The Prevention of Early-Onset Neonatal Group-B Streptococcal Disease
(V 2)

Guideline Readership

The purpose of this guideline is to provide guidance for obstetricians, midwives and neonatologists within the Heart Of England Trust (HEFT) on the prevention of early-onset neonatal group B streptococcal (EOGBS) disease. Prevention of late-onset GBS and treatment of established GBS disease is not considered beyond initial antibiotic therapy.

All care is tailored to individual patient needs, with an in-depth discussion of the intended risks and benefits of either undergoing or declining intervention or any procedure.

Guideline Objectives

To provide evidence based information to clinicians to deliver appropriate care to women with confirmed Group-B Streptococcal colonisation and/or infection with a potential to lead to EOGBS.

Other Guidance

RCOG Green-top Guideline no. 36. Prevention of early onset neonatal Group B Streptococcal Disease. 3rd Edition. September 2017 (Fully compliant)

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Guideline Author: Dr Pallavi Karkhanis, Consultant Obstetrics and Gynaecology

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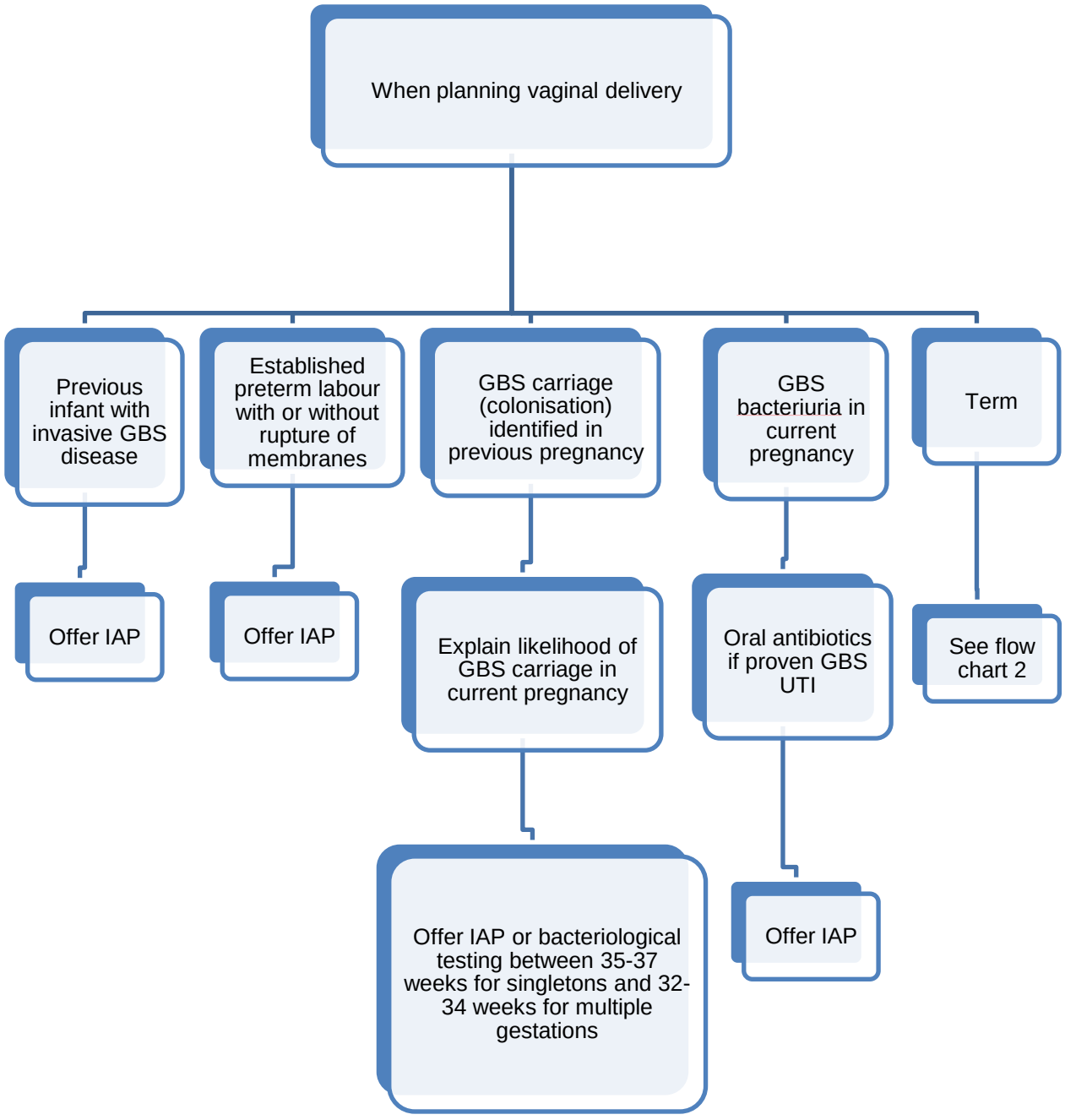
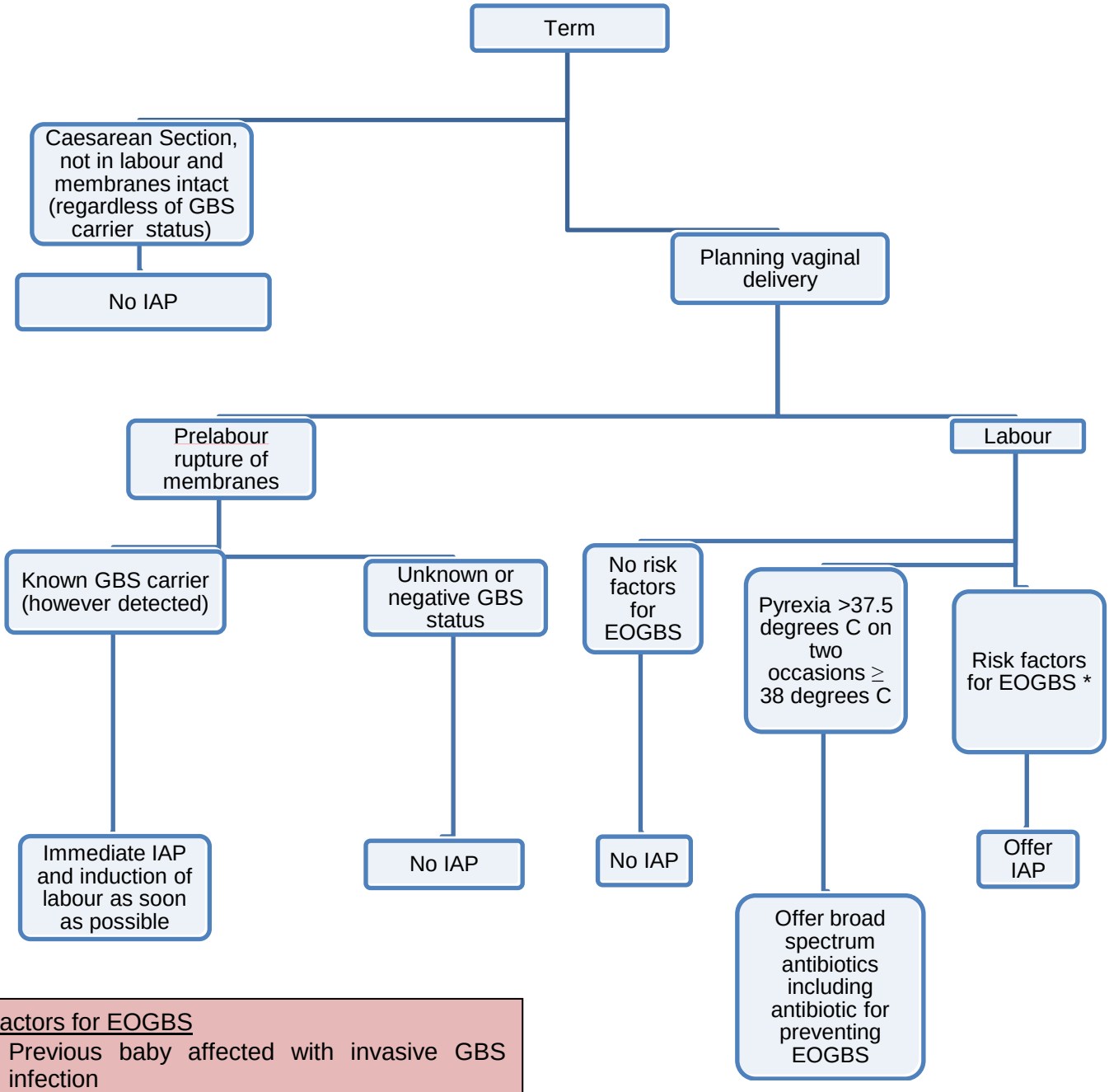
Flowchart 1. Pathway of care for women planning vaginal delivery with risk factors for early onset group B streptococcal disease



