Reference Number: UHBOBS052 Version Number: 10	**Date of Next Review: Previous Trust/LHB Reference Number:**

Management of Maternal Group B Streptococcus Colonisation

Introduction and Aim

One in four pregnant women in the UK carry GBS in the gut and genital tract. Approximately 50% of babies whose mothers are GBS carriers will also be colonised with GBS and of those 3% will develop early-onset GBS (EOGBS) infection. EOGBS infection is caused by GBS bacteria ascending from the maternal genital tract during pregnancy (usually in the presence of ruptured membranes, although can occur with intact membranes) or labour. EOGBS infections tend to manifest as pneumonia and sepsis. It has been estimated to EOGBS infection causes more than 40 neonatal deaths and approximately 25 cases of long-term disability every year, with mortality rates higher for preterm babies.

Current practice in the UK follows the UK National Screening Committee (NSC) which recommends “not to screen for maternal GBS carriage in the general population” due to the absence of randomised trial data on either its effectiveness or cost-effectiveness. The key findings of the latest NSC review were that introduction of testing would result in tens of thousands of women being offered and having IAP administered unnecessarily, whilst the long term effects of this widespread intervention remain unknown. The key issue, when considering testing at 35-37 weeks of gestation, was the lack of randomised trial data, evidence of efficacy, and the accuracy of this antenatal testing as an indication of neonatal risk status at delivery. The review recommended a randomised controlled trial (RCT) to address these issues, therefore the GBS3 trial has been developed.

THE GBS3 study is a cluster randomised trial to address the research question: does routine testing of women for GBS colonisation either in late pregnancy or during labour reduce the occurrence of early-onset neonatal sepsis compared to the current risk factor-based strategy. The trial will also address secondary questions of effectiveness, cost-effectiveness, acceptability and implementation. The study aims to recruit 320,00 women across the UK to address these outcomes. UK sites are randomly assigned to one of three groups; testing in late pregnancy, testing during labour or usual care/risk factor-based group. Our site has been randomised to routine testing in late pregnancy at 35-37 weeks.

Objectives

The aim of this guideline is to provide support for obstetricians, midwives and neonatologists on the prevention of early-onset neonatal group B streptococcus (EOGBS) disease and to provide information to women, their partners and family.

Scope

This policy applies to all healthcare professionals in all locations including those with honorary contracts

Equality Health Impact Assessment	*An Equality Health Impact Assessment (EHIA) has not been completed.*
Documents to read alongside this Procedure	*Antenatal Care Guideline*
Approved by	*Maternity Professional Forum*

Accountable Executive or Clinical Board Director	*Jason Roberts, Executive Nurse Director*
Author(s)	*Louise Dowler, Interim Women's Experience Midwife* *Abi Holmes, Consultant Midwife*

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	Dec 2005	Dec 2005	
2	Dec 2008	Dec 2008	Alex Rees, Julia Sanders
3	Nov 2011	Dec 2011	Pina Amin
4	Sept 2013	Nov 2013	Sybil Barr, Julia Sanders, Alex Rees
5	July 2014	July 2014	Sybil Barr, Julia Sanders, Alex Rees
6	October 2018	Feb 2019	Louise Dowler, Abi Holmes
7	2020	2020	Amendment to antibiotics January 2020
8	May 2023	2023	Updated to include Maternity section updated by Sarah James, consultant midwife Neonatal section updated by Alok Sharma, neonatologist
9	October 2023		Further updates to neonatal section. Not linked to neonatal sharepoint guideline as refers to NICE, this is not used in C&V

Contents

’ The words woman and women have been used throughout this document as this is the way that the majority of those who are pregnant and having a baby will identify. For the purpose of this document, this term includes girls. It also includes people whose gender identity does not correspond with their birth sex or who may have a non-binary identity’.

1. Antenatal Care

For the time period May 2023 until March 2024. Appendix GBS3 trial SOP will be followed.

2. Intrapartum Care

Women who have a known allergy to Penicillin should be offered Clindamycin. This group of women should be offered care on the CLU and cared for on the Normal Labour Care Pathway.

