

Royal College of Obstetricians & Gynaecologists

Audit of current practice in preventing early-onset neonatal group B streptococcal disease in the UK









Commissioned by:



UK National Screening Committee



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Second report

January 2016







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UK National Screening Committee

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Abbreviations

| AMU | alongside midwifery unit |
|--------|--|
| ECM | enriched culture medium |
| EOGBS | early-onset neonatal group B streptococcal disease |
| FMU | freestanding midwifery unit |
| g | grams |
| GBS | group B streptococcus |
| GBSS | Group B Strep Support, a UK charity that aims to offer information and support to families affected by GBS, to inform health professionals about how EOGBS can be prevented, and to support research into EOGBS prevention |
| GMC | General Medical Council |
| HES | Hospital Episode Statistics |
| HoMS | Heads of Midwifery Services |
| IAP | intrapartum antibiotic prophylaxis (against early-onset neonatal group B streptococcal disease) |
| IOL | induction of labour |
| IV | intravenous |
| LSHTM | London School of Hygiene and Tropical Medicine |
| MIS | Maternity Information Systems project, Royal College of Obstetricians and Gynaecologists |
| MLU | midwife-led unit |
| NHS | National Health Service |
| NICE | National Institute for Health and Care Excellence |
| PHE | Public Health England |
| PHLS | Public Health Laboratory Service |
| PIL | patient information leaflet |
| RCM | Royal College of Midwives |
| RCOG | Royal College of Obstetricians and Gynaecologists |
| UK NSC | UK National Screening Committee |

Glossary of terms

Alongside midwifery unit

Care for women with straightforward pregnancies during labour and birth. Alongside midwifery units are situated in the same hospital or the same site as an obstetric unit, with access to obstetric, neonatal or anaesthetic care on the same site. If obstetric care is required, transfer is usually by trolley, bed or wheelchair to the obstetric unit. Midwives have primary professional responsibility for labour care.^{1,2}

Freestanding midwifery unit

Care for women with straightforward pregnancies during labour and birth. Freestanding midwifery units are not situated on the same site as an obstetric unit or neonatal unit. Diagnostic and treatment medical services, including obstetric, neonatal and anaesthetic care, are not available immediately. If obstetric care is required, transfer is usually by car or ambulance. Midwives have primary professional responsibility for labour care.^{1.2}

Obstetric unit

Care for low- to high-risk women, provided by a team in hospital. Diagnostic and treatment medical services, including obstetric, neonatal and anaesthetic care, are available on site. Obstetricians have primary professional responsibility for women at high risk of complications during labour and birth, and for women who develop complications during labour and birth. Midwives have primary professional responsibility for labour care of women with straightforward pregnancies.^{1,2}

Selective testing (for group B streptococcus colonisation during pregnancy)

Testing of some pregnant women for group B streptococcus colonisation based on the presence of selective (risk) factors.

Universal screening (for group B streptococcus colonisation during pregnancy)

Screening of all pregnant women for group B streptococcus colonisation with swabs as part of routine maternity care (typically between 35–37 weeks of pregnancy).

Foreword

This is the second and final report from the audit on current practice in preventing early-onset neonatal group B streptococcal disease (EOGBS) in the UK. The report provides further important evidence to support efforts in maternity services on reducing neonatal infections.

Group B streptococcus (GBS), or Streptococcus agalactiae, is the most common cause of severe infection in babies during the first 3 months of life, and early-onset GBS occurs during the first 6 days of life. Although EOGBS is rare, the mortality rate associated with the infection has been reported to be approximately 5% to 10% and relatively little is known about the long-term effects of EOGBS. A national surveillance study is due to report up-to-date figures relating to the epidemiology of EOGBS later in 2016. Current national guidelines on the topic recommend a risk-based approach to EOGBS prevention.^{3,4}

In March 2015, we published the first findings from the audit: those relating to NHS obstetric units in the UK and analyses of maternity data.

In this report, we present the findings from midwife-led units; a review of local protocols for preventing EOGBS; and a review of written patient information on GBS infection. We found that a substantial proportion of midwife-led units accept women for delivery who have risk factors for EOGBS and GBS-specific intravenous (IV) antibiotics were available in almost all of these units. Given the serious risk of infection to mother and baby when intrapartum antibiotic prophylaxis (IAP) is indicated but is either unavailable or declined, obstetricians and midwives must discuss the suitability of different delivery settings with women to allow women to make an informed choice on where to give birth.

Surprisingly, we found that only a minority of local protocols on preventing EOGBS contained evidence of regular review. Where protocols were reviewed at least every 3 years, it was reassuring to find that local guidance adhered closely to national policy. However, there remains worrying variation between local protocols and national guidance, for instance in the recommended benzylpenicillin regimen for GBS-specific IAP.

Our review of written patient information on GBS found that leaflets were generally consistent with national guidance in terms of the information provided on most key topics. Yet, over half of the leaflets did not reference any clinical evidence or national guidelines and all leaflets had poor readability. We previously found that many units (37.5%) use information provided by a charity called Group B Strep Support (GBSS).⁵ The GBSS patient information leaflet provided additional information on testing for GBS colonisation using enriched culture medium (ECM), which is predominantly conducted by private laboratories and is not endorsed by the RCOG or the UK NSC.

Based on the findings of variation in some aspects of local practice and policy from this audit, we recommend that the national guidelines are updated to reduce discrepancies between units. We also recommend that a written patient leaflet is developed nationally for use by all NHS trusts and should reflect national guidance. The revised national guidelines and a nationally-used patient information leaflet should reflect the findings from this audit, the forthcoming review of screening by the UK National Screening Committee and results from the recent national GBS surveillance study.