GBS- Group B Streptococcus
IAP- Intrapartum Antibiotic Prophylaxis
UTI- Urinary Tract Infection

<u>Flowchart 2.</u> Pathway of care for women during labour with risk factors for early onset group B streptococcal disease



*<u>Risk factors for EOGBS</u>

- Previous baby affected with invasive GBS infection
- Vaginal swab positive for GBS in current pregnancy
- Urinary infection with GBS in current pregnancy
- Established preterm labour (labour <37 weeks) with and without rupture of membranes irrespective of GBS carrier status.
- Prelabour prolonged rupture of membranes > 18 hours
- Maternal pyrexia
- Chorioamnionitis

GBS- Group B Streptococcus
IAP- Intrapartum Antibiotic Prophylaxis
EOGBS – Early onset Group B streptococcal disease

i. Executive Summary & Overview

The Lancefield Group B streptococcus *(Streptococcus agalactiae GBS)* is recognised as the most frequent cause of severe early onset (at less than 7 days of age) infection in newborn infants.

GBS is present in the bowel flora of 20-40% of adults (this is called colonisation). People who are colonised are called 'carriers' and this includes pregnant women.

The incidence of early onset Group B streptococcus (EOGBS) disease in the UK in the absence of systematic screening or widespread intrapartum antibiotic prophylaxis (IAP) is 0.5/1000 births (2015).

IAP has been shown to significantly reduce the risk of culture-positive early–onset but not late-onset disease. There is also indirect evidence of an impact on neonatal deaths.

A Cochrane review of three trials (all at high risk of bias) including 500 women concluded that IAP for colonised mothers reduced the incidence of EOGBS disease (relative risk 0.14; 95% CI 0.04–0.74) although the numbers of deaths were too small to assess the impact of the intervention on mortality.

There have been no studies addressing whether routine screening has had any impact on all-cause mortality. Antenatal screening and treatment may carry disadvantages for the mother and baby. These include anaphylaxis, increased medicalisation of labour and the neonatal period, and possible infection with antibiotic-resistant organisms, particularly when broad spectrum antibiotics such as amoxicillin are used for prophylaxis.

The UK National Screening Committee examined the strategies for the prevention of EOGBS disease in 2016-17 and in March 2017 recommended that routine screening using bacteriological culture or near-patient testing techniques should not be introduced into UK practice.

ii. Body of Guideline

Screening for GBS

- **Universal bacteriological screening of all pregnant women for antenatal GBS carriage is not recommended.**
    - Many women carry the bacteria and, in the majority of cases, their babies are born safely and without developing an infection.
    - Screening women late in pregnancy cannot accurately predict which babies will develop GBS infection.
    - No screening test is entirely accurate. Between 17% and 25% of women who have a positive swab at 35–37 weeks of gestation will be GBS negative at delivery. Between 5% and 7% of women who are GBS negative at 35–37 weeks of gestation will be GBS positive at delivery.
    - In addition, many of the babies who are severely affected from GBS infection are born prematurely, before the suggested time for screening.
    - Giving all carriers of GBS IAP would mean that a very large number of women would receive treatment they do not need; this may increase adverse outcomes to mother and baby.

- **Risk factors for GBS transmission leading to EOGBS include**
    - Previous baby affected with invasive GBS infection (early or late-onset)
    - Vaginal swab positive for GBS in current pregnancy
    - Urinary infection with GBS in current pregnancy
    - Established preterm labour (labour <37 weeks) with and without rupture of membranes irrespective of GBS carrier status. Please refer to the HEFT guideline on Preterm Labour.
    - Prelabour prolonged rupture of membranes > 18 hours
    - Maternal pyrexia (defined as: ≥37.5^{0}c on two occasions more than 2 hours apart, or >38^{0}c on a single occasion)
    - Chorioamnionitis

- **If GBS was detected in a previous pregnancy but the baby was unaffected, the option of IAP or a repeat bacteriological test in late pregnancy should be discussed in the subsequent pregnancies.** IAP must be offered if the test is still positive.

