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Experience of Implementing A Non-Invasive ffDNA RhD Screening Service

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Transfusion Bites Presentation March 2021

Overview

- What is non-invasive prenatal testing (NIPT)?
- Accuracy of NIPT ffDNA Rh D screening test
- Why is it being introduced into routine practice?
- Implementation process – factors involved
- Summary data since implementation
- Incidents identified

NICE Guidelines (DG25) Recommendation

- NICE Guideline DG25 – High-throughput non-invasive prenatal testing for fetal RHD genotype (2016)
- “High-throughput non-invasive prenatal testing (NIPT) for fetal *RHD* genotype is recommended as a cost-effective option to guide antenatal prophylaxis with anti-D immunoglobulin, provided that the overall cost of testing is £24 or less. This will help reduce unnecessary use of a blood product in pregnant women, and conserve supplies by only using anti-D immunoglobulin for those who need it.”

Non-Invasive Antenatal Testing (NIPT)

- The detection of cell free fetal DNA (cffDNA) circulating in the maternal plasma used to determine the predicted Rh D status of the fetus.
- Categorizes pregnancies as either low or high risk regarding the possible development of HDFN caused by immune Anti-D.
- Therefore, Rh D negative pregnant women can avoid receiving unnecessary Anti-D prophylaxis if they are predicted to be carrying a Rh D negative fetus.

