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2013 National Comparative Audit of Anti-D Ig Prophylaxis

M Rowley, T Davies, T Hawkins, J Hibbert and J Grant-Casey

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The National Comparative Audit Programme

- A series of audits designed to look at the use and administration of blood components & products
- Open to all NHS Trusts and Independent hospitals in the UK
- Collaborative programme between NHS Blood and Transplant & Royal College of Physicians
- Funded in England by NHS Blood and Transplant

Impact of anti-D immunoglobulin prophylaxis on neonatal deaths

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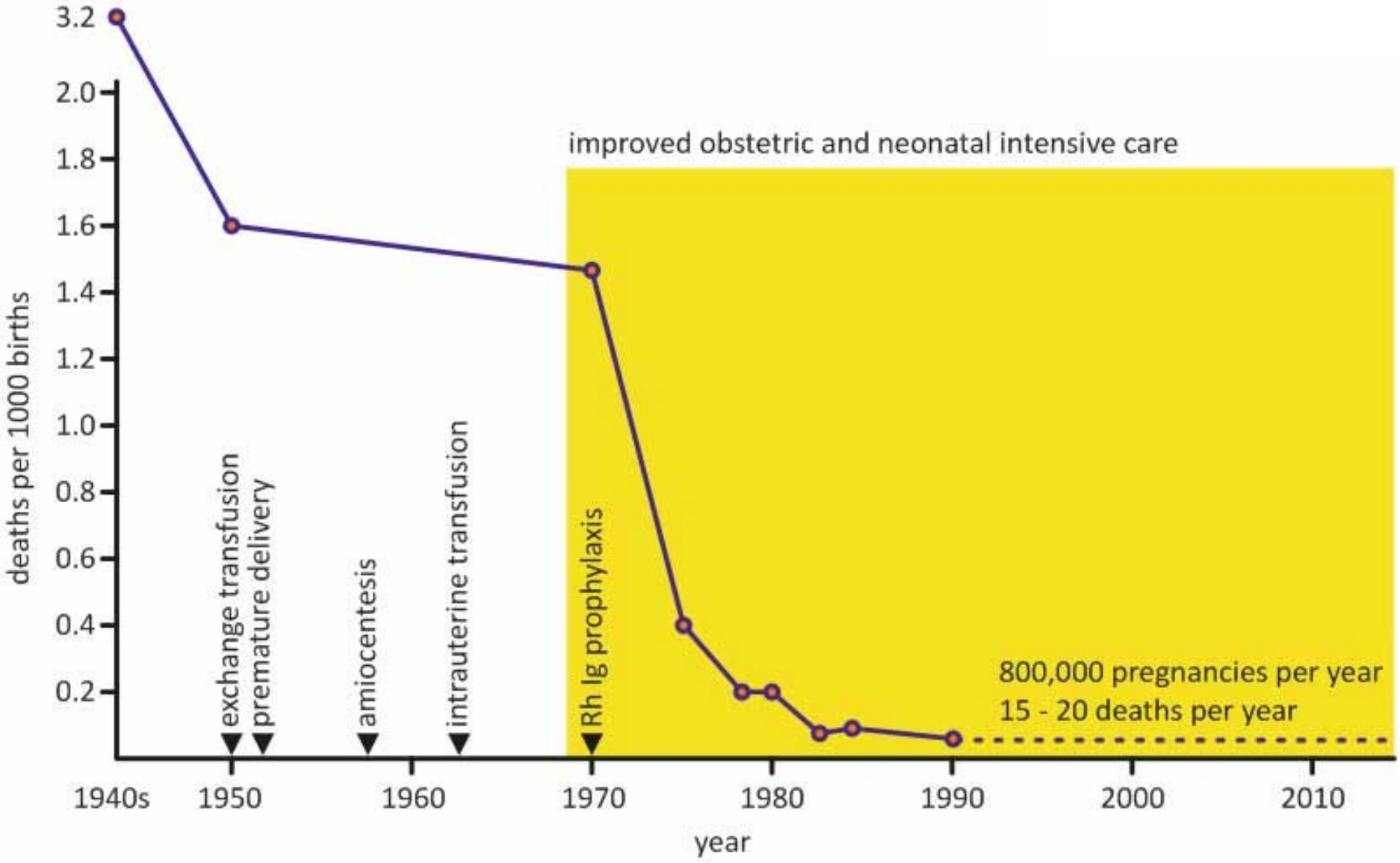

