

Summary This Guideline provides guidance for two standard approaches used to identify women for whom intrapartum antibiotic prophylaxis should be offered, to reduce the risk of intrapartum transmission of Group B Streptococcus (GBS) to the neonate and minimise the risk of early-onset neonatal GBS sepsis

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MATERNITY - MATERNAL GROUP B STREPTOCOCCUS (GBS) AND THE MINIMISATION OF NEONATAL EARLY - ONSET GBS SEPSIS

PURPOSE

This Guideline provides guidance for two standard approaches used to identify women for whom intrapartum antibiotic prophylaxis (IAP) should be offered to reduce the risk of intrapartum transmission of Group B Streptococcus (GBS) to the neonate and minimise the risk of early-onset Group B Streptococcus (EOGBS) sepsis.

KEY PRINCIPLES

This Guideline provides Local Health Districts (LHD) with current, evidenced-based information to facilitate LHDs to ensure:

- Women are identified for whom intrapartum antibiotic prophylaxis (IAP) should be
 offered to reduce the risk of intrapartum transmission of GBS to the neonate and
 minimise the risk of EOGBS
- Appropriate assessment, detection, and escalation of neonates at risk of, or exhibiting signs and symptoms of EOGBS which occurs in the first 0 - 7 days following birth
- The importance of information and support for maternal choice is acknowledged.

USE OF THE GUIDELINE

The Chief Executives of NSW LHDs are responsible to:

- Select either a routine antenatal culture-based approach or a risk factor-based approach
- Ensure the development and implementation of local protocols or operating procedures in line with the approach chosen across all maternity facilities offering maternity services
- Ensure the chosen approach is consistently applied and neonatal morbidity and mortality associated with EOGBS sepsis is monitored and reviewed as per NSW Health <u>PD2011_076 Deaths - Review and Reporting of Perinatal Deaths</u> and NSW Health Policy Directive <u>PD2009_003 Maternity - Clinical Risk Management</u> <u>Program.</u>

REVISION HISTORY

Version	Approved by	Amendment notes
January 2017	Deputy Secretary of	Replaces GL2016_021
(GL2017_002)	Strategy and Resources	Updated advice on treatment of GBS positive urine culture Updated advice on discharge review of the well neonate ≥37 weeks gestation whose mother received antibiotic prophylaxis ≥4 hours before birth



August 2016 (GL2016_021)	Director of The Office of Kids and Families	Replaces GL2016_017 Revisions to web links and references revised
July 2016 (GL2016_017))	Deputy Secretary, Strategy and Resources	Replaces PD2005_240. Provides up to date evidence for screening for Group B Streptococcus in pregnancy and guidance on clinical care for specific neonatal presentations and algorithms as quick reference guides for staff.
January 2005 (PD2005_240)	Deputy Director- General, Primary Health and Community Partnerships	Circular 2002/28 released February 2002. Issued as a policy in January 2005.

ATTACHMENT

1. Maternity - Maternal Group B Streptococcal (GBS) Screening and the Minimisation of Neonatal Early - Onset GBS Sepsis: Guideline.



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1 BACKGROUND

International consensus has not been reached on the best approach to the prevention of neonatal early-onset Group B streptococcus (EOGBS)¹. There is limited high level evidence to support a prescriptive approach to the adoption of either 'routine antenatal culture-based approach' or a 'risk factor-based approach'. Either approach can be used to identify women who may have Group B streptococcus (GBS) colonisation and for whom intrapartum antibiotic prophylaxis (IAP) should be offered to minimise intrapartum GBS transmission and the risk of neonatal EOGBS sepsis. Local Health Districts (LHDs) are encouraged to adopt either approach and ensure that it is well implemented¹ and closely monitored. The application of either approach should acknowledge a woman's right to make an informed choice in relation to her care².

The overall incidence of EOGBS sepsis is approximately 0.5/1000 births and is the most frequent cause of severe sepsis in neonates during the first week of life³. A mortality rate of 4% to 6%, with confirmed GBS sepsis, is reported⁴. In 80% of cases that present with EOGBS sepsis, signs and symptoms in line with 6.1 Signs and Symptoms of Neonatal Sepsis, will present in the first 6 hours while 90 - 97% of cases are evident within the first 24 hours of age (median 8 hours of age)^{3,4,5}. The evidence suggests that more than 60% of confirmed cases of neonatal EOGBS sepsis occur among neonates born to women who had a negative GBS culture at 35-37 weeks gestation⁴, which highlights the need to remain vigilant and to assess all neonates to identify signs and symptoms consistent with sepsis.