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January 2016

Executive summary

This is the second and final report from the audit on current practice in preventing early-onset group B streptococcal disease (EOGBS). The audit was commissioned by the UK National Screening Committee and launched in 2013. Its aims were to investigate the implementation of the Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline No. 36³ in NHS obstetric units, examine variations in preventive care for EOGBS across the UK, and identify areas for improving adherence to the guideline and practice. The UK National Screening Committee (UK NSC) also funded the previous RCOG audit on the prevention and management of GBS disease in obstetric units across the UK (2007).⁶

The first report of the current audit, published in March 2015, featured two of the six components of the audit: the survey of obstetric units; and the analysis of maternity data. This report features three of the remaining four components of the audit: the survey of midwife-led units; review of local protocols for preventing EOGBS; and review of written patient information on GBS infection. The final component of the audit, case vignettes to examine the impact of risk factors on practice, will follow as a standalone publication.

Key findings from across the audit are summarised below.

Survey of midwife-led units

- Interpretation of the survey results should be made with consideration of the relatively low participation rate: 50.6% of eligible units.
- A substantial proportion of participating units (38.2%) reported that they accept women in labour with confirmed GBS colonisation.
- GBS-specific IV antibiotics were reported to be available in almost all (91.2%) of the units where women with confirmed GBS colonisation were reported to be accepted.
- In a third of participating units where survey responses and admissions criteria were received (33.3%), reported practice on whether women with current GBS colonisation were accepted for delivery did not fully reflect the admissions policy.

Review of local protocols

- Contrary to national guidelines, a small proportion of protocols (6.5%) stated that selective (risk-based) testing for GBS colonisation was offered to pregnant women.
- There were some discrepancies in the definitions of clinical indications for IAP (e.g. minimum temperature for fever during labour) and in the recommended benzylpenicillin regimen for GBS-specific IAP.
- Evidence that the protocol was updated at least every 3 years was present in less than a third of protocols (30.1%).
- Where there was evidence of regular review, local guidance adhered closely to national guidelines. However, publications referenced by some protocols were outdated and/or obsolete.

Review of written patient information

- Over half of the patient information leaflets, PILs, (57.6%) did not reference any clinical evidence or national guidelines.
- Reviewed PILs, including the leaflets produced by the RCOG and GBSS, had poor readability (e.g. long blocks of text and complex word structures).

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- All PILs, including the leaflets produced by the RCOG and GBSS, were generally consistent in their reporting of risk factors for GBS infection, signs of GBS infection in newborn babies and detection (or inference) of GBS colonisation during pregnancy by swabs or urine. However, the GBSS leaflet provided additional information on testing using enriched culture medium (ECM), which is predominantly conducted by private laboratories and is not endorsed by the RCOG or Public Health England (PHE).
- Most provider-developed leaflets (at least 77.4%) stated the three clinical indications for GBSspecific IAP that are recommended by the RCOG.

Survey of obstetric units (first report)

- A minority of participating units (3.7%) reported offering universal screening for GBS colonisation to pregnant women.
- Of the five clinical indications for IAP recommended by the RCOG, the three indications for GBS-specific cover were reported to be closely followed and adherence has remained stable since the first RCOG audit (2007). Adherence to the remaining two indications (for broad-spectrum cover) was lower but both indicators were adhered to by at least 83.7% of units.
- There were discrepancies between some reported practices and the RCOG guidelines, e.g. swab-based testing for GBS in pregnant women with risk factors and clinical indications for GBS-specific IAP that were contrary to national guidance.
- There were discrepancies between responses from obstetricians and midwives working in the same unit.

Analyses of maternity data (first report)

- We estimated 1.2 to 1.4 cases of EOGBS per 1000 live births using Hospital Episode Statistics (HES) but this is likely to be an overestimate of the culture-confirmed rate as we were unable to exclude suspected but unconfirmed cases.
- Data fields on GBS were poorly completed from eight NHS providers that participated in the RCOG Maternity Information Systems (MIS) pilot project. However, there is potential to improve the completeness and range of fields on GBS as other data fields had much higher completeness (up to 100%).

Recommendations

- I National guidelines should be updated to reflect the findings from this audit, the forthcoming review of screening by the UK NSC and the forthcoming results from the recent national GBS surveillance study. The revision of national guidelines should address the care of women who are considering or plan to give birth in locations besides an obstetric unit.
- 2 National guidelines should be applied to all NHS trusts to reduce future deviations in local practice and policy. Local protocols should be reviewed at least every 3 years to ensure they are fit for purpose and that they reflect current national guidance. The last review date should be recorded on the current protocol and the recording of the last review date should be monitored in national audits.
- 3 Future studies on preventive care for EOGBS should address care provided in midwife-led units as this audit found that pregnant women with risk factors for EOGBS are accepted for delivery in these units.
- 4 Admission criteria and practice in midwife-led units should be informed by national guidelines on preventing EOGBS, including the availability of GBS-specific IV antibiotics.
- 5 A nationally produced patient information leaflet should be used locally by all NHS trusts. The material should reflect the findings from this audit, the forthcoming review of screening by the UK NSC and the forthcoming results from the recent national GBS surveillance study. The leaflet should be accessible to patients with low literacy.

I Introduction

This is the second and final report from the audit of current practice in preventing early-onset neonatal group B streptococcal disease (EOGBS) in the UK. The report presents the results from three of the six components of the audit: the results from the survey of midwife-led units; review of local protocols for preventing EOGBS; and review of patient information on GBS infection.

The first audit report was published in March 2015 and featured results from two components of the audit: the survey of obstetric units; and the analysis of maternity data. The results of the final component of the audit, case vignettes to examine the impact of risk factors on practice, will follow as a standalone publication. This first chapter of the report presents an overview of the audit and the context in which it was conducted. The following chapters feature the results of the three audit components.

I.I Group B streptococcal disease

Group B streptococcus (GBS) or *Streptococcus agalactiae* is the most common cause of severe infection in babies during the first 3 months of life.⁷⁻⁹ GBS disease can be defined as early-onset (before 7 days old) or late-onset (7 to 90 days old). Early-onset GBS (EOGBS) is most often due to transmission from mother to baby around the time of birth. Late-onset GBS disease is more commonly due to infection from other sources, acquired in hospital or in the community.