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Anti-D Immunoglobulin Prophylaxis

- Since 1969 post-delivery anti-D Ig injections given to RhD negative women have prevented haemolytic disease of the fetus and newborn due to immune anti-D
- Routine antenatal anti-D prophylaxis was recommended by NICE in 2002 and guidance was updated in 2008
- RhD alloimmunisation continues to occur and errors of anti-D Ig administration have been reported to SHOT

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Audit Aims and Methods

- Midwives and transfusion teams in participating UK hospitals audited the transfusion laboratory and maternity records of pregnant RhD-negative women during one month in 2013 against four audit standards based on UK guidelines* on anti-D Ig prophylaxis
- Cases identified at BOOKING (September 2012) and followed to DELIVERY (April/May 2013) and then data collected retrospectively from June to October 2013

*NICE, RCOG, BCSH guidelines

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Participation

161 sites (232 maternity units) participated in the audit

- 5972* clinical cases audited in one month of 'bookings'
- Median cases audited per site = 33 (IQR 19-49)

Annual deliveries for the participating sites

- Median annual deliveries = 4233 (IQR 2922-5765)
- Grand total annual deliveries = 607, 338
- Assumed 15% of pregnancies were to RhD negative women*

**Estimate* that 78% of eligible RhD negative deliveries were audited

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Anti-D Ig product and dose

What *product* is used for anti-D Ig prophylaxis?

Anti-D Ig products	BPL D-Gam	CSL Rhophylac
RAADP	41%	56%
Post delivery	68%	31%
PSE <20 weeks	86%	14%
PSE >20 weeks	69%	31%

What *dose* is used for anti-D Ig prophylaxis?

Dose anti-D Ig	250 IU	500 IU	1500 IU	Other
RAADP	-	3%	95%	2%
Post delivery	-	66%	33%	1%
PSE <20 weeks	71%	14%	13%	2%
PSE >20 weeks	(1%)	66%	32%	1%

Organisational questionnaire, 147 sites

HIGHER ANTI-D Ig DOSES THAN THE 'MINIMUM REQUIREMENT'