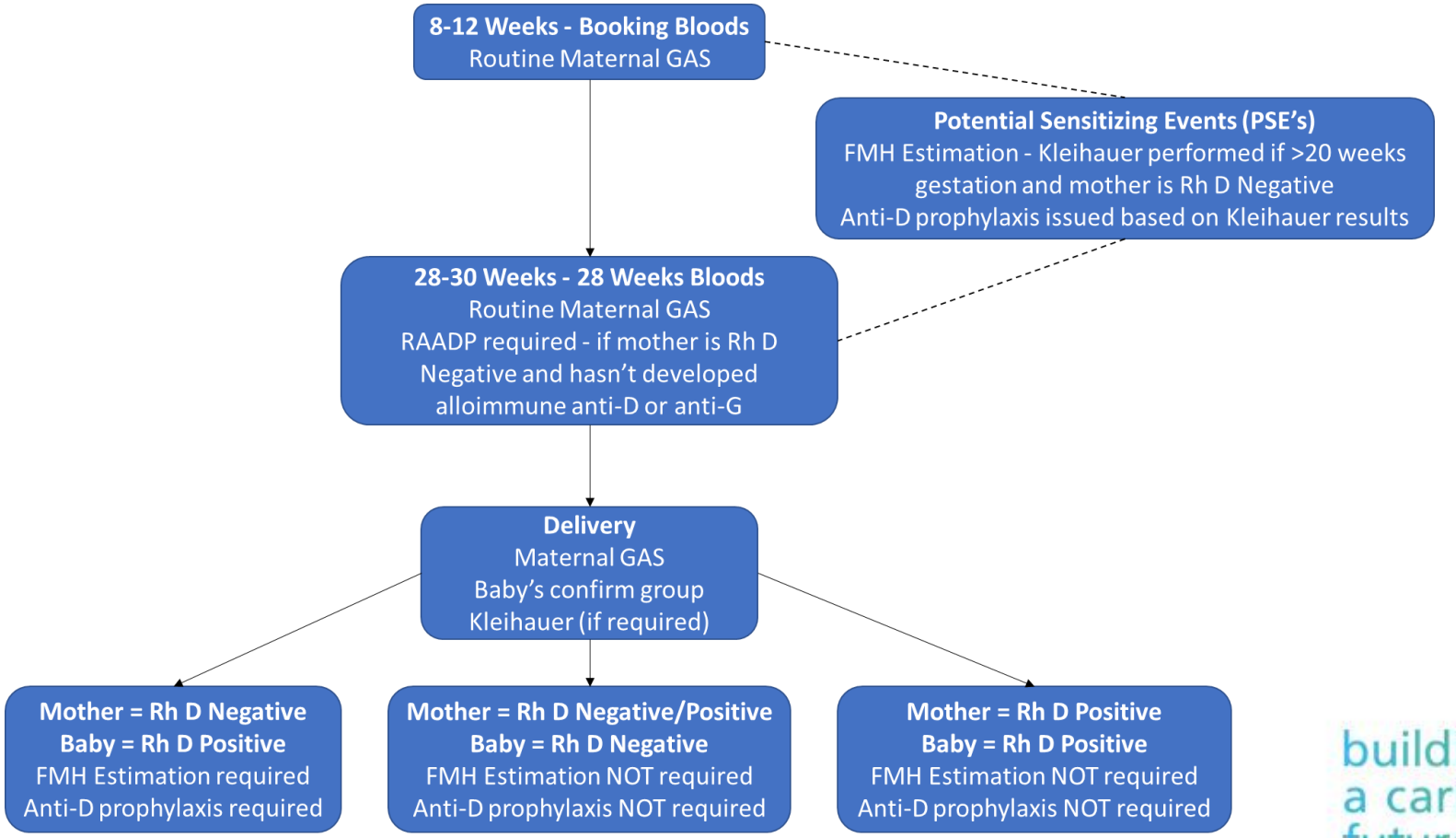
Accuracy of NIPT

- >99.9% Negative predictive value. Fewer than 1:1000 babies will be falsely predicted to be Rh D negative when test is performed after 11^{+2} weeks gestation.
- Approximately 2% of all tests will produce a false positive result where the fetus is predicted to be Rh D Positive, but tests as Rh D negative at delivery.
- Around 8% of all tests will be inconclusive – these patients will be treated as high risk and receive RAADP.

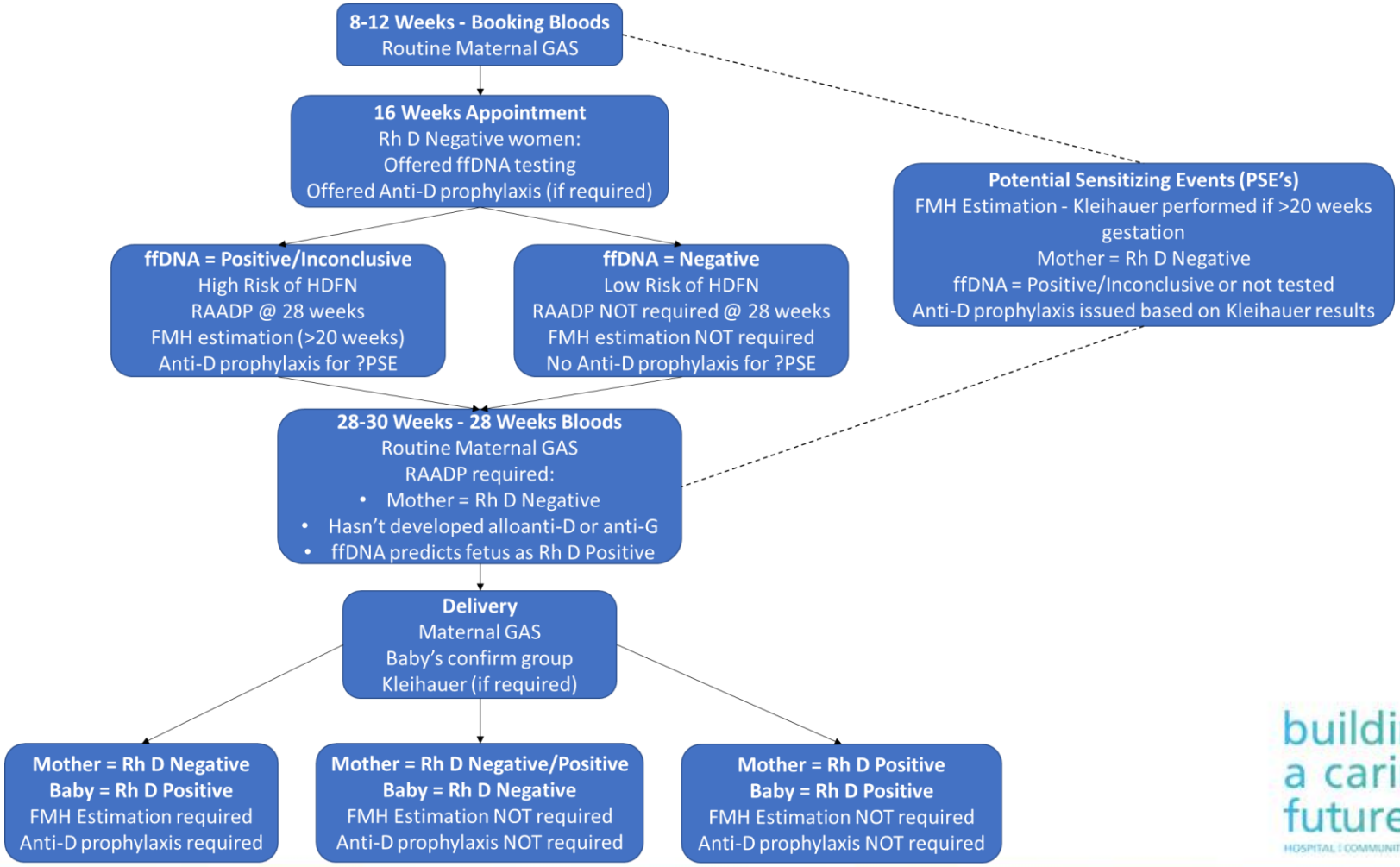
Why is it being introduced into practice?

