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HEALTHCARE SAFETY INVESTIGATION BRANCH

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National Learning Report

Severe brain injury, early neonatal death and intrapartum stillbirth associated with group B streptococcus infection

Independent report by the
Healthcare Safety Investigation Branch I2020/003

July 2020


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About HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients.

The recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability to individuals.

Considerations in light of Covid-19

A number of investigations were in progress when the Covid-19 pandemic significantly affected the UK. Observation and engagement visits to hospitals necessarily ceased at this time. A decision needed to be made as to whether investigations were sufficiently advanced to publish their findings or to wait until they could be recommenced. For this report, even though the impact of Covid-19 may have adjusted the processes being carried out in the clinical setting, it was thought that the findings would be unlikely to change and so it was agreed to publish the report. Any alterations to clinical care due to Covid-19, with a patient safety impact, may be the subject of a future investigation.

National learning reports

These reports offer insight and learning about recurrent patient safety risks in NHS healthcare that have been identified through HSIB investigations. The reports present a digest of relevant, previously investigated events, highlight recurring themes and, where appropriate, make safety recommendations. National learning reports can be used by healthcare leaders, policymakers and the public to aid their knowledge of systemic patient safety risks and the underlying contributory factors, and to inform decision making to improve patient safety.

A note of acknowledgement

Thank you to the families affected by group B streptococcus whose experiences were shared with us during their investigation and are written about in this report. We are grateful to them for generously giving their time and openly sharing their thoughts.

We would also like to thank the trusts and members of staff who participated in the investigation processes and openly shared their perceptions of the incidents and maternity services with us, as well as expressing their empathy for the families involved.

To preserve anonymity, the families are referred to as the mother and the father throughout. Up until birth, babies may be referred to as 'the fetus', 'fetal' or 'the baby'; after birth they are referred to as 'the baby'.

We are thankful for the involvement of the charity Group B Strep Support and for its contribution to this report.

Our investigations

Our team of investigators and analysts have diverse experience working in healthcare and other safety critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

Maternity investigations

From 1 April 2018, we have been responsible for all NHS patient safety investigations of maternity incidents which meet criteria for the **Each Baby Counts programme** (Royal College of Obstetricians and Gynaecologists, 2015) and also maternal deaths (excluding suicide). The purpose of this programme is to achieve learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the trust remains responsible for meeting the Duty of Candour and for referring the incident to us. We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly back to the families and to the trust. Our safety recommendations are based on the information derived from the investigations and other sources such as audit and safety studies, made with the intention of preventing future, similar events. These are for actions to be taken directly by the trust, local maternity network and national bodies.

Our reports also identify good practice and actions taken by the Trust to immediately improve patient safety.

Since 1 April 2019 we have been operating in all NHS Trusts in England.

We aim to make safety recommendations to local and national organisations for system-level improvements in maternity services. These are based on common themes arising from our trust-level investigations and where appropriate these themes will be put forward for investigation in the National Programme. More information about our maternity investigations is available on our **website**.

National investigations

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider potential incidents or issues for investigation based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, and the learning potential to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements.

More information about our national investigations including in-depth explanations of our criteria, how we investigate, and how to refer a patient safety concern is available on our **website**.

HSIB maternity investigations – emerging learning 2019/2020

The Healthcare Safety Investigation Branch (HSIB) published **'Summary of themes arising from the Healthcare Safety Investigation Branch maternity programme (April 2018-December 2019)'** in February 2020. This described eight themes for further exploration in order to highlight opportunities for system-wide learning; one of these themes was group B streptococcus (GBS).

Group B streptococcus – summary and context

Group B streptococcus (GBS) is a naturally occurring bacterium, often found in the mother's vagina, which can be dangerous for babies during labour and immediately after birth. The mothers carry this bacterium in the birth canal without any problem to themselves. Giving antibiotics to the mother during labour reduces the incidence of GBS infection passing on to the baby (National Institute for Health and Care Excellence, 2012).

There are no UK randomised clinical research trials assessing the efficacy of screening programmes for GBS. The UK National Screening Committee currently does not recommend routine screening for GBS in pregnancy. A large UK multicentre randomised study (GBS3) will start in 2020 to evaluate the impact of screening mothers during pregnancy or testing for the presence of GBS at the onset of labour.

The Royal College of Obstetricians and Gynaecologists (RCOG) has produced guidance on the treatment of mothers who are found to be carrying GBS (Royal College of Obstetricians and Gynaecologists, 2017). HSIB investigations found that mothers are not always provided with all the information recommended by the RCOG in relation to GBS. Investigations found that in some cases this limited their ability to make decisions relating to the use of antibiotics during labour and their timely attendance to the hospital.

As in theme two (safety of intrapartum care), investigations observed maternity triage services encouraging mothers to stay at home for as long as possible. In some cases, this was due to information not being shared between clinicians, the right questions not being asked by the call receiver or problems with the documentation of a mother's GBS status. RCOG guidance suggests that mothers identified as carrying GBS should be seen earlier to allow antibiotic therapy to be given.

In addition, investigations found problems where positive tests for GBS were not communicated to the mother or noted clearly in the case records. As a result, the recommended care and antibiotic treatment in labour was not given. Also, the identification and escalation of care for babies who show signs of GBS infection after birth was missed. This has resulted in severe brain injury and death for some of the affected babies.