Maternal intravenous (IV) IAP has been shown to be the most reliable method of reducing the incidence of neonatal EOGBS³. However, the use of IAP has not been shown to significantly reduce the incidence of late onset GBS, neonatal mortality from GBS sepsis, or neonatal mortality from sepsis caused by bacteria other than GBS⁵.

Strategies to minimise neonatal morbidity and mortality from neonatal EOGBS sepsis should begin before birth with the identification of women for whom IAP is indicated, and continue after birth with appropriate assessment, detection, and escalation of neonates at risk of, and / or exhibiting signs and symptoms of neonatal EOGBS sepsis.

1.1 Scope

This Guideline applies to all clinicians caring for antenatal and intrapartum women and neonates, regardless of the models of maternity care and irrespective of the place of birth.



1.2 Key definition

Early onset Group B streptococcal sepsis - refers to neonatal GBS sepsis that presents in the first 0-7 days of age⁵

Late onset Group B streptococcus - refers to neonatal GBS sepsis that presents after 7 days and up to 3 months of age⁵

Intrapartum antibiotic prophylaxis - the intravenous administration of antibiotics following the onset of labour

Should - indicates actions that ought to be followed unless there are justifiable and documented reasons for taking a different course of action

Recommended - suggest (something) as a course of action.

1.3 Relevant NSW Health policy directives and guidelines

This Guideline should be read in conjunction with the following Policy Directives and Guidelines:

<u>Australian Health Ministers' Advisory Council 2014, Clinical Practice Guideline:</u>
Antenatal Care- Module 2, Australian Government Department of Health, Canberra

PD2013_049 Recognition and Management of Patients who are Clinically Deteriorating

Clinical Excellence Commission: Newborn Sepsis Pathway

PD2005_406 Consent to Medical Treatment - Patient Information

PD2010 022 Maternity - National Guidelines for Consultation and Referral

PD2009 003 Maternity - Clinical Risk Management Program

PD2011_076 Deaths - Review and Reporting of Perinatal Deaths

GL2016_018 NSW Maternity and Neonatal Service capability Framework.

2 STANDARD APPROACHES

There are two standard approaches to the identification of women for whom IAP should be offered to reduce the risk of intrapartum transmission of GBS to the neonate and minimise the risk of neonatal EOGBS sepsis in line with <u>Section 2.1</u> and <u>Section 2.2</u>. The standard approaches to screening for GBS colonisation are a risk factor-based approach and routine antenatal culture-based approach.



2.1 Risk factor-based approach

A risk factor-based approach means that women are *not* routinely swabbed for GBS colonisation during pregnancy but are assessed for risk factors which increase the risk of neonatal EOGBS sepsis^{4,6}.

Risk factors which increase the risk of neonatal EOGBS sepsis are:

- Previous GBS affected infant
- GBS bacteriuria at any time during the current pregnancy
- Preterm (<37⁺⁰ weeks) in established labour
- Maternal intrapartum pyrexia ≥38°C
- Signs and symptoms of suspected chorioamnionitis
- Rupture of membranes ≥18 hours.

If any of these risk factors are present IAP should be recommended in labour^{3,4,6}.

2.2 Routine antenatal culture-based approach

This approach recommends all pregnant women between 35⁺⁰ and 37⁺⁰ weeks gestation are offered a routine antenatal culture for GBS colonisation^{3,6}. Either a combined low vaginal-perianal or a combined vaginal-rectal swab should be collected. Maternal GBS colonisation can be transient, so testing for GBS prior to 35⁺⁰ weeks gestation reduces the predictive value of the test¹. Screening is therefore not recommended prior to 35⁺⁰ weeks gestation.

If a woman has had a previous baby diagnosed with GBS sepsis or she has been confirmed as having GBS bacteriuria in her current pregnancy, further antenatal screening is not required, but IAP is indicated^{4,2}.

Women booked for an elective caesarean section still require routine antenatal GBS screening as prelabour rupture of membranes and colonisation of the fetus may occur prior to planned caesarean section⁴.