Women with known GBS status should be invited into the unit when calling for labour, rupture of membranes or reduced membranes at the first phone call.

1) Intrapartum Antibiotic Prophylaxis (IAP)) should be administered as per our patient group directives for any women with GBS detected on LVS / HVS, MSU or anorectum during her current pregnancy.
2) If a woman has had a previous GBS infected infant, IAP should be offered.
3) If a woman is anxious about GBS and requests IAP, it should be offered.
4) **The antibiotic of choice is Penicillin 3G IV as soon as possible after onset of labour (if no SROM) and thereafter 1.5G four hourly until birth. The dose should be mixed with at least 20mls of 0.9% saline or water for injections and administered over at least 10minutes by slow injection or infusion in a 50ml 0.9% saline bag. Following administration, the line should be flushed.**
5) The need for IAP should not be viewed as a contraindication to use of the pool for labour and birth.
6) GBS carrier status is not an indication for continuous fetal heart rate monitoring in labour.
7) Women with no additional risk factors can deliver on the MLU with IAP
8) Any additional risk factors for sepsis, CLC is required on the CLU.

9) If chorioamnionitis is suspected commence the maternal sepsis pathway.

3. Elective Caesarean Section

IAP is not necessary for women undergoing elective caesarean section with intact membranes.

4. Induction following SROM at term (CLU women)

1) In order to identify women who are GBS positive, records on Welsh Clinical Portal, relating to the current pregnancy, should be checked for all women reporting SROM at term.

2) After SROM at term, with GBS detected in pregnancy, immediate admission should be advised and induction of labour should be planned to commence as soon as practicable.

3) IAP should be offered immediately to GBS positive women with confirmed SROM at term.

5. Assessment following SROM at term (MLC women)

1) In order to identify women who are GBS positive, records on the clinical portal, relating to the current pregnancy, should be checked for all women reporting SROM at term.

2) After SROM at term, with GBS detected in pregnancy, immediate admission to the MLU is advised. The loading dose of Benzylpenicillin (3g) is given regardless of stage of labour. A full assessment should take place.

3) If in established labour, to remain MLC and follow the MLU pathway for IAP.

4) If not in established labour, offer women the option for immediate transfer to first floor for IOL or the midwife to use clinical judgement as to whether active labour is likely to establish soon. If deemed likely, the woman may remain on MLU and have a repeat full assessment after 4 hours. If established in labour, please refer to GBS: MLU pathway for IAP. If not established in labour within this timeframe, transfer to first floor for IOL and for continued IAP should be facilitated.

6. Preterm SROM and GBS detected in pregnancy

1) Confirm SROM

2) Give oral Erythromycin

3) If in labour/early labour offer intrapartum antibiotic prophylaxis (IAP) for GBS

(All women with confirmed preterm labour ruptured membranes should be offered IAP once in labour or induced irrespective of GBS status).

4) If unwell during antenatal period, give IAP for GBS and plan delivery.