Background information about GBS

GBS is carried in the intestines of 20 to 40% of the population where it causes no problems (Hughes et al., 2017). Approximately 20% of women worldwide carry GBS in the vagina (known as GBS colonisation or GBS positive); for these women there is a risk during pregnancy and childbirth of uterine infection and transmission of GBS to the baby. This may result in early onset GBS infection (EOGBS) in the baby or stillbirth. GBS is the most common cause of severe infection in babies within the first week of life (Hughes et al., 2017), with a further 40% of GBS infections developing in babies aged 7 to 90 days (O'Sullivan et al., 2018). Cases of mothers carrying GBS or GBS infection in newborns was found in 13% of the first 296 completed HSIB maternity investigations (excluding those for maternal deaths).

GBS may enter the amniotic fluid by secretion of an enzyme that creates microscopic holes in the fetal membranes (Feldman, 1998), and thereby infect the baby, or the baby can acquire the bacteria during their passage through the birth canal and show signs of infection in the newborn period. 60% of neonatal infections (infections in newborn babies) are apparent at birth or in the first week of life having been acquired before birth.

If a mother is known to be carrying GBS, intrapartum (during labour and birth) antibiotic prophylaxis (IAP)[1] has been shown to be effective in reducing EOGBS infection (Ohlsson 2014). However, IAP carries some risks. The most used antibiotic is penicillin based. 10% of the population report an

allergy to penicillin, although, of these, the rate of true allergy is estimated to be only around 20% of the reported allergy rate (BMJ, 2017). The mother may rarely have a severe, potentially fatal, allergic reaction (anaphylaxis) to the antibiotic used for IAP (McCall et al., 2018). The use of intravenous IAP requires the insertion of a drip and birth would generally be recommended in a hospital setting, which may increase the medicalisation of a mother's labour and affect her choice of place of birth. The use of IAP may affect the normal bowel bacteria in the baby; the results of studies looking into this are not consistent and the long-term effects of this on the infant are uncertain (Hughes et al., 2017). There are also concerns regarding the rise of neonatal infection with antibiotic-resistant organisms that is associated with the use of broad-spectrum antibiotics to prevent infection, particularly in low birth weight babies when the recommended antibiotic is not used (Stoll et al., 2002). Increasing use of broad-spectrum antibiotics has also been associated with Clostridium difficile infection in the wider community (National Institute for Health and Care Excellence, 2015).

Methodology

Approach

All maternity investigations are reviewed, and themes identified by a multi-professional panel. The Healthcare Safety Investigation Branch (HSIB) identified a subgroup of cases that were suitable for inclusion in this national learning report.

In this subgroup, group B streptococcus (GBS) infection was identified as a factor that contributed to severe brain injury, intrapartum stillbirth[2] or early neonatal death.

Selection criteria

In January 2020 the HSIB database of 296 completed maternity investigations was interrogated. Reports relating to maternal deaths were excluded from this review. The keywords used to identify investigation reports where GBS was a factor were:

- group B streptococcus
- GBS
- group B
- strep
- streptococcal

Analysis

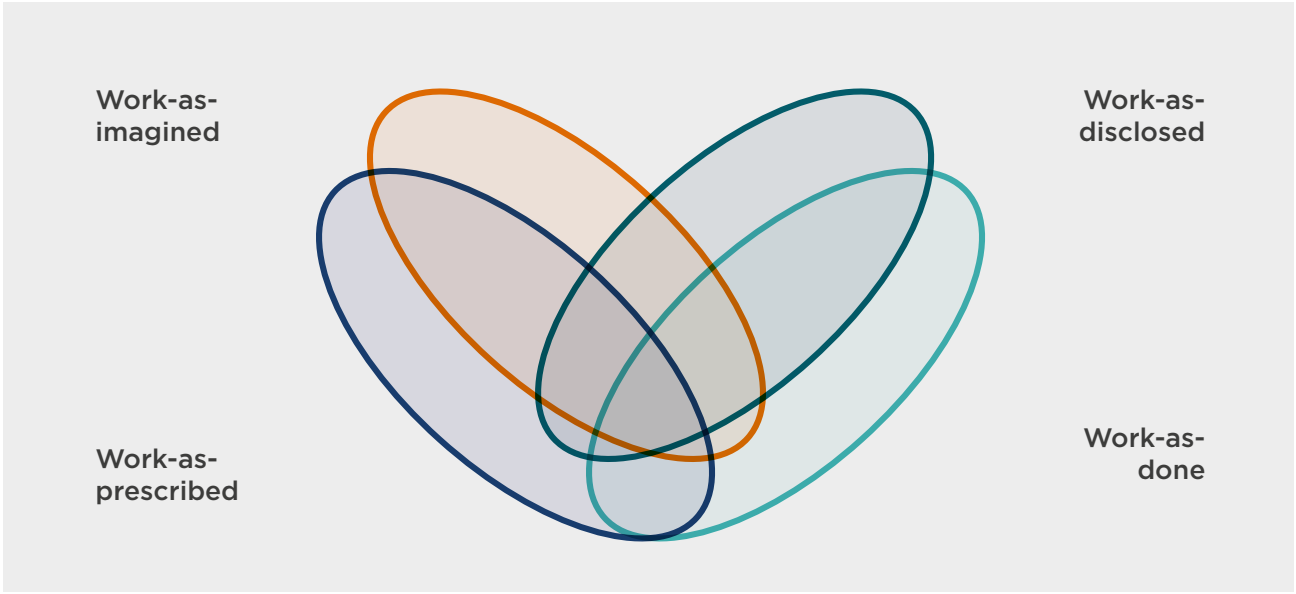
The keyword search resulted in the identification of 39 reports. In 24 of the 39 investigations, HSIB identified that the presence of GBS did not contribute to the outcome for the baby. In the 15 babies where GBS infection was considered to have contributed to the outcome, there were six neonatal deaths in the first week of life, six intrapartum stillbirths and three babies that met the criteria for a severe brain injury (see Table 1).

