Rh program in Australia

Dr Kobie von Wielligh
Transfusion Medicine Specialist
Lifeblood

Acknowledgement of Country

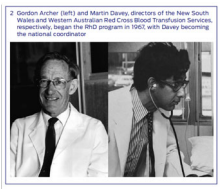
We acknowledge and pay our respects to the past, present and future Traditional Custodians and Elders of this land and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

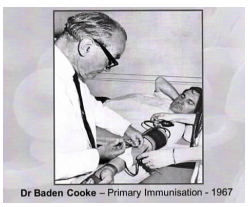
Outline of presentation

1. History of Rh program in Australia
2. Teams involved
3. How to identify suitable plasma donors
4. Red cell donors
5. Immunisation methods
6. Sustainability of program including ethics

Timeline Rh D Ig in Australia

- 1966 11th congress of ISBT in Sydney successful trials anti-D presented
- Sydney August 1967 Rh D program start Australia
- 1969 Self-sufficient post-partum 356 donors
- 1984 Decline in donor numbers, HIV crisis Test developed April 1985
- 1995-1997 shortages, Importing RhD Ig
- 1999 best practice antenatal prophylaxis @ 28 & 34 w 2002 staged implementation
- 2006 self-sufficient IM RhD Ig





Dr Baden Cooke – Primary Immunisation - 1967

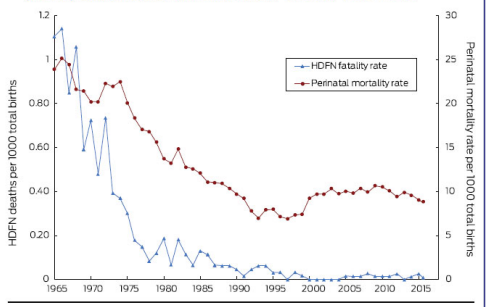
56 years of protecting babies

Rh Program:

- Ensures Australian supply of life-giving Anti-D immunoglobulin-protecting babies from RhD Haemolytic disease of the fetus and newborn (HDFN)
- Recruit donors for the collection of anti-D plasma
- Maintain current Rh Program plasma donor panel with periodic red cell infusions with accredited O positive red cells
- Monitor Anti-D antibody levels in plasma donors

Haemolytic Disease of the Fetus and Newborn

4 Rates of death from haemolytic disease of the fetus and newborn (HDFN) and perinatal mortality rate in Victoria, 1965–2016



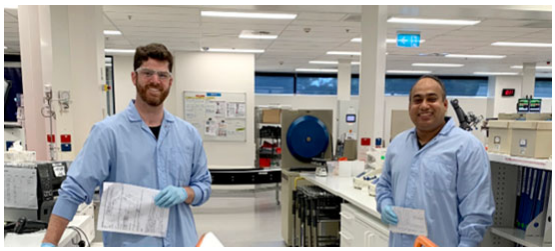
Source: Consultative Council on Obstetric and Paediatric Mortality and Morbidity.[5] The anti-D program with post-natal prophylaxis began in Australia in 1967, and intrauterine transfusion was also introduced. A staged implementation of antenatal, in addition to post-natal, prophylaxis occured from 2002 to 2006. ◆

Now very few deaths due to HDFN recorded in Australian health statistics.

Records from Victoria during the period 1965 to 2016 show that death from HDFN has declined from **1.1 per 1000 births** before the introduction of the RhD program (1967) and intrauterine transfusion to an average of **0.01 per 1000 births** since the year 2000.

Lifeblood Rh Teams

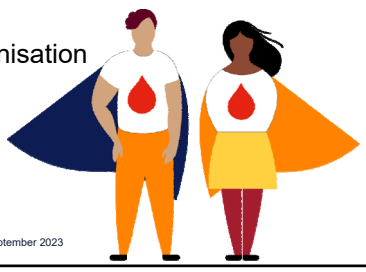
Many Business Units across Lifeblood contribute to the success of the Rh Program



Lifeblood Rh Program Donors

Rh negative donors are either:

- Pre-formed Anti-D antibodies due to allo-immunisation (rarer)
  - ❑ Pregnancy
  - ❑ Transfusion
- No Anti-D antibodies
  - ❑Require primary immunisation



Donor Selection Criteria

– And how do we find suitable donors

Who is eligible? –

- RhD Negative blood group
- Meet all donor eligibility criteria
- Commit to regular apheresis plasma donations
- Male
- Female > 50 years of age and postmenopausal >12 months post LMP, or any age post hysterectomy
- Health history (malignancies, allergies, medication)