Women who are positive in the routine antenatal screen for GBS colonisation (within 3 - 5 weeks prior to birth), should be:

• Informed of their status and receive the recommended IAP treatment to minimise the risk of sepsis in their neonates^{2,4}.

Women who are negative in the routine antenatal screen for GBS colonisation in their current pregnancy:

• Do not require IAP for GBS^{1,7}.

Women who have a history of GBS colonisation in a previous pregnancy should not be assumed to be positive in the current pregnancy and should be tested in the current pregnancy.



Practice Point

- Vaginal-rectal swabbing increases the number of GBS positive women detected compared to vaginal swabbing alone³. However, research indicates that the detection rate is not significantly different between vaginal-perianal and vaginal-rectal and that vaginal-perianal swabbing causes less discomfort to the woman^{7,8}. If the routine antenatal culture-based approach is chosen by the LHD either the combined <u>low</u> vaginal-perianal or combined <u>low</u> vaginal-rectal should be the swab technique employed.
- Women should be provided with information to enable them to self-collect this culture should they wish².

2.3 Local Health District responsibilities

LHDs should:

- Adopt either
 - A routine antenatal culture-based approach OR
 - A risk factor-based approach

to identify women for whom intrapartum antibiotic prophylaxis (IAP) should be offered to reduce the risk of intrapartum transmission of GBS to the neonate and minimise the risk of neonatal EOGBS

- Develop and implement local guidelines or protocols in line with the chosen approach:
 - That acknowledge the importance of information and support for maternal choice. Where women choose care that is outside this guideline it is recommended clinicians follow the PD2010_022
 Maternity National Midwifery Guidelines for Consultation and Referral
 - Ensure the appropriate assessment, detection, and escalation of neonates at risk of, or exhibiting signs and symptoms of neonatal EOGBS sepsis.
- Adherence to the adopted approach is paramount in order to maximise the
 effectiveness of care irrespective of the approach used. Monitoring of
 adherence should be in line with PD2009 003 Maternity Clinical Risk
 Management Program and PD2011 076 Deaths Review and Reporting of
 Perinatal Deaths
- Develop and implement local protocols outlining regimens for the administration of intrapartum antibiotic prophylaxis in line with the Therapeutic Guidelines (eTG): Antibiotic prophylaxis in obstetric patients (available on <u>CIAP</u>)



3 ANTENATAL CONSIDERATIONS

- Identified maternal GBS colonisation in the urine during this pregnancy does not require further routine culture-based screening as these women should be offered IAP irrespective of subsequent urine results in line with the <u>Practice Point</u> below
- Antibiotics for identified maternal GBS colonisation from vaginal-rectal / perianal swab detected during pregnancy is not required at the time of detection as it does not reduce the likelihood of GBS colonisation at time of birth²
- A plan to minimise the risk of EOGBS should be developed in consultation with the woman who has identified GBS colonisation. This plan should be documented in the woman's health record and her hand held record²
- Women who have prelabour rupture of membranes at term and are known to be colonised with GBS or who have GBS bacteriuria in this pregnancy or who previously gave birth to a neonate who had EOGBS sepsis should be offered immediate induction of labour and IAP^{3,8}.

Practice Point

In asymptomatic women, the treatment of GBS in the urine is recommended where there is bacteriuria, >10⁸ colony forming units /Litre^{3,4}.

4 ELECTIVE CAESAREAN CONSIDERATIONS

- Antibiotic prophylaxis specific for GBS is not required for women with intact membranes undergoing planned caesarean section regardless of GBS colonisation status²
- Women who have ruptured membranes and/or contractions prior to planned elective caesarean section should be considered for antibiotic prophylaxis specific to GBS if they are GBS positive¹ or any risk factors are present in line with <u>Section 2.1</u>.



5 INTRAPARTUM CONSIDERATIONS

Flowchart 1 is a pathway designed to assist clinicians to provide care in line with the GBS screening method chosen by their LHD and to provide appropriate care for those whose care falls outside of those pathways. The pathway identifies those women who need IV IAP to prevent neonatal EOGBS.