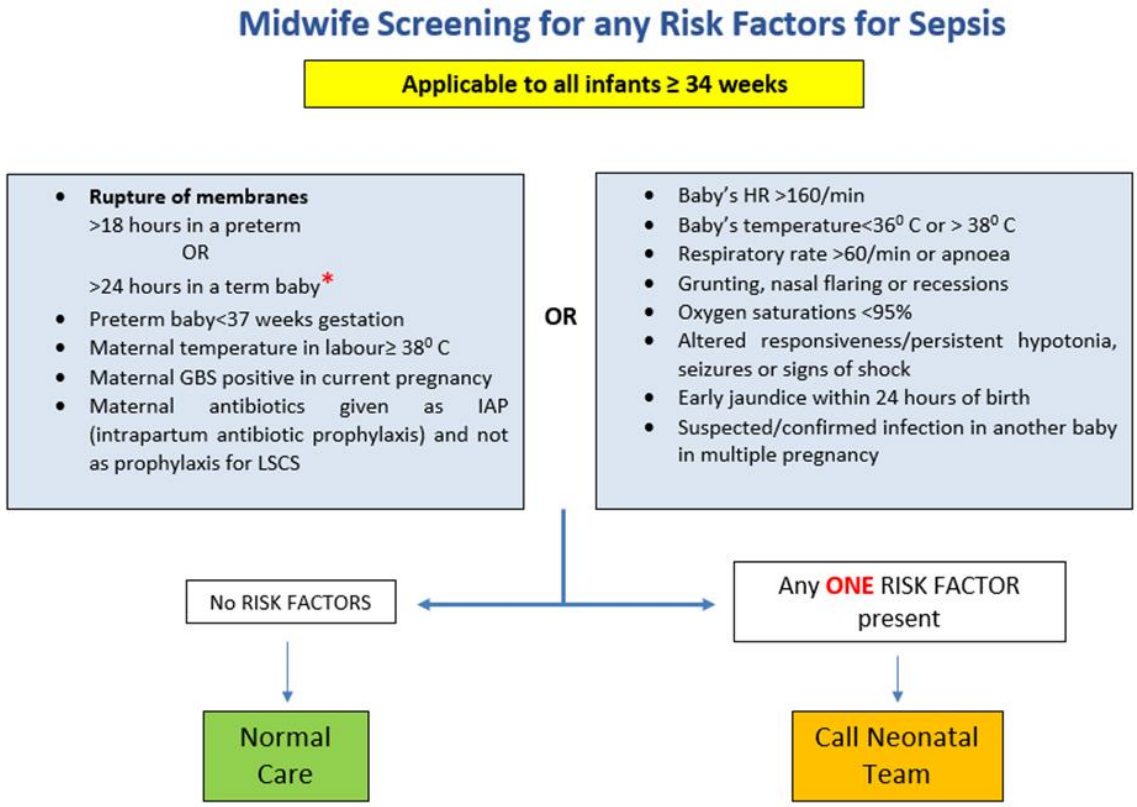
7. Neonatal care for babies exposed to GBS

For ease of clinical use and to ensure uniformity of care for babies in all postnatal ward areas (Delivery suites/Transitional care/ MLU) the midwife should **contact the neonatal team for ALL babies born via VAGINAL birth exposed to GBS. The neonatal team will review and perform the sepsis risk calculator.**

For babies born via caesarean section birth, with intact membranes and not in labour, referral to neonatologist is NOT required. Routine care.

The following generic principles apply in all situations and supersede any sepsis algorithm

1. All infants symptomatic of sepsis must be investigated and treated promptly with antibiotics within 1 hour of the decision to treat. This is irrespective of their sepsis risk score. If you are unsure seek senior help.
2. Investigations for sepsis should include a blood culture **(a minimum of 1ml of blood must be inoculated into the blood culture bottle)**, FBC and a CRP. The latter should be repeated in 18- 24 hours.
3. Where there is a history of confirmed Group B Streptococcal sepsis or death of a neonate in previous pregnancy, **AND** the mother **has not** received adequate intrapartum prophylaxis in this pregnancy, the newborn infant should be screened and presumptively treated irrespective of the sepsis risk score.



*Please see the addendum and the flow chart below for MLU deliveries (appendix)

8. References

Royal college of obstetricians and gynaecologists (RCOG) Prevention of early-onset neonatal Groups B streptococcal disease 2017

Neonatal infection: antibiotics for prevention and treatment (NG195). Published April 2021. www.nice.org.uk/guidance/ng195

Goel N, Shrestha S, Smith R …… Banerjee S. Screening for early onset neonatal sepsis: NICE guidance-based practice versus projected application of the Kaiser Permanente sepsis risk calculator in the UK population. Arch Dis Child Fetal Neonatal Ed. 2020;105:118-22

Morris R, Jones S, Banerjee S et al. Comparison of the management recommendations of the Kaiser Permanente Sepsis Risk Calculator with NICE guideline CG149 in infants ≥ 34 weeks gestation who developed early onset sepsis. Arch Dis Child Fetal Neonatal Ed 2020;105:F581-F586

