

# Serological Problems following Implementation of the NICE Guidelines for RAADP

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# Some Facts.....

- Each year 105,000 (17%) of all births are to Rh D Negative women and approx 62,000 (59%) of these babies are Rh D Positive.
- Between 25 - 30 babies die from HDN each year
- Approx 15 children suffer major developmental problems as a result of HDN and a further 30 children will have minor developmental problems

# BACKGROUND TO NICE GUIDELINES FOR RAADP

- Prior to introduction of antenatal anti-D prophylaxis (AADP) in 1969, the mortality rate due to HDN caused by anti-D antibodies was 46 per 100,000 births.
- The implementation of AADP and advances in neonatal care have reduced the mortality rate due to Anti-D HDN to 1.6 per 100,00 births.

Figures from NICE Technology Appraisal Guidance No.41, 2002

# However the problem persists.....

- In the UK nearly 1000 women continue to become sensitised each year as a result of
  - Anti-D prophylaxis not administered to Rh D Negative women following a Rh D Positive delivery
  - Failure to give Anti-D prophylaxis following an antepartum sensitising event
  - Sensitisation due to silent bleeds

# Clinical Evidence Suggestions..

- Able to reduce the rate of sensitisation from 1% to less than 0.2% by administering Routine Antenatal Anti-D Prophylaxis (RAADP) at 28 and 32 weeks gestation.

# NICE Recommendations

- RAADP offered to all non-sensitised pregnant women who are Rh D Negative unless they fulfill the criteria when RAADP becomes neither necessary or cost effective.

# WBS ANTENATAL TESTING SERVICE

- Provides a Routine Antenatal Antibody Screening Service for 7 hospitals within the region, testing approximately 29,000 samples per year
- Provides Anti-D Quantitation service for 15 hospitals within the region.

# What is the dilemma for the WBS?

- How do we approach testing these patients following RAADP implementation
  - Do we continue to test detecting prophylactic anti-D, with subsequent quantitation and follow-up procedures
  - Avoid the problem by not testing!

# What is the scale of the problem?

- Scale of the problem would depend on:
  - How many hospitals implement RAADP?
  - Whether antenatal screening is required by the hospitals following RAADP?

# Current Situation

- 14/15 blood banks currently undertaking or planning to undertake RAADP
- 1 Hospital implemented RAADP 2003, further 2 at the beginning of this year: 11 hospitals sometime in the future
- No change at present to WBS antenatal screening protocol for Rh D Negative mothers.

# Our experience so far.....

- 1 hospital currently undertaking RAADP. Mean of 15 samples per year received for quantitation over the previous 5 years increased to 101 samples in 2003. Equivalent to a 673% increase in the number of samples tested for anti-D quantitation from the one hospital.

