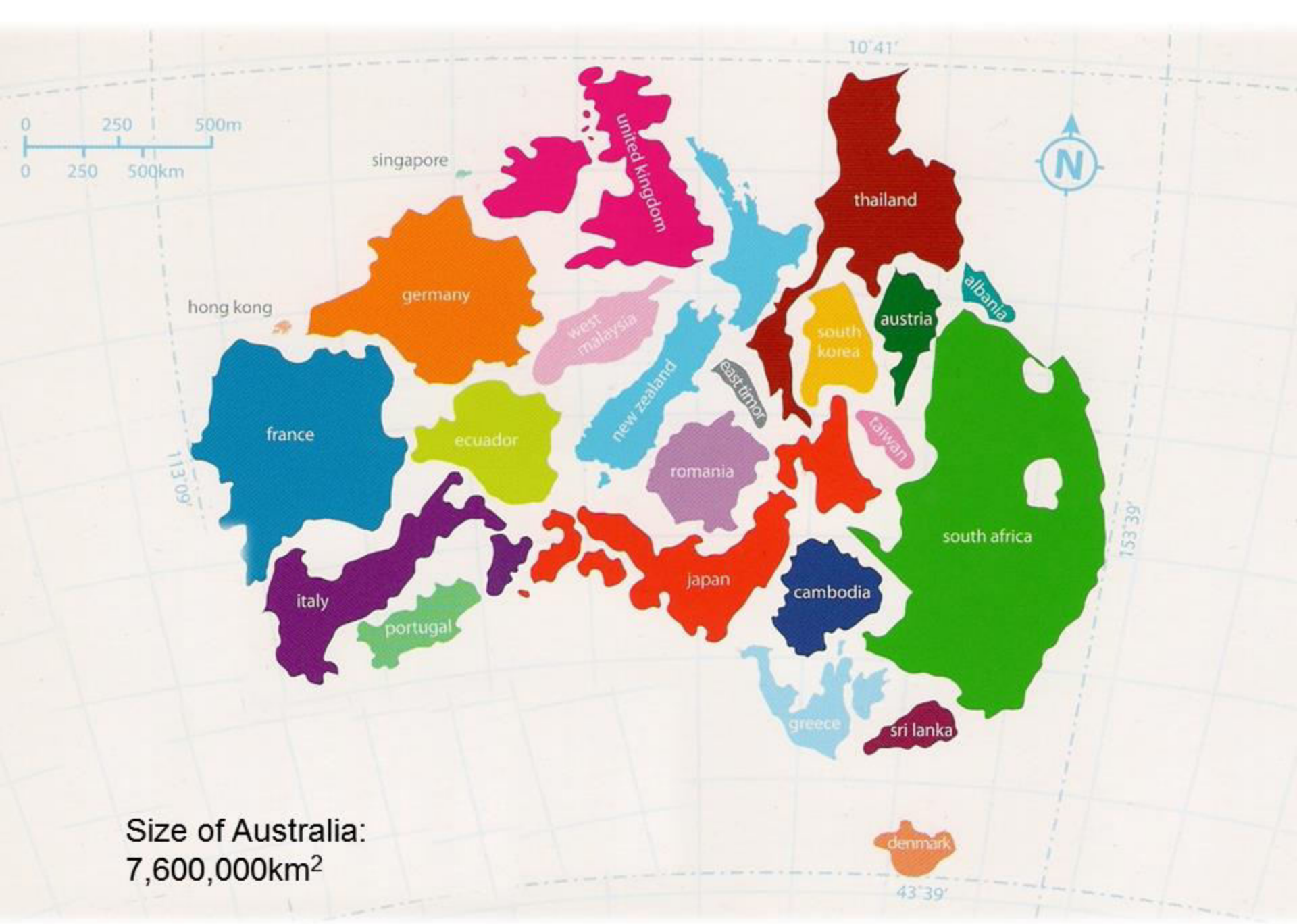
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Suppliers of blood and blood products