  This is because if GBS is detected in previous pregnancy, the likelihood of carriage in a subsequent pregnancy is around 50%.
  If the swab/MSU is positive, this increases the risk of developing EOGBS to 1:400 and intrapartum antibiotic prophylaxis must be offered. If the test result is negative, the risk is much lower 1:5000 and the patient may choose not to have the antibiotics.

  If performed, bacteriological testing should ideally be carried out at 35–37 weeks of gestation or 3–5 weeks prior to the anticipated delivery date, e.g. 32–34 weeks of gestation for women with twins.

- **Testing for GBS**
    - When testing for GBS carrier status, a swab should be taken from the lower vagina and then the anorectum. A single swab (vagina then anorectum) is to be used.
    - The clinician must indicate that the swab is taken for GBS.

Management

- **Antenatal management**

- Women with confirmed GBS are NOT suitable for midwifery led care. However, birth in a pool (waterbirth) is not contraindicated if the woman is a known GBS carrier provided she is offered appropriate IAP.

- Antibiotic treatment in women found to be colonized on vaginal or rectal swab in the antenatal period does not reduce risk of colonisation at delivery and is therefore **not** recommended. Instead IAP should be offered to GBS-colonised women.

- Women with GBS urinary tract infection (growth of greater than 10^5 cfu/ml) during pregnancy should receive appropriate treatment at the time of diagnosis as well as IAP.
  If persistently generating positive cultures discuss management with microbiology. (Refer to UTI in pregnancy guideline)

- **Induction of labour**

  - Method of induction should not vary according to GBS carrier status and membrane sweeping is not contraindicated.

  - Induction of labour as soon as reasonably possible should be offered to those women who are GBS carriers and present with prelabour rupture of membranes at 37 weeks and more.

    In women where the carrier status is negative or unknown, induction of labour should be offered immediately or expectant management up to 24 hours. Beyond 24 hours, induction of labour is appropriate.

  - In those women who are GBS carriers and present with preterm prelabour rupture of membranes, induction of labour is advisable between 34-36 weeks.

See the HEFT guideline on 'Management of pre-term rupture of membranes & extremely preterm rupture of membranes (PPROM & EPPROM) & pre-labour rupture of membranes at term (PROM)' for individualised management.

- **Caesarean section**

  - All women having caesarean section should receive broad-spectrum antibiotic prophylaxis in line with the Trust clinical guideline Caesarean section.
  - Women undergoing planned caesarean delivery in the absence of labour or membrane rupture do not require additional penicillin antibiotic prophylaxis specifically for GBS i.e. IAP, regardless of GBS carrier status. The risk of neonatal EOGBS disease is extremely low in this circumstance.
  - Women who are known GBS carriers who are to be delivered by caesarean section after spontaneous rupture of membranes should be offered IAP and delivered by category 2 or 3 caesarean depending on other clinical findings.

- **Intrapartum management**

Intrapartum antibiotic prophylaxis (IAP) is indicated and offered in the following circumstances-

a. Vaginal colonisation with GBS confirmed in the current pregnancy
b. Confirmed urinary infection with GBS in the current pregnancy
c. Women with a previous baby infected by GBS regardless of GBS status in current pregnancy
d. Suspected chorioamnionitis

IAP should be considered if the following risk factors are present-

a. Preterm labour- the risk of GBS infection is higher with preterm delivery and the mortality rate from infection is increased (20-30% vs 2-3% at term).
b. Preterm prolonged rupture of membranes > 18 hours.
See the HEFT guideline on 'Management of pre-term rupture of membranes & extremely preterm rupture of membranes (PPROM & EPPROM) & pre-labour rupture of membranes at term (PROM)' for individualised management.
c. Intrapartum pyrexia defined as ≥37.5^{0}c on two occasions more than 2 hours apart, or >38^{0}c on a single occasion. Women with pyrexia in labour should be treated with broad-spectrum antibiotics including an antibiotic for prevention of neonatal EOGBS.

- **Antibiotics for IAP**

3g intravenous benzylpenicillin as soon as possible after the onset of labour followed by 1.5g every four hours until delivery.

Women with known or suspected penicillin allergy:

In those patients who <u>do not report a severe allergy</u> to penicillin i.e. no history of anaphylaxis, angioedema, respiratory distress or urticaria,
1.5g intravenous cefuroxime loading dose followed by 750mg every 8 hours.

In cases of <u>severe allergy</u> to penicillin i.e those with history of anaphylaxis, angioedema, respiratory distress or urticaria,
1g intravenous vancomycin every 12 hours.

