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2013 National Comparative Audit of Anti-D Ig Prophylaxis

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UK NEQAS/BTLP Meeting 11th November 2014

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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

Impact of anti-D immunoglobulin prophylaxis on neonatal deaths in the UK

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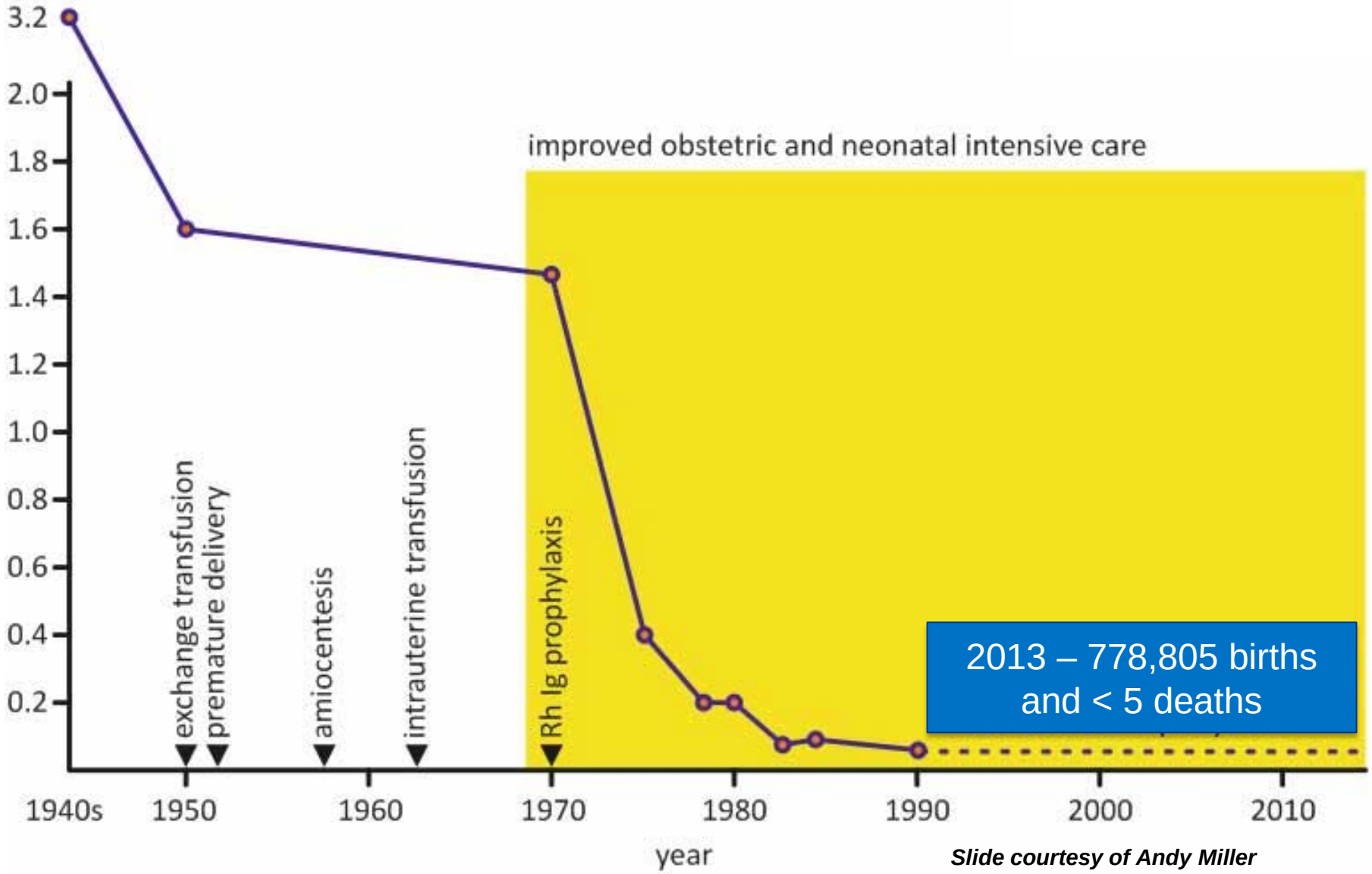

Slide courtesy of Andy Miller

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What are we auditing?