29% of maternity units use >250 IU for PSEs less than 20 weeks

32% of maternity units use >500 IU for PSEs after 20 weeks

33% of maternity units use >500 IU post delivery

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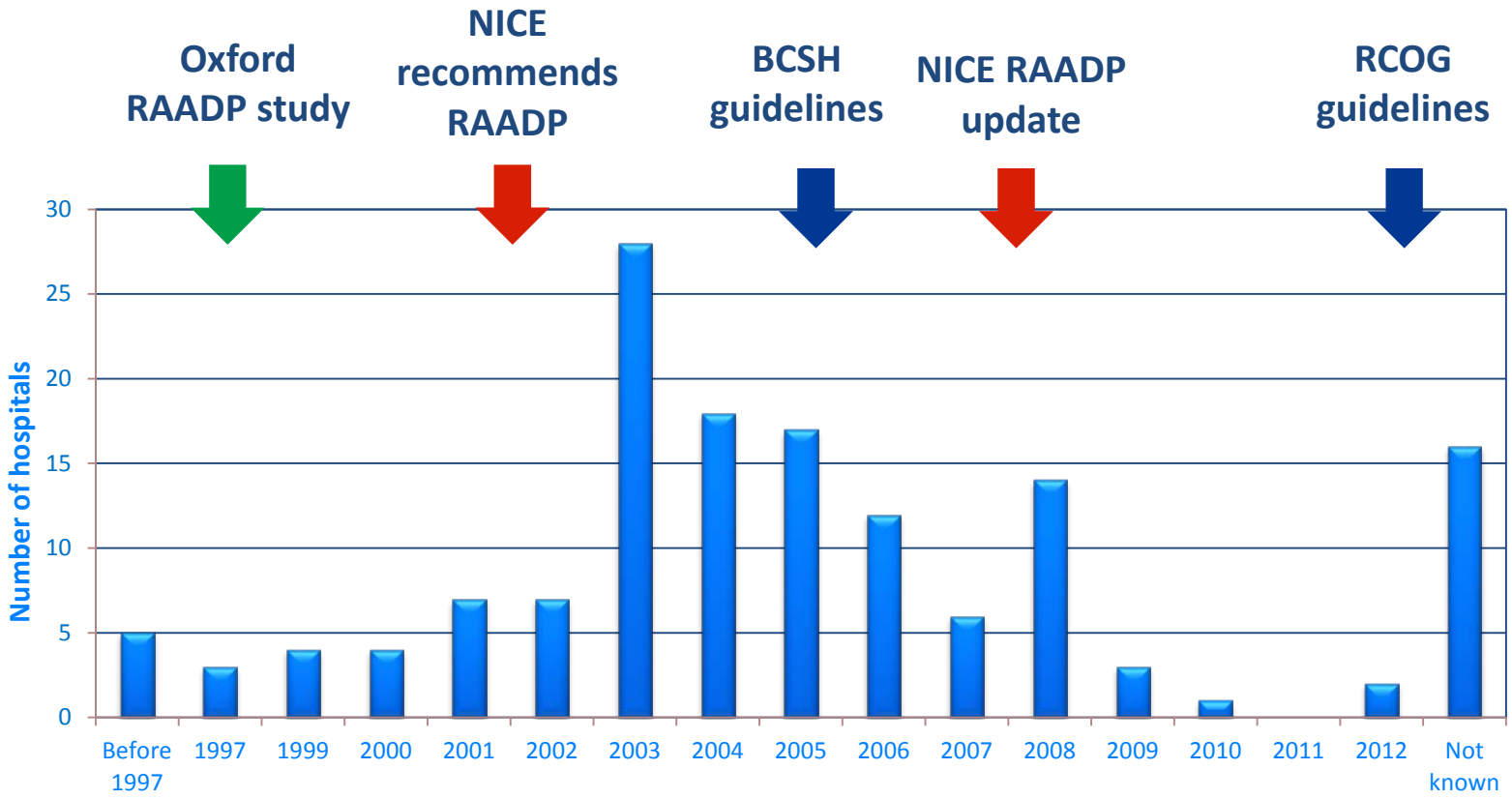
ROUTINE ANTENATAL ANTI-D PROPHYLAXIS

STANDARD 1: Did all eligible RhD negative women receive routine antenatal anti-D Ig prophylaxis at the correct dose and the correct time?

Comparison of the year RAADP was introduced in audited hospitals compared to when evidence and guidelines were published



Organisational questionnaire, 147 sites

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‘Acceptable’ reasons for not receiving RAADP (n=696, 11.7%)

Reason anti-D not given	Number	%
Not eligible for RAADP *Confirmed immune anti-D* *Miscarriage <28w 0d* *Terminations of pregnancy (TOP)* *Delivered before 28w*	296	5.0%
Decision not to give RAADP *Father known to be RhD negative* *Declined*	114	1.9%
Not under the care of the unit at the time of RAADP *Late bookers (>30w)* *Transferred elsewhere before RAADP* *DNA*	125	2.1%
Unable to classify (lack of information)	161	2.7%

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Compliance with RAADP

5276 (of 5972) RhD negative pregnant women eligible for RAADP

- Single-dose 1500 IU at 28-30 weeks (n=4887)
  - 99% received the anti-D Ig injection
  - 89.9% received the dose at the right time
- Two-dose 500 IU at 28 and 34 weeks (n=389)
  - 98.7% received at least one anti-D injection
  - 58.6% received both doses at the right time

93% of women audited were treated in units using single-dose RAADP

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RAADP not given

Single-dose:

- 47/4887 (1%) not given RAADP

Two-dose:

- 10 (2.6%) not given first injection
- 21 (5.4%) not given the second injection
- 5 (1.3%) not given either injection

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POST-DELIVERY ANTI-D

STANDARD 2: Did all RhD negative pregnant women delivering a RhD positive baby receive at least 500 IU anti-D Ig prophylaxis within 72 hours?

