GBS3 trial – UHDB site specific operational guidance

Reference no.: GBS3/UHDB/11:22

Contents

1. Introduction to the GBS3 trial

UHDB Maternity Services is participating in the GBS3 Trial (the clinical and cost effectiveness of testing for Group B Streptococcus in pregnancy: a cluster randomized trial with economic and acceptability evaluation).

- UHDB has been randomized to routine Enriched Culture Medium (ECM) testing at 35-37/40 weeks' gestation weeks (or 3-5 weeks prior to planned IOL or delivery date) using a vaginal-rectal swab
- Intrapartum Antibiotic Prophylaxis (IAP) will be offered if the test is positive for GBS and a vaginal birth is anticipated
- This will be standard practice for 12 months from the trial start date, replacing the current risk factor-based strategy.

2. Eligibility

2.1. Inclusion criteria

- Singleton pregnancies: ≥35 weeks gestation OR 3-5 weeks prior to the planned IOL date for those women with a scheduled induction of labor prior to 40 weeks
- Multiple pregnancies: between 32-34 weeks gestation

2.2. Exclusion criteria

- Women who do not provide verbal consent to have a swab
- Women who have had a baby with previous GBS infection (early or late onset) and who want IAP. These women can still be offered a test and be given IAP regardless of the result (if requested by the woman)
- Women in preterm labour (suspected, diagnosed, established) <37 weeks gestation should be offered IAP routinely
- Known congenital anomaly incompatible with survival at birth, of a singleton or all multiple fetuses
- Known prelabour intrauterine death in the current pregnancy of a singleton or all multiple fetuses

3. Trial procedure

- The GBS3 trial and routine testing for GBS should be discussed with the woman at the first booking appointment and the **trial specific** RCOG/Group B Strep Support Leaflet provided (available printed and on the UHDB Maternity App)
- The GBS3 trial and routine testing for GBS should be discussed again at the 28/40 community midwife appointment. In addition to the RCOG leaflet, patients can be given the *'Routine testing for Group B Streptococcus (GBS3) Participant Information Sheet – Enriched Culture Medium'* if requested (see 5.0). Also available on the UHDB Maternity App
- Verbal consent for the swab should be obtained and documented
- The swab should be obtained between 35-37 weeks gestation (or 3-5 weeks prior to planned delivery date for women with an IOL prior to 40 weeks)
- In the case of multiple pregnancy, the swab should be obtained between 32-34 weeks gestation
- A single swab will be used and will be taken from the lower vagina first and then from the rectum, using the same swab for each orifice
- Women can self-swab but this must be documented on the request form and on maternity electronic records. GBS3 leaflet on self swabbing to be given and discussed prior to swabbing.
- Should lubrication be required to minimise discomfort, the swab should be moistened with sterile water or saline only as lubricating gels contain preservatives which may interfere with the ECM test
- Swabs should be ordered electronically where possible, selecting "Group B Strep Screening", but clearly identified as GBS3 trial samples using GBS3 trial-specific orange stickers on the tube. If a request form is used, use the GBS3 stickered request form or add an orange GBS3 sticker
- If the swab is only taken from the vagina, this must be documented on the tube and in the notes
- Results should be checked at the 38/40 Community Midwife appointment (or earlier if practicable) and documented in the notes
- If a vaginal-rectal swab is not collected at 35-37/40 gestation, testing should still be offered providing a result can practically be achieved and communicated back to the clinical team and or/the woman in advance of the onset of labour.
- ECM testing should be repeated if the anticipated delivery date is >5 weeks from the original swab date to ensure accurate detection of GBS carriage.
- In the case of suspected pre-term labour requiring speculum examination, a standard HVS should be taken rather than a GBS3 trial swab.

4. Documentation and management of GBS3 swab results

- Both positive and negative results should be clearly documented in the maternal record
- **If the ECM test is positive:**
  - **The woman should be informed and IAP should be recommended when she is in labour.**
  - As per clinical guidelines, IAP is not required in the case of elective section with intact membranes.
  - **A 'Baby Alert'** should be generated (add on the White Baby Notes)
- **If the ECM test is missed or declined, or the result is not available, follow the UHDB Clinical guidelines with usual risk factor based guidance**

5. Intrapartum Antibiotics regardless of ECM result

IAP should be offered routinely (see full clinical guidelines), irrespective of ECM test result, in the following situations:

- Women who have had a previous baby with GBS infection (early or late onset), if requested by the woman
- GBS detected in MSU during current pregnancy
- Preterm labour <37 weeks gestation