To optimise the efficacy of IAP, the first dose should be given at least 4 hours prior to delivery.
Clindamycin can no longer be recommended as the current resistance rate in the UK is 16%.

<u>Administration of medication via intravenous (IV) route</u>

<u>Please refer to the HEFT Medicines Management Policy- Intravenous Infusions and Intravenous Medicines Administration Procedure</u>
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<u>Treatment of anaphylaxis during/following intravenous therapy</u>

There is a small but serious risk of immediate, severe and potentially lethal anaphylactic reaction to parenteral use of Penicillin and other antibiotics.

It may manifest as laryngeal oedema, bronchospasm, cardiovascular collapse. Usually occurs during first few minutes of administration.

Treatment of severe allergic reaction:

• Stop IV antibiotic drip
• Call for help –Adult and Obstetric Emergency 2222
• Check airway, breathing, circulation (ABC)
• Give high flow oxygen (10 l/min) via face mask with reservoir bag
• Give adrenaline 500 micrograms IM (0.5 ml adrenaline in 1:1000)
• IV crystalloids
• Secondary therapy
• Hydrocortisone 100-200 mg slow IV injection
• Chlorpheniramine 10-20 mg slow IV injection if needed

Please complete a Datix/IR1 if there has been a severe allergic or anaphylactic reaction and ensure this event is documented in the patient's hospital records as well as the discharge summary to the GP.

Neonatal Management

Ampicillin given to mothers in pregnancy has been associated with an increase of resistance gram-negative infection in the newborn. Also, Co-Amoxiclav (Augmentin) has specifically been linked with an increased risk of Necrotising Entercolitis (NEC) in the pre-term infant. These antibiotics are thus best avoided unless specifically indicated.

Well babies should be evaluated at birth for clinical indicators of neonatal infection and have their vital observations carried out at 0, 1, 2 and every 2 hours until 12 hours of age and documented on the neonatal observation sheet. These monitor the baby's temperature, heart and respiratory rate, general well-being and feeding.

Breast feeding should be encouraged irrespective of GBS status.

Neonates of mothers who are positive for GBS in the current pregnancy or had a previous GBS affected pregnancy need to be observed for the following signs and **urgent medical advice should be sought-**

- Abnormal behaviour eg. inconsolable crying or listlessness or
- Unusually floppy or
- Has developed difficulties with feeding or with tolerating feeds or
- Has an abnormal temperature unexplained by environmental factors <36 degrees C or >38 degrees C or
- Rapid breathing or
- Change in skin colour

The following babies should be referred to a neonatologist -

- Babies born to mothers who should have received IAP but did not
- Babies born to mothers who received the first dose of IAP less than 4 hours prior to delivery
- Preterm babies whose mothers received IAP
- Babies who mum is having fever and/or unwell with infection after birth

Documentation

GBS infection in pregnancy warrant a **perinatal alert** form to be completed during the antenatal period to generate a plan of care for the neonate during the postpartum period. One copy should be secured in the maternal hospital notes, and a further copy stored securely on labour ward and the neonatal unit (NNU).
The plan of care should be clearly documented on the Badgernet Maternity Information System. Also, any maternal infections in pregnancy (incl. GBS) and/or perinatal alerts should be clearly documented on the Badgernet in the antenatal, intrapartum and postnatal (for mother and baby) notes.
Don't forget to affix a **'perinatal alert' sticker** on patient handheld as well as main medical notes and to give the patient information leaflet.

At present HEFT is using the patient information leaflet issued by Group B Strep Support charity organization. These are available at antenatal clinics, maternity assessment centres and antenatal wards.
(http://gbss.org.uk/wpcontent/uploads/2014/06/ProtectLeaflet_May2017_WEB.pdf)

iii. Reason for Development of the Guideline

The guideline provides information to all clinicians for the management of patients at risk of delivering a neonate affected by GBS. Therefore, aiming to reduce the risk of maternal and neonatal mortality and morbidity associated with GBS in pregnancy.

iv. Methodology

Development of the guidelines adheres to a process of examining the best available evidence relevant to the topic, incorporating guidance and recommendations from national and international reports.
Each guideline is circulated widely for comments to an agreed panel of clinical expertise.