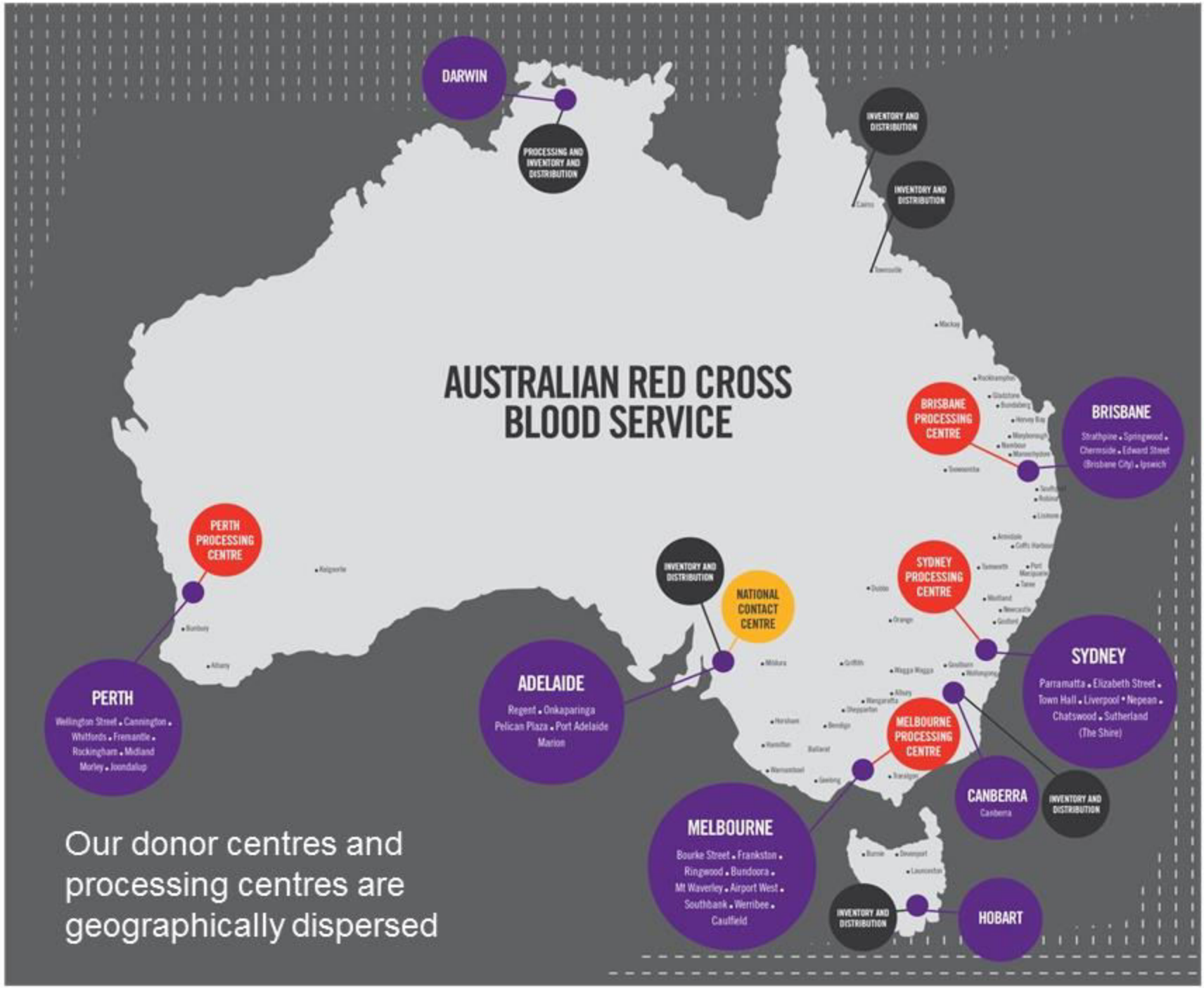
Australian Red Cross BLOOD SERVICE

Suppliers of blood and blood products

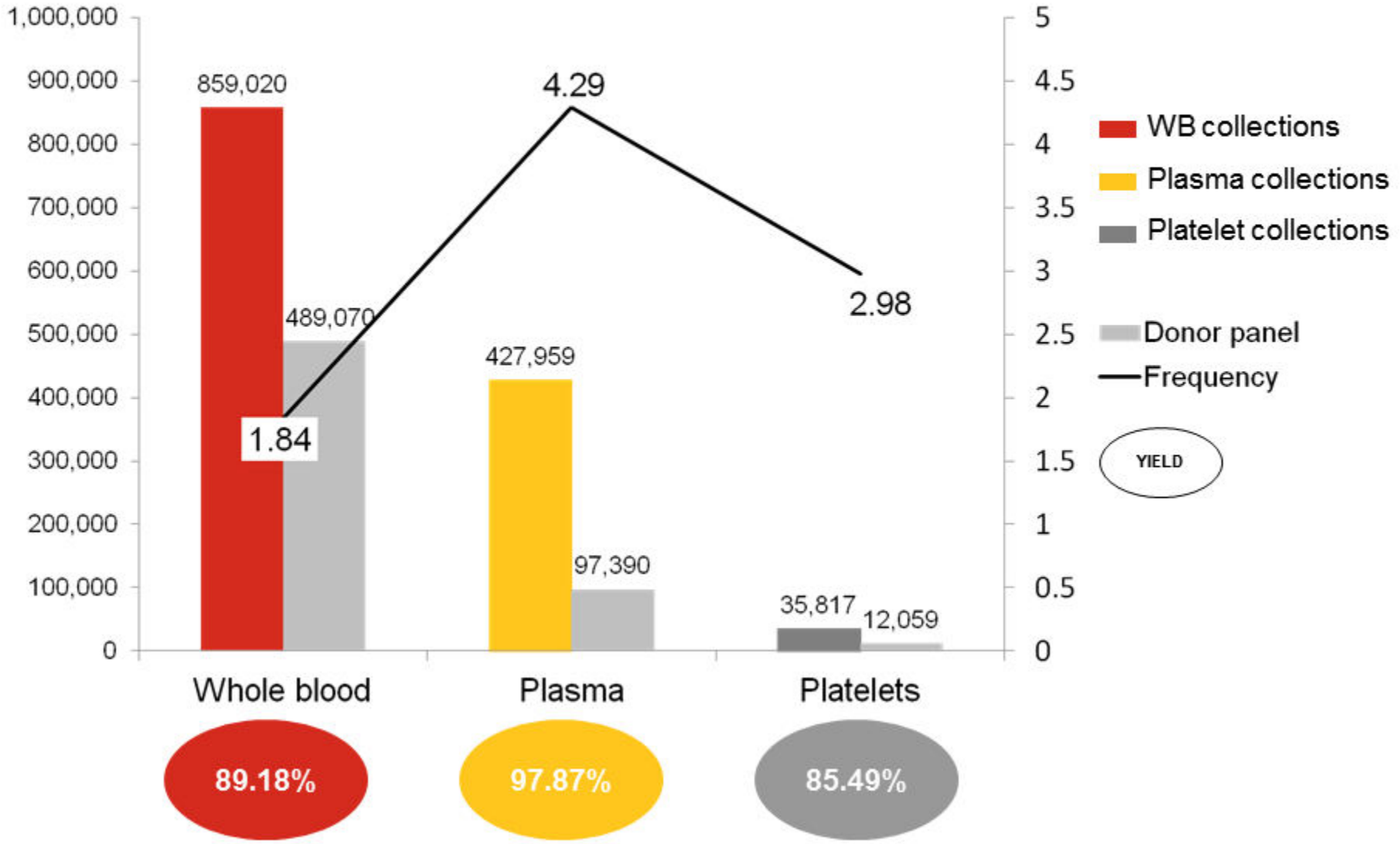
CSL
Pfizer
octapharma



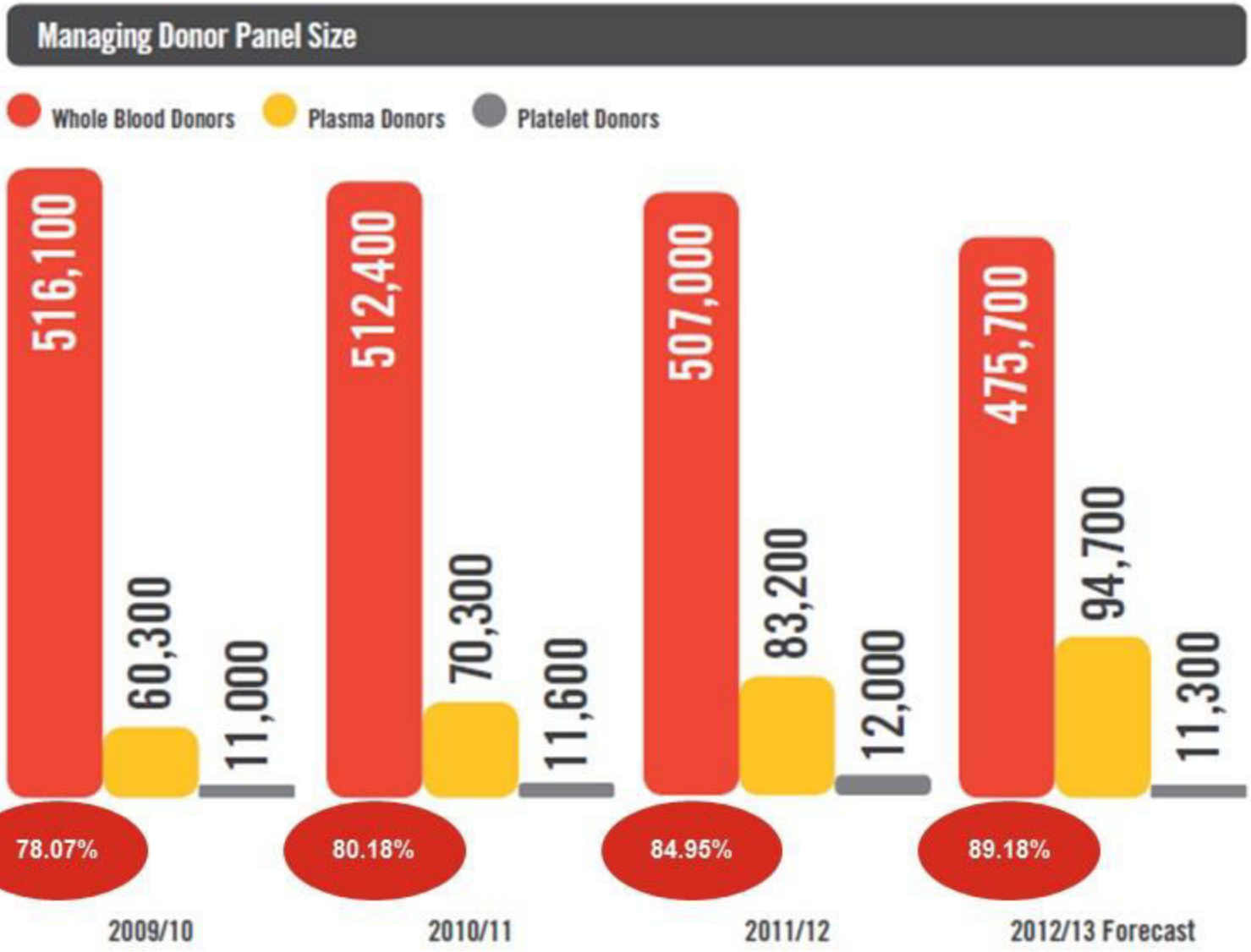
Size of Australia:
7,600,000km^2


AUSTRALIAN RED CROSS BLOOD SERVICE
DARWIN
PROCESSING AND INVENTORY AND DISTRIBUTION
INVENTORY AND DISTRIBUTION
INVENTORY AND DISTRIBUTION
BRISBANE PROCESSING CENTRE
BRISBANE
Strathpine • Springwood • Chermside • Edward Street (Brisbane City) • Ipswich
PERTH PROCESSING CENTRE
PERTH
Wellington Street • Cannington • Whitfords • Fremantle • Rockingham • Midland Morley • Joondalup
INVENTORY AND DISTRIBUTION
NATIONAL CONTACT CENTRE
ADELAIDE
Regent • Onkaparinga Pelican Plaza • Port Adelaide Marion
SYDNEY PROCESSING CENTRE
SYDNEY
Parramatta • Elizabeth Street • Town Hall • Liverpool • Nepean • Chatswood • Sutherland (The Shire)
MELBOURNE PROCESSING CENTRE
CANBERRA
Canberra
INVENTORY AND DISTRIBUTION
MELBOURNE
Bourke Street • Frankston • Ringwood • Bundoora • Mt Waverley • Airport West • Southbank • Werribee • Caulfield
INVENTORY AND DISTRIBUTION
HOBART
Our donor centres and processing centres are geographically dispersed

COLLECTION STATISTICS FY12/13

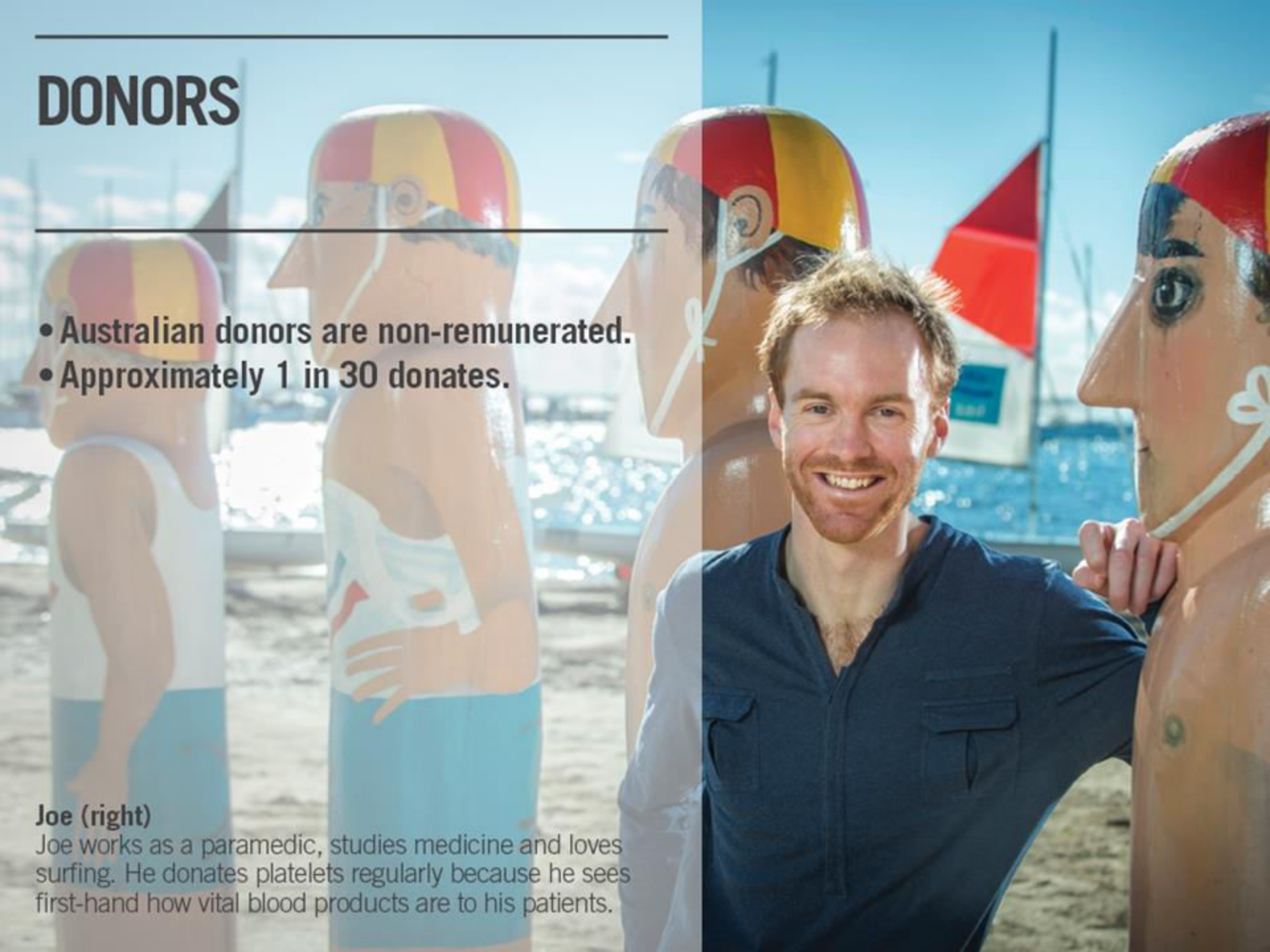


AUSTRALIAN DONOR PANELS



DONORS

- Australian donors are non-remunerated.
- Approximately 1 in 30 donates.