1.1.1 Early-onset neonatal group B streptococcal disease

In the United Kingdom (UK), between 5% and 30% of pregnant women are known to carry GBS, but for most of these women this causes no complications to themselves or their babies.¹⁰⁻¹² EOGBS typically occurs within the first 24 hours of life (90% of cases) and accounts for approximately 30% to 50% of neonatal infections.^{7–9,13,14} The rate of infection varies by the presence of individual risk factors, but the incidence of culture-proven EOGBS in the UK is estimated to be approximately I case per 2000 live births, with a mortality rate between 5–10%.^{15–17} This equates to between 350–400 cases and between 25–40 neonatal deaths due to EOGBS per year.^{15,18} There is a lack of evidence on morbidity due to EOGBS, but meningitis, sepsis and pneumonia and long-term complications such as cerebral palsy, deafness, blindness and learning difficulties have been reported in a minority of infected babies.^{15,19,20}

1.1.2 Preventing early-onset neonatal group B streptococcal disease

Screening of all pregnant women for GBS rectovaginal colonisation occurs in some countries, e.g. the United States of America.²¹ In the UK, screening evidence is reviewed by the UK National Screening Committee (UK NSC). The committee reviewed the national policy for preventing EOGBS in 2003, 2008 and 2012, and concluded that in the UK, it is inappropriate to introduce universal screening in pregnant women.²² Instead, the Royal College of Obstetricians and Gynaecologists (RCOG) recommends offering intrapartum antibiotic prophylaxis (IAP) to women with a risk factor that is associated with invasive GBS disease in their newborn baby:^{3,4}

- previous baby with invasive GBS infection (GBS-specific IAP is recommended)
- GBS bacteriuria in the current pregnancy (GBS-specific IAP is recommended)
- vaginal swab positive for GBS in current pregnancy (GBS-specific IAP is recommended)
- pyrexia (>38 °C) in labour (broad-spectrum IAP with GBS cover is recommended)
- chorioamnionitis (broad-spectrum IAP with GBS cover is recommended).

The RCOG recommends against adopting the following practices:

- routine bacteriological screening of all pregnant women for antenatal GBS colonisation
- testing for GBS or the administration of IAP to women in whom GBS colonisation was detected in a previous pregnancy
- antenatal treatment for GBS colonisation with benzylpenicillin
- GBS-specific antibiotic prophylaxis in women with any of the following presentations:
 - undergoing planned caesarean section in the absence of labour and with intact membranes
 - with term prelabour rupture of membranes, unless there is known GBS colonisation in which case immediate induction of labour and IAP should be offered
 - in established preterm labour with intact membranes, unless there is known GBS colonisation
 - with preterm rupture of membranes (to be managed according to the RCOG Green-top Guideline No. 44 and NICE Guideline CG149).^{23,24}

I.2 The first RCOG audit

During 2005 and 2006, the RCOG led an audit on the prevention and management of GBS disease in obstetric units across the UK.⁶ The audit found that most obstetric units (78%) had a documented risk-based IAP strategy.²⁵ Yet there continues to be variation in practice, with inconsistent adherence to local policies and the RCOG Green-top Guideline No. 36.^{6,25} Furthermore, the nature and extent of this variation, and the appropriateness of current practices in preventive care, are unclear.

I.3 The current RCOG audit

Given the need for up-to-date information about care, the UK NSC suggested 'a formal audit' of practice on preventing neonatal GBS disease and to establish the extent that the updated RCOG guideline is implemented across the UK.²² The rationale for a pragmatic audit design was described in the first report.⁵ The one year project began in October 2013. The project group consisted of a lay adviser, clinicians, academic researchers and advisers from the RCOG. Data collected in this audit were stored centrally at the RCOG. Microsoft Excel 2013 and STATA version 11 were used for data management and analyses.

1.3.1 Aims of the audit

The current audit was intended to provide a comprehensive picture of current practice and policy on preventing EOGBS in the UK, taking into account recommendations from the first RCOG audit and the RCOG revised Guideline (2012).^{4,6,25}

The three aims of the audit were to:

- I investigate the implementation of the RCOG Green-top Guideline No. 36 (2012) in obstetric units in the UK
- 2 examine variation in preventive care for EOGBS in the UK
- 3 identify areas for improving guideline adherence and practice.

1.3.2 Topics included in the audit

The four key topics of investigation in this audit were:

I Written protocol on preventing early-onset neonatal group **B** streptococcal disease

Locally relevant guidelines that reflect national recommendations support staff to deliver consistently good-quality care. Written protocols with defined standards of care are

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essential for monitoring the performances of individual clinicians, hospital units and providers (hospital trusts and health boards).

- 2 Written patient information on group B streptococcus infection The General Medical Council (GMC) recommends that doctors provide patients with '... information they want or need to know in a way they can understand'.²⁶ Written patient information is a useful resource for patients to aid decision making and to reinforce, and expand on, information provided during their hospital appointment. However, for this material to be of value to patients, the information must be accurate and presented in accessible formats.
- **3** Testing for group B streptococcus colonisation in pregnant women Although universal screening and selective testing for GBS colonisation during pregnancy are not recommended in the UK, there is known variation in practice. It is important to understand the extent of, and the reasons for, deviations from recommended practice so that all pregnant women in the UK receive appropriate care.
- 4 Intrapartum antibiotic prophylaxis against early-onset neonatal group **B** streptococcal disease

The RCOG recommends that IAP should be offered to pregnant women with one of five clinical indications. However, the first RCOG audit (2007) highlighted that women with other presentations are offered GBS-specific IAP. Despite the introduction of national guidelines, inconsistent practice continues. A detailed description of how GBS-specific antibiotic prophylaxis is currently used will help to standardise care and inform future revisions of national and local policies on preventing EOGBS.

1.3.3 Components of the audit

The four key topics were investigated by six audit components. Topics three to five feature in this report:

- I survey of all NHS obstetric units in the UK (first report)
- 2 analysis of routinely collected maternity data (first report)
- 3 survey of NHS midwife-led units in the UK
- 4 review of local protocols for preventing EOGBS
- 5 review of patient information on GBS infection
- 6 case vignettes to examine the impact of risk factors on practice (pending publication).