Finalised guidelines will ultimately be approved and ratified by the directorate locally.
Any notable differences in organisation of care across trust sites will be listed in each individual guideline.

v. Implementation in HEFT & Community – Communications

Following approval the guideline will be disseminated and available for reference to all members of the multidisciplinary team via the Trust intranet site as well as Practice posters, emails, newsletters and Trust Communications emails. A paper copy will be stored in a marked folder within a designated clinical area.

vi. **Monitoring**

Adherence and efficiency of clinical guideline will be monitored through continuous clinical audit, arranged by the clinical audit lead and performed by allocated junior doctors and midwives. This will be audited bi-annually, but where clinical incidents where shoulder dystocia has been noted then these are collated monthly on the maternity dashboard, reported to the O&G governance group meetings; and will be investigated on an individual basis according to risk management procedures.

Multidisciplinary auditing of a clinical guideline will be allocated and overseen by the Clinical Audit Lead.

Elements to be monitored	**Tool**	**Frequency**
Minimum requirements: • Number of women diagnosed with GBS at delivery • A documented management plan of women and babies diagnosed as having GBS • Management of the newborn where there is known GBS present in either mother or newborn	Badgernet MIS Maternal notes Neonatal notes	Annually 1% of all health records of women and neonates diagnosed with GBS

Reporting arrangements	**Acting on recommendations and lead(s)**	**Change in practice and lessons to be shared**
The completed reports will go to the clinical governance group and be presented at the departmental audit meetings. Action plans will be documented in minutes.	The leads will use the electronic tracker system for audit to track action plans, which will have stated time frames	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders. Non-compliance to actions from audit will be escalated to the Directorate governance meetings; further non-compliance will be finally escalated to the Women's and Children's Quality and Safety for resolution.

Following clinical audit of a guideline an addendum to change in clinical practice may be necessary. Any change to a clinical guideline requires that it must be ratified by the Directorate locally.

Review dates for guidelines will be set at a period of three years; however this set period can be overridden in the light of new clinical evidence.

All unused/previous guidelines will be logged and archived electronically, and in paper format within the trust.

References

1. RCOG Green-top Guideline no. 36. Prevention of early onset neonatal Group B Streptococcal Disease. 3rd Edition. Sept 2017.
2. Ohlsson A, Shah VS. Intrapartum antibiotics for known maternal Group B streptococcal colonization. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD007467. DOI: 10.1002/14651858.CD007467.pub4
3. Group B Strep Support. http://gbss.org.uk/.
4. NICE Guidance on Intrapartum care https://www.nice.org.uk/guidance/cg190 - (currently being updated)
5. NICE Guidance on Neonatal infection (early onset): antibiotics for prevention and treatment: https://www.nice.org.uk/guidance/CG149 (currently being updated)

Meta Data

Guideline Author:	Dr Pallavi Karkhanis
Guideline Sponsor:	Obstetrics and Gynaecology Directorate
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Date of CGG Ratification:	18th October 2017
Date of Launch:	8th January 2018
Review Date:	8th January 2021
Key Words	GBS, EOGBS, Neonatal sepsis
Related Policies / Topic / Driver	*Antibiotics in Obstetrics* *HEFT Medicines Policy* *Midwifery Led guidelines* *Neonatal unit guidelines* *Pre-term labour and pre-labour rupture of membranes*

Revision History

Version No	Date of Issue	Author	Reason for Issue
1	Apr 2006	S. Hutchon, M. Dobson, C. Rhodes, E. Andrews, R. Daniels, D. Pillay & E. Frost (previously recorded as 'Infections in Pregnancy')	Merger
2	Dec 2010	J. Chu M. Dobson	Review
3	Dec 2011	H. Honest	Review p. 4 urine sample to be sent following treatment of UTI p.5 individualised management with PPROM/SROM

4	Apr 2014	H. Honest	Addendum to practice: p 4. Women with confirmed GBS NOT suitable for midwifery led care p.5 IAP should be considered if the following risk factors are present: Prematurity (<37 weeks), prolonged rupture of membranes (>18 hours) (individualized management with reference to HEFT PPROM/SROM guidelines i.e. where GBS was identified earlier in the current pregnancy (by a swab taken for other reasons or as UTI), immediate induction of labour and IAP should be offered) and intrapartum pyrexia.
5	Dec 2017	Karkhanis P	Full review

Clinical Guideline Group Lead: Pallavi Karkhanis

Clinical Director: **Signed:** 

Name: Richard Kennedy
Date: 18 December 2017