Joe (right)
Joe works as a paramedic, studies medicine and loves surfing. He donates platelets regularly because he sees first-hand how vital blood products are to his patients.

RED CELLS

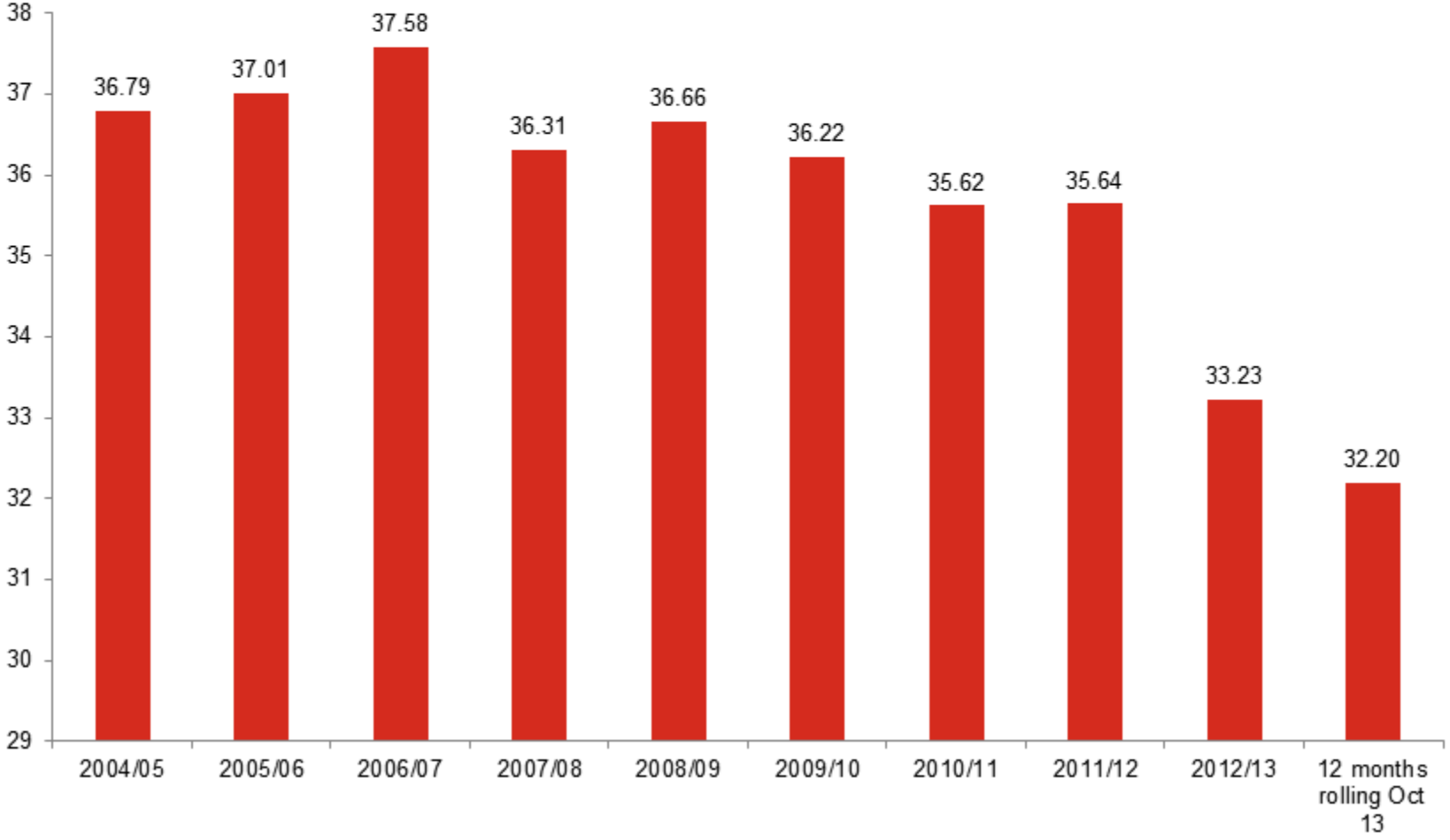
- Declining red cell demand
- ABO split and proportion of O NEG
- Effective donor management

RED CELLS

- Issued 769,822 red cells in 2012/13
- These were issued at a mean age of 9 days
- 82% of stock was issued less than 15 days from collection
- Unprecedented year of changing demand (prior average closer to 94% < 15 days)
- Proportion of O negative being issued is increasing

DEMAND FOR RED CELLS IS DECLINING

Red cells supplied per 1000 population, 2004/05 to October 2013

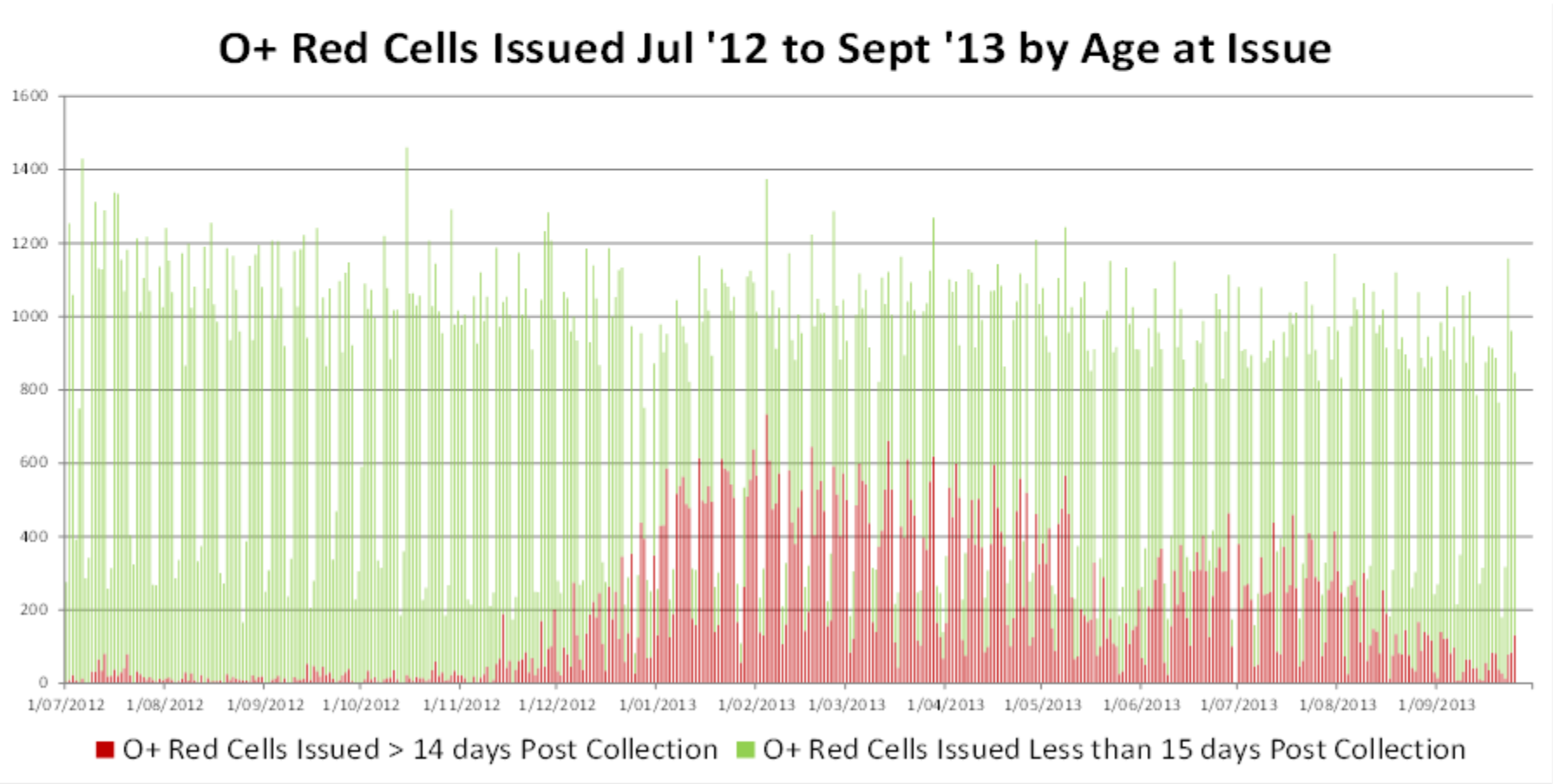


FACTORS DRIVING DECREASED DEMAND FOR RED CELLS

- Introduction of patient blood management strategies
- Focus on recycling activities designed to ensure unused products from regional and remote laboratories are returned to larger metro hubs with sufficient time for transfusion
- Roll-out of a common IT platform to all customers (hospitals and pathology laboratories) that track product fate.