The management of RhD negative women who present for antenatal care, to see if they are managed in accordance with UK guidelines on anti-D immunoglobulin prophylaxis in pregnancy

The management of early miscarriages and termination of pregnancy was not included in this audit

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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 for one month 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 (Local)

161 UK 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)

*If we compare the actual audited cases to the number you would expect from the number of annual deliveries in the participating units we estimate that 78% of eligible RhD negative women were audited during the month selected**

* Assuming 15% of women are RhD negative

Participation (National)

2013*	England and Wales	Scotland	Total
Live Births	698,512	56,014	754,526

RhD negative women would deliver 113,179 babies per year and 9431 per month (assuming 15%)

- Grand total annual deliveries for the participating sites in England, Wales and Scotland in 2012 was **607, 338 = 80% of all deliveries**
- **5972** audited RhD negative women is estimated to be **63%** of all the RhD negative women delivering in England, Wales and Scotland in one month

* Data from the Office for National Statistics (ONS)

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Audit Standards

All RhD negative women receive the **correct dose of** anti-D Ig prophylaxis **correct time** for:

STANDARD 1: RAADP in third trimester

STANDARD 2: POST DELIVERY of a RhD positive baby

STANDARD 3: PSEs throughout pregnancy

Audit Standards

STANDARD 4: RhD negative women are given information about anti-D Ig prophylaxis and consent to receive the injections is documented. If anti-D Ig prophylaxis is declined, the reason is recorded

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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?

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

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

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Compliance with RAADP

ALL HOSPITALS GIVE 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

**But this was a much narrower time-window

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When did eligible RhD negative women get RAADP?

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	N	%
RAADP single dose regime N=4887		
Single dose at right time (28-30 weeks)	4388	89.8
Single dose before 28w 0d **EARLY**	235	4.8
Single dose after 30w 6d **LATE**	217	4.4
Single dose not given	47	1.0
RAADP two-dose regime N=389		
Both doses given at right time	228	58.6
Only first dose given at right time	57	14.6
Only second dose given at right time	43	11.1
Neither dose given at right time including 5 cases where no anti-D Ig dose was given	61	15.7

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RAADP not given

Single-dose:

- 47/4887 (**1%**) not given RAADP injection

Two-dose:

- 10/389 (2.6%) not given first injection
- 21*/389 (5.4%) not given the second injection
- 5**/389 (**1.3%**) not given either RAADP injection

* 11 and ** 2 cases were because of pre-term labour

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Impact of simultaneous PSE and RAADP

Single dose regime:

- 14/235 cases where RAADP had been given early, a PSE was recorded at 28-30 weeks gestation (5.6%)
- 97/4388 cases where RAADP was given on time a PSE was recorded at 28-30 weeks gestation (2.2%)

Two-dose regime:

- 6/389 women missed the first, second or both doses because a PSE was recorded at the same time (2.5%)

Recommendation

Staff should be made aware that national guidelines specifically recommend that RAADP and prophylaxis for PSEs should be regarded as **separate events** and anti-D Ig given for both at a dose indicated by the local policy

Recommendation

Hospitals using the two-dose RAADP regime should review their compliance with both anti-D Ig injections and, if it is inadequate, they should take action to improve compliance including giving consideration to the single dose regime which, in this audit, shows better compliance.