The proportions of intrapartum stillbirths and neonatal deaths in the cohort of babies where GBS infection contributed to the babies' outcome, compared to the wider HSIB maternity investigation cohort, led HSIB to consider mothers carrying GBS as one of the areas for further exploration in a national learning report.

Table 1 Distribution of GBS positive cases by outcome category

	GBS positive – contributed (out of 15)	GBS positive – incidental (out of 24)	HSIB completed maternity reports (out of 296)
Severe brain injury	3 (20%)	19 (79%)	225 (76%)
Neonatal death	6 (40%)	3 (13%)	33 (11%)
Intrapartum stillbirth	6 (40%)	2 (8%)	38 (13%)

Fig 1 The varieties of human work



Work as prescribed versus work as done

Considering the varieties of human work described by Shorrock (2016), shown in Figure 1, can give insight into how staff work in a clinical environment (Healthcare Safety Investigation Branch, 2019a).

HSIB observed the interplay between these types of work in many of the investigations associated with GBS.

Staff reported that there was inconsistency between local guidelines and local practice (**'work as prescribed'** versus **'work as done'**), as well as inconsistency between different guidelines and practice expectations (**'work as prescribed'** versus **'work as imagined'**). For example, practice is commonly focused on supporting mothers to remain out of a clinical setting until they are in established labour, which conflicts with the need to administer IAP in a timely way to a mother colonised with GBS. We have also seen examples where the workload within the maternity unit influences the staff decision making process for inviting mothers in from their home, one reason why **'work as done'** deviates from **'work as prescribed'**.

Current practice in England

National GBS guidance (Hughes et al., 2017) offers maternity providers wide-ranging guidance on current best practice with regards to sharing GBS information with mothers; antenatal testing (testing during pregnancy); antenatal and intrapartum care for mothers carrying GBS and GBS diagnosis and treatment for mothers and babies. It recommends that intrapartum antibiotic prophylaxis (IAP) should be offered to mothers who have been identified as carrying GBS during their current pregnancy, those who have had a previous baby affected by GBS infection, mothers in preterm (early) labour and those with a raised temperature or suspected infection during labour – a risk-based strategy. It also recommends that if a mother has been shown to carry GBS in a previous pregnancy she should be offered GBS testing during the pregnancy or IAP. This represents **'work as prescribed'**.

The detection of GBS using an enriched culture medium (ECM) test is superior to standard microbiology testing as it avoids the overgrowth of other microorganisms and is the most sensitive way to detect whether a woman is carrying GBS (Public Health England, 2018). 10% of UK trusts and health boards report that they are using the Royal College of Obstetricians and Gynaecologists recommended ECM test (Group B Strep Support, 2020). An alternative to the ECM test is intrapartum near-patient rapid testing[3], which can deliver positive results in less than 30 minutes. At present this test is rarely used in the NHS outside of a research setting.

The UK National Screening Committee currently does not recommend routine screening for all mothers to check if they are carrying GBS during pregnancy , nor the use of near-patient testing following spontaneous rupture of membranes (SROM – a mother's waters breaking) or the onset of labour (UK National Screening Committee, 2017).

The screening committee gives the following reasons for this:

- Many mothers carry GBS and, for the majority, their babies are born safely and without developing an infection.
- Screening mothers late in pregnancy cannot accurately predict which babies will develop GBS infection.
- No screening test is entirely accurate. Between 17% and 25% of mothers who have a positive swab at 35 to 37 weeks of gestation will be GBS negative at delivery. Between 5% and 7% of mothers who are GBS negative at 35 to 37 weeks of gestation will be GBS positive at delivery.
- Many of the babies who are severely affected by GBS infection are born prematurely, before the suggested time for screening.
- Giving IAP to all carriers of GBS would mean that a very large number of mothers would receive treatment they do not need; this may increase adverse outcomes to mother and baby (UK National Screening Committee, 2017).

It is acknowledged that some mothers choose to have GBS screening undertaken outside of NHS services during pregnancy. National advice is to offer IAP to mothers with a positive private GBS screen providing the test is performed by an accredited laboratory (Hughes et al., 2017).

Current international practice

At least 60 countries have a national policy for a form of microbiological screening and antibiotic use in pregnancy to prevent newborn GBS disease (Le Doare et al., 2017). The prevention of early onset GBS disease in newborns broadly falls into two different approaches followed by IAP:

- routine antenatal screening by microbiological culture for GBS recommended to all pregnant women
- a clinical risk factors-based system targeting those with the presence of indicators for GBS infection.

The implementation and execution of any agreed national GBS policy is variable around the world, whether this is by universal screening or risk factor based approach. Factors that limit the uptake of microbiological screening and subsequent IAP include lack of agreement with the national guideline, access to skilled care, limited resources and the labour and delivery taking place away from healthcare institutions, for example at home, particularly in low-income countries.

A European consensus statement was published in 2015 which recommended universal intrapartum GBS screening, or where this is not possible strict adherence to antenatal screening (Di Renzo et al., 2015). The Centers for Disease Control and Prevention in the USA has advised universal screening since 2002 (Hughes et al., 2017). There is variable adherence to this advice due to inconsistent timing of screening, the type of antibiotic prescribed, when the first dose was received during the labour process and IAP not achieved, particularly in precipitate (fast) labours (Le Doare et al., 2017; Australian Government Department of Health, 2019).

A recent systematic review suggests that screening-based protocols reduce the incidence of EOGBS compared to risk-based protocols (Hasperhoven et al., 2020). Analysis of the potential barriers to effective screening and subsequent IAP included unclear guidelines, concerns regarding antibiotic resistance, concerns regarding false negative or false positive screening results, and concerns regarding the potential for screening to impact on capacity and resources in hospitals (Schrag et al., 2002).