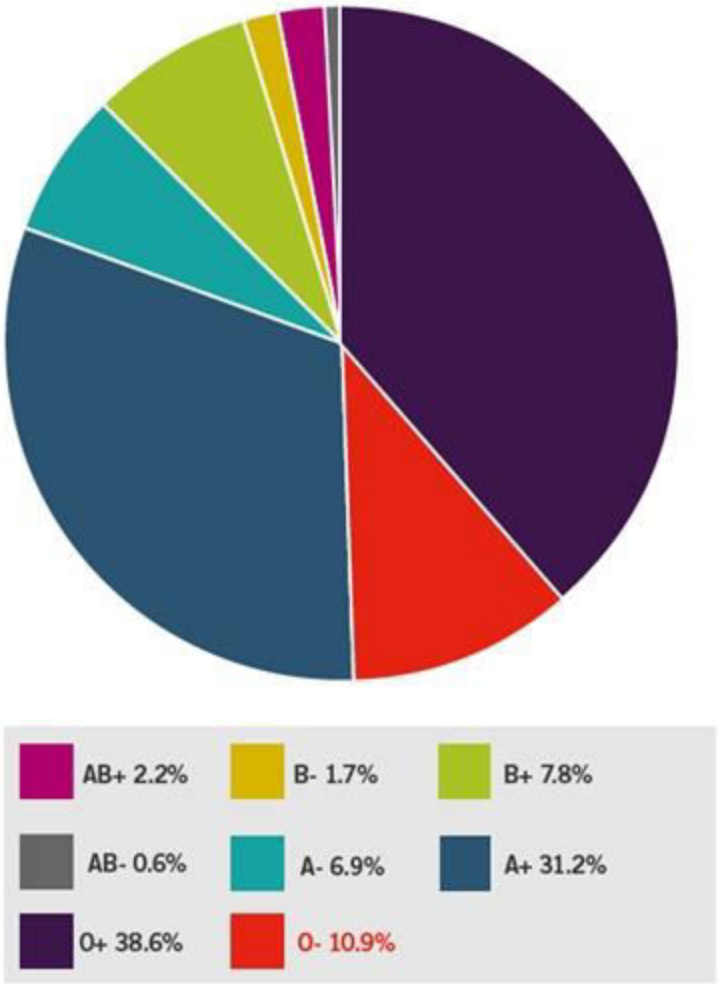
MEETING HEALTH PROVIDER EXPECTATIONS

Potential Reduction in Group O+ Inventory Relative to Red Cells Issues Over 14 Days

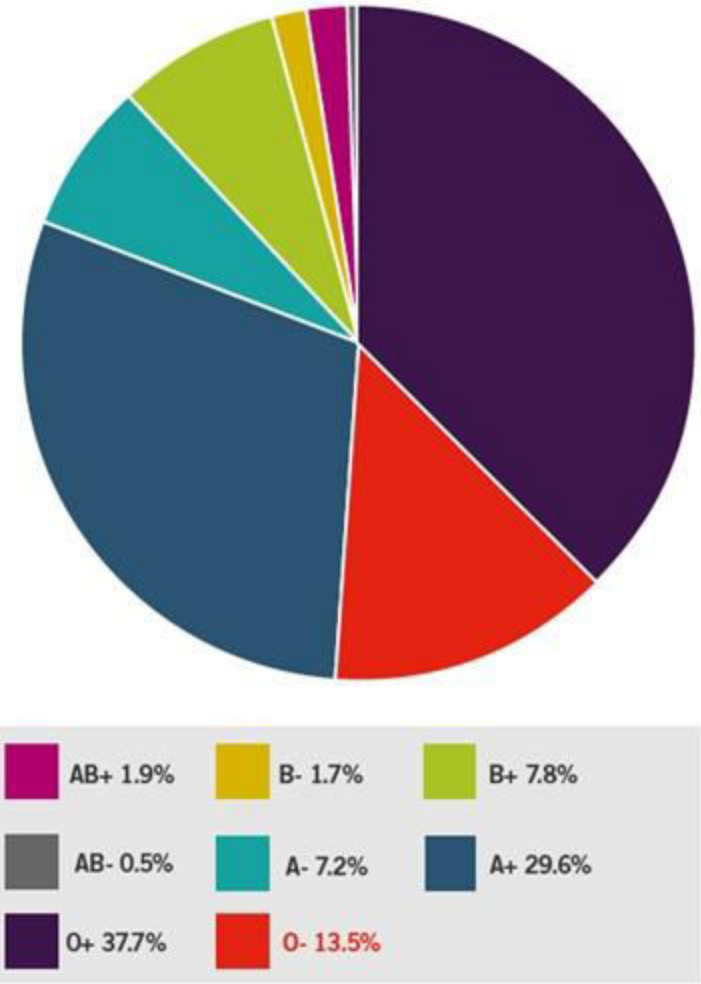


CHANGES IN ABO SPLITS

09-10 ABO Splits



13-14 ABO Splits



WEEKLY BALANCING OF DEMAND AND SUPPLY

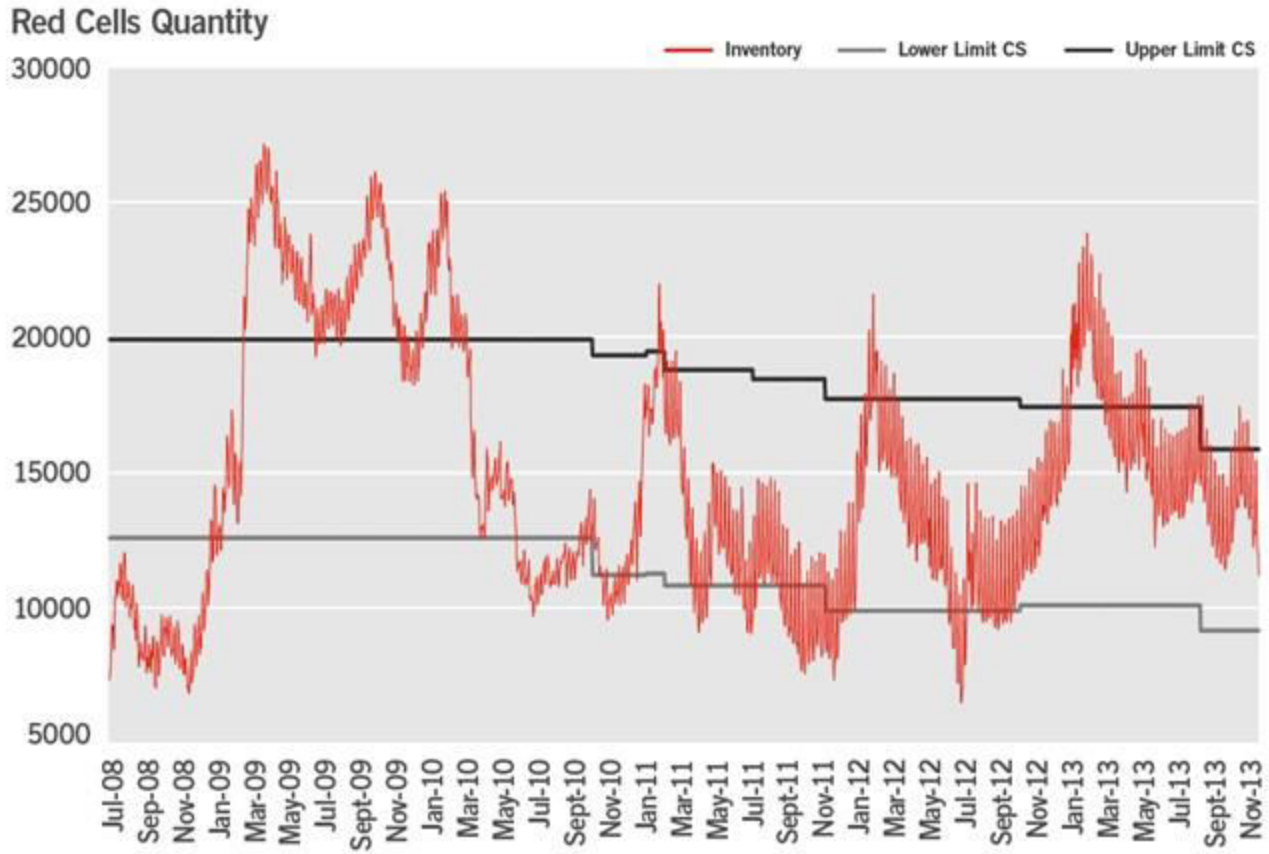
- The Blood Service has adopted the practice of locking the forecast within a 3 month window and refreshing 4-36 months within the S&OP planning cycle.
- The first 3 months are the “demand control period” and a number of tools are employed to manage the balance of supply and demand within this period, including:
  - Issuing daily collection targets to donor centres
  - Daily tracking of product issue and collections
  - Daily inventory reporting, covering both Blood Service inventory and that held with customers
  - Tracking of inventory against upper and lower inventory sufficiency bands for each blood type.