1.3.4 Findings published in the first report

The first report published findings from the survey of obstetric units and found that:

- A minority of participating units (3.7%) reported offering universal screening for GBS colonisation to pregnant women (n=6/161).
- Of the five clinical indications for IAP recommended by the RCOG, the three indications for GBS-specific cover were reported to be closely followed and adherence has remained stable since the first RCOG audit (2007). The remaining two indications (for broad-spectrum cover) were less well adhered to, which may be due to how participants interpreted the survey question but might also reflect practice that is consistent with RCOG guidance to use broad-spectrum IAP rather than GBS-specific IAP for these two indications.
- There were discrepancies between some reported practices and the RCOG guidelines, e.g. some units undertook swab-based testing for GBS in pregnant women with risk factors and offered GBS-specific IAP for clinical indications other than those in the national guidelines.
- There were discrepancies between responses from obstetricians and midwives working in the same unit.

The first report also presented findings on analyses of maternity data:

- We estimated 1.2 to 1.4 cases of EOGBS per 1000 live births using Hospital Episode Statistics (HES) but this is likely to be an overestimate of the culture-confirmed rate as we were unable to exclude suspected but unconfirmed cases.
- Data fields on GBS were poorly completed from eight NHS providers that participated in the RCOG Maternity Information Systems (MIS) pilot project. However, there is potential to improve the completeness and range of fields on GBS as other data fields had much higher completeness (up to 100%).

2 Survey of midwife-led units

The first RCOG-led audit on the prevention and management of GBS included only obstetric units (2007).⁶ Midwife-led units (MLUs) were included in the current audit as more women are choosing to give birth in this setting. It is therefore important to include these locations in reviews of maternity practice. This decision was underpinned by advice from the midwifery representative in the project group who indicated that confirmed GBS colonisation may not always be a contraindication for admission to midwife-led units.

Supporting this view was anecdotal evidence from some participants of the audit pilot study conducted during December 2013, who reported that women with known GBS colonisation during their current pregnancy could be admitted to an alongside midwifery unit (AMU) in their hospital trust or health board. However, participants of the pilot study also reported that not all AMUs offer IAP against EOGBS (i.e. GBS-specific IAP). National guidelines recommend that women with confirmed GBS colonisation in their current pregnancy should be offered IAP.

Given the limited resources of the current audit, we could not conduct a full-scale survey of NHS MLUs in the UK so a feasibility study was launched in parallel with the full audit. This consisted of an online survey about current practice and a review of the admission policy (acceptance criteria) used by alongside (AMU) and freestanding (FMU) midwifery units. The study was supported by the Royal College of Midwives (RCM) by coordinating the dissemination of the survey to midwife-led units.

2.1 Aims of the survey of midwife-led units

This feasibility study was intended to provide an overview of current practice related to preventing EOGBS in MLUs across the UK. Specifically, the study focused on whether women with risk factors for EOGBS are admitted to MLUs and the availability of intravenous (IV) antibiotics against EOGBS in the units. The results from this study could be used to inform future audit and research into maternity care for preventing EOGBS.

2.2 Sample of midwife-led units

At present there is no centralised, up-to-date source of data on the total number of MLUs in the UK. Calculation of the number of eligible units was hampered by temporary closure of individual units to new patients as well as permanent closures. Eligibility was defined as NHS-funded units that were accepting new patients at the start of the study. To estimate a baseline number of MLUs for the feasibility study, data from several sources were used: results of the survey of obstetric units from the current audit, the BirthChoiceUK Professional website and the babycentre.co.uk website.^{5,27,28} We estimated there to be 175 eligible MLUs in the UK at the start of the study (April 2014).

2.2.1 Recruitment of participants

Heads of Midwifery Services (HoMS) in the UK were contacted by the RCM on behalf of the audit in April 2014. An email invitation to participate in the study was sent from the RCM Directors for England, Wales, Scotland and Northern Ireland to all HoMS in each respective country. The email asked HoMS to nominate a senior midwife in each MLU in their hospital trust or health board to complete the online survey and to submit the admission policy (acceptance criteria) for each MLU. Three email reminders to participate in the study were sent to all HoMS on behalf of the audit between May and June 2014, including reminders from RCM regional officers to support survey participation.

2.3 Development of survey questions

The online survey consisted of 15 questions (Appendix 1). It was developed and administered online, using the SurveyMonkey platform. The survey was piloted by two midwives in one hospital in England during April 2014. The two participants reported that the survey instructions were clear and the survey was easy to complete.

2.4 Results of the survey of midwife-led units

Between April and June 2014, 140 survey responses were received including multiple responses from MLUs. Responses were included in the analyses if they were complete (i.e. unfinished survey responses were not included) and if the responses related to individual units (rather than whole trusts). There were 89 eligible responses. Based on our estimate, a valid completed survey was received from 50.6% of eligible MLUs in the UK (n = 175).

2.4.1 Participants and midwife-led units

The majority of participants specifically reported that they were midwives (92.1%, n=82/89), including team leaders and modern matrons. A minority of participants reported that they were in managerial roles at ward- or department-level (7.9%, n=7/89). Approximately half of participants (53.9%) were employed at band 7, with 42.7% at band 8 and the remaining 3.4% employed at band 6 (n=89). Two-thirds of participants worked in MLUs in England (67.4%, n=60/89). The remaining participants worked in Wales (14.6%, n=13/89), Scotland (11.2%, n=10/89) or Northern Ireland (6.7%, n=6/89).

More participants were reported to work in AMUs (61.8%, n=55/89) than in FMUs. Over half of participants reported that antenatal, intrapartum and postpartum care were available in their unit (55.1%, n=49/89). Few participants (11.2%) reported that only intrapartum care was available in their unit (n=10/89).