Finding suitable donors

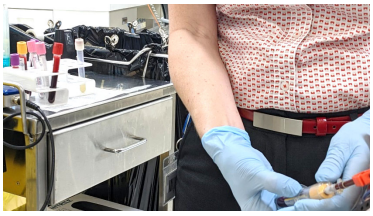
Finding suitable donors

- Lifeblood reports – donors with preformed Anti-D, frequent plasmapheresis donors within 30min of boosting centre, frequent plasma donors 30min-120min from boosting centre
- Donor Centre Staff
- Lifeblood Social Media
- Media Stories

Rh Program: Donor Interview

- Donors are interviewed on two separate occasions
- First Interview - Educating the donor about the Rh Program & getting to know the donor
  - Explain the purpose of the Rh Program – what is involved and answer any questions the donor might have
  - Provide the donor with written information to take away and consider
  - Inform them about red cells we use for infusion & the need to wear a medic alert bracelet
  - Potential Risk
    - (a) Transmission of infectious disease
    - (b) Reaction due to incompatibility between donor and red cells given
    - (c) Fever and allergic reaction
    - (d) Local effect on the infusion site
    - (e) Development of red cell antibodies and blood transfusion

Tests Pre-Infusion and 2nd Interview



Prior to Primary immunisation dose / First boosting dose

- Phenotyping on two separate donations
- EPG
- Archive Sample

Second Interview

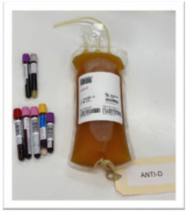
- Confirm donor's understanding of Rh Program – has discussed with family and GP?- and if donor decides to proceed – donor and Rh Program MO sign the consent form

Testing prior to each infusion: must be done within 3 months of a red cell infusion

- ABO/RH
- AB SCREEN
- AB IDENT
- D Quant
- Mandatory infectious disease screening, FBC, Igs, total protein

Follow up testing

Samples at 1, 2, 3- month testing
- AB screen
- AB IDENT
- Anti-D quant
- Mandatory infectious screening



6-month testing
- As above - in addition
- Total Protein, IgG, IgM, IgA, FBC

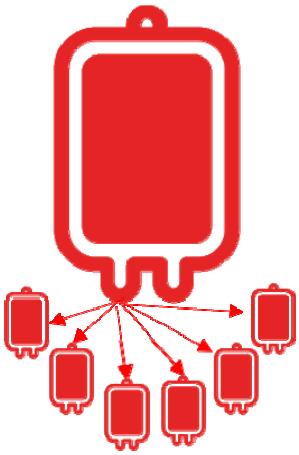
12 months for Primary immunisation donor without anti-D detected at 6-month testing
- AB screen
- AB IDENT
- Anti-D quant

Matching plasma donors with red cell donors

- Each plasma donor is matched with two red cell donors
  - Panel of red cell donors ~ 45 nationally
  - Donate every 3 months
  - Undergo additional testing to accredit frozen donations
- Need to be compatible with extended phenotype
  - Plasma donor may match only a few or all of cell donors available
  - Ensure no extra antibodies form

	C	D	E	c	e	C^w	K	k	Kp^a	M	S	s	Fy^a	Fy^b	Lu^a	Jk^a	Jk^b	Wr^a
Plasma donor	-	-	-	+	+	-	+	+	-	-	+	-	+	+	-	+	+	-
Cell donor	-	+	-	-	+	-	-	+	-	-	+	-	-	+	-	+	-	-

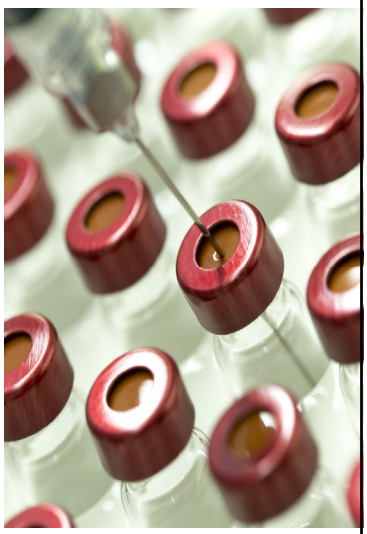
Accredited Red Cells



- Search required phenotype, test 2x
- Meet specific criteria to be red cell donor
- Only accredited donations used (after 12 months or more of testing at prescribed intervals)
- All mandatory infectious screen testing negative