There is a large gap between having a documented national policy (‘work as prescribed’) and the implementation or execution of it in practice (‘work as done’); this appears to be an international problem and not limited to the health service in England. The contributory factors or solutions to this gap in practice are not well explored. One small-scale quality improvement intervention using electronic order reminders, added to the IT software used by clinicians, was found to increase uptake of screening in a study conducted in the USA (Edwards et al., 2015).

HSIB investigation themes

In the cohort of 39 Healthcare Safety Investigation Branch (HSIB) maternity investigations, 16 mothers carrying group B streptococcus (GBS) received care in line with local and national guidance, and for 11 of the 16 mothers the GBS colonisation was incidental to the events that unfolded. Due to the nature of HSIB investigations, the focus of the themes and learning inevitably focuses on situations where there was a gap between **'work as prescribed'**, **'work as imagined'** and **'work as done'**, highlighting the potential for system-wide learning.

As HSIB maternity investigations are individual to a specific family and trust, extracts and example recommendations are used from a number of investigations to illustrate the main areas of learning identified from the analysis of the 39 investigation reports.

Antenatal (during pregnancy)

1 Antenatal information regarding GBS

The Royal College of Obstetricians and Gynaecologists (RCOG) recommends that all mothers receive antenatal information about GBS, not just those mothers identified to be colonised with GBS.

> 'All pregnant women should be provided with an appropriate information leaflet.'
> (Hughes et al., 2017)

HSIB observed that this was not always happening in practice, with only 50% of trusts and health boards reporting giving GBS information leaflets to all pregnant mothers (Group B Strep Support, 2020). In the HSIB GBS cohort, eight reports identified that the information shared with mothers during pregnancy was insufficient.

HSIB investigations have shown that antenatal information sharing with mothers known to be carrying GBS, about the condition and the recommended care plan in labour, is variable. Some mothers reported not being clear when to attend maternity services.

> 'They (the mother and father) did not recollect being told actions were required if the mother went in to labour or the waters around the baby started to leak before she went in to labour. They did not receive written information about GBS.'

> 'The mother recalled that when her membranes ruptured, she waited for her contractions to start and did not arrive at the maternity unit until 10 hours later. During interview, the mother stated that she could not recall a conversation or having information about what to do when membranes rupture.'

Recommendations have been made to three trusts regarding the provision of antenatal information to mothers colonised with GBS.

Examples of HSIB maternity investigation safety recommendations

- The information about group B streptococcus (GBS) and the prevention of early-onset neonatal GBS disease provided for mothers, both written and verbal, must make it clear what events require a mother to attend/re-attend the maternity unit.
- The Trust to ensure all mothers using their maternity service are aware of and are provided with patient information on group B streptococcus. This should be undertaken at an appropriate time during their pregnancy, typically between 28 and 34 weeks, to avoid information overload.

HSIB has observed that although GBS information leaflets are used in many healthcare environments, they may not always be in a format or language accessible to parents. The importance of sharing understandable information with them will be explored in a future HSIB national learning report on cultural considerations for safe maternity care.

Example of HSIB maternity investigation safety recommendation

> The Trust must ensure that any written information about group B streptococcus and the prevention of early-onset neonatal GBS disease is available in a range of fully accessible formats including languages spoken within the local area.

2 Local practice not in line with national guidance

The RCOG published updated national guidance, **'Prevention of early-onset neonatal group B streptococcal disease'** in 2017 (Hughes et al., 2017).

HSIB highlighted examples of antenatal care being given that is not in line with national guidance. For example, a mother was not offered a membrane sweep[4] from 40 weeks as the clinician was concerned about performing the procedure in a mother carrying GBS. Membrane sweeps can be performed in mothers carrying GBS (Hughes et al., 2017) and the mother may have benefited from the procedure.

If a mother is found to have a significant growth of GBS in a urine culture during pregnancy national guidance (Hughes et al., 2017) recommends antibiotics are prescribed both for treatment of the urinary tract infection (UTI), as well as IAP when she is in labour. This contrasts with when GBS colonisation is identified from a vaginal or rectal swab during pregnancy, which would not usually require antenatal antibiotics, and only requires the recommendation of IAP (Hughes et al., 2017). This difference in recommended actions has led to care not in line with national guidance. Within the HSIB cohort, four mothers were not treated with antenatal antibiotics when GBS was found in a urine specimen. The investigations found that staff had a variety of different care recommendations for GBS found in urine when compared to GBS found on vaginal swabs.

'The results of a urine sample taken at the first appointment reported a bacterial infection with group B streptococcus (GBS). The mother was informed by telephone of the result and advised that a vaginal swab should be taken to check for the presence of GBS.'

Example of HSIB maternity investigation finding
There was no clear local guidance for staff and no action was taken on the identification of urinary GBS, which may have impacted on the subsequent chorioamnionitis (infection in the placenta and membranes).

A further example demonstrates how the care provided varied from both local and national guidance. HSIB investigations found that staff do not always feel they have clarity about best practice when GBS is identified in a mother's urine during pregnancy, which can lead to different care being delivered.

'During pregnancy, GBS was identified from a urine specimen taken at the booking appointment. The mother did not receive antibiotic treatment following the GBS detection at booking. The urine test was repeated, and the second result did not show signs of GBS.

The Trust guideline recommends that antibiotic treatment at the time of diagnosis is advised when GBS is found in a urine test in pregnancy. Repeat testing is not advised. This is supported by national guidance (RCOG, 2017). The Trust guideline for the management of GBS was not followed in this instance.'