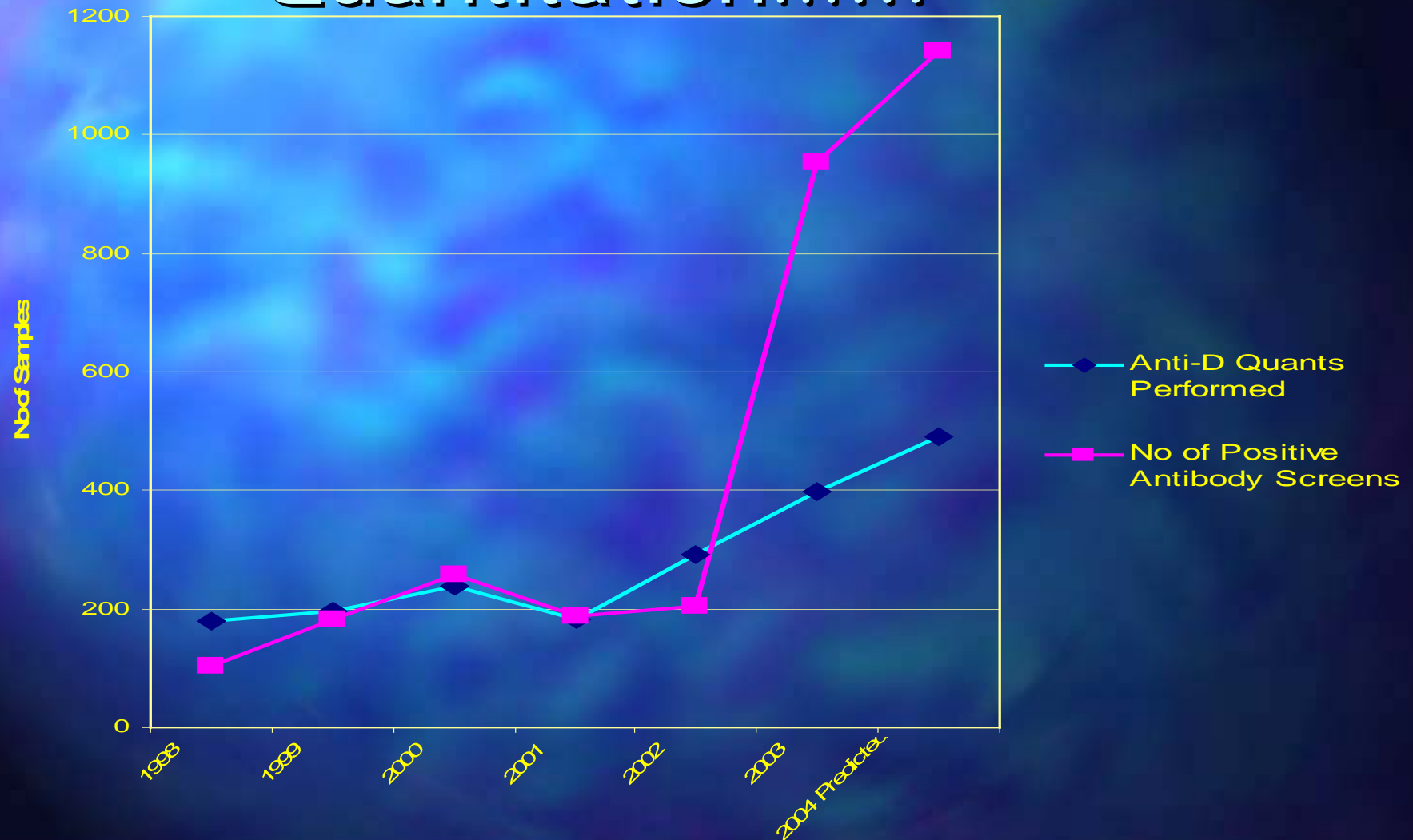
# BCSH GUIDELINES

" where no red cell antibodies are detected at booking all pregnant women should be re-tested once during 28-36 weeks gestation"

# Testing Regime after RAADP

- No further routine antenatal screening after 28 weeks gestation- 7 Hospitals
- Further routine screening at 32 - 34 weeks gestation - 5 Hospitals (3 of which will screen vs rr cells)
- Screening protocol not yet decided - 2 Hospitals.

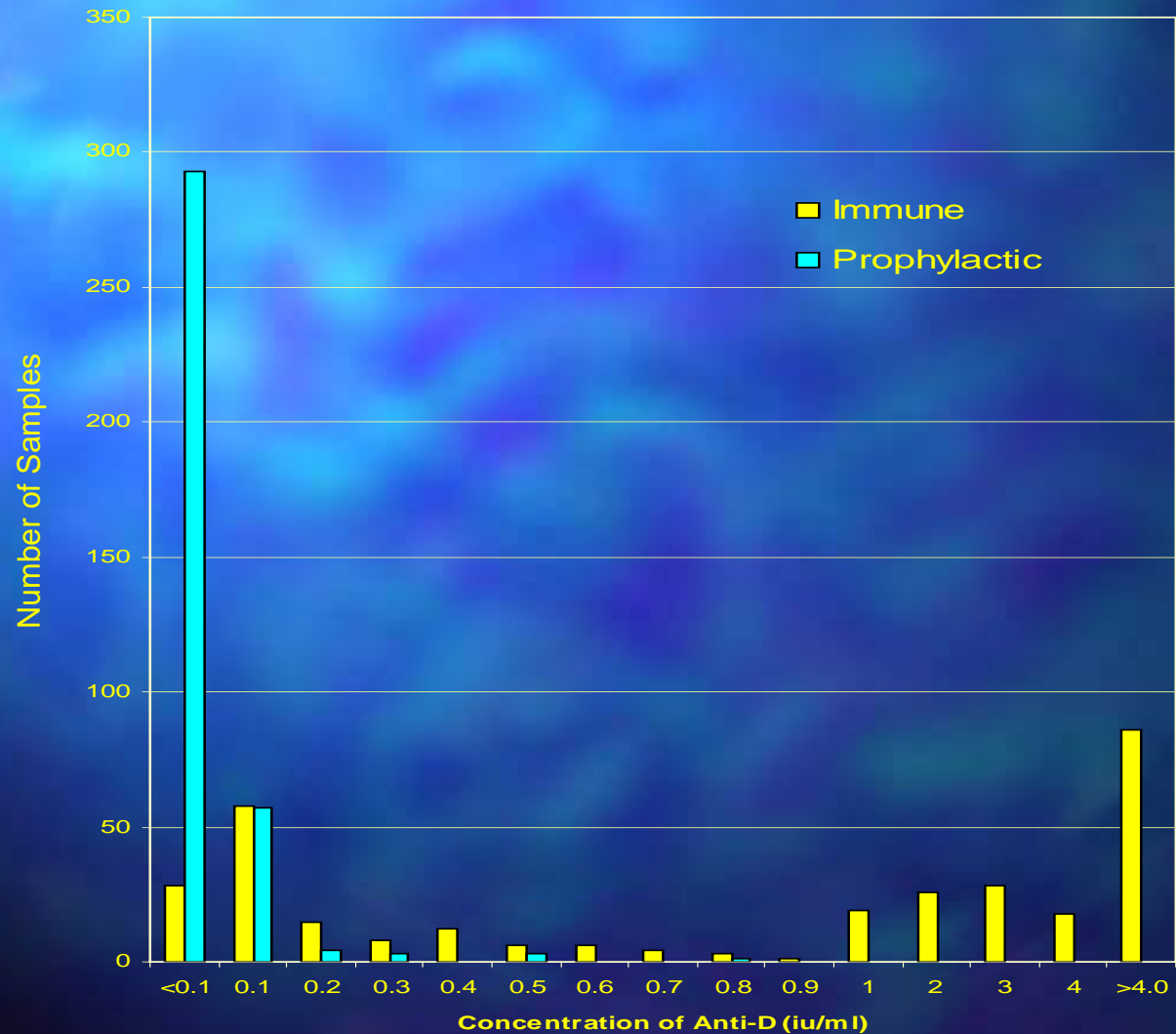
# Predicted workload for Anti-D Quantitation.....