Since RAADP implementation 71% of sites have changed to the single-dose regime

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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 Anti-D Prophylaxis Post Delivery

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

***STANDARD DOSE ANTI-D Ig**

66.5 % received 500 IU
33.5 % received 1500 IU

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When was post-delivery prophylaxis given? (n=3392)

+ 6.9%

	%	
Dose of at least 500 IU, given within 3 days of delivery	91.6	3106
Dose of at least 500 IU, given later than 3 days of delivery	0.9	29
Dose of at least 500 IU, timing not stated	1.7	57
Dose not stated, given within 3 days of delivery	4.3	146
Anti-D Ig not given	1.0	33
Delivered elsewhere, post natal anti-D administration unknown	0.4	13
Unknown, no post-natal records	0.2	8

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Post–delivery anti-D Ig not given (n=33)

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Total eligible women =3392 Total omissions = 33	N
Immune anti-D at delivery	2
Hysterectomy or sterilisation post delivery	3
Declined anti-D Ig	9
Total where anti-D Ig was omitted and deemed appropriate (0.5% of eligible women)	14
No postnatal bloods taken	1
Did not attend for anti-D Ig injection	2
Laboratory error	2
Recent anti-D Ig for PSE so anti-D 'not deemed necessary'	3
No comment on omission of anti-D	4
Omission investigated but reason unknown	7
Total where anti-D Ig should have been given appeared to have been omitted in error (0.5% of eligible women)	19

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Kleihauer (FMH) test

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

- 88.1% (2748/3120) ≤2mL fetal cells and needed no confirmatory testing and no follow-up
- 8.9% had confirmatory testing but FMH was <4mL so no follow-up needed
- 93 women needed follow-up FMH testing
- 14 women needed additional anti-D Ig

42.8% no fetal cells

45.3% ≤2mL of fetal cells

3% ≥4mL fetal cells

0.5% needed additional anti-D Ig

Recommendation

Post delivery anti-D prophylaxis is vital to prevent sensitisation and women who are eligible should not be able to leave hospital without the injection, or a robust plan in place for them to receive the anti-D Ig and any additional dose of anti-D Ig as indicated by the result of the Kleihauer test.

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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

Anti-D Ig for PSEs

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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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Recommendation

Maternity units and associated transfusion laboratories have a duty of care to deliver anti-D Ig prophylaxis to RhD negative women at the correct dose and the correct time. The organisation of maternity services should ensure that women are aware that they are eligible for anti-D Ig and that service delivery is matched to this requirement.

Recommendation

Where women move from the jurisdiction of one maternity service to another, the results of screening blood tests and record of anti-D Ig administration should be transferred to the new maternity record and, where any omissions are identified, they should be investigated, documented and rectified in as timely a way as possible

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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 with 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

	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%
0ther	2	1.5%
No reason given	34	26%
Total	**131**	

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Recommendation

Patient information about anti-D prophylaxis is currently available from anti-D Ig manufacturers or can be locally produced. The information provided to RhD negative women must provide accessible and accurate information to support consent and decision-making. It should be available for midwives and obstetricians to use at the time of counseling RhD negative women and the consultation and any outcomes should be recorded in the maternity record.

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 always 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

Recommendation

Any errors in requesting and administration of anti-D Ig that could lead to sensitisation and development of immune anti-D, or inappropriate administration of a medicinal blood product, should be investigated locally and reported to SHOT.

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Recommendation

All staff groups involved with anti-D prophylaxis should receive appropriate education and updates.