- Current practice – all Rh D negative pregnant women are treated as high risk for developing HDFN caused by immune Anti-D.
- These women will therefore receive routine antenatal anti-D prophylaxis (RAADP) at 28-30 weeks gestation.
- Approximately 15% of the UK population are Rh D negative - around 60% of all newborns will be Rh D positive; 40% will be Rh D negative.
- NICE Guidelines (DG25)

"Current" Practice



Proposed Post-Implementation Practice



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Implementation Process

- Multiple factors and services to consider before implementation can occur:

- NHSBT – sample requirements, transport, results.
- Laboratory – staff training, SOP's, LIMS, reporting results.
- Financial – is introduction of testing a cost-effective approach?
- Midwifes – staff training of test and results, updates to policies/procedures.

NHCT Data – NHSBT Requirement

- Sample must be taken after 11^{+2} weeks gestation, but before 25 weeks gestation if original sample rejected.
- Must be at least 4ml.
- Dating scan must have been performed and the EDD stated.
- Sample must be tested within 7 days of collection (transport logistics).
- TAT for results is 10 working days – reported to SP-ICE.
- Not eligible for testing if mother has already produced alloanti-D or alloanti-G.

NHCT Data – Transfusion Laboratory

- New sets created for LIMS system – with automated comments.
- Staff training regarding understanding of testing process and how to interpret and act upon results for ?PSE and anti-D requests.
- Updating laboratory SOP's and forms.
- Updating request forms from antenatal services.
- Reporting of results onto LIMS and sending to requester.

NHCT Data – Finance

- Initial costing exercise undertaken to evaluate cost-efficiency of current process against proposed process post-implementation of ffDNA testing.
- Suggested that implementation of ffDNA testing would be at worst cost-neutral (although may acquire a small cost saving).
- Cost of ffDNA testing would be offset by savings accrued from reduction in use of anti-D prophylaxis and performance of Kleihauer testing.

NHCT Data – Midwives/Antenatal Service

- Review and updates to current policies/procedures and subsequent pathways – required approval from governance.
- Staff training of new pathways:
  - Understanding of test
  - When to offer the test to patients?
  - How to act upon results?

Post-Implementation Review

- Implementation of ffDNA testing was successful.
- Few issues encountered.
- 80 requests received in initial 3 months – of which 37 tested positive and 34 tested negative.
- Quality Objectives:
  - Reduced administration of unnecessary blood product to Rh D negative women carrying a Rh D negative fetus.
  - Decreased requirement for follow-up anti-D quantitation following administration of RAADP.

NHCT Data – Since Implementation

- Between 01/08/2019 – 31/01/2021

- Total ffDNA requests received = 689 (657 were tested)
- Positive ffDNA results = 384 (58.45%)
- Negative ffDNA results = 254 (38.66%)
- Inconclusive ffDNA results = 19 (2.89%)
- Rejected ffDNA requests = 32

Incidents

2 incidents reported to SHOT since implementation:

- 2020/010/030/HV1/005 – Unnecessary issue and administration of Anti-D prophylaxis.

- 2020/012/004/HV1/005 - ffDNA result predicted RhD Positive foetus; Post-delivery confirm result was RhD Negative.

More Information

- IBGRL Website
  - https://ibgrl.blood.co.uk/services/molecular-diagnostics/fetal-rhd-screen/
- NICE Guidelines (DG25)
  - https://www.nice.org.uk/guidance/dg25
- BSH Guidelines
  - https://b-s-h.org.uk/guidelines/guidelines/use-of-anti-d-immunoglobin-for-the-prevention-of-haemolytic-disease-of-the-fetus-and-newborn/
  - https://b-s-h.org.uk/guidelines/guidelines/blood-grouping-and-antibody-testing-in-pregnancy/
  - https://b-s-h.org.uk/guidelines/guidelines/the-estimation-of-fetomaternal-haemorrhage/

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Questions?