Goel N, Cannell S, Davies G et al. Implementation of an adapted Sepsis Risk Calculator algorithm to reduce antibiotic usage in the management of early onset neonatal sepsis: a multicenter initiative in Wales, UK. Arch Dis Child Fetal Neonatal Ed 2021;0: F1–F8. doi:10.1136/archdischild-2020-321489

9. Appendix 1

Reference Number: **Version Number: 1**	**DATE OF REVIEW:** **Date of Next Review:**

STANDARD OPERATING PROCEDURE.

GBS3 Trial – Routine testing for GBS at 35-37 weeks

Introduction and Aim

This guideline is for health professionals within maternity services, to support clinical practice and the care of women participating in the GBS3 study within Cardiff and Vale NHS trust. This involves standardized routine testing for GBS at 35-37 weeks.

Objectives

- To set out the standards of care during participation in the GBS3 study (approx. 10-12 months) which involves routine GBS testing between 35-37 weeks.
- To set out guidelines to ensure all women are informed about GBS testing at booking, have swab packs at 28 weeks, have a swab sent off at 35-37 weeks and ensure the appropriate action is taken following a swab result.

Scope

This policy applies to all healthcare professionals working in maternity services including those with honorary contracts

Equality Health Impact Assessment	*An Equality Health Impact Assessment (EHIA) has not been completed.*
Documents to read alongside this Procedure	*GBS3 Trial Protocol*
Approved by	

Accountable Executive or Clinical Board Director	*Jason Roberts, Executive Nurse Director*

Author(s)	*Claire Bertorelli, Emma Pugh, Angela Strang*

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1			NEW DOCUMENT

1 What is this Standard Operating Procedure for?

This SOP describes the standardised care and procedures that maternity staff need to follow for the duration of the GBS3 study. This involves routine antenatal testing for GBS between 35-37 weeks for all women via a vaginal-rectal swab. This SOP will allow the research team to achieve the 80% recruitment target of all women, as designed by the trial study team, by ensuring all staff are aware of actions to be taken throughout pregnancy and labour to fulfil the requirements of routine standardised GBS testing at 35-37 weeks.

2 Background

One in four pregnant women in the UK carry GBS in the gut and genital tract. Approximately 50% of babies whose mothers are GBS carriers will also be colonised with GBS and of those 3% will develop early-onset GBS (EOGBS) infection. EOGBS infection is caused by GBS bacteria ascending from the maternal genital tract during pregnancy (usually in the presence of ruptured membranes, although can occur with intact membranes) or labour. EOGBS infections tend to manifest as pneumonia and sepsis. It has been estimated to EOGBS infection causes more than 40 neonatal deaths and approximately 25 cases of long-term disability every year, with mortality rates higher for preterm babies.

Current practice in the UK follows the UK National Screening Committee (NSC) which recommends "not to screen for maternal GBS carriage in the general population" due to the absence of randomised trial data on either its effectiveness or cost-effectiveness. The key findings of the latest NSC review were that introduction of testing would result in tens of thousands of women being offered and having IAP administered unnecessarily, whilst the long term effects of this widespread intervention remain unknown. The key issue, when considering testing at 35-37 weeks of gestation, was the lack of randomised trial data, evidence of efficacy, and the accuracy of this antenatal testing as an indication of neonatal risk status at delivery. The review recommended a randomised controlled trial (RCT) to address these issues, therefore the GBS3 trial has been developed.

THE GBS3 study is a cluster randomised trial to address the research question: does routine testing of women for GBS colonisation either in late pregnancy or during labour reduce the occurrence of early-onset neonatal sepsis compared to the current risk factor-based strategy. The trial will also address secondary questions of effectiveness, cost-effectiveness, acceptability and implementation. The study aims to recruit 320,00 women across the UK to address these outcomes. UK sites are randomly assigned to one of three groups; testing in late pregnancy, testing during labour or usual care/risk factor-based group. Our site has been randomised to routine testing in late pregnancy at 35-37 weeks.