LearnBloodTransfusion

Anti-D prophylaxis
Clinical and Laboratory
Modules

HDN awareness resources

Transfusion guidelines website

SHOT resources

Checklist
Posters
Articles

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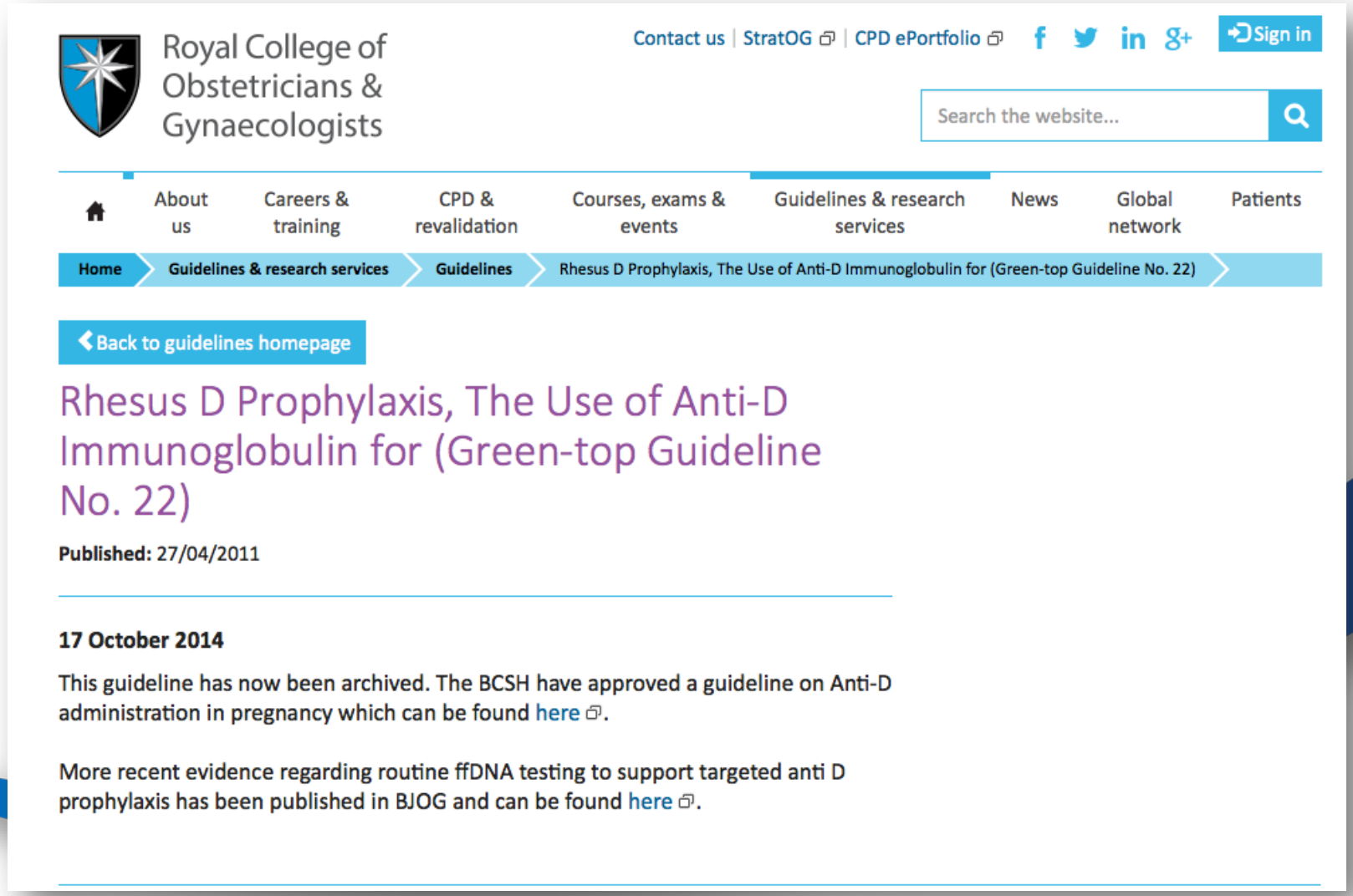
STOP PRESS!



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Back to guidelines homepage

Rhesus D Prophylaxis, The Use of Anti-D Immunoglobulin for (Green-top Guideline No. 22)

Published: 27/04/2011

17 October 2014

This guideline has now been archived. The BCSH have approved a guideline on Anti-D administration in pregnancy which can be found here.

More recent evidence regarding routine ffDNA testing to support targeted anti D prophylaxis has been published in BJOG and can be found here.