INVENTORY BANDS BY BLOOD TYPE

Inventory bands are based on a safety stock calculation that considers:

- Lead time (collection to inventory)
- Issues (customer demand)
- Supply (collections and production)

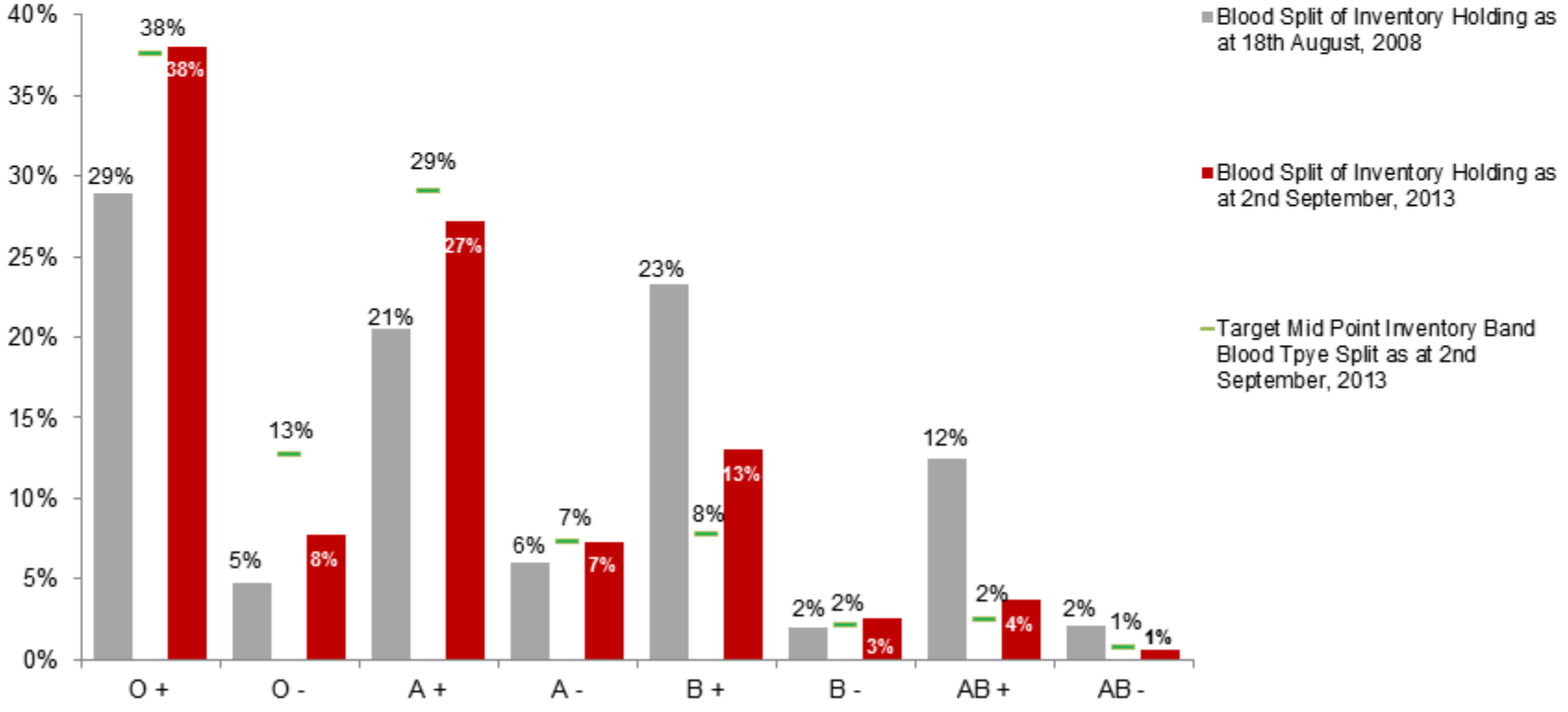
Blood Service Red Cell Inventory



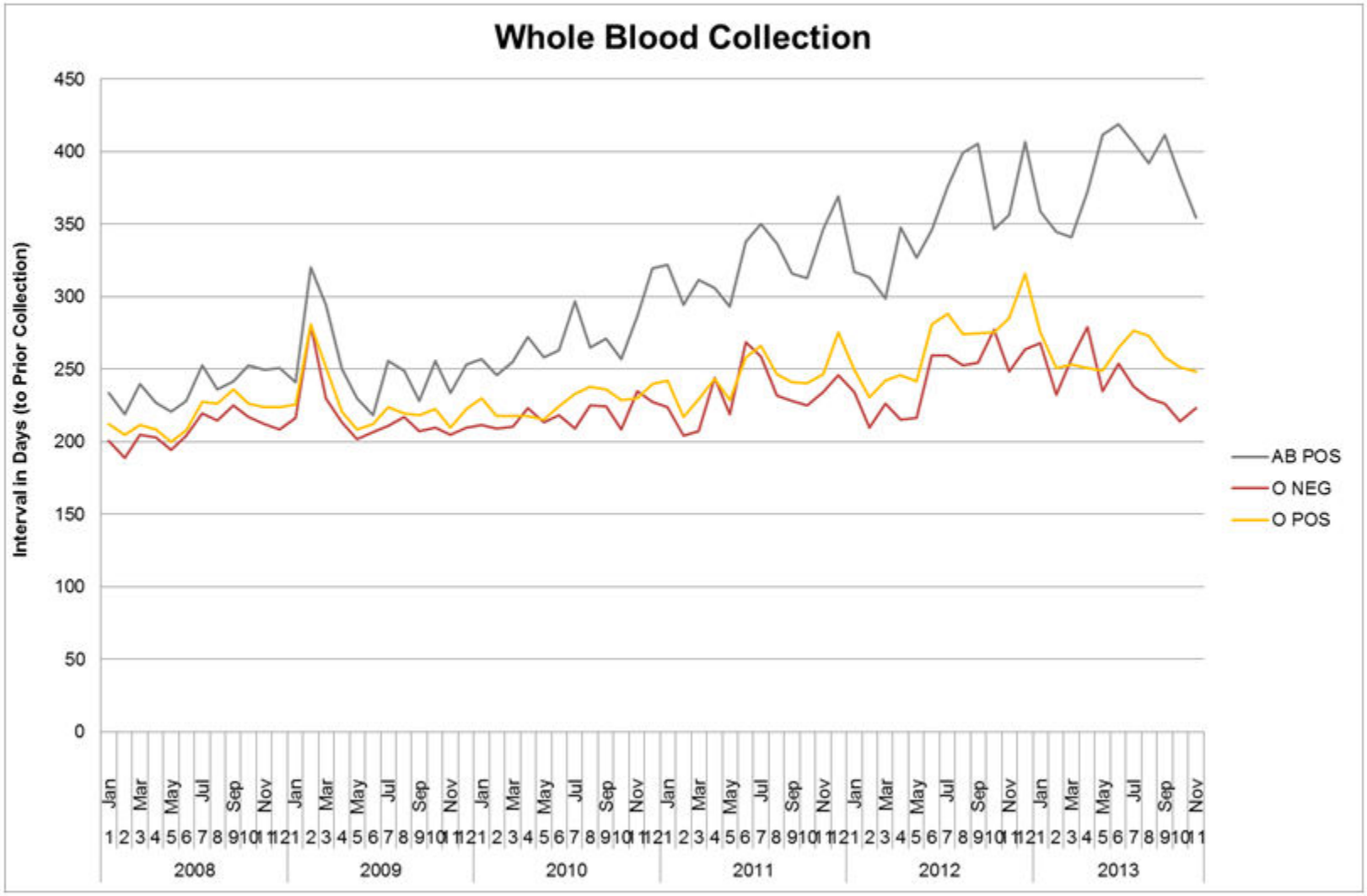
WEEKLY BALANCING OF DEMAND AND SUPPLY

- Australia is appointment driven
- The National Contact Centre make over 50% of all of the appointments per annum
- Activity is controlled through ABO / region specific call lists that are generated based on current inventory, future demand and forecast appointment levels
- Retention and frequency initiatives aim to further differentiate activity between donors of different blood groups