Flowchart 1: Intrapartum Antibiotic Prophylaxis Pathway 1,7

Antenatal **Established GBS GBS** risk factor-based culture-based risk of approach transmission approach Does the woman have any of the following risk factors? Culture collection GBS bacteriuria in between 35 & 37 weeks gestation^{1,2,7}. Preterm (< 37 weeks) this pregnancy established labour **Previous GBS** proven sepsis² (not Maternal intrapartum pyrexia just colonisation) ≥ 38°C Signs & Symptoms of GBS suspected Chorioamnionitis culture Rupture of membranes ≥18 status hours in established labour¹ unknown^{1,7} Recommend **GBS GBS** intrapartum risk culture antibiotic positive positive prophylaxis Intrapartum GBS **GBS** antibiotic risk culture prophylaxis is negative negative not necessary

Practice Point

Intrauterine sepsis (suspected or overt) is often manifested by signs and symptoms suggestive of chorionamnionitis and this requires intrapartum broad spectrum antibiotic treatment irrespective of GBS status.

Women who accept IAP should have IV Penicillin-G or Ampicillin commenced as soon as possible after the onset of labour and continued regularly until the birth of the baby^{9,10}. For prescribing guidance in line with Therapeutic Guidelines (eTG): Antibiotic prophylaxis in obstetric patients (available on CIAP).

Adequate intrapartum chemoprophylaxis is defined as appropriate IV antibiotic therapy given ≥4 hours prior to the birth^{3,9}.

Women who are administered Penicillin without history a of β -lactam allergy have a risk of anaphylaxis of 4/10,000 to 4/100,000⁴. Mortality is rare and is offset by the



reduction in incidence of neonatal and maternal sepsis³. Staff should discuss with women the risks and benefits of treatment. For prescribing guidance in line with the Therapeutic Guidelines (eTG): Antibiotic prophylaxis in obstetric patients (available on CIAP).

5.1 Vaginal disinfection

Vaginal disinfection with Chlorhexidine during labour has been proposed as an alternate strategy to reduce the risk of EOGBS sepsis for neonates born to women who decline IAP. However, current evidence suggests that while this method results in a statistically significant reduction in GBS colonisation of neonates, it is not associated with a reduction in the incidence of EOGBS sepsis or mortality in preterm and term neonates^{3,5,11}.

6 NEONATAL CONSIDERATIONS

Approximately 90 to 95% of neonates with EOGBS will present in the first 24 hours of age⁴. Neonates who have more than one risk factor for EOGBS or who have exhibited signs of fetal distress or low Apgar scores are more likely to present with EOGBS³.

Preterm neonates are four (4) times more likely to develop EOGBS than term neonates^{1,3}.

Regardless of the screening method used to determine maternal risk¹ EOGBS may still present following a negative prenatal screen¹⁰. Therefore, neonatal assessment for signs and symptoms of sepsis is essential in line with Section 6.1.

6.1 Signs and symptoms of neonatal sepsis

Clinicians should be aware that signs and symptoms of EOGBS can be subtle and non-specific or may be profound. For further information see the <u>Clinical Excellence</u> <u>Commission</u> Newborn Sepsis Pathway.

Where neonates are at greater risk of EOGBS sepsis clinicians should:

- Increase the frequency of assessments and record the findings on the NSW Health Standard Neonatal Observation Chart (SNOC) available on the Clinical Excellence Commission Between the Flags Program
- Escalate the care of any neonate for whom they have concerns, who have abnormal assessments and or signs and symptoms of sepsis in accordance with the LHD CERS: <u>PD2013_049 Recognition and Management of Patients</u> <u>who are Clinically Deteriorating</u>.



6.2 Neonatal management

IAP given to prevent EOGBS prophylaxis ≥4 hours prior to birth has been found to be highly effective in preventing GBS^{3,4}. However, if a neonate shows signs and symptoms of EOGBS care should be provided in line with the <u>Clinical Excellence</u> <u>Commission</u> Newborn Sepsis Pathway.

Antibiotic treatment of the neonate, in line with locally endorsed antibiotic prescribing guidelines, should be given as soon as possible within one hour of sepsis recognition.

Consider consultation for advice and/ or escalation of care within the Tiered Maternity and Neonatal Network in line with <u>GL2016_018 NSW Maternity and Neonatal Service Capability Framework.</u>

The use of routine blood tests to guide neonatal management is not well supported³. The evidence suggests that full blood counts may not be sufficiently sensitive to rule out early onset sepsis and so are not recommended as a diagnostic tool¹⁰.