2013 Anti-D Ig Prophylaxis Audit

Acknowledgements

- We acknowledge the huge efforts made by laboratory, transfusion and midwifery staff in order to provide us with audit data
- 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

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SUPPLEMENTARY SLIDES

Anti-D Ig product and dose

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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

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

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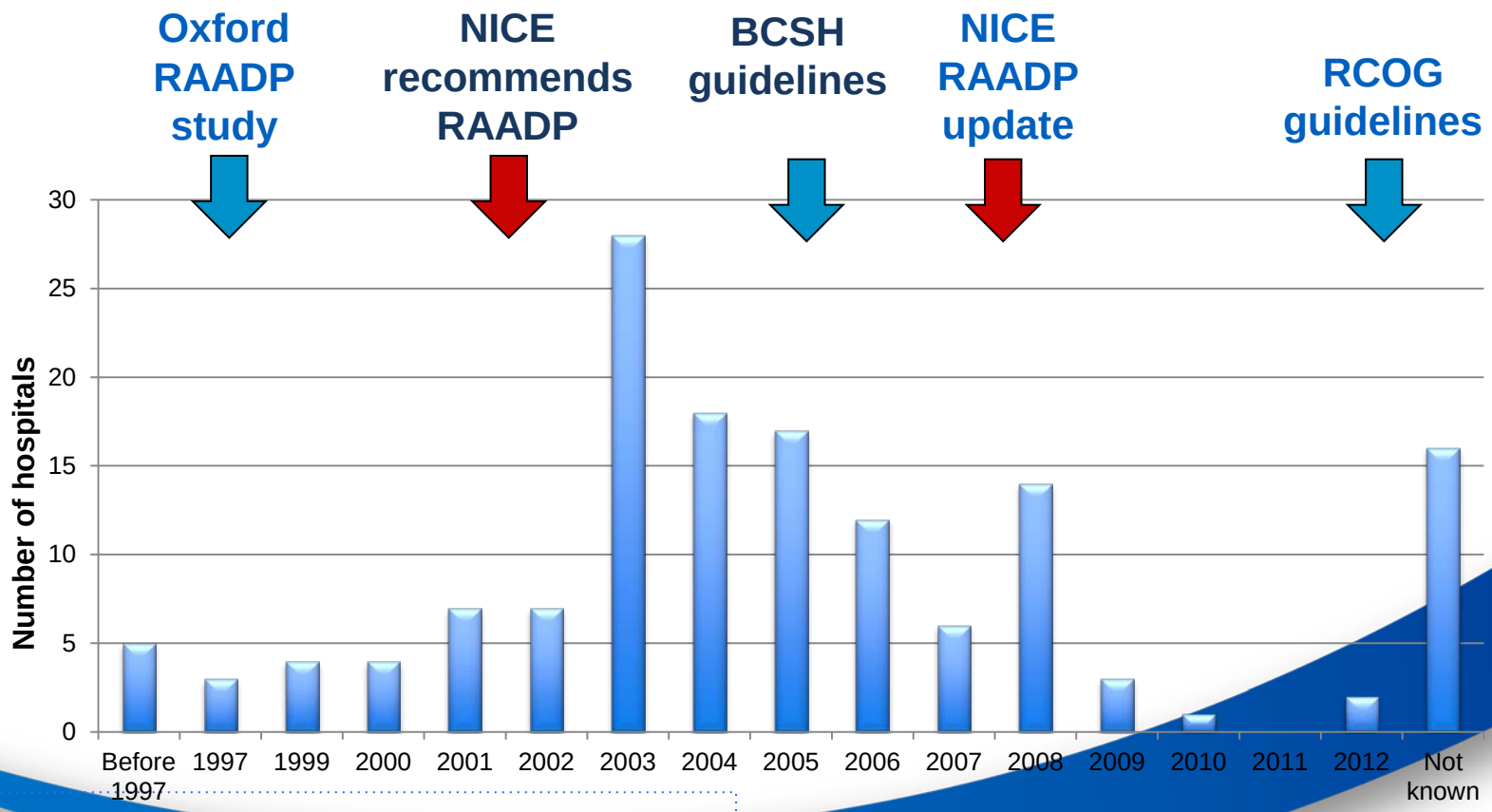