MEETING REQUIREMENTS BY BLOOD TYPE

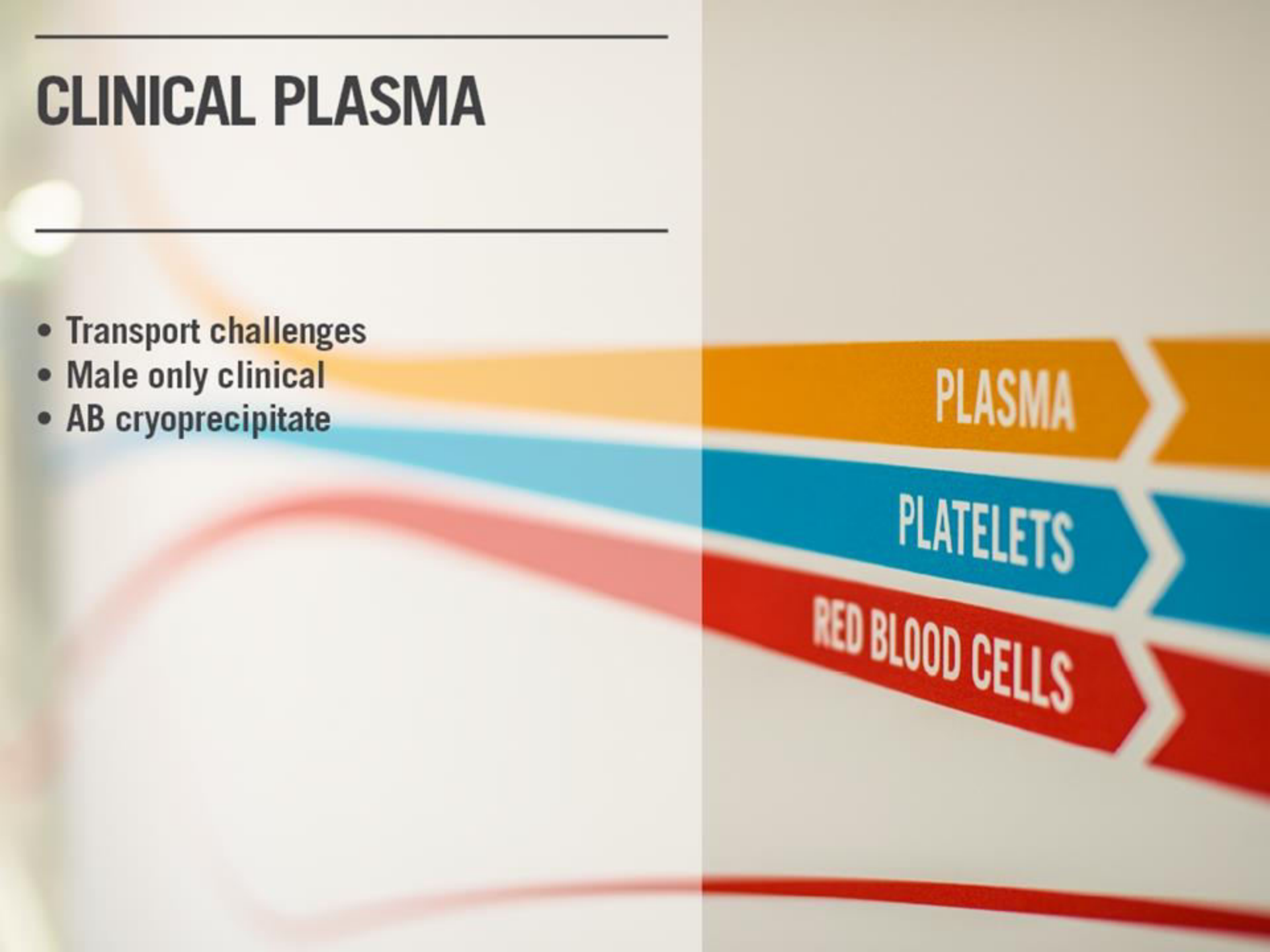


DIFFERENTIATION HAS BEEN POSSIBLE



CLINICAL PLASMA

- Transport challenges
- Male only clinical
- AB cryoprecipitate

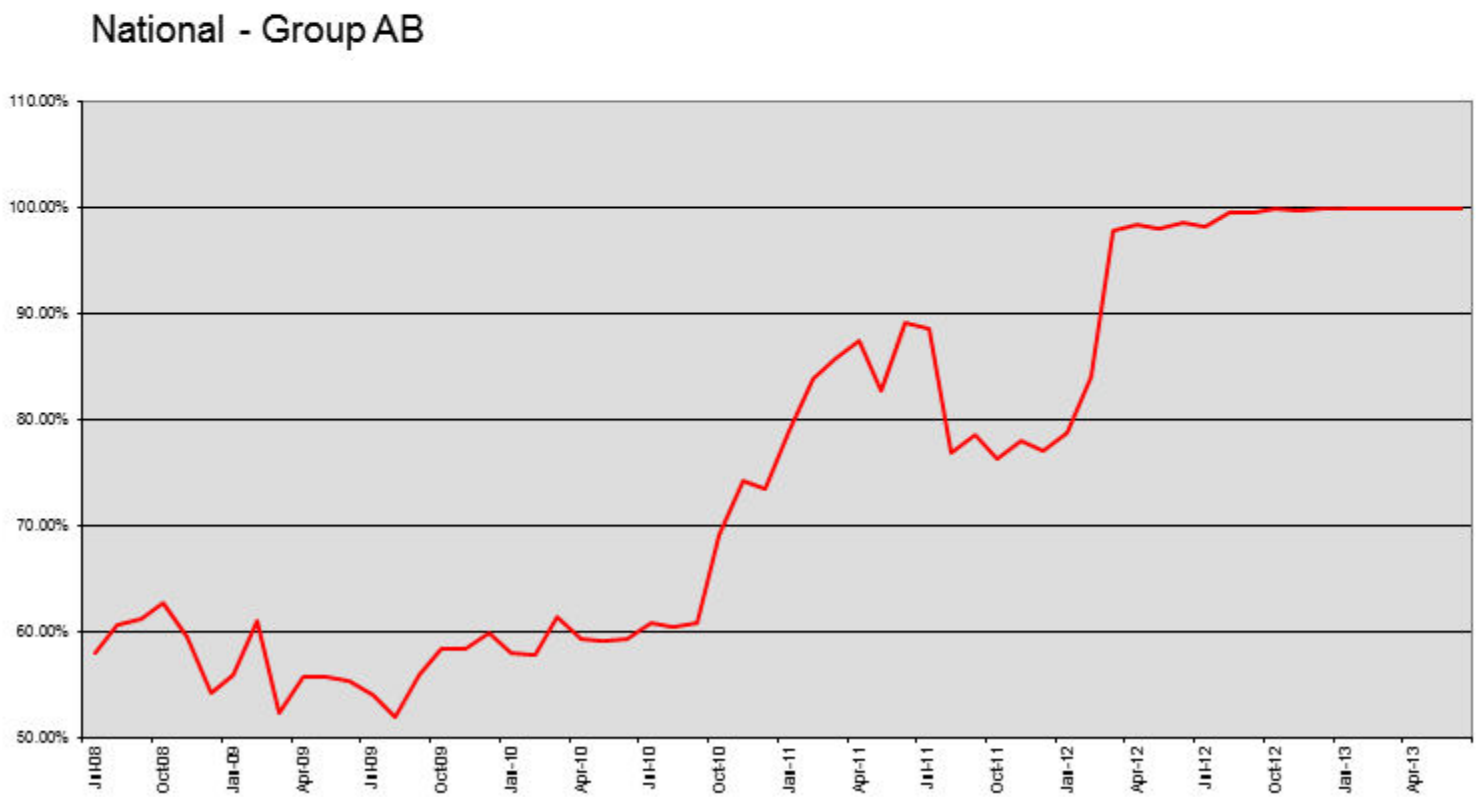


TRANSPORT

- Regulated to Council of Europe Guidelines:
  - 6hr collection to freeze requirement for apheresis clinical plasma
  - 18hr for whole blood
- Requires multiple pick-ups from donor centres during the day
- Priority manufacturing decisions are both system controlled and process driven

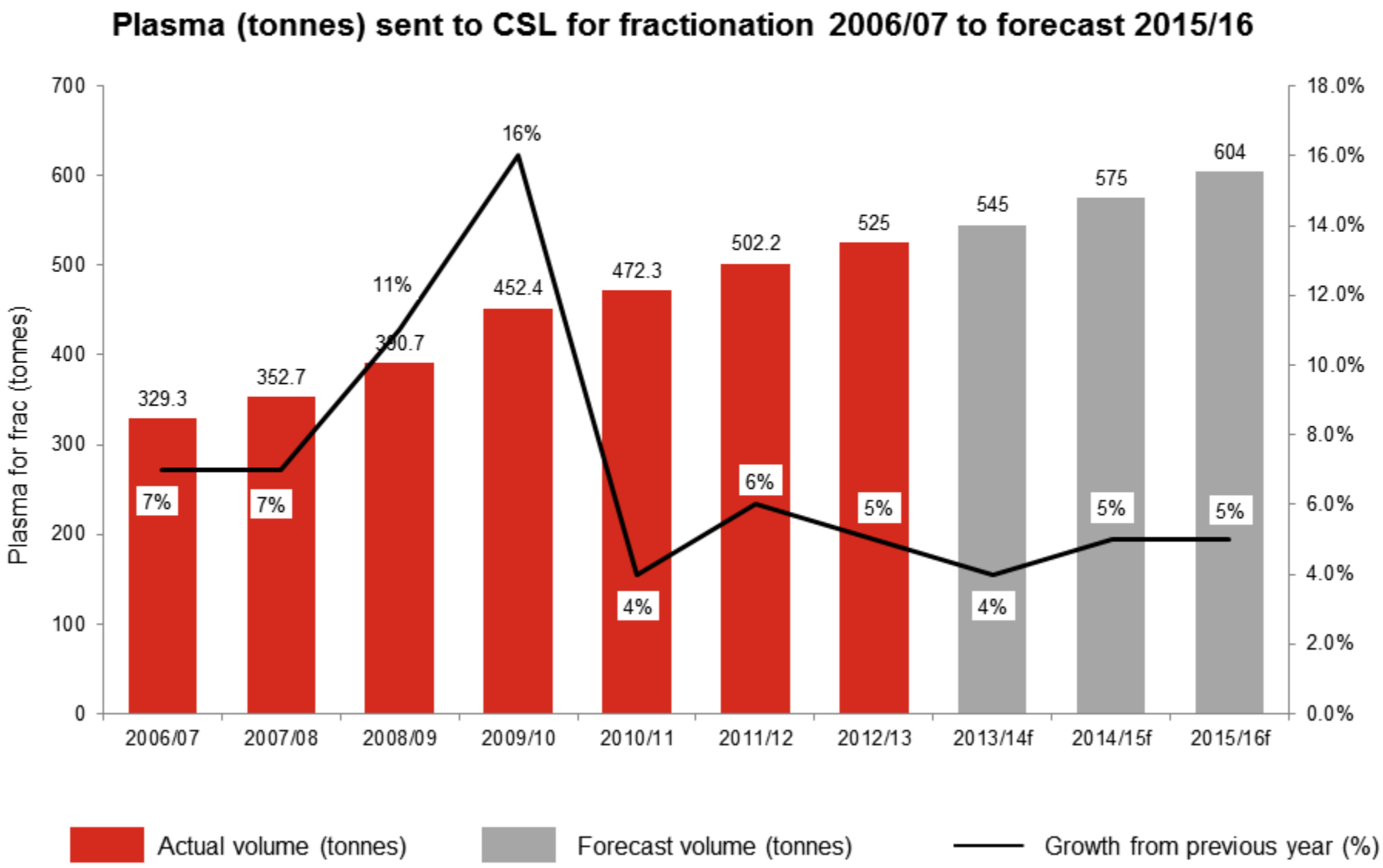
CLINICAL PLASMA

- Male only to mitigate Transfusion Related Acute Lung Injury (TRALI)



PLASMA FOR FRACTIONATION

PLASMA


Plasma (tonnes) sent to CSL for fractionation 2006/07 to forecast 2015/16
Plasma for frac (tonnes)
700
600
500
400
300
200
100
0
18.0%
16.0%
14.0%
12.0%
10.0%
8.0%
6.0%
4.0%
2.0%
0.0%
329.3
352.7
390.7
452.4
472.3
502.2
525
545
575
604
7%
7%
11%
16%
4%
6%
5%
4%
5%
5%
2006/07
2007/08
2008/09
2009/10
2010/11
2011/12
2012/13
2013/14f
2014/15f
2015/16f
Actual volume (tonnes)
Forecast volume (tonnes)
Growth from previous year (%)

THANK YOU

ANY QUESTIONS?

Acknowledgement:
Australian governments fully fund the Blood Service to provide blood, blood products and services to the Australian community.

Donor selection for blood safety: is it still necessary?