6.3 Neonatal care pathway

Use Flowchart 1 to identify women who: are GBS positive; who have had a previous baby with EOGBS sepsis or who had GBS bacteriuria this pregnancy; or who have identified risk factors for intrapartum transmission of GBS to the neonate. Flowchart 2 and Table 1 outline the recommended care of the neonate who was born to a woman with identified risk factors for intrapartum transmission of GBS and therefore are at risk of neonatal EOGBS sepsis^{3,4}.

7 DISCHARGE CONSIDERATIONS

Parents should be advised both verbally and in writing to contact the hospital, the general practitioner or present to the emergency department if:

- They become concerned about their baby
- The baby is behaving unusually
- The baby is floppy or excessively sleepy
- The baby is crying excessively or unable to settle to sleep
- The baby has difficulties feeding
- The baby has rapid or difficult breathing
- The baby has a high temperature or changing skin colour¹².

Prior to discharge, staff should discuss with parents if there is ready access to a phone to call for help, and or if they have access to transport to reach medical services in a timely fashion.

When a baby who has been diagnosed with GBS sepsis is discharged from hospital the mother should be advised that:



- In subsequent pregnancies antibiotic prophylaxis will be recommended during her labour
- Subsequent babies will be at increased risk of EOGBS and
- She should inform future maternity care providers of this baby's diagnosis of EOGBS¹².

Copies of the discharge summary should be given to the woman for herself and for other care providers, regarding the care she and her baby have received. This should include any follow up care required.

Did the mother have intrapartum antibiotic prophylaxis ≥4 hours before birth^{3,4} to reduce the risk of EOGBS No investigations unless abnormal assessments or medical review indicates need (see unwell neonate No Yes Well neonate whose mother received Not suitable for midwifery review Discharge Check antibiotics <4 hours Should assess regularly for 48 hours following birth, in hospital for signs & symptoms of EOGBS Observe and record 4 hourly assessments for 24 hours on the SNOC prior to birth or no antibiotics o Consider further assessments during the subsequent 24 hours If born at home it is recommended the neonate be transferred to hospital for 48 hour assessment Medical Review and use clinical judgement to consider: limited investigation (see Table 1) & IV Antibiotics (see local Well neonate endorsed guidelines) whose mother had Should assess for 48 hours following birth, in hospital for signs & symptoms of EOGBS signs & symptoms of Observe and record 4 hourly assessments for 24 hours on the SNOC chorioamnionitis7 or Consider further assessments during the subsequent 24 hours a sibling who had If born at home the neonate **should** be transferred to hospital for 48 hour assessment proven GBS sepsis Antibiotic treatment should be given as soon as possible within one hour of decision to treat No investigations or treatment unless abnormal assessments or medical review indicates need (see unwell Well neonate neonate below) Not suitable for midwifery Discharge Check ≥35 & <37 weeks Assess for initial 24 hours following birth in hospital for signs & symptoms of EOGBS 4 hourly assessments for 24 whose mother had hours and record on the SNOC antibiotics ≥4 hours Assess for a further 24 hours in hospital to ensure well & meeting all discharge criteria before birth It is recommended that the neonate born at home is transferred to hospital for 48 hours assessment. No investigations or treatment unless abnormal assessments or medical review indicates need (see unwell neonate below) Well neonate If in hospital for the first 24 hours of life observe and record 4 hourly assessments for signs and symptoms of ≥37weeks EOGBS on the SNOC whose mother had If neonate is well on clinical review (in line with local guidelines) & the model of care includes discharge home antibiotics ≥4 hours <24 hours of age, the following criteria must be met: follow up with a midwife within 24 hours of discharge; before birth education to parents on signs & symptoms of sepsis; ready access to phone; transport & readmission The neonate who is born at home does not require admission if the same criteria are met as above (for discharge home <24 hours of age)

Unwell neonate with abnormal assessments, clinical signs & symptoms of sepsis, deterioration or concern follow CEC: Newborn Sepsis Pathway. Escalate as per local CERS protocol for medical review. Monitor & record neonatal assessments on the SNOC. Admit to neonatal unit. Consider consultation for advice and/ or escalation of care within the Tiered Maternity and Neonatal Network