Example of HSIB maternity investigation safety recommendation

The Trust must ensure that the group B streptococcus and prevention of early-onset neonatal GBS disease guideline is disseminated to staff.

Intrapartum

Guidance by the National Institute for Health and Care Excellence (NICE) (2012) and the Royal College of Obstetricians and Gynaecologists (Hughes et al., 2017) recommend intrapartum antibiotic prophylaxis (IAP) to prevent early onset of GBS (EOGBS) neonatal infection for mothers who:

- are in preterm labour
- have had a previous baby with an invasive group B streptococcal infection
- have group B streptococcal colonisation, bacteriuria (bacteria in the urine) or infection in the current pregnancy
- have a raised temperature or signs of infection during labour.

National Institute for Health and Care Excellence (2012) states.

'If the woman decides to take intrapartum antibiotic prophylaxis, give the first dose as soon as possible and continue prophylaxis until the birth of the baby.'

A definition suggested by NICE for **'as soon as possible'** is that the first dose is given within one hour of the onset of active labour, or within one hour of admission if the mother is already in active labour (National Institute for Health and Care Excellence, 2014).

A recurrent theme in HSIB maternity investigations was delayed or missing IAP; 22 cases were identified in the HSIB GBS cohort. Lack of staff availability was noted in four reports, with staff attending other mothers or undertaking other tasks at the time when IAP needed to commence.

1 Advice and management during early labour

Practice is commonly focused on supporting mothers to remain out of a clinical setting until they are in established labour, which can conflict with the need to administer IAP in a timely way to a mother carrying GBS. If the mother stays at home for too long there may be insufficient time between the IAP being administered and the birth. This needs to be balanced with the knowledge that progress in spontaneous labour can be slowed in an unfamiliar environment, leading to additional clinical interventions that might have been avoided. Investigations have noted examples where the current workload within the maternity unit influences decision making for mothers in the community.

Investigations identified that the advice given to mothers in the early stages of labour who are at home can be variable. HSIB also identified that when mothers telephone the maternity unit for advice, full risk assessments are not always completed. Within the HSIB GBS cohort two mothers were not spoken to directly (the father or another family member talked to the clinician) and four mothers known to be GBS positive were advised to stay at home although regular contractions had been reported.

> 'During the hours between 08:00 and 20:00 hours, mothers can access midwives who are specifically trained to recognise 'red flags', give appropriate telephone advice and complete a telephone proforma. Overnight, the triage telephone line is diverted to the labour ward, so there is no designated professional taking these calls and completing the telephone proforma.
>
> The staff recalled that it was the end of a busy night shift and the midwife answering the telephone could have been focused on other tasks … There was constant activity on the labour ward, with midwives focused on providing safe, one to one care for mothers in labour.
>
> In human factors terms … managing and prioritising of multiple tasks, can present an individual with goal conflict. … the competing demands of patients and tasks … can outstrip mental resource, particularly at that time of the day, and could lead to an incorrect decision … human error is systematically connected to people's tools, tasks and working environment (Dekker 2014). The appropriate advice to a … mother who could be in labour, who is known to be a GBS carrier, would have been to come into hospital after the first telephone call. The mother and father were surprised by the advice to stay at home, as they had been advised … that once labour had started, they should attend the labour ward as antibiotics should be administered as soon as possible.'

> 'The mother and father were aware that labour could be quicker with a second baby and that prophylactic antibiotics for the GBS colonisation should be given at least 2-4 hours before the birth of the baby. They felt that their concerns about getting into hospital in time were not heard.'

Documenting of telephone contact is variable; in maternity units where proformas or telephone logs are used these were often not fully completed and were missing key information.

> '… following the telephone advice given to the mother, the contact sheet was placed in the 'to call back' pile, meaning that another telephone call was anticipated from the mother … prior to any possible admission. Due to the increased workload during the nightshift, the information on the contact sheet was not transferred to the mother's electronic patient record … The investigation noted that entries into the electronic patient record were … entered almost a full day after the calls were taken.'

When mothers make more than one telephone call for advice, they may not speak to the same clinician each time. An HSIB maternity investigation observed that for one mother the record made during the first telephone call was not referred to during her second telephone call.

In another case, two telephone calls were made to the hospital, the first by the mother and a second by another member of the family. The telephone calls were answered by different members of staff and it was not clear whether the second member of staff had access to all the information that was given on the initial telephone call. The mother was recorded as carrying GBS on the first telephone call.

A full assessment of the mother was not undertaken as recommended in local guidance. There was limited documentation recorded during the telephone conversations.

'The mother recalls contracting regularly when she was in the bath. She was advised to stay at home.'

Several hours later an ambulance was called by the family when the baby was partially born at home. Sadly this baby died and while GBS did not contribute directly to the death, earlier admission to hospital may have increased the baby's chances of survival.

Example of HSIB maternity investigation safety recommendation

The Trust to ensure information gathered during telephone triage is collected in a structured manner to ensure all relevant information is captured and recorded accurately. The Trust to ensure that when assessment of a mother in labour over the phone is being carried out that the staff speak directly to the mother (or to a family member in the same room as the mother) if possible.

2 Management of pre-labour rupture of membranes (ROM)

National guidance (Hughes et al., 2017) recommends.

'women who are known GBS carriers should be offered immediate intrapartum antibiotic prophylaxis and induction of labour as soon as reasonably possible after rupture of membranes.'

A mother known to be colonised with GBS with pre-labour rupture of membranes called the hospital from home and was not invited in for admission.

'The mother and father reported that they were not made aware of the induction element of this advice. The mother should have been invited into the unit for assessment following her second call to maternity triage. The mother had the required three doses of IV antibiotics in labour, there was a missed opportunity to start these earlier.'