# Problems with RAADP for Antenatal Testing

When anti-D is detected at low levels, such as after administration of anti-D prophylaxis, we are unable to distinguish serologically between immune and prophylactic anti-D

# Immune vs Prophylactic Anti-D



# Importance of distinguishing between Immune and Prophylactic anti-D

- Incorrectly assume prophylactic anti-D -  
Patient does not receive follow-up
- Incorrectly assume Immune anti-D -  
Patient will not receive further  
prophylaxis.

# Data regarding increasing quant

CASE No.	Early Quant Result (iu/ml)	Last Quant Result (iu/ml)	Significant Increase	Clinical Outcome
1 (MF)	0.06 13/05/02	13.40 08/08/02	3 <sup>rd</sup> TRIMESTER (0.09iu/ml on 04/07/02)	Del'd - 10/08/02, No TX
2 (RD)	0.47 30/10/02	7.4 24/03/03	3 <sup>rd</sup> TRIMESTER 0.9iu/ml on 23/12/02	Del'd – 27/03/03 No TX Cord Hb 17.4
3 (DD)	0.76 02/04/02	9.7 26/09/02	3 <sup>rd</sup> TRIMESTER 1.3iu/ml on 23/08/02	Del'd 03/10/02 No TX
4 (SH)	0.44 21/05/02	12.50 20/09/02	NOT KNOWN 0.44iu/ml ON 10/07/02	No Info available
5 (SE) **	0.28 26/09/02	34.6 22/01/03	3 <sup>rd</sup> TRIMESTER 2.85iu/ml ON 17/12/02	Del'd 26/02/03 IUT'S received
6 (KJ)	0.13 14/02/03	17.0 28/05/03	3 <sup>rd</sup> TRIMESTER 2.81iu/ml on 31/03/03	03/06/03 EX-TF Req

\*\* Patient required IUTs due to the presence of Platelet antibodies

# NBS PROTOCOLS

- 3/5 of the centres responding do not perform routine screening/quantitation following RAADP at 28 weeks
- 1 hospital routinely refers samples to 1 centre for quantitation at 34 weeks following RAADP.
- All centres perform quantitation if AADP information is unavailable.

# Conclusion.....

- Continue with current testing protocol i.e. test all antenatal samples referred whether having received RAADP.
- When AADP or RAADP has been administered no additional follow-up sample will be requested, but all tests will be performed

## Conclusion (contd)

- When it cannot be ascertained whether RAADP or AADP administered, treat as for immune anti-D and request sequential monthly samples to monitor by the IAT and anti-D quantitation.
- Due to low levels of anti-D, further AADP is recommended for these patients when required.