3 Duties and responsibilities

All community midwives to follow the standardised care for swabbing all women between 35-37 weeks. Please see care planning.

Antenatal clinic staff to ensure all consultant led women have swabs done between 35-37 weeks. Please see section 4 - pathway.

All staff to be responsible for recording on E3 if women decline/opt-out of the study, decline GBS swabs or have a GBS positive result.

4.Pathway

<u>Booking appointment</u>

Antenatal clinic staff to put GBS3 information pack in all maternity notes. Information pack includes RCOG GBS information sheet, GBS3 Trial information card, blue microbiology form, instructions for taking swab and GBS3 sticker to put on the front of all maternity notes)

Antenatal clinic staff to put GBS3 study sticker on front of all maternity notes.

Information sheets available in 5 different languages.

28/40 appointment

Community midwives and antenatal clinic staff – to give all women the GBS3 swab pack if not already received one. Women to be informed to do vaginal-rectal swab the day of their 35-37 week appointment and bring with them.
No formal consent needed, only verbal consent (CAG approval in place).

32-34/40 appointment (twins/multiples only)
Swab for all twin/multiple pregnancies should be sent to labs.

34/40 appointment

Community midwives and antenatal clinic staff to remind women, either face to face or via text reminder, to bring their swab to their 35-37 week antenatal appointment.

35-37/40 appointment

Community midwives or antenatal clinic staff to collect swab from all women and send to lab.
Any women who forget their swab need to be given another one to complete at this appointment to be sent off.
If the women does not want to do the swab herself it can be performed by a midwife/antenatal clinic staff.
Instruction sheets for completing the swab will be provided at 28 weeks – the vagina and rectum must both be swabbed and no gel to be used.

Swab procedure

All women will have an information leaflet in their notes about how to perform the swab themselves.
Use black charcoal swabs.
A small orange GBS sticker should be stuck on the request bag/form for the labs to identify these samples and on the swab.
The test should be requested on WCP under “GBS screening”. Put one sticker on the swab and write whether the swab is vaginal and rectal OR vaginal only OR rectal only.
If hand writing the forms please write “GBS screening” under “investigations required”. Write vaginal and rectal OR vaginal only OR rectal only in the “specimen type”.
ANC staff to request under Elizabeth Cleavely and community midwives to request under community midwives.
Please get the sample to the labs ASAP, preferably within 24 hours. Please store at room temperature.

Missed swabs

If a swab is missed at a 35-37 week appointment it can be collected at their next antenatal appointment and sent to the local labs. Missed swabs cannot be taken during labour.

Result reporting to women

Only women who test positive need to be informed, this needs to be recorded on E3. It is the responsibility of the community midwife or antenatal clinic (whoever sent the swab) to give the woman their result if they test positive, it should be marked on E3 that the woman has been informed. Information must be given to them surrounding the care for women with GBS in labour as described in the Trust GBS guidelines.

Decline/Opt-out of GBS3

Women need to opt-out of the study as testing for GBS at 35-37 weeks will be standardised care.
If women decline/opt-out of testing – this must be documented on E3 and on the GBS sticker on the front of the notes.

Women excluded from testing

Women whose baby has a congenital abnormality incompatible with life.
Women with known prelabour IUD.
Women who decline/opt out.

References

University of Nottingham. 2021. The clinical and cost-effectiveness of testing for Group B Streptococcus in pregnancy: a cluster randomised trial with economic and acceptability evaluations (GBS3).

Centers for Disease Control and Prevention. Early-onset and late-onset neonatal group B streptococcal disease--United States, 1996-2004. MMWR Morbidity and mortality weekly report. 2005;54(47):1205-8.

National Screening Committee. The UK NSC recommendation on Group B Streptococcus screening in pregnancy. 2017.

UK National Screening Committee. Antenatal screening to prevent early onset group B streptococcus (GBS) infection. 2015.