One HSIB maternity investigation observed that a mother rang the hospital for advice when she was in early labour. The maternity triage telephone log-book was completed during the first call and maternal GBS colonisation was documented. The mother rang back several hours later reporting a gush of fluid; she thought her membranes had ruptured. She was not having contractions. The same page of the log-book was used to document the second telephone call by a different staff member. GBS was not documented during the second call, and the prompt regarding GBS colonisation was only present in the part of the proforma where the first call was documented. The mother was not invited into the hospital. In this case the mother came to the hospital later that night. She was in established labour and IAP was started as per local guidance, though this could have been started earlier if she had been invited to attend when she contacted the hospital on the second occasion. This example highlights the importance of the design of documentation in ensuring important information is collected and referred to when staff are making key clinical decisions.

A recommendation has been made to a Trust regarding the management of pre-labour ROM in association with GBS.

Example HSIB maternity investigation safety recommendation

The Trust should communicate with mothers and their partners in relation to the increased risk of infection including GBS in labour and the neonatal period following pre-labour rupture of membranes.

3 Local guidelines

Investigations have concluded that some units' guidelines lack clarity in certain areas of the labour pathway, with advice regarding **'pre-labour'** spontaneous rupture of membranes (SROM) which was not always interpreted as being relevant to mothers in early labour with ROM. One Trust had not updated its local guidance for over six years, and its guidance did not reflect the most recent national recommendations (Hughes et al., 2017).

'The Trust's ... GBS policy was written in November 2012 and was due for update in November 2015. The contents do not reflect the subsequent changes in national guidance on GBS, including the management of pre-labour rupture of membranes (waters breaking before labour starts, or PROM) in women at term (greater than 37 weeks) with unknown GBS status.'

Examples of HSIB maternity investigation safety recommendations

- The Trust should ensure a system is in place to review and assess new national guidance ... The Trust should ensure that its ... GBS policy is updated as a matter of urgency. As part of this the Trust should ... offer immediate induction of labour to women with term pre-labour rupture of membranes.

- The Trust should ensure that their local group B streptococcus guidance is in line with the RCOG guidance on the prevention of early-onset neonatal GBS disease (RCOG, 2017) with particular reference to the immediate administration of antibiotics and provision of printed information for mothers.

4 Delays incurred due to workload and staffing

Lack of staff availability was seen in four reports; staff were attending other mothers or undertaking other tasks at the time IAP needed to be commenced.

In one example IAP was delayed when the mother had ruptured her membranes at home and arrived at the maternity unit almost nine hours later.

> 'The mother could not recall a conversation or having information about what to do when her membranes ruptured.'

Her augmentation (acceleration) of labour did not start until five hours later.

The reason for the delay was documented as.

> '... the mother not being reviewed by obstetricians until mid-afternoon when a ward round took place and waiting for an anaesthetist to administer epidural before starting an infusion of intravenous oxytocin (drug to accelerate labour).'

The first dose of intravenous (IV) antibiotics was administered over 14 hours after the SROM and almost six hours after the mother's admission to the maternity unit. The investigation found that the additional delay was due to the obstetric team caring for another mother in the operating theatre and not being available to prescribe the antibiotics.

In some situations, delays are caused by multiple factors. An HSIB maternity investigation observed a mother arriving on the labour ward in advanced labour. When the father had contacted the labour ward earlier, he had been advised to stay at home with the mother. The mother had been having regular contractions and the history of the mother carrying GBS was known. On admission there was a further delay of 50 minutes before the prescription and administration of the antibiotics. The baby was born one hour later in a poor condition, requiring resuscitation.

> 'The mother and father felt that the prenatal advice to call the hospital early on in labour, the assurances that they would be taken straight in for assessment, and/or early antibiotics would be administered, was completely at odds with what occurred.'

In other examples there were delays in obtaining a prescription.

> 'The mother's arrival on the unit coincided with the joint midwifery and medical handover. The handover was interrupted to seek an obstetric review for the mother considering her need for IV antibiotics and a review of the CTG [cardiotocography – used to monitor the baby's heartbeat and mother's contractions]. The medical handover ... took priority over what was understood to be the clinical need. In terms of human factors, those attending the handover will be task focused, and it can therefore be challenging for an individual to penetrate that focus to make a request, unless there is an obvious emergency ... During handovers, it is important that staff not involved in handover, have an identified point of contact for advice about any concerns ...'

For nine mothers within the HSIB GBS cohort, IAP was indicated as required and not given. In one example the induction of labour management proforma was partially completed. The mother's positive GBS status and the requirement for IAP during labour were not documented. The mother did not receive IAP during labour.

Other examples of IAP being missed are due to unsuccessful attempts at siting cannulae[5] to gain intravenous access to administer the antibiotics. When such clinical difficulties occur, an anaesthetist may be asked to attempt the procedure. On this occasion the anaesthetist was busy in the operating theatre and unable to attend. The labour progressed rapidly without the mother receiving the antibiotics, staff considered

> '... all reasonable efforts to achieve IV access in order to administer antibiotic had been made. During her interview the mother expressed that she would have preferred to have the anaesthetist to insert the cannula straight away on admission as she was aware that it may be difficult to insert a cannula.'

In both these examples the neonatologist (a doctor specialising in care for newborn babies) was informed of the missed IAP. IV antibiotics were administered to the babies soon after birth in each case.

Recommendations have been made to trusts regarding minimising delays in IAP.