Dr. C K Lin

Chief Executive and Medical Director

Hong Kong Red Cross Blood Transfusion Service

Blood Donor Selection

- Protect transfusion recipient by collecting blood from donors at no/low risk for any transfusion transmissible infection
- Protect donor by selecting suitable ones that are fit for blood donation
- Safeguard sufficiency of blood supply by deferring only those who are not suitable to donate

Donor Selection Process

- Pre-donation information
- Health history questionnaire filled by donors
- Confidential interview by trained personnel
- Physical examination

Donor Selection in Enhancing Blood Safety

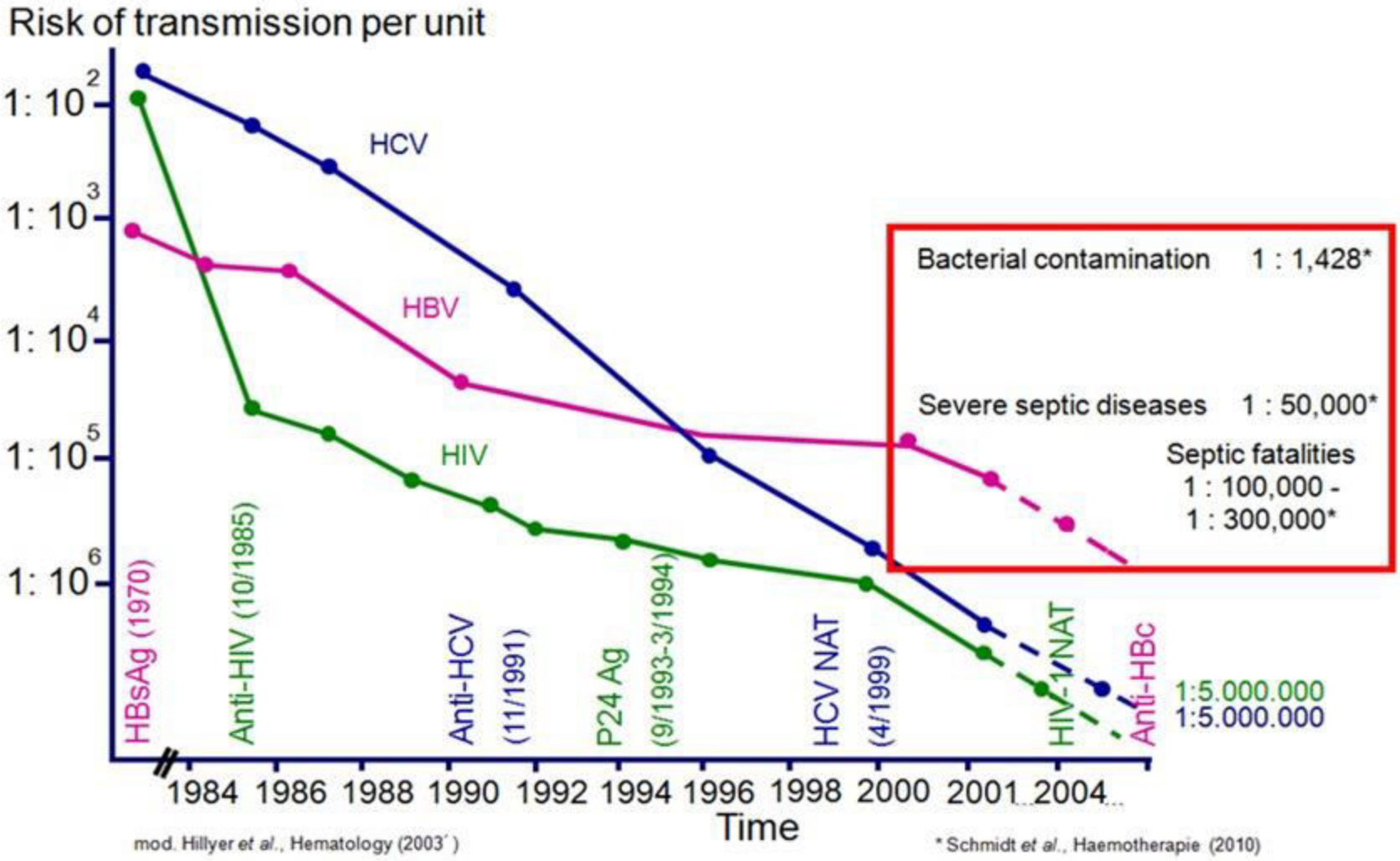
- To fill the gap due to limitations of laboratory testing technology, i.e. window period
- To cover emerging infections that are not routinely tested or have no suitable test available for screening
- To enhance cost-effectiveness of blood supply by screening donor through selection instead of donated blood by laboratory testing for non-endemic or imported infection

Infectious markers screening

HIV-1 & HIV-2	• a combination of HIV antigen-antibody or HIV antibodies
Hepatitis B	• hepatitis B surface antigen (HBsAg)
Hepatitis C	• combination of HCV antigen-antibody or HCV antibodies
Syphilis (Treponema pallidum)	• specific treponemal antibodies

WHO: Screening donated blood for transfusion-transmissible infections. 2010

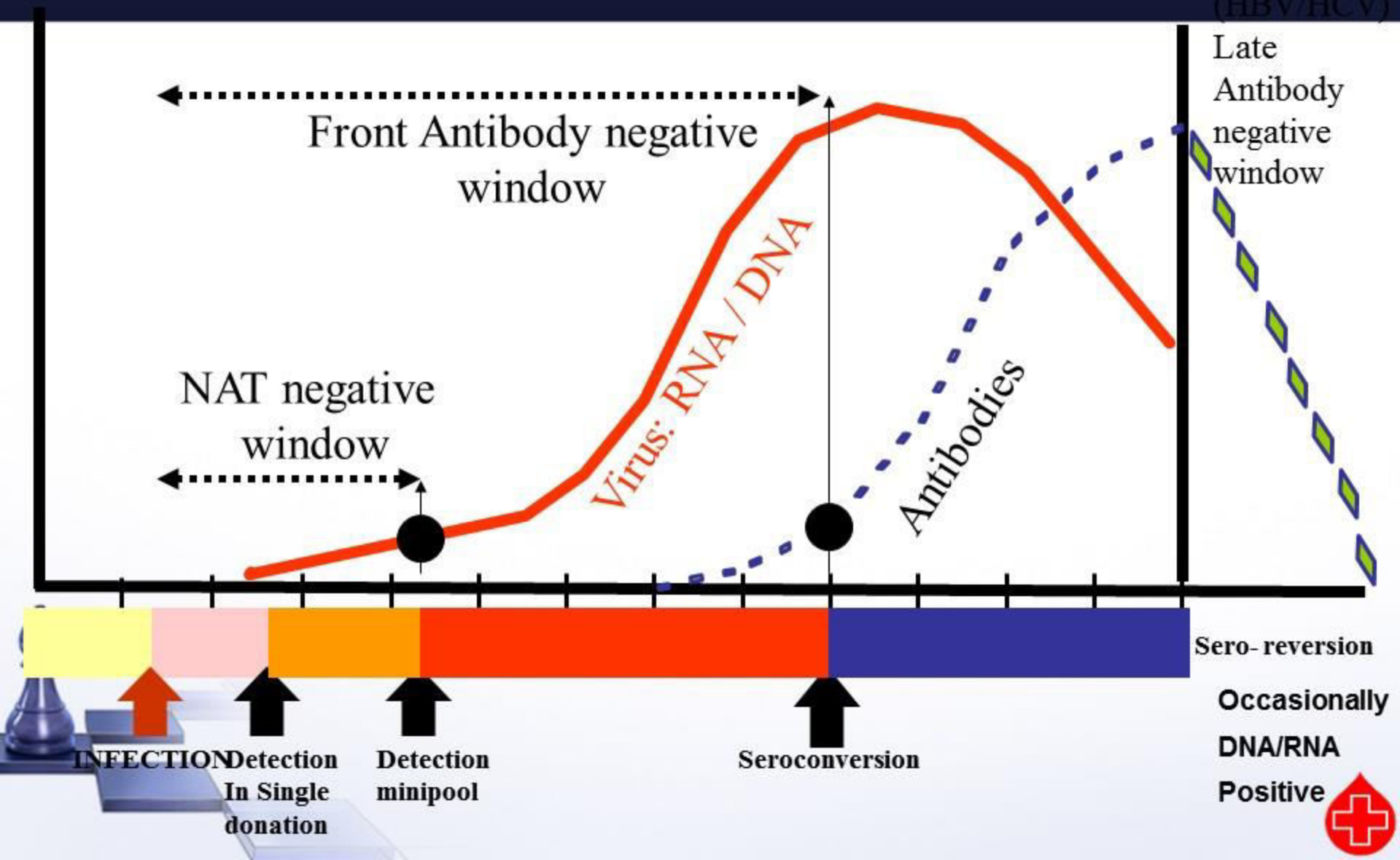
Risk of Infection Transmission



Residual Risks of HIV, HCV and HBV

Infection	Current estimation	Estimate of residual risk with tested blood per unit 2007-09
HIV	Approximately 1 in 5.7 mn	Approximately 1 in 2.4 mn
HCV	Approximately 1 in 26 mn	Approximately 1 in 8 mn
HBV	Approximately 1 in 55,000	Approximately 1 in 58,000