2.4.2 Practice in the midwife-led units

The majority of participants (75.3%) reported that women identified with GBS colonisation in a previous pregnancy or outside of pregnancy would be accepted for care (n = 67/89). Figure I shows that that this practice was reported more often by participants working in AMUs than FMUs. Over a third of all participants (38.2%) reported that women identified with GBS colonisation in their current pregnancy were accepted for care during labour (n = 34/89). Most of these 34 participants worked in AMUs. Among the 34 participants, 50% reported that women were accepted if GBS

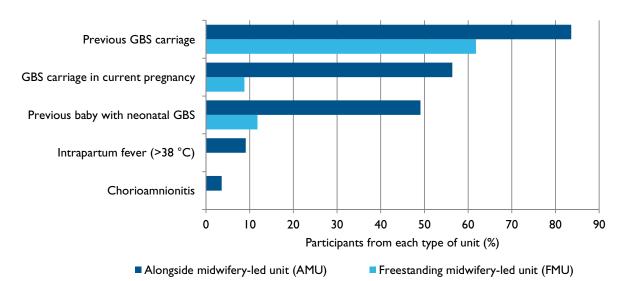


Figure 1 Acceptance of women in labour with specific conditions for delivery by type of unit, n = 89

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colonisation in their current pregnancy was identified from urine and vaginal specimens (n = 17/34), while 38.2% reported acceptance of women where GBS colonisation was identified by a combination of urine, vaginal and rectal specimens (n = 13/34) but only 11.8% reported acceptance where diagnosis was made by vaginal specimens only (n = 4/34). Few participants (8.8%) who reported that women with current GBS colonisation were accepted in labour reported that IV antibiotics against EOGBS was not available in their unit (n = 3/34).

Just over a third of participants reported that women in labour who had a previous baby with neonatal GBS infection would be accepted in their unit (34.8%, n=31/89). Most of these 31 participants worked in AMUs. The majority of these participants (77.4%) reported that IV antibiotics against EOGBS were available to women in labour in their unit (n=24/31). Very few participants reported that women who develop a fever (>38 °C) during labour could continue to give birth in their unit (5.6%, n=5/89). Participants of two of these five units noted in the comments section of the survey that staff in the MLU and obstetric unit worked closely together. Less than 5% of participants reported that staff in the MLU and obstetric unit worked closely together. Less than 5% of participants reported that staff in the midwife-led and obstetric units worked closely with each other. All of the participants who reported that women with intrapartum fever could continue to give birth in their unit, or reported that women with chorioamnionitis would be accepted for delivery in their unit, worked in AMUs.

2.4.3 Comments from participants

Some participants provided additional comments at the end of the survey as free text. Four participants reported that the admission policy in their unit related to accepting women with current or previous GBS colonisation was under review but these patient groups were currently not accepted. It was also reported that women with current GBS colonisation were accepted for water birth (n=2), or accepted for delivery with advice on childbirth options, including information about the availability (or lack of availability) of IAP (n=12).

2.4.4 Admission criteria

19 sets of admission criteria were received, including two sets of criteria covering all of Wales and Scotland, respectively. These two documents contained guidance on hospital-based birthing options for women with GBS colonisation but the criteria were excluded from the analyses as they did not correspond to individual MLUs or providers, and therefore could not be compared with other submitted criteria. A further submission was excluded because it was a single page assessment form and two other sets of criteria were excluded as there was no mention of GBS at all.

The remaining 14 sets of admission criteria covered 16 MLUs (two sets of criteria each covered an AMU and a FMU). The distribution of admission criteria by type of MLU and country are shown in Table 1.

| | Alongside midwifery units (AMUs) | Freestanding midwifery units (FMUs) | All midwife-led units (MLUs) |
|-------------------------|-------------------------------------|--|---------------------------------|
| England | 10* | 3* | 13 |
| Wales | I. | 0 | I |
| Scotland | I | 0 | I |
| Northern Ireland | 0 | I | I |
| Sub-total for unit type | 12 | 4 | _ |

 Table I
 Number of eligible admission criteria by type of midwife-led unit and country

*Includes two sets of criteria that each covered an AMU and FMU

2.4.5 Acceptance of women with confirmed GBS colonisation

Only half of the reviewed admission criteria stated the date of publication (n=7/14), ranging from April 2011 to March 2014. The guidance on acceptance of women with current GBS colonisation was mixed. The criteria for all four FMUs stated that women with confirmed GBS colonisation would not be accepted for delivery. For AMUs, the same guidance was applicable for five out of 12 AMUs. The criteria for the remaining seven AMUs indicated that women with confirmed GBS colonisation might be considered for admission based on review of the individual case. Additional information was provided in the admission criteria for five of the seven AMUs:

- admission requires discussion with, or referral from, consultant
- admit but only after advice to deliver in the obstetric unit
- admit but administer antibiotics during labour with management in the pool room
- admit only if asymptomatic and no previous babies with GBS.

2.4.6 Comparison between survey and admission criteria

No survey response was received from one AMU. Survey responses and admission criteria were matched for ten MLUs (n=6 AMUs, n=4 FMUs) where both sources either reported that women with confirmed GBS colonisation in current pregnancy would not be accepted for delivery without exception, or would be accepted, respectively. However, Table 2 shows that in the remaining five MLUs, there were discrepancies between survey responses and guidance in the admission criteria.

| Type of | Number of | Accepta | Acceptance of women with confirmed GBS colonisation | | |
|---------|-----------|---------|--|--|--|
| unit | units | Survey | Admission criteria | | |
| AMU | 2 | Yes | Yes | | |
| AMU | 4 | No | No | | |
| FMU | 4 | No | No | | |
| AMU | 2 | Yes | Maybe – only if asymptomatic and no previous babies with GBS, or delivery in obstetric unit advised but women able to make informed choice on place of birth | | |
| AMU | 2 | No | Maybe – antibiotics during labour and management in the pool room, or requires referral by consultant obstetrician | | |
| AMU | I | No | Maybe – must discuss with consultant obstetrician | | |

 Table 2
 Acceptance of women with confirmed GBS colonisation from survey and admission criteria

In the two AMUs where survey responses and admission criteria guidance indicated that women with confirmed GBS colonisation would be accepted for delivery, it was also reported in the survey that these units offered IV antibiotics against EOGBS to women at risk during labour. Among the five AMUs where the survey responses conflicted with the admissions criteria, only two units were reported to offer IV antibiotics against EOGBS during labour.