10. Appendix 2

Ymddiriedolaeth GIG
Caerdydd a'r Fro

Cardiff and Vale NHS Trust

University Hospital of Wales
Ysbyty Athrofaol Cymru

Parc Y Mynydd Bychan,
Caerdydd CF14 4XW

Heath Park,
Cardiff CF14 4XW

Phone 029 2074 7747
Ffôn 029 2074 7747

ROUTINE TESTING FOR GROUP B STREP

Date

Dear

I am writing to inform you the vaginal/rectal swab you had taken shows that you have a bacterial infection known as Group B Streptococcus (GBS).

Around 20-40% of women carry this infection in their birth canal, and are free from symptoms. You do not need treatment in pregnancy as GBS is not harmful to you but it can be passed to your baby at birth. Therefore you will be offered antibiotics in labour on delivery suite or midwifery led unit. Please state you have a GBS positive result anytime you call the hospital if you have any concerns. If your waters break after 37 weeks and you do not go into labour we will offer induction of labour and antibiotics, please call the unit ASAP. In addition, some babies may require observations on the postnatal ward after birth.

Please read the RCOG GBS information leaflet in your notes regarding this infection in pregnancy or follow the QR code:
If you have any concerns or queries regarding the matter please contact your community midwife on 02920 745030 or the obstetric assessment unit on 02920 744658.

Please file this letter with your maternity notes so that your midwife will see this information.

Yours sincerely

Community/Antenatal Clinic Midwife

12 Appendix 3

DIRECTORATE OF OBSTETRICS AND GYNAECOLOGY

Patient Group Directive for The supply of Intrapartum Antibiotic Prophylaxis, Benzylpenicillin 3g/1.5g to midwifery-led women to reduce the risk of early onset Group B Streptococcus disease of the neonate

PGD comes into effect	
Review date	
Expiry date	
Name of Medicine	IV Benzylpenicillin 3g/1.5g
Professionals to which PGD applies	Registered midwives employed within Cardiff & Vale University Health Board working as part of the countermeasures framework who have demonstrated competency
Clinical Director for Obstetrics	Anju Kumar
On behalf of Cardiff & Vale University Health Board Service Director for Pharmacy and Medicines Management	Mr Darrell Baker
Medical Director	Dr Graham Shortland
Nurse Director	Mrs Ruth Walker
Clinical Condition	Reducing the risk of Neonatal Group B Streptococcal (GBS) infection
Criteria for Inclusion	Women identified at risk of neonatal Group B Streptoccocal infection:

	GBS detected on a HVS during pregnancy GBS detected on a MSU during pregnancy Previous baby with a GBS infection Maternal choice
Criteria for exclusion	Allergy to Penicillin or hypersensitivity to any of the ingredients Renal impairment Hepatic impairment Diabetic women Cardiac impairments
Additional risk factors resulting in CLU care	Any comorbidities Prolonged rupture of membranes Pre-labour SROM Pyrexia Suspected infection
Seek Further Advice	In case of any doubt further advice must be sought from the appropriate health professional and recorded as having been sought before the drug is given Refer clients who are excluded to a doctor

Description of treatment	
Name of medicine	Benzylpenicillin
Legal status of Medicine	GSL
Form	Intravenous injection/infusion
Strength: Loading dose: Maintenance dose	3g 1.5g
Dosage	3g on the onset of labour or confirmation of rupture of membranes and then 1.5g 4hrly until birth
Total daily dose	N/A
Route of administration	Intravenous (IV) injection or infusion
Frequency of administration	Loading dose and then 4hrly until birth
Duration of treatment	From onset of established labour until delivery.
Total treatment quantity	A loading does of 3g then 1.5g every 4hours until delivery under this PGD.