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Compliance with Post Delivery anti-D

3392 RhD negative pregnant women delivered a RhD positive baby and were eligible for post-delivery anti-D

- 98.5% received post delivery anti-D Ig
  - 91.6% received the right dose at the right time
- 0.56% (19 cases) should have been given anti-D Ig and weren't
- 97% had an Kleihauer (FMH) test

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Post –delivery anti-D not given n=33

ANTI-D OMISSIONS	Number	%
Declined anti-D Ig	9	27%
Hysterectomy or sterilisation post delivery	3	9%
Immune anti-D at delivery	2	6%
Acceptable reason for omission of anti-D	14	
No postnatal bloods taken	1	3%
Did not attend for anti-D Ig injection	2	6%
Recent anti-D Ig for PSE so anti-D 'not deemed necessary'	3	9%
Laboratory error	2	6%
Omission investigated but reason unknown	7	22%
No comment on omission of anti-D	4	12%
Anti-D should have been given and wasn't	19	

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POTENTIALLY SENSITISING EVENTS

Standard 3: Did All RhD negative pregnant women receive the right dose of anti-D immunoglobulin prophylaxis within 72 hours for any potentially sensitising events during pregnancy?

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Compliance with anti-D prophylaxis for Potentially Sensitising Events

924 RhD negative pregnant women experienced one or more Potentially sensitising event (total PSEs= 1052)

- 95.7% were given anti-D Ig
  - 79% probably received the anti-D dose within 3 days of the event
- 3.7% insufficient anti-D for gestational age
- 87% PSEs at 20 weeks or later had a Kleihauer

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Anti-D Ig for PSEs

Potentially sensitising event	Cases	Correct dose	Correct time
Antepartum haemorrhage	438	92%	79%
Miscarriage & Stillbirth	278	92%	77%
Fall/trauma	198	91%	83%
Amniocentesis	49	88%	65%
External cephalic version	47	100%	92%
Amniocentesis	49	88%	65%
In-utero procedure	11	82%	46%
Total	1052	92%	79%

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Kleihauer (FMH) test

Post delivery 97% (3274/3392) had a FMH test

- 88.1% (2748/3120) < 2mL of fetal cells
- 3% had a confirmed FMH of >4mL
- 0.5% (15 cases) needed additional anti-D Ig

PSEs >20 weeks 87% (729/835) had an FMH test

- 1.6% (11 cases) had a confirmed FMH of more than 4mL

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CONSENT and PATIENT INFORMATION

Standard 4: RhD negative women are given information about anti-D Ig prophylaxis and consent to receive the injections is documented

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Compliance Patient Information and Consent

5972 RhD negative pregnant women

- 36% received patient information about anti-D Ig prophylaxis
- 57% consented to receive anti-D Ig prophylaxis
- 74% of the women who declined anti-D Ig prophylaxis had a reason recorded in the maternity record

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Reasons given for declining anti-D Ig

Reason for declining anti-D	N	%
Partner RhD negative	76	58%
Personal objections or concerns	6	4.7%
Fully informed but declined	5	3.8%
No further pregnancies planned	2	1.5%
Allergy	2	1.5%
Needle phobia	2	1.5%
Religious reasons, Jehovah's Witness	2	1.5%
Other	2	1.5%
No reason given	34	26%
Total	131	

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Comments on the Audit

- Some hospitals found it difficult to identify the women who booked for delivery
- The transient nature of maternity care and the variety of data sources means that in many cases we cannot successfully demonstrate that Anti-D Ig is administered within the guidelines
- Some case notes were incomplete or missing, suggesting that future models of auditing should adopt a prospective method

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Summary and Conclusions

- There was good compliance with anti-D Ig prophylaxis
- Where anti-D Ig was not given, and should have been, it was not possible to find out why in most cases
- Prospective real-time monitoring of the whole pathway would deliver better patient care but how do we resource this?
- There may be insufficient involvement of the women themselves in the decision-making process
- Staff administering the process need better education