Organisational questionnaire, 147 sites

Booking BMI of 5340 RhD negative women

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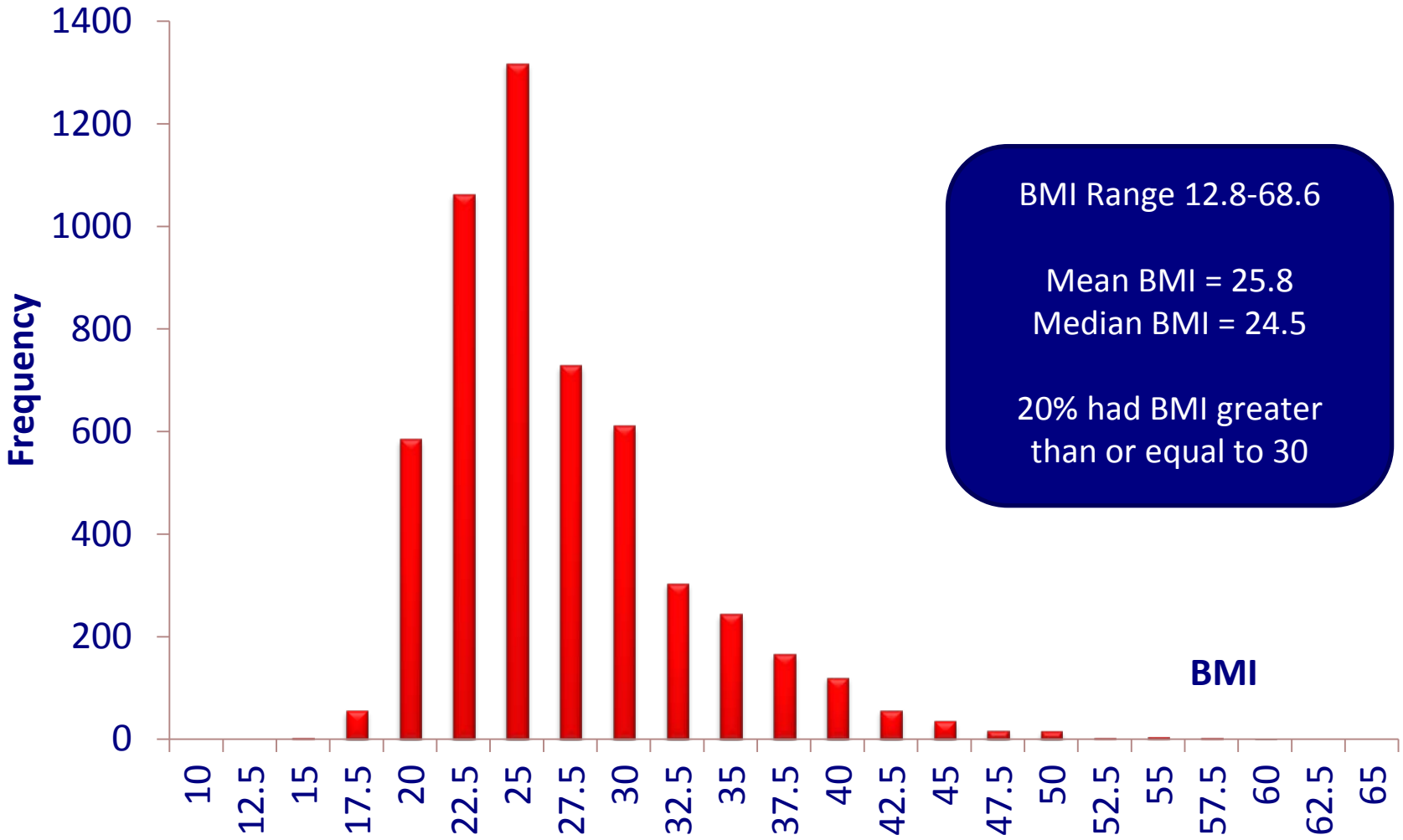