Window Period of TTI



Window Period of TTI

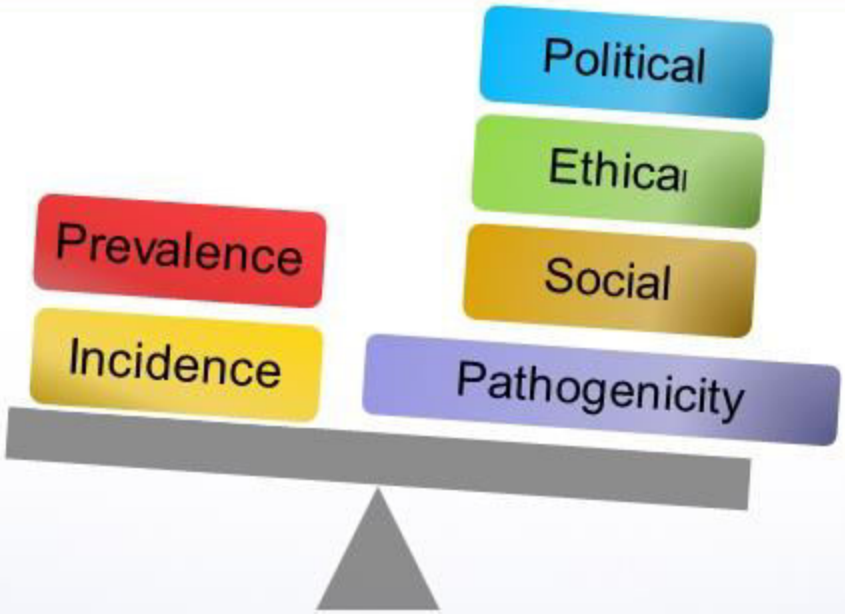
Infection	Window (days)	
	Serology	NAT
HIV	22	5.5
HCV	82	4.9
HBV	59	20.6

Other Transfusion Transmissible Infection

- Other known TTI
  - Bacterial
  - Protozoan, e.g Malaria, Chagas
  - Viral, e.g. dengue, WNV, parvovirus B19
  - Prion
- Unknown emerging infection
  - HIV in 1980s
  - Outbreak may be explosive & worldwide, e.g. SARS coronavirus started in Southern China in 2003

Testing Strategy for Donated Blood

Cost-effectiveness and other considerations in deciding testing strategies



Selection based on Donor's Medical History

Minor illness

Non-communicable diseases

- Haematological disorders
- Cardiovascular diseases, including hypertension
- Gastrointestinal diseases
- Immunological diseases
- Respiratory diseases
- Metabolic and endocrine diseases
- Musculoskeletal diseases

Non-communicable diseases

- Skin diseases
- Central nervous system diseases
- Renal diseases
- Malignant disease
- Psychiatric disorders

Selection based on Donor's Medical History

- Transfusion-transmissible infections
  - Viruses
  - Bacteria
  - Rickettsia
  - Protozoa
- Medical and surgical interventions
  - Immunizations
  - Medications
  - Blood transfusion, organ and tissue transplantation
- Surgical procedures including dental treatment
- Diagnostic procedures
- Alternative, complementary and traditional medicine

Selection based on Donor's Occupation and Lifestyle

- Country of residence and travel history
- Occupation and leisure activities
  - Donor risks
  - Blood safety risks
- High risk behaviour
  - High risk sexual behaviours
  - Use of recreational drugs
  - Incarceration in prisons and penal institutions
- Cosmetic treatments and rituals

Is Donor Selection Still Necessary?

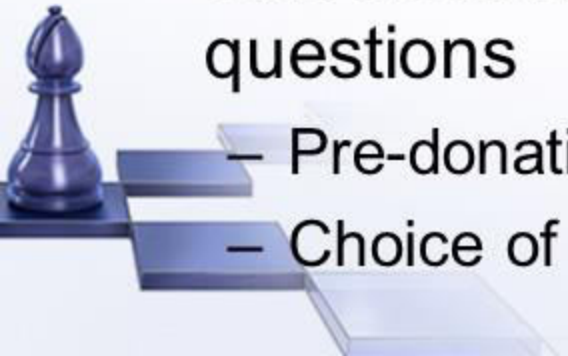
YES!

But there are critical issues we need to address

Donor Compliance

Effectiveness of donor selection critically depends on compliance of donors to the questionnaire

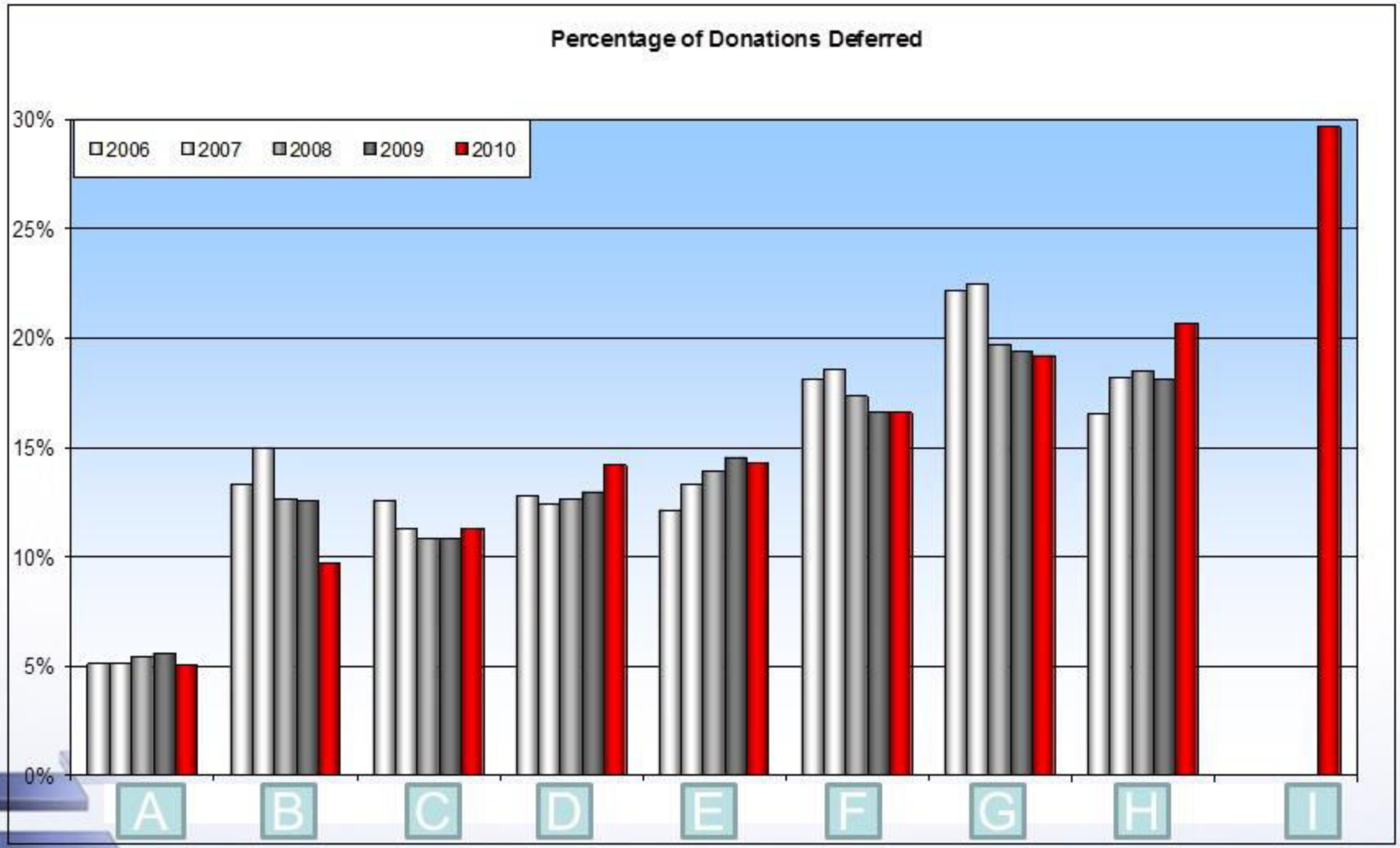
- Feel comfortable to disclose sensitive personal information
  - Protection of donors' privacy
  - Skill of staff conducting the confidential interview
  - Management of deferral and counselling
- Understand the background rationale of questions
  - Pre-donation information and education
  - Choice of questions and their wordings



Donor Wastage

- Selection causes lost in blood donors and can potentially result in inadequate blood supply
- Should aim effectively selecting suitable donors to give blood, not the safest
- Deferred donors should be properly counselled including information related to re-entry to minimize donor wastage

Donor Deferral



Deferral to Prevent One TTI is high

TTI	Deferrals to prevent one case (no.)
HBV	39,760
HCV	564,600
HIV	352,875
Syphilis	42,772

* De Kort et al., 2013

Risk and Evidence Based Questions and Selection Criteria

- What is the nature and size of the risk, e.g. tattoos, MSM?
- What is the prevalence / incidence of the risk?
- What is the validity of the laboratory test, the donor selection question and criteria?
- What is the overall cost-effectiveness?

* De Kort et al., 2013

WHO Recommendations

Good practice for donor selection

1

- National donor selection guidelines and criteria should be based on epidemiological and/or scientific evidence or, where evidence is limited or lacking, on best practices

2

- Donor acceptance and deferral policies for the prevention of TTI should be based on up-to-date information on the local epidemiology of infections, the markers screened for, the availability of suitable blood screening and confirmatory assays, and the technologies in use

World Health Organization

Blood donor selection. Guidelines on assessing donor suitability for blood donation. 2012

Good practice for donor selection

3

- National donor selection criteria should defined conditions of acceptance and deferral for each criterion

4

- Adequate resources, including a sufficient number of qualified and trained staff, should be made available for the consistent and reliable assessment of donor suitability for blood donation

World Health Organization od donor selection. Guidelines on assessing donor suitability for blood donation. 2012

Good practice for donor selection

5

- Quality systems should be in place for blood donor selection, including selection criteria, staff training and documentation

6

- Blood transfusion services should establish mechanisms for monitoring and evaluation to assess the implementation and effectiveness of donor selection criteria

World Health Organization Blood donor selection. Guideline on assessing donor suitability for blood donation. 2012

Conclusion

- Blood donor selection is still necessary for protecting donors, recipients and blood supply
- For effective prevention of TTIs, it should be based on up-to-date information and evidence on the local epidemiology, the availability of suitable blood screening and confirmatory assays, and the technologies in use
- Donor compliance in providing truthful responses is critical
- Unnecessary deferral should be minimized

THANK YOU