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Acknowledgements

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- Our thanks go to the Project Group: Dr. Megan Rowley, Dr. Edwin Massey, Tracie Taylor, Tony Davies, Jane Hibbert, Linda Rough, Tanya Hawkins, Derek Lowe, David Dalton & JGC

Booking BMI of 5340 RhD negative women

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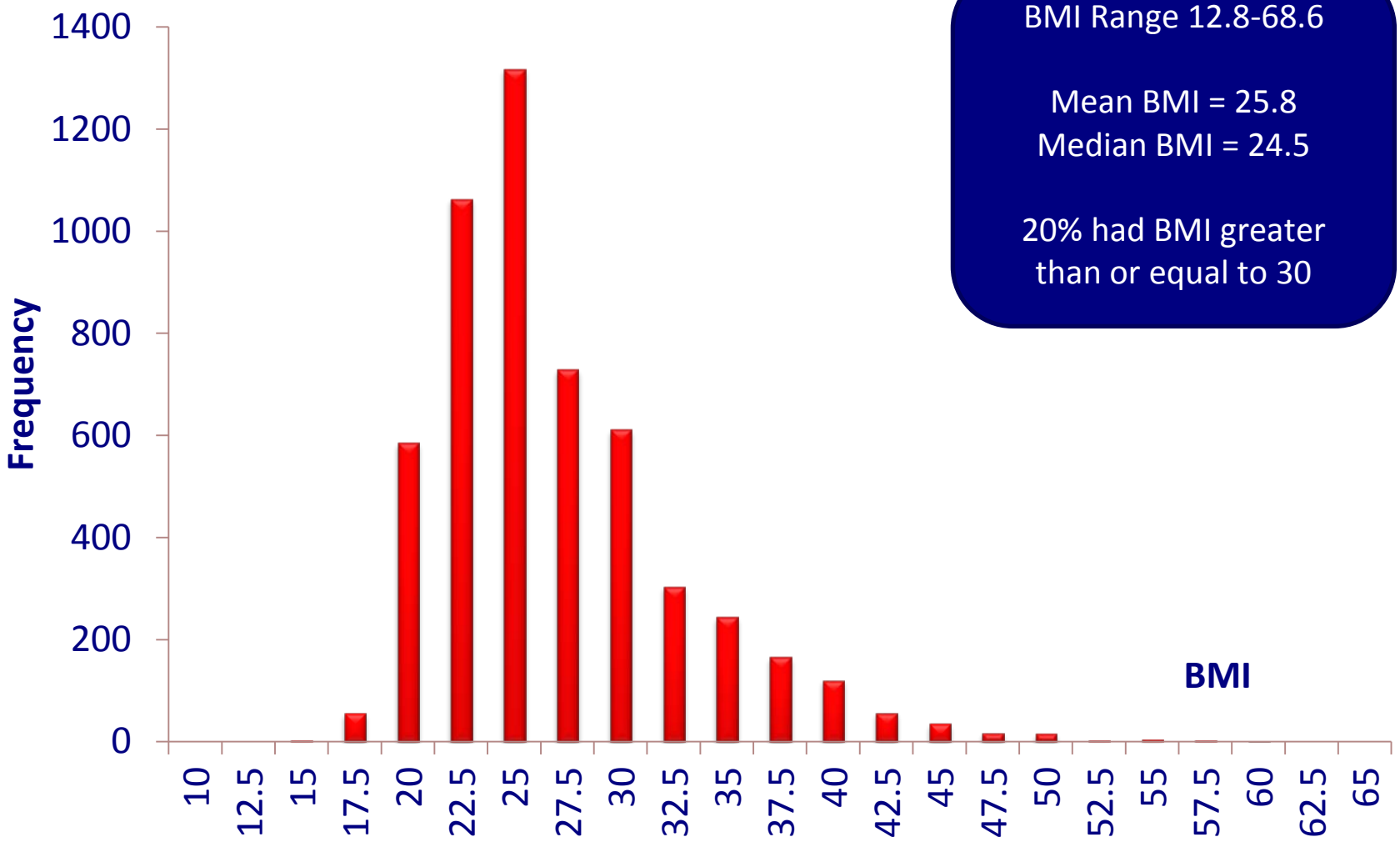