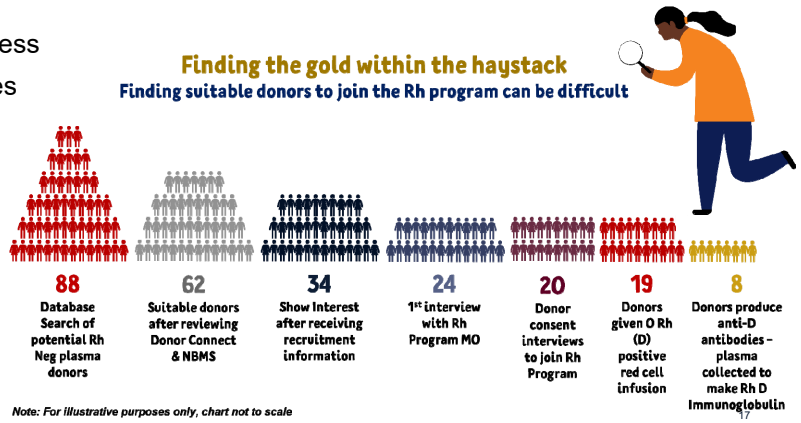
Primary immunisation

- Donor with no anti-D
- Consent to participate
- Primary immunisation 20-40mL packed red cells
- Standard minimum interval between infusions 3 months
- Subsequent primary immunisation dose 2.5-5.0 mL packed red cells
- Boosting dose 0.5-2.5mL packed red cells (for primary immunisation donors and pre-formed donors)
- Aim for anti-D level >45 IU/mL
- Maximum of 5 infusions within a 12-month period
- Only given to reach a personal peak antibody level
- Once peak is reached- boost ~ 6-monthly personalised to that donor
- If primary donor has not developed anti-D after 2 infusions- unlikely to occur subsequently



Challenges for the Rh Program

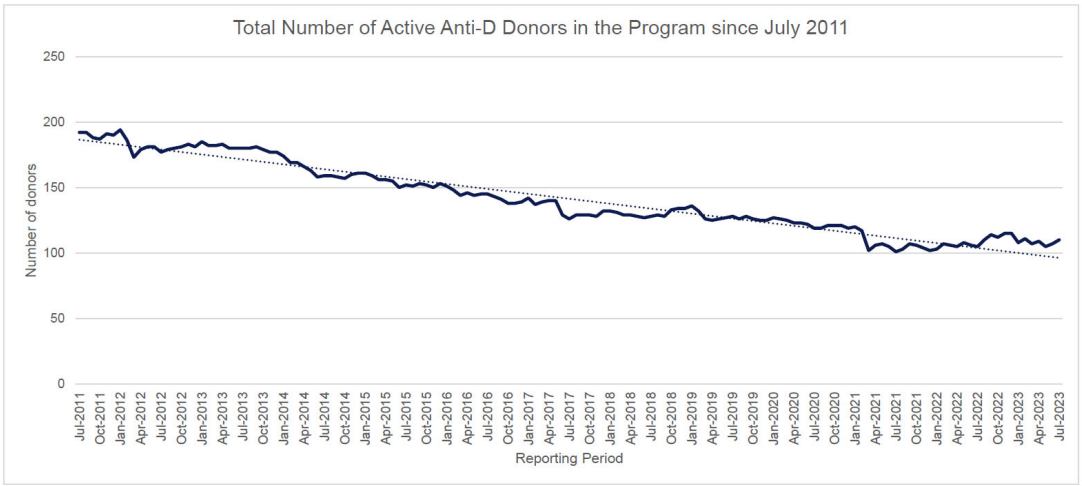
- Very few Pre-formed anti-D donors (meeting criteria)
- Selection criteria – small percentages of donors are suitable
- Ageing donor panel
- Lengthy boosting and testing process
- Distance of donors to boost centres
- ~50% seroconversion rate



Life-giving donations for life-changing outcomes.

Challenge | Anti-D Supply decline of donor

5.2. National summary of Rh Program active donors since July 2011



Ethics

Initial ethics was approved when the program started in Australia

Strong governance principals are applied

Primary immunisation only to meet the needs of the Australian population

Alternatives explored- NIPA and targeted prophylaxis may reduce the demand for RhD Ig by estimated 28% in Australia

- Rh program team
- Especially the following team members in assisting with preparation of this presentation
  - MO Clinical Lead-Dr Jackie Coughlin
  - Rh program coordinators lead-Jessie Wallis
  - RCRL- Rebecca Foulis, Tanya Powley
    - Dr Joanne Pink
- Amazing Rh program donors

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We're united through the power of humanity to build a healthier nation.

We are Australia's Lifeblood.