Examples of HSIB maternity investigation safety recommendations

- The Trust should identify a system whereby mothers found to be GBS positive have antibiotics prescribed and administered within one hour of the onset of active labour, or within one hour of admission if the mother is already in active labour.
- The Trust to ensure, where there are identified risk factors for early onset neonatal GBS, there is early administration of IAP.
- The Trust to ensure that mothers who require IAP are aware of when to attend the maternity unit and what care to expect, so they are empowered to ensure they receive care in line with national guidance.

5 Delayed knowledge of positive GBS results

In one investigation within the HSIB GBS cohort, results showing the mother was colonised with GBS were available via the computerised results system. These were not accessed by the clinical team providing care during labour and the mother did not receive IAP.

> 'The high vaginal swab that was obtained when the mother attended the maternity assessment centre was documented in the diary. There is an informal process in place for acknowledging the test has been taken and a perception by staff that the result will be followed up using the diary page in a timely way (work as imagined). In reality, although the tests appear to be well recorded in the diary, the review of results and the subsequent action relies on a member of staff being available to look up the results. This task is not routinely allocated to a member of staff and there is no monitoring or failsafe to ensure that it has been actioned. Staff reported that they were able to look up results when staffing levels and capacity allows; in this case, seven days following the result being available (work as done). If the result had been looked up in a timely manner … this would have given time for intravenous antibiotics to have been administered during the mother's labour and may have made a difference to the outcome. The mother did not receive the letter until she was discharged home, after her baby had died. She had not been made aware that she required antibiotics in labour.'

Example of HSIB maternity investigation safety recommendation

The Trust must ensure that there is a robust system for ensuring all maternal investigations are reviewed in a timely way to allow appropriate actions to be taken.

Postnatal

1 Delayed recognition of early onset neonatal infection

HSIB maternity investigations have observed that clinicians often do not have the correct information or prompts on the neonatal documentation to optimise recognition of a baby's deteriorating condition.

> 'The baby's temperature, feeding history, grunting and oxygen saturation level, if plotted on the Newborn early warning trigger and track (NEWTT) chart, would have fallen into three amber and one red categories. This would have triggered a neonatal medical review … the doctor was not aware of the whole clinical picture of the baby …. If the results had been plotted this may have given a clearer picture of all emerging potential risk factors.'

The HSIB national investigation report 'Recognising and responding to critically unwell patients' (Healthcare Safety Investigation Branch, 2019b) identified a similar theme.

> 'There were indications that staff may have focused on the latest physiological observations and resulting Emergency department early warning score (ED EWS) as opposed to examining the overall trend.'

Example of HSIB maternity investigation safety recommendation

The Trust should consider the use of Newborn early warning score (NEWS) charts for all babies in order to record observations to support the communication of observations and the recognition of babies at risk of deterioration.

'The baby had persistent reluctance to feed .... This was the only potential sign of emerging sepsis with all the baby's other observations within normal parameters. Reluctance to feed does not appear on the local NEWS chart as a concerning feature.'

'The 'warning' triggers on the NEWS chart for feeding are 'vomiting' or 'vomiting green bile', refusal to feed/reluctance to feed does not appear as a concerning feature. According to the NICE Guideline on Neonatal Sepsis, feed refusal should be considered a 'red flag' symptom in a baby at risk of sepsis. The NEWS chart used to record observations did not support staff to recognise reluctance to feed as a potential sign of sepsis.'

'The significance of the change in the baby's feeding pattern was not connected by staff with the 'prolonged rupture of membranes' and a potential indication of sepsis.'

Examples of HSIB maternity investigation safety recommendations

- Reluctance to feed as a potential sign of sepsis must be included in infant feeding training for all staff caring for postnatal women, and infant feeding education delivered to women.
- The Trust should use a neonatal warning chart which incorporates more detail in relation to the baby's behaviour and feeding.

There is no NEWS chart in use in England. Trusts use either a local chart or may use the NEWTT chart produced by the British Association of Perinatal Medicine (2015). The use of different charts in different units may be confusing for staff and increase the potential for error.

NICE (2012) guidance on treatment for early onset neonatal infection identifies risk factors and clinical indicators which indicate the need to give the baby antibiotics. Clinical indicators include feeding refusal, signs of respiratory distress (problems with breathing), reduced oxygen saturation levels (levels of oxygen in the blood) (below 90%), and a low temperature below 36.0C. Antibiotics are recommended if two or more factors are present. If only one clinical indicator is present, such as feeding difficulty, the guideline recommends that clinical judgement be used to decide whether antibiotics should be prescribed or further observation is needed, which should continue for at least a further 12 hours.

'Infection acquired at delivery takes time to develop. Observations taken and features observed suggest a developing illness. Staff were falsely reassured, as the abnormal features were borderline and not sustained.'

'The mother mentioned that she attributed the baby's sleepiness and lack of interest in feeding to having pethidine [a pain relief drug] in labour, as this was the information given to her by staff.' 'The staff did not believe it was necessary to keep the mother and baby in hospital until the baby had fed. They believed it a temporary problem and knew the mother was experienced in breast feeding.'

Examples of HSIB maternity investigation safety recommendations

- Babies who are considered suitable for discharge early should have a risk assessment completed that incorporates feeding establishment (NICE, 2012).
- The Trust should implement a mechanism to appropriately assess and communicate risk, prior to the early discharge of a baby. This would support identification of emerging signs of concern, including reluctance to breast feed (NICE, 2012).

2 Neonatal collapse[6]

Parents and carers were not always aware of the signs of a baby's condition deteriorating while they were at home. An understanding of these signs may have led to earlier contact for medical advice and assessment.

'After the baby was born, the mother and father were not aware of the risk of the baby developing an infection and the rationale for increased observations. They were unaware of the significance of reluctance to feed in a baby at risk of sepsis.'