Among the eight MLUs where both survey responses and admission criteria indicated that women with current GBS colonisation would not be accepted for admission, one unit (an AMU) was reported to accept women who had a previous baby with neonatal GBS infection. Five units (n=3 AMUs, n=2 FMUs) were reported by survey participants to accept women who had confirmed GBS colonisation in a previous pregnancy or outside of pregnancy.

2.5 Summary

This feasibility study demonstrated that it is possible to collect data on current midwifery practice related to preventing EOGBS in MLUs across the UK. However, as only approximately half of eligible MLUs in the UK participated in the study and far fewer units submitted admission criteria,

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there needs to be caution in generalising our findings despite participation of units from all four countries in the UK. The participation rate of this study might have been improved by the availability of a centralised database of MLUs in the UK to ensure that all eligible units were included in the study. We demonstrated in the survey of obstetric units that a very high participation rate can be achieved by following up with individual non-responders directly. This approach was not possible for the survey of MLUs as units were contacted on behalf of the audit by the RCM and the audit had no direct communication with individual units.

2.5.1 Acceptance of women for delivery with risk factors for EOGBS

Over a third of participants reported that their MLU accepted women with confirmed current GBS colonisation for delivery, and IV antibiotics against EOGBS was available in almost all (91.2%) of these units. Three-quarters of participants reported that their unit accepted women with previous GBS colonisation. These findings were more frequently reported by participants working in AMUs than FMUs. There were very few MLUs where it was reported that women with intrapartum fever could continue to give birth in the unit or where women with chorioamnionitis were accepted for delivery.

2.5.2 Consistency between reported practice and local policy

For two-thirds of MLUs, reported practice from the survey responses and admission policy were in agreement on whether women with current GBS colonisation would be accepted for delivery. However, for the remaining third of MLUs, there were discrepancies in which the admission criteria indicated a case-by-case decision process that often required additional review by a consultant obstetrician or advice to women to deliver in the obstetric unit.

3 Review of local protocols

All maternity units and other birth settings should use evidence-based guidelines or protocols for intrapartum care as part of a robust and transparent clinical governance framework.²⁹ These guidelines should be reviewed at least every 3 years and be approved by the maternity risk management group of the healthcare provider.²⁹ There are national guidelines for maternity care published by organisations such as the RCOG and the National Institute for Health and Care Excellence (NICE). Guidelines developed locally by individual providers should reflect recommendations in the national publications to support staff to deliver consistently good-quality care. Written protocols that contain explicitly defined standards of care are essential for monitoring the performances of individual clinicians, hospital units and providers.

3.1 The first review of local protocols

In the first RCOG-led audit (2007), a review of local protocols from 171 obstetric units on preventing EOGBS found variation among local guidelines in the inclusion of the five clinical indications for IAP against EOGBS that are recommended by the RCOG.⁶ Almost all protocols (93%) contained guidance to offer IAP against EOGBS to women who had a previous baby affected by EOGBS but only approximately two-fifths of protocols (39%) stated that IAP for GBS should be offered to women in labour with suspected chorioamnionitis.⁶ Furthermore, some protocols included indications not endorsed by the RCOG such as offering IAP to women with confirmed GBS colonisation in a previous pregnancy.⁶ The audit also found inconsistencies in the quality of the protocols, including a lack of a next review date in 32% of reviewed protocols and 12% of protocols containing no references to any clinical evidence.

3.2 Aims of the review of local protocols

The current review of local protocols on preventing EOGBS was intended to determine whether the quality of protocols developed and used by NHS healthcare providers in the UK has improved since the first audit. In particular, the review examined local guidelines on testing for group B streptococcus colonisation in pregnant women to support understanding of deviations from the recommended practice. Local guidance on IAP against EOGBS was also explored to support the standardisation of national and local policies on preventing EOGBS.

3.3 Sample of obstetric units

As described in the first report from the current audit, a contact list of clinical directors for maternity services at all eligible NHS providers was extracted from the RCOG Members database and used to recruit participants for the different audit components.⁵ There were 190 obstetric units at 156 providers in the UK that were eligible to participate in the current audit (that is, NHS-funded units that were open to patients during February 2014). A list of providers that participated in one or more component of the audit can be found in Appendix 2.

3.3.1 Obtaining local protocols

At the start of the current audit in February 2014, we asked the clinical directors for maternity services to act as local coordinators and to submit the currently used protocol for preventing EOGBS at their hospital trust or health board. Paper-based and electronic protocols were accepted for review.

3.3.2 Results from the pilot study

As part of the pilot study in December 2013, local protocols on the prevention of EOGBS were submitted electronically to the project lead by clinical directors for maternity services, clinical leads or other nominated staff at six NHS obstetric units in the UK. The protocols ranged from three pages to 19 pages. The purpose of reviewing the submitted protocols was to test the electronic data extraction form for clarity of the instructions and data fields, and feasibility of completing the form.

The pilot review found that all except six fields in the data extraction template could be populated from the content of the reviewed protocols. Despite unavailability of data to answer six questions in the pilot review, these questions were retained for the full review as they were considered to be of clinical interest and they only required short answers.

3.3.3 Recruitment of clinical reviewers

We recruited four reviewers with relevant clinical expertise, i.e. midwives, clinical research fellows or specialist registrars. Reviewers were recruited through the RCOG, the RCM and from recommendations made by members of the project group.

3.3.4 Reviewer training

Before starting the reviewing process, each of the four reviewers received training coordinated by the project lead (CT) during February 2014. The six local protocols submitted to the audit's pilot study in December 2013 were reviewed by each reviewer. The answers were compared with the original reviews conducted during the pilot study and all discrepancies were discussed with individual reviewers by email or telephone.

The quality of reviews was continuously monitored by CT. Each completed review was checked for data completeness (missing answers) and accuracy (invalid data, e.g. alphabetical instead of numeric answers). Inter-rater agreement and reliability were assessed during initial training and at two pre-specified time points during the reviewing period (55th and 78th protocols in chronological order by date submitted) when all four reviewers were asked to review the same protocol.