Adverse reactions	Skin rash or itchy skin

	Difficulty in breathing or tightness of the chest Puffiness of the eyelids, face or lips Swelling or redness of the tongue Fever Diarrhoea Joint Pains Swollen lymph nodes Convulsions Haemolytic anaemia Low levels of potassium in the blood High levels of sodium in the blood
Written & verbal advice for patient/carer	Verbal advice from midwife regarding reasons for treatment Patient information leaflet
Follow up	Midwives to refer women to consultant ANC for review
Arrangements for referral for medical advice	See GP/Obstetrician
Records of administration for audit	The following to be recorded in patients notes Dose, frequency and the quantity of medicine supplied Date of supply to patient Batch number and expiry date Signature of person supplying the medication

Staff:	
Professional qualifications	Registered midwife
Training	Demonstrates evidence of competency Has completed PGD training Familiar with the BNF entries for this product Recognises the adverse drug reactions Recognition and treatment of anaphylaxis
Continuing education	Relevant update training Aware of any updates made to the product in the BNF
Signature of individual accepting responsibility and accountability to perform this PGD	

Addendum for Midwifery Led Unit (MLU) deliveries

All Wales Neonatal Network Guideline

Early Onset Sepsis Risk Assessment for Infants >37 Weeks Gestation Born in Midwifery led settings with total duration rupture of membranes >24 hours.

Where a woman is in established labour within 24 hours of rupture of membranes (ROM) and is otherwise suitable for midwifery led intrapartum care, a midwifery led setting is a safe birthing environment and no additional monitoring is recommended during labour or in the postnatal period. The chance of early onset neonatal sepsis (EOS) is very low[1,2].

Where a woman is not in established within 24 hours of ROM (pre-labour rupture of membranes) obstetric led care is appropriate with birth recommended in a unit where there is access to neonatal services[1]. This is standard care and women should be informed of this recommendation in the antenatal period.

When birth occurs in a midwifery led setting and total duration rupture of membranes is more than 24 hours, the EOS risk assessment will not be applied to these infants. Current routine postnatal care will be provided in line with national guidance[1,2,3,4], this will include routine neonatal observation and early discharge at 2-3 hours of age where appropriate. Parents will need to be informed of the different EOS risk assessment that would be applied when compared to birth in obstetric led secondary care environment, and provided with the opportunity to make an informed choice about the sepsis risk assessment and newborn observations.