NICE (2012) advises that parents and carers should be given written and verbal advice that they seek medical help if they are concerned that the baby

'... is showing abnormal behaviour (e.g. inconsolable crying or listlessness) or is unusually floppy, or has developed difficulties with feeding or tolerating feeds, or has an abnormal temperature unexplained by environmental factors, or has rapid breathing, or has a change in skin colour.'

In one case, there was a delay with starting treatment following ineffective communication within the clinical team.

> 'The prescription for intravenous antibiotics was not communicated to other staff members. Once it was realised that antibiotics had been prescribed … the clinician caring for the mother and baby went to prepare them immediately. On their return, the decision had been made to transfer the baby to the special care unit (SCU) where a different antibiotic would be given. The staff looking after the baby on SCU recalled that they were aware that antibiotics needed to be administered, they considered that the medication for intubation[7] needed to be prioritised.
>
> …intravenous access was difficult to manage as the baby was admitted with one peripheral cannula. The baby required intravenous access for seven different infusions and boluses, including the medication for intubation. It was reported that the first hour the baby was in SCU was spent performing the admission checks, one of which showed a very low blood glucose reading of 1.1 mmol/L [millimoles per litre]. Low blood glucose in newborns is the most common preventable cause of brain damage and so the team moved quickly to manage this. The HSIB clinical panel noted that the prescription for antibiotics was written over five hours before they were administered. … this delay may have been a factor in the baby's death since earlier administration of antibiotics could have made a difference to the outcome.'

Example of HSIB maternity investigation safety recommendation

> The Trust should introduce a system to improve communication within the multidisciplinary team to ensure that clinical plans are communicated to the member of staff who needs to carry out the recommended plan.

Future developments for reducing the impact of neonatal GBS infection

A multicentre randomised trial (GBS3[8]) will consider the clinical and cost effectiveness of testing for group B streptococcus (GBS) colonisation either in late pregnancy using enriched culture medium (ECM) or during labour using a near-patient test. These strategies will be compared with the current risk factor-based strategy as recommended by the Royal College of Obstetricians and Gynaecologists (Hughes et al., 2017). The estimated sample size for the study is 320,000 women from up to 80 maternity units in England, Wales and Scotland. The study is due to commence in mid-2020. The primary outcome for the study is **'all-cause early neonatal sepsis'**.

Maternal antibodies such as immunoglobulin G (IgG)[9] are known to cross the placenta and provide a newborn baby with passive immunity to infection. A vaccine for GBS has been developed against some of the 10 GBS serotypes (strains) and is subject to research trials. An antenatal GBS vaccine would be acceptable to mothers (Hughes et al., 2017). This may be another strategy for reducing neonatal GBS infection in the future.

Summary of learning

Following the analysis of the 39 reports in the Healthcare Safety Investigation Branch group B streptococcus (GBS) cohort relating to mothers carrying GBS, the main findings are:

- Not all mothers are receiving antenatal information about GBS as recommended in national guidance.
- Mothers who are carrying GBS are not always clear about when they should contact or attend the maternity unit at the onset of labour.
- Mothers with a GBS urine tract infection in the antenatal period are not always being prescribed antibiotic treatment at the time of the positive urine culture, as well as receiving antibiotics during labour.
- Intrapartum antibiotic prophylaxis is delayed or not given to all mothers that require it. Competing demands on the available staff resource was noted to contribute to this.
- Mothers who are known to be colonised with GBS are not always invited into the maternity unit in early labour and this may contribute to delayed intrapartum antibiotic prophylaxis.
- Some local guidelines differed from current national guidance.
- Some local guidelines led to staff confusion regarding the recommended care for mothers in early labour with ruptured membranes.
- GBS culture results were not always known by the clinical team during labour, which led to no intrapartum antibiotic prophylaxis being administered.
- There were earlier opportunities to detect that a newborn baby was unwell. The use of a newborn early warning score chart may have prompted staff to recognise deterioration sooner. There is no universal newborn early warning score chart in use in England.
- Poor neonatal feeding is an important sign that can be related to neonatal infection.
- Delayed neonatal antibiotic administration contributed to some of the poor outcomes.

Considerations for trusts

Maternity care providers should consider the above findings and make necessary changes to their local systems to ensure that mothers and babies receive care in line with national guidance. The Healthcare Safety Investigation Branch will keep the theme of group B streptococcus under review and consider a future national investigation to explore this subject further.

Up-to-date information for mothers and healthcare professionals can be found on the **Royal College of Obstetricians and Gynaecologists**, **National Institute for Health and Care Excellence** and **Group B Strep Support** websites.

Endnotes

[1] Antibiotics given to prevent infection in the baby in a mother who is colonised with GBS.
[2] When the baby was thought to be alive at the start of labour but was born with no signs of life. For more information see RCOG Each Baby Counts.
[3] A test that can be done during labour in the delivery suite, that does not need to be sent to a laboratory.
[4] A membrane or cervical sweep involves having a vaginal (internal) examination that separates the membranes of the amniotic sac surrounding the baby from the cervix (neck of the womb). This separation releases hormones (prostaglandins) that may trigger natural labour. It is not uncommon for the mother to experience some discomfort or slight bleeding afterwards.
[5] A small plastic tube inserted into a vein in order to administer intravenous medicines or fluids.
[6] A sudden and unexpected deterioration in a baby's health.
[7] Placing a breathing tube in the trachea (windpipe), to assist the baby's breathing.
[8] The GBS3 trial is looking at whether testing pregnant women for group B streptococcus reduces the risk of infection in newborn babies. For more information visit: **www.gbs3trial.ac.uk**
[9] Antibodies/immunoglobulins are part of the immune system that identify and assist in the removal of infections.

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