BMI Range 12.8-68.6

Mean BMI = 25.8
Median BMI = 24.5

20% had BMI greater than or equal to 30

Booking weight of 5430 RhD negative women

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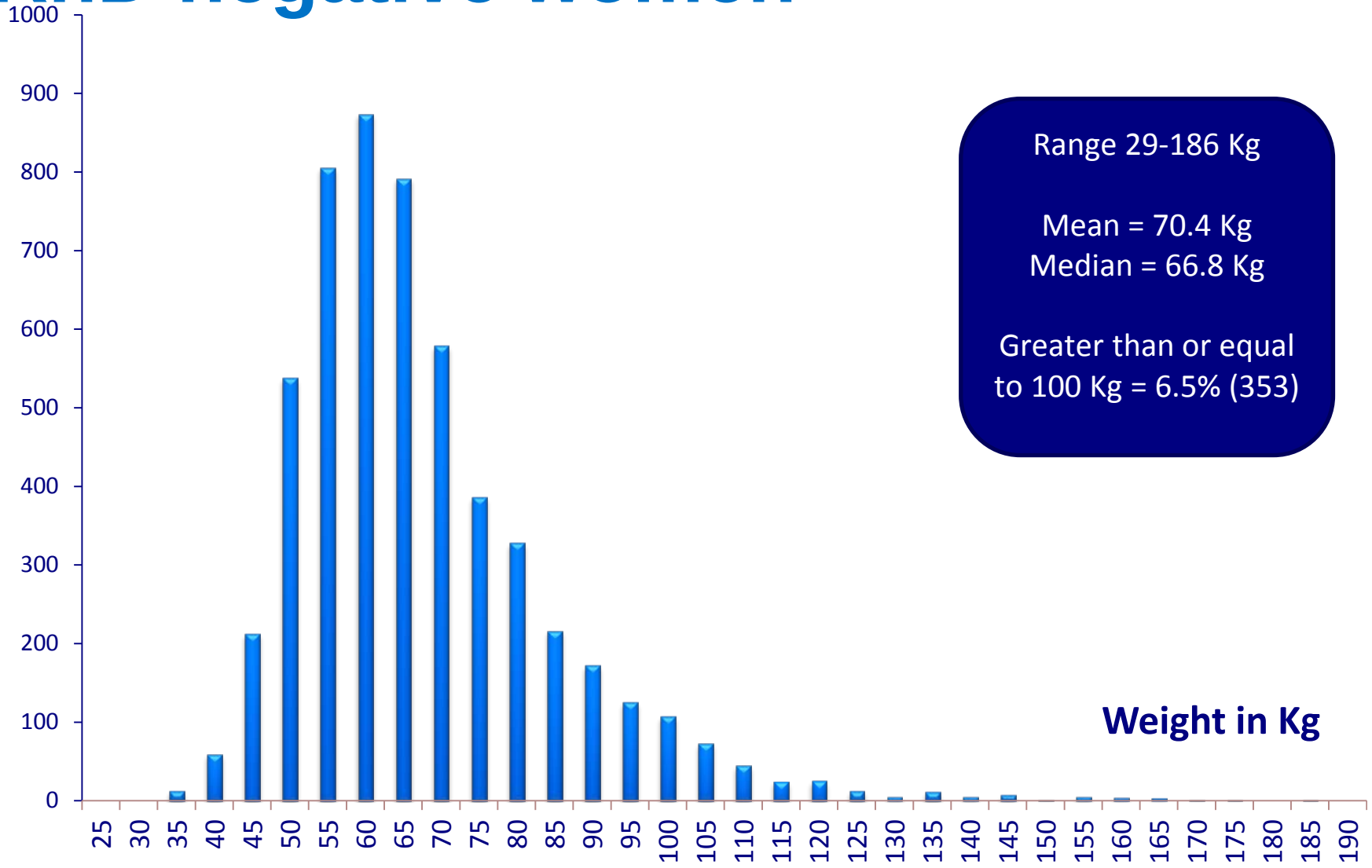