3.3.5 Review process

The reviews began in February 2014 using a data extraction template in Excel that had been developed by the project lead and reviewed by the project team. All reviews were managed online using Teaming, a shared secure workspace hosted by the London School of Hygiene and Tropical Medicine (LSHTM). This electronic system had the benefits of enabling reviewers to complete all the reviews remotely and it also allowed for a streamlined process of allocating reviews, carrying out quality assessments and monitoring the review completion rate. To avoid potential bias, reviewers did not assess the protocol of their employer (where a protocol was submitted).

3.4 Results of the full review of protocols

Between February and May 2014, protocol documents were received from 125 providers. Two documents were excluded from the review for the following reasons: patient information leaflet rather than a protocol for hospital staff (n=1) or protocol on the management of EOGBS in neonates without any guidance on the prevention of EOGBS (n=1). A total of 123 protocols were reviewed, representing 78.9% of eligible providers. In this section of the report, the results of the current review will be compared with the results from the first audit wherever possible and appropriate. Although there is a discrepancy in the unit of analysis (obstetric unit in the first review of protocols versus provider in the current review), the two sets of results will be comparable with each other as protocols are typically applied across an entire hospital trust or health board (i.e. for all maternity services in any given provider) rather than being specific to individual obstetric units.

3.4.1 Testing for group B streptococcal colonisation in pregnant women

The majority of protocols stated that universal testing for GBS colonisation was not offered to pregnant women (80.5%, n=99/123). A minority of protocols did not explicitly state whether testing for GBS was offered or not offered (13.0%, n=16/123), while even fewer protocols explicitly stated that selective (risk-based) testing for GBS colonisation was offered (6.5%, n=8/123). The reasons for selective testing, the site of the specimen sample and timing of testing stated in the eight protocols are shown in Table 3.

| Clinical scenario | Specimen sample site | Timing of testing |
|---|----------------------|-------------------|
| GBS colonisation in previous pregnancy but baby is unaffected | Vagina | 36 weeks |
| GBS colonisation in previous pregnancy that ended in miscarriage or required IV antibiotics during labour for GBS | Vagina | 37 weeks |
| Confirmed GBS colonisation and wanting a home birth | Introital and rectum | 37 weeks |
| Previous GBS colonisation and: | Vagina and perineal | Not stated |
| • Preterm rupture of membranes (<36 weeks); or | | |
| • Prelabour rupture of membranes as soon as confirmed; or | | |
| Intrapartum pyrexia; or | | |
| • GBS urinary tract infection; or | | |
| Threatened or actual preterm labour; or | | |
| Threatened or actual mid-trimester loss | | |
| Preterm (<37 weeks) rupture of membranes | Introital | At least weekly |
| Preterm prelabour rupture of membranes | Vagina | Not stated |
| Prelabour rupture of membranes | Vagina or liquor | Not stated |
| Term prelabour rupture of membranes | Lower vagina | Not stated |
| Abnormal discharge | Lower and upper | Not stated |
| | vagina or sweeping | |
| Previous serious adverse event* to woman or baby in previous | Urine and vagina; | 23 to 24 weeks; |
| pregnancy | upper vagina | 35 to 37 weeks |

Table 3 Reasons for selective testing for group B streptococcal colonisation, n = 8 protocols

GBS = group B streptococcal disease; IV = intravenous

*Serious adverse event was not defined or described

3.4.2 Requests to test for GBS colonisation during pregnancy

Seven protocols provided guidance specifically on managing requests for testing for GBS colonisation (Appendix 3). Six out of the seven protocols stated that requests would be accepted, including two protocols where it was indicated that the decision to test lay with individual clinicians. Five of the seven protocols also advised staff to inform women that testing for GBS colonisation was not recommended for their clinical scenario or there was a lack of clinical evidence to support IAP based on the results of selective testing arising from the given clinical scenario.

3.4.3 Clinical indications for intrapartum antibiotic prophylaxis

Most protocols stated that where there was clinical indication for antibiotic prophylaxis against EOGBS, this would be offered in the intrapartum period (92.7%, n = 114/123) rather than the antenatal period. Table 4 also shows that all five of the clinical indications for IAP recommended by the RCOG featured in the most frequently stated indications in the reviewed protocols. Nevertheless, two of the five indications (for broad-spectrum IAP) recommended by the RCOG were only documented in a minority of protocols, intrapartum pyrexia (31.7%) and chorioamnionitis (14.6%), and the proportions of protocols were smaller than observed in the first audit.

| Indication | Current audit, <i>n</i> = 123 | | First audit, n | = 171 |
|--|-------------------------------|------|----------------|-------|
| | Protocols (n) | % | Protocols (n) | % |
| GBS bacteriuria or urinary tract infection (due to GBS) in current pregnancy (determined incidentally)*‡ | 121 | 98.4 | 146 | 85.4 |
| Previous baby with neonatal GBS disease* | 118 | 95.9 | 159 | 93.0 |
| Vaginal swab positive for GBS in current pregnancy $^{*\$}$ | 118 | 95.9 | 144 | 84.2 |
| Intrapartum pyrexia (>38 °C)* | 39 | 31.7 | 104 | 60.8 |
| Preterm labour (<37 weeks of gestation) | 22 | 17.9 | 84 | 49.I |
| Chorioamnionitis (suspected or confirmed)* | 18 | 14.6 | 66 | 38.6 |
| Term prolonged rupture of membranes (≥18 hours) | 11 | 8.9 | _ | _ |
| Preterm (<37 weeks of gestation) prolonged rupture of membranes (≥18 hours) [†] | 7 | 5.7 | _ | - |
| Previous pregnancy with GBS colonisation | 7 | 5.7 | 29 | 17.0 |
| Preterm prelabour (<37 weeks of gestation) rupture of membranes [†] | 6 | 4.9 | - | _ |

Table 4 Ten most frequently stated clinical indications for intrapartum antibiotic prophylaxiscompared with the first audit

* Clinical indications for which the RCOG recommends IAP against EOGBS⁴

 $^{\dagger}\,Recommended$ by National Institute for Health and Care Excellence (2012)^{24}

 $^{\ddagger}\mbox{Bacteriuria}$ in current pregnancy only (without urinary tract infection) in first audit