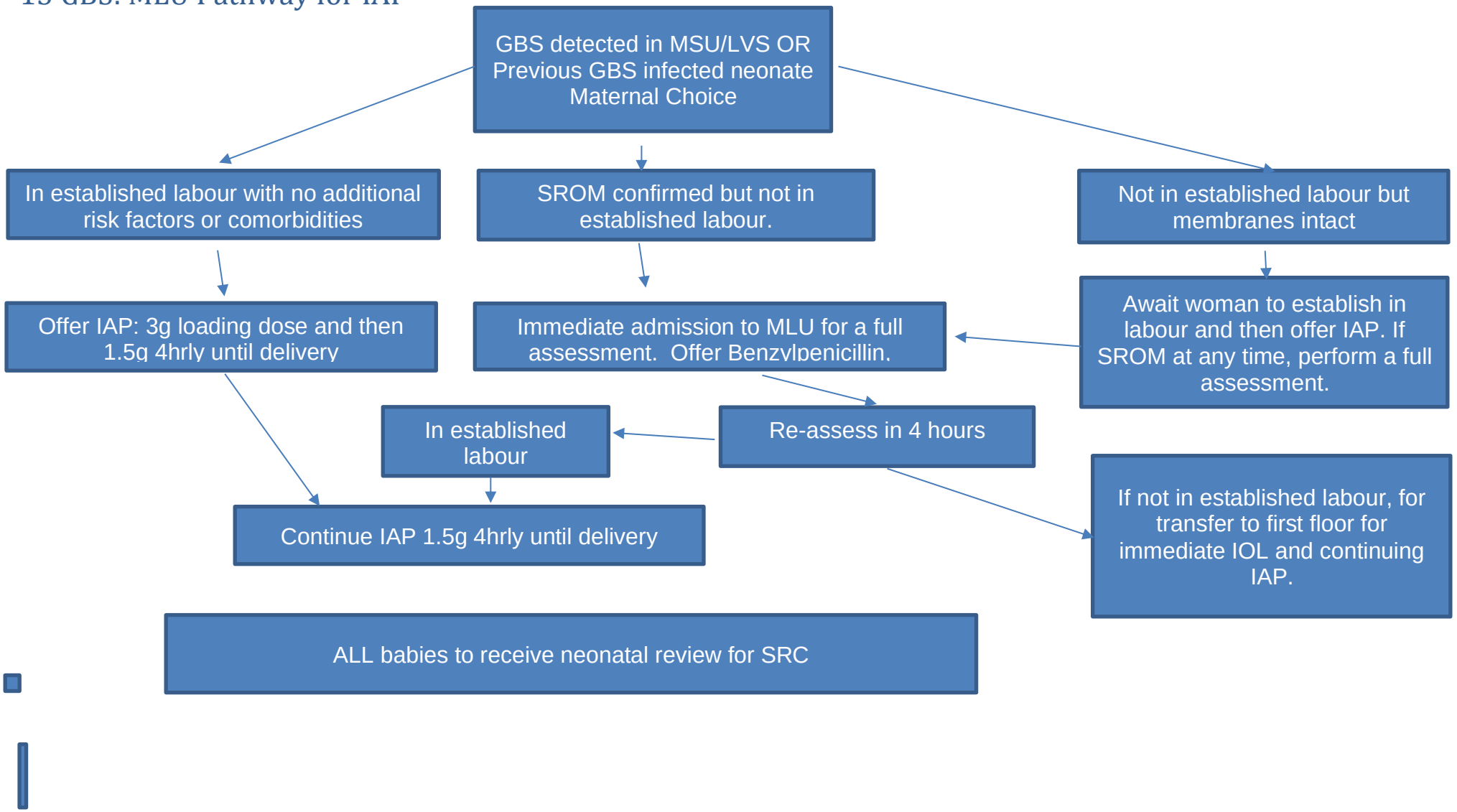
Midwifery actions in the case of total duration of rupture membranes of more than 24 hours at birth, with no co-existing complication:

- Babies with this history will be identified at birth.
- Parents of identified babies will be provided with the Parent Information leaflet, and should be informed that; in a healthy term baby the risk of EOS in this instance is low < 1/1000. In healthy babies **where no red flag/non-red flag events*** (see Appendix 1 below) are identified as per NICE (2021) 'enhanced' neonatal observation, screening or antibiotic therapy would not be required, the guideline would recommend routine postnatal care (NICE 2021b). Within the EOS risk assessment guideline initial review by the neonatal team would be recommended and observation for 24 hours would be offered.
- If parents wish to be referred to the neonatal team for initial assessment as per EOS risk assessment guideline,
- Transfer to nearest obstetric / neonatal hospital unit should be arranged in after discussion with the neonatal /midwifery team.
- Observation of the baby will be completed, in the midwifery setting, and documented on a NEWTTS chart at 1 and 2 hours of age.
- Where all observations are within normal parameters, transportation will be via parents own car or hospital taxi, a midwife will not need to accompany the baby during transfer from the FMU or home birth

Reference list

1. National Institute for Health and Care Excellence (2014). *Intrapartum care: care of healthy women and their babies during childbirth*. Retrieved from: https://www.nice.org.uk/guidance/cg190/resources/guidance-intrapartum-care- care-of-healthy-women- and-their-babies-during-childbirth-
2. National Institute for Health and Care Excellence (2021) Neonatal infection: antibiotics for prevention and treatment. Retrieved From: https://www.nice.org.uk/guidance/ng195.
3. National Institute for Health and Care Excellence (2021b). Postnatal Care. Retrieved from: https://www.nice.org.uk/guidance/ng194
4. Welsh Government (WG) (2020) The All Wales Clinical Pathway for Normal Labour. Cardiff: Welsh Government

13 GBS: MLU Pathway for IAP



14 Pathway of care (RCOG 2017)