Range 29-186 Kg

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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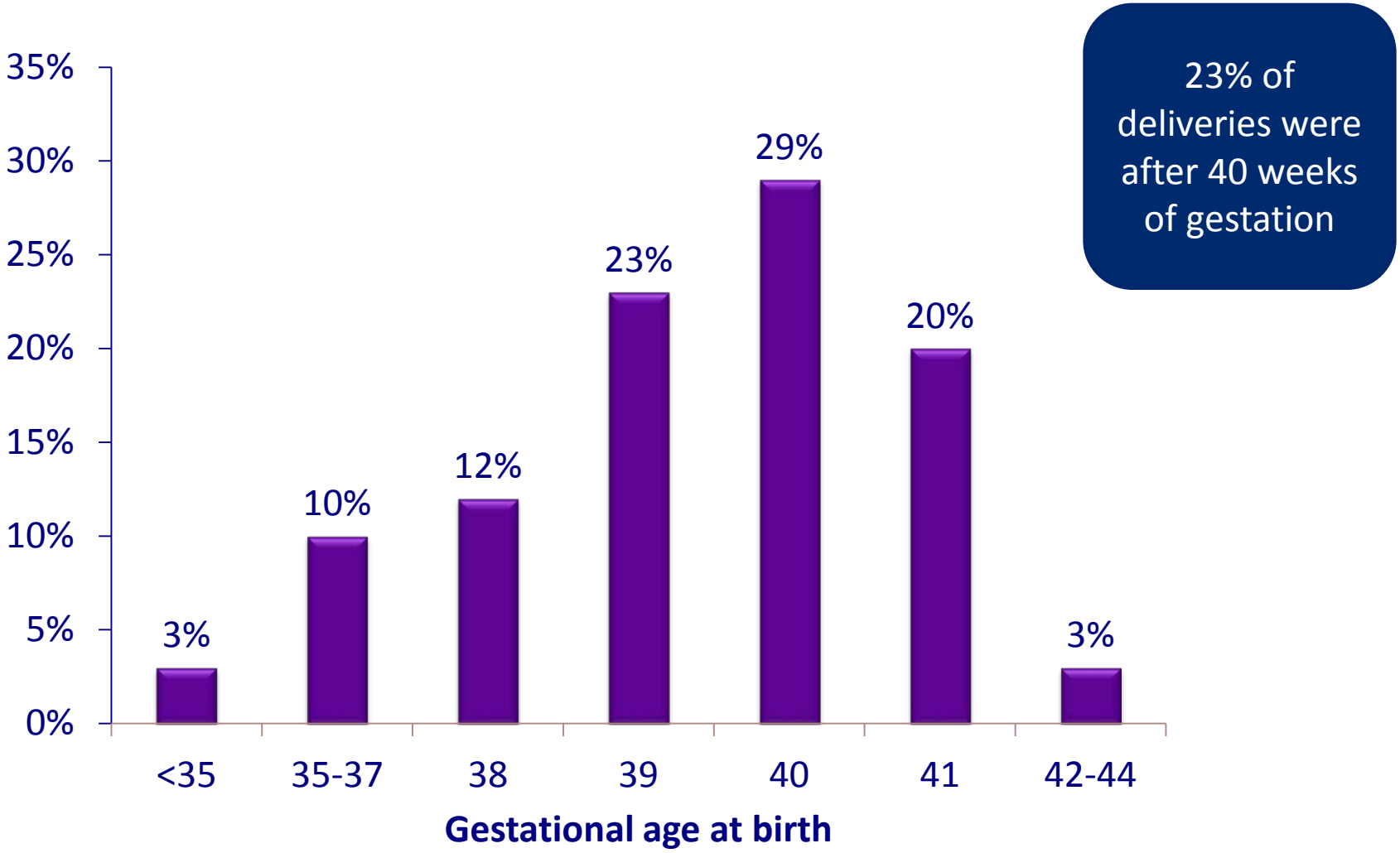

23% of deliveries were after 40 weeks of gestation