Booking weight of 5430 RhD negative women

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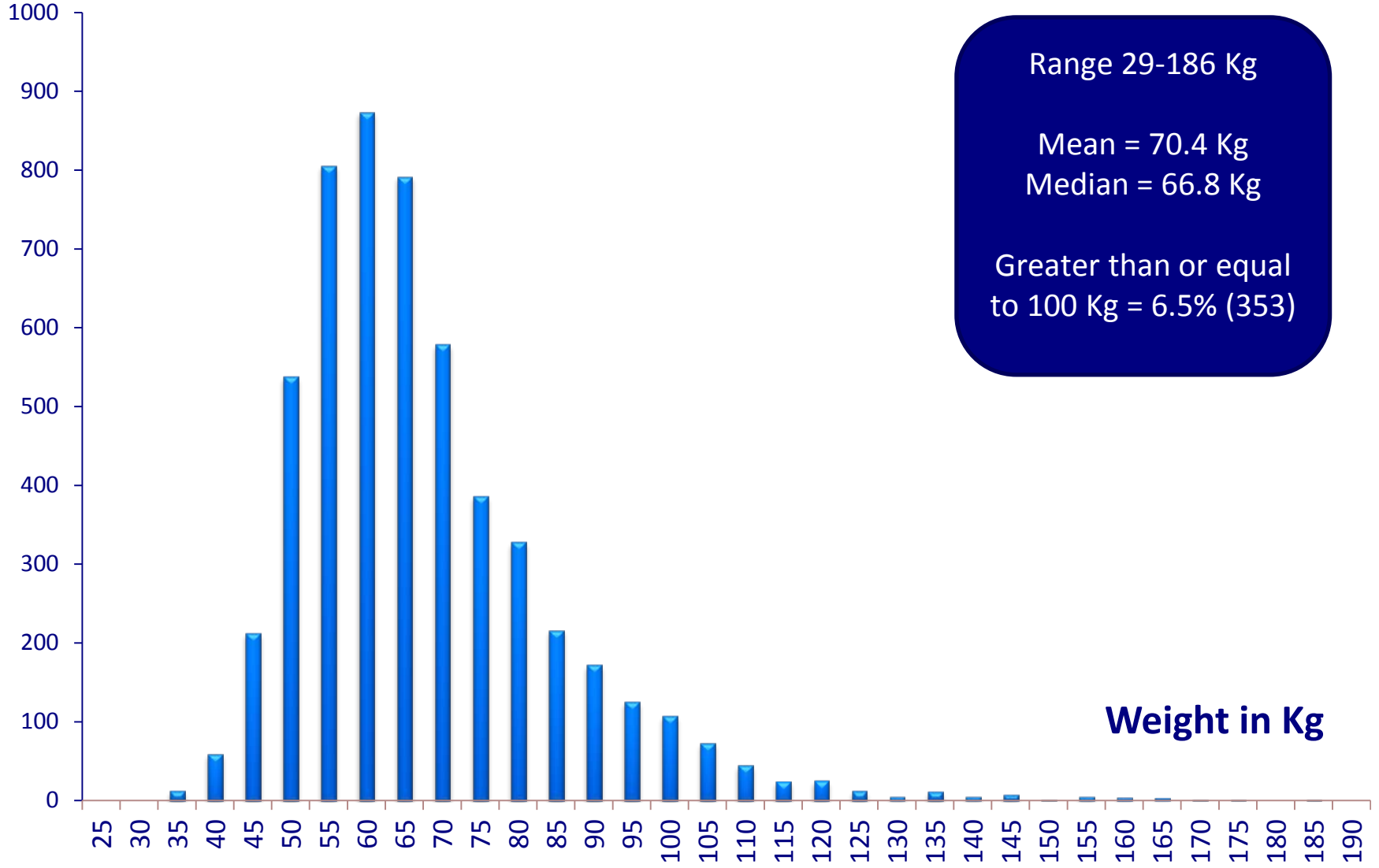

