Ashford and St. Peter's Hospitals NHS
NHS Foundation Trust

STANDARD OPERATING PROCEDURE

GBS3 Trial (Routine Enriched Culture Medium Testing for Group B Streptococcus)

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RATIFIED BY: Perinatal Governance Group	**DATE: January 2023**
VERSION 1.0	**REVIEW DATE: January 2025**

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STATEMENT

GBS3 Trial

- The maternity unit is participating in the GBS3 Trial (the clinical and cost effectiveness of testing for Group B Streptococcus in pregnancy: a cluster randomised trial with economic and acceptability evaluations).
- The unit has been randomised 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 (replacing the current risk factor-based strategy) for 12 months from the trial start date.

EXECUTIVE SUMMARY

- To guide midwifery, obstetric and neonatal practice for the duration of the GBS3 trial.
- To ensure adherence to trial protocol.

ROLES AND RESPONSIBILITIES

Midwives

- Discuss GBS3 trial with pregnant women and inform them that the maternity unit has been randomised to routine antenatal testing of all women at 35-37 weeks (or 3-5 weeks prior to planned IOL or delivery date). Document this discussion in the maternal records on Badgernet.
- Provide trial-specific version of RCOG/Group B Strep Support “Group B Streptococcus (GBS) in pregnancy & new-born babies” information leaflet.
- Obtain and document verbal consent for swab.
- Give swab pack to woman who choose to self-swab. Advise women to post the swab to the testing laboratory on the day they swab via normal Royal Mail post (any post box).
- Obtain vaginal-rectal swab (if women request midwife to obtain swab) between 35-37 weeks' gestation (or 3-5 weeks prior to planned IOL date). Give women the completed swab pack to post to the testing laboratory the same day via Royal Mail.
- Document on request form and tube if women self-swab and if swab is taken from vagina only.
- Check and clearly document result of swab in maternal record on Badgernet.
- If swab is positive for GBS, inform woman and recommend IAP.
- If swab is positive for GBS, generate ‘Baby Alert’.

- Administer IAP to women with GBS positive result and IVAB to babies for whom this is clinically indicated.

Midwives, nurses, nursery nurses

- Complete neonatal observations for babies

Obstetricians

- Discuss GBS3 trial with women as appropriate, use results of ECM test to inform decision-making and prescribe treatment as required.

Neonatal staff

- Use results of ECM test to inform decision-making and prescribe treatment as required.

DISSEMINATION OF DOCUMENT

This SOP will be disseminated through staff training and at staff and unit meetings highlighting the change in practice. The full guideline review process has been followed prior to publication. This document will be published on the Trust intranet.

PROCESSES AND PROCEDURES

Eligibility

Inclusion criteria:

All women anticipating a vaginal birth and women booked for elective caesarean section are eligible for routine testing at:

- ≥ 35 weeks' gestation OR
- 3-5 weeks prior to the planned induction of labour date for those women with a scheduled induction of labour to 40 weeks' gestation OR
- Between 32 – 34 weeks' gestation in the case of multiple pregnancy

Exclusion criteria:

- Women who do not provide consent to have a swab
- Women who have had a previous baby with 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), at ≤37 weeks' gestation should be offered IAP routinely.
- Known congenital anomaly incompatible with survival at birth, of a singleton or all multiple foetuses. Known prelabour intrauterine death in the current pregnancy, of a singleton or all multiple foetuses.

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.
- 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 reference).

- Verbal consent for the swab should be obtained and documented in the maternal record on Badgernet.
- The swab should be obtained between 35-37 weeks pregnancy (or 3-5 weeks prior to planned delivery date for women with an IOL prior to 40/40).
- In the case of multiple pregnancy, the swab should be taken between 32-34 weeks.
- 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 Badgernet. Women will be encouraged to self-swab but the midwife can obtain the swab if the woman requests this.
- 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 still be ordered using the standard HVS request on CERNER (this is to ensure swab results are followed up).
- If the swab is only taken from the vagina, this must be documented on the tube, the request form and Badgernet
- Women who have had **a previous baby with GBS infection (early or late onset)** can still be offered a test. She will be offered IAP **irrespective of the result.**
- Results should be checked at the 38/40 Community Midwife appointment (or earlier if practicable) and documented on Badgernet.
- 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.

Documentation and management of GBS3 swab results

- Both positive and negative results should be clearly documented in the maternal record on Badgernet.
- **If the ECM test is positive, the woman should be informed and IAP recommended when she is in labour.** IAP is not required in the case of EL LSCS with intact membranes.
- **If the ECM test is positive, place an alert on Badgernet, and highlight the need for IAP in the intrapartum management plan on Badgernet.**
- **If a swab is missed, declined, or the result is not available, usual risk-factor based guidance should be followed.** See *'Prevention of Early Onset Neonatal Group B Streptococcal Infection'* guideline.
- In the case of **suspected or diagnosed pre-term labour**, IAP should be offered routinely irrespective of ECM test result.

Management of pre-labour ROM >37/40

- Pre-labour ROM with a positive ECM test should be managed as per *Prevention of Early Onset Neonatal Group B Streptococcal Infection* guidelines.

Management of prolonged SROM

- If there is prolonged SROM in the presence of a negative ECM test, IAP is not required **in the absence of any clinical indication**. ***However, if a maternal fever develops or there is a diagnosis or clinical suspicion of chorioamnionitis, broad-spectrum antibiotics should be administered*** as per *Prevention of Early Onset Neonatal Group B Streptococcal Infection* guideline.

Management of incidental finding of GBS on standard swab during GBS3 trial

- If GBS carriage is detected on standard swab before the ECM test is taken, **clinical decisions should be based on the ECM test 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 couple and the obstetric team and clearly documented on Badgernet.

Management of GBS urine infection

- Women with a GBS urine infection should receive appropriate antibiotics at diagnosis and also IAP, as per *Group B Streptoccocal (GBS) Prevention and Management* guideline (MIDW/GL/92).
- In the case of GBS urine infection where ECM testing is declined/result is not available, revert to usual practice as per *Prevention of Early Onset Neonatal Group B Streptococcal Infection'* guideline.
- It is **mandatory to send a repeat urine culture 7 days after completion of antibiotic treatment as a test of cure.**

Women who decline part or all of routine ECM testing

- Women who decline routine testing should be counselled on the prevalence of GBS colonisation, the risk of early-onset Group B Streptococcus infection (EOGBS) and 80% reduction in EOGBS with IAP.
- **If routine testing is declined, usual risk-factor based guidance should be followed.** See *'Prevention of Early Onset Neonatal Group B Streptococcal Infection'* guideline.
- 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.
- The reason for declining all or part of the routine screening must be documented in the maternal record on Badgernet.

Management of neonate

- See Management of Early Onset Sepsis in Term Neonates guidelines.

REFERENCES

- University of Nottingham, Nottingham Clinical Trials Unit, GBS3 (2021) *Routine testing for Group B Streptococcus (GBS3). Participant Information Sheet - Enriched Culture Medium.* Version 3.0 26th Jan 2021 - [revised versions may be provided during the trial by the GBS3 trial team]. Nottingham: GBS3 Trial Team; badged and distributed internally by Milton Keynes University Hospital NHS Foundation Trust Research & Development Department.

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- National Institute for Health Research (2019; Last updated 2021) *The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3).* [HTA – 17/86/06]. [Online]. Available from: https://www.journalslibrary.nihr.ac.uk/programmes/hta/178606/#/

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