6. Management of incidental findings of GBS on standard swab during GBS3 trial

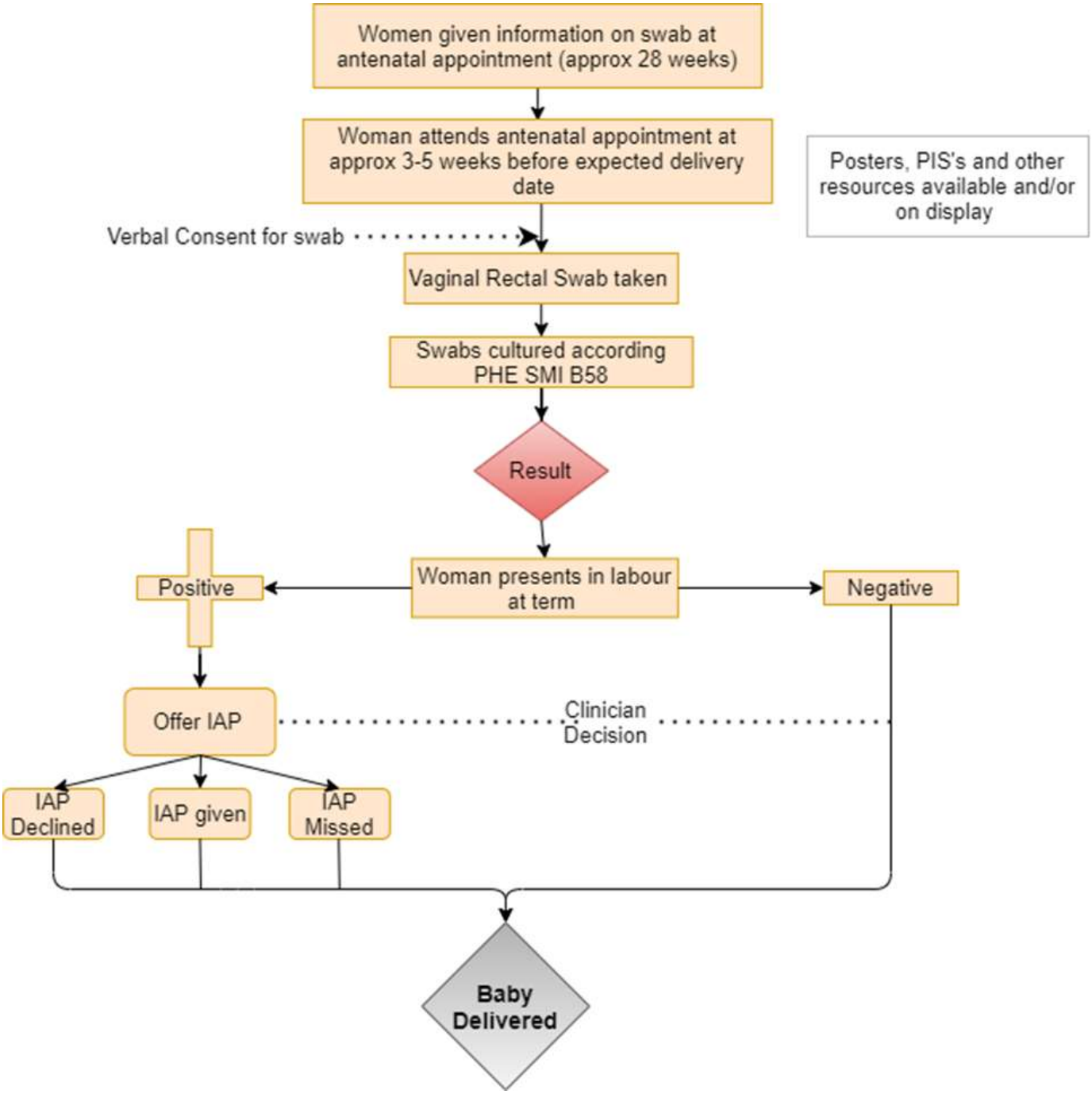
- If GBS carriage is detected on standard swab taken before the ECM result test is taken, clinical decisions should be based on the ECM result
- If a standard swab is positive but the ECM test is negative, and a woman requests IAP, this may be facilitated after discussion with the woman and the obstetric team and clearly documented in the notes

7. Women who decline part or all of routine ECM testing

- Women who decline routine testing should be counselled re the prevalence of GBS colonization, the risk of early onset Group B Streptococcus infection (EOGBS) and 80% reduction in EOGBS with IAP
- **If routine testing is declined, follow full UHDB Clinical guidelines on KOHA**
- Women can decline the rectal swab but should be counselled that taking a swab from the rectum as well as the vagina results in improved detection of GBS colonisation
- Reason for declining all or part of the routine screening must be documented in the maternal notes

8. References

GBS3 trial. NIHR Health Technology Assessment Programme; sponsored by the University of Nottingham. Managed by the Nottingham Clinical Trials Unit.


Women given information on swab at antenatal appointment (approx 28 weeks)
Woman attends antenatal appointment at approx 3-5 weeks before expected delivery date
Posters, PIS's and other resources available and/or on display
Verbal Consent for swab
Vaginal Rectal Swab taken
Swabs cultured according PHE SMI B58
Result
Positive
Woman presents in labour at term
Negative
Offer IAP
Clinician Decision
IAP Declined
IAP given
IAP Missed
Baby Delivered

Documentation Control

Reference Number:	**Version: UHDB Version 1**		**Status: FINAL**	
Version / Amendment	Version	Date	Author	Reason
	1	Nov 2022	Mrs Kara Dent – Obstetric Consultant; Principal Investigator for UHDB	Trial commenced
Intended Recipients:				
Training and Dissemination: Cascaded electronically through lead sisters/midwives/doctors via NHS.net, Published on Intranet, Article in Business unit newsletter;				
To be read in conjunction with: UHDB Clinical GBS guidelines				
Keywords: GBS; GBS3				
Consultation with:	Not applicable			
Business Unit sign off:	Nov 2022: Maternity Governance Mrs K Dent (CD)			
Divisional sign off:	Nov 2022 Divisional Governance			
Implementation date:	Nov 2022			
Review Date:	To be used for the duration of the GBS3 trial			
Key Contact:	Laura Johnson – research midwife			