Range 29-186 Kg

Mean = 70.4 Kg
Median = 66.8 Kg

Greater than or equal to 100 Kg = 6.5% (353)

Gestational age at birth for 5263 RhD negative women

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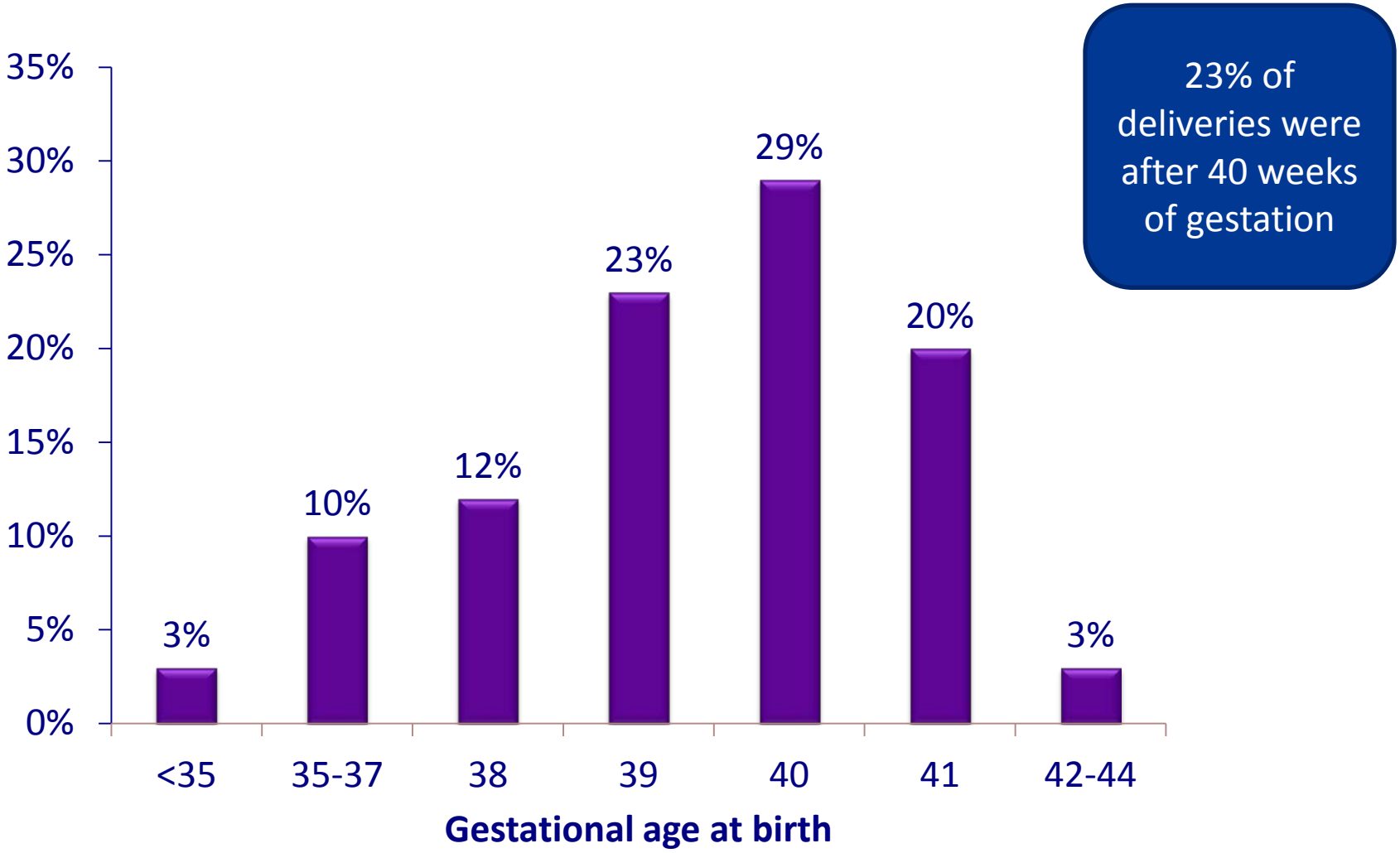

23% of deliveries were after 40 weeks of gestation