Table 1: Clinical Care of Neonates Whose Mothers Have Identified Risk Factors For Neonatal EOGBS Sepsis^{3,4} This information is also presented as a clinical pathway in <u>Flowchart 2</u>: Neonatal Care Pathway to Minimise the Risk of EOGBS Sepsis

Neonatal Presentation	Clinical care	Recommended Investigations and treatment
Unwell neonate With clinical signs and symptoms of sepsis, deterioration or concern	 Recognise as per Clinical Excellence Commission: Newborn Sepsis Sepsis Pathway Escalate as per local CERS protocol Monitor and record neonatal assessments on the SNOC Admit to neonatal unit 	As per the Clinical Excellence Commission: Sepsis Newborn Sepsis Pathway Consider consultation for advice and / or escalation of care within the Tiered Maternity and Neonatal Network.
2. Well neonate Whose mother had signs and symptoms of chorioamnionitis ^{4,7} regardless of the mother having received IAP ≥4 hours before the birth OR Who has a sibling (same mother) who had EOGBS proven sepsis³ (ie: not just colonisation)	Should assess for 48 hours following birth, in hospital, for signs and symptoms of EOGBS Observe and record 4 hourly assessments for 24 hours on the SNOC Consider frequency of further assessments during the subsequent 24 hours If born at home the neonate should be transferred to hospital for a 48 hour assessment Note: Antibiotic therapy should commence as soon as possible within one hour of decision to treat	Medical review and use clinical judgement to consider Ilimited investigation, Blood culture Full Blood count at birth and/or 6-12 hours following birth IV antibiotic therapy in line with locally endorsed antibiotic prescribing guidelines, review cultures at 24 hours and cease antibiotics at 36-48 hours if clinically well and cultures negative
3. Well neonate whose mother received prophylaxis <4 hours before birth OR whose mother did not receive antibiotics	 Should assess for 48 hours following birth, in hospital, for signs and symptoms of EOGBS⁴ Observe and record 4 hourly assessments for 24 hours on the SNOC Consider further assessments during the subsequent 24 hours If born at home it is recommended the neonate be transferred to hospital for 48 hour assessment 	 No investigations or treatment required (unless abnormal assessments or medical review indicates need) Not suitable for Midwifery Discharge Check
4. Well neonate ≥35 and <37 weeks gestation AND whose mother had intrapartum antibiotic prophylaxis ≥4 hours prior to the birth⁴	 Assess for initial 24 hours following birth, in hospital, for signs and symptoms of EOGBS³ 4 hourly for 24 hours and record on the SNOC Assess for further 24 hours in hospital¹⁰ to ensure well and meeting discharge criteria If neonate born at home recommend transfer to hospital for 48 hours assessment 	 No investigations or treatment required (unless abnormal assessments or medical review indicates need) Not suitable for Midwifery Discharge Check
5. Well neonate ≥ 37 weeks gestation AND whose mother received antibiotic prophylaxis ≥4 hours before birth	 If in hospital for the first 24 hours of life ¹³ Observe and record 4 hourly assessments for signs and symptoms of EOGBS <u>Clinical Excellence Commission</u>: Newborn Sepsis Pathway If neonate is well on clinical review (in line with local guidelines) and the model of care includes discharge home <24 hours of age the following criteria must be met Follow up with a midwife Education to parents on the signs and symptoms of sepsis Ready access to phone, transport and readmission⁹ The neonate who is born at home does not require admission if the same criteria are met as above (for discharge < 24hours of age) 	No investigations or treatment required (unless abnormal assessments warranting a medical review)



8 CLINICAL AUDIT

Compliance with the approach chosen by the LHD, and the morbidity and mortality associated with all episodes of neonatal EOGBS sepsis, should be subject to regular multi-disciplinary clinical audit in accordance with PD2009_003_Maternity - Clinical Risk Management Program and PD2011_076 Deaths - Review and Reporting of Perinatal.

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10 ABBREVIATIONS

Table 2: Abbreviations		
CERS	Clinical Emergency Response System	
GBS	Group B streptococcus (Streptococcus agalactiae)	
LHD	Local Health District	
SNOC	Standard Neonatal Observation Chart	
EOGBS	Early Onset Group B streptococcus	
IAP	Intrapartum antibiotic prophylaxis	
FBC	Full Blood Count	