 $^{\$}$ Incidental finding of GBS only in first audit

Suspected chorioamnionitis only in first audit

Just over a fifth of protocols (21.1%, n = 26/123) stated that there needed to be at least two clinical indications present before IAP against EOGBS was offered to women. These combinations of clinical indications were presented either with or without additional reference to one or more of the five indications for IAP recommended by the RCOG. Table 5 shows that the most frequently stated combinations of indications for IAP featured two or more from preterm labour, prolonged rupture of membranes and intrapartum pyrexia (n = 13).

| Combinations of clinical indications | Protocols (n) | % |
|---|---------------|------|
| Two or more of: preterm labour, prolonged rupture of membranes and/or intrapartum pyrexia | 13 | 10.6 |
| Two or more of: preterm labour, prolonged rupture of membranes, intrapartum pyrexia and/or at least one of the following* | 7 | 5.7 |
| Prolonged rupture of membranes and either (intrapartum pyrexia and/or factor indicative of chorioamnionitis [†]) or (preterm labour and/or intrapartum pyrexia) | 2 | ۱.6 |
| GBS colonisation in current pregnancy and (preterm labour, prolonged rupture of membranes and/or intrapartum pyrexia) | 2 | ۱.6 |
| Term prolonged rupture of membranes, intrapartum pyrexia and/or factor indicative of chorioamnionitis † | I | 0.8 |
| GBS colonisation in current pregnancy, evidence of maternal sepsis and/or previous baby with neonatal GBS disease | I | 0.8 |

*Chorioamnionitis, GBS colonisation in previous pregnancy, GBS colonisation in current pregnancy, previous baby with neonatal GBS disease, preterm rupture of membranes, preterm prelabour rupture of membranes, preterm prolonged rupture of membranes

[†]Uterine tenderness, maternal tachycardia, fetal tachycardia

Compared with the first audit, fewer protocols defined prolonged rupture of membranes as \geq 24 hours (19.9% in first audit versus 8.9% in current audit) instead of the more conventional timescale

of \geq 18 hours. Most of the protocols that included intrapartum pyrexia in combinations of indications for IAP stated the conventional definition of intrapartum pyrexia as >38 °C (76.0%, *n* = 19/25) but there were some exceptions:

- >37.8 °C
- >37.5 °C on two occasions or 38 °C on one occasion
- 38 °C on two occasions and at least I hour apart
- 38°C for I hour or more
- >37.4 °C but <38 °C.</p>

3.4.4 Requests for intrapartum antibiotic prophylaxis

Seven protocols provided guidance on managing maternal requests for IAP against EOGBS (Appendix 4). All except one of the clinical scenarios stated in these seven protocols described GBS colonisation in a previous pregnancy (on its own or in addition to other clinical scenarios). Six of the seven protocols stated that a request for IAP given the specific clinical scenario would be accepted with informed consent, or dependent on agreement from individual clinicians or if there was a positive test result for GBS colonisation. The remaining protocol stated that women who received IAP in a previous pregnancy and who request IAP in their current pregnancy should be advised that clinical evidence does not support the use of GBS-specific IAP when there are no risk factors present. The number of protocols that addressed the topic of maternal requests for IAP was the same as found in the first audit (seven protocols in each audit).⁵

3.4.5 Refusals of intrapartum antibiotic prophylaxis

Specific guidance was provided in 18 protocols on managing the care of women who refused IAP when prophylaxis against EOGBS was clinically indicated. These protocols contained one or more of the following guidance: acknowledge woman's right to decline IAP (n=8); document in the notes that offer of IAP has been declined (n=6); discuss the risk of GBS infection with the woman (n=5); advise the woman that her baby will require antibiotics after birth and will need care according to the hospital guidelines on preventing neonatal infection (n=4); or advise the woman that her baby will require observation after birth (n=2). The guidance in one of the I8 protocols was for the management of women who refused both induction of labour (IOL) and IAP, while another protocol advised on the management of women who wish to have a home birth but who also have clinical indications for IAP and have refused IAP. This topic was not addressed in the first audit.

3.4.6 Intrapartum antibiotic prophylaxis regimens

Most protocols stated that the firstline drug for GBS-specific IAP was benzylpenicillin, also known as penicillin G, (95.1%, n = 117/123). Of the remaining protocols, five did not specify which penicillin (4.1%, n = 5/123). The remaining one protocol did not state the name of the firstline drug for IAP against EOGBS. Among the 117 protocols where benzylpenicillin was named as the firstline drug, the majority (84.6%) also stated the loading and maintenance doses recommended by the RCOG; 3g then 1.5g 4-hourly. Compared with the first audit when 74.1% of protocols stated the recommended regimen, there has been greater adherence to national guidelines. However, Table 6 shows that there was some deviation from this regimen in local protocols.

Furthermore, only approximately two-thirds of protocols (61.5%) where benzylpenicillin was stated as the firstline drug also stated that the drug should be administered at least 2 hours before delivery for maximum efficacy, as recommended by the RCOG (n=72/117).⁴ Almost a fifth of protocols (18.8%) did not recommend a minimum length of time before delivery for administering the drug (n=22/117). All except one protocol stated clindamycin as the alternative to the firstline drug (n=122/123). Protocol adherence to national guidance of administering 900 mg of clindamycin 8-hourly (96.7%, n=118/122) was greater than in the first audit, when only 83.0% of protocols stated this advised practice.^{4,5}

Table 6 Benzylpenicillin regimens compared with the first audit

| Regimen | Current audit, <i>n</i> = 117 | | II7 First audit, n= | |
|---|-------------------------------|------|---------------------|-------------------|
| | Protocols (n) | % | Protocols (n) | % |
| 3 g then 1.5 g 4-hourly | 99 | 84.6 | 126 | 74.I |
| 3g then 1.2g 4-hourly | 6 | 5.1 | 10 | 5.9 |
| 3 g then 1.8 g 4-hourly | 7 | 6.0 | 6 | 3.5 |
| 2.4g then 1.2g 4-hourly | 2 | 1.7 | 6 | 3.5 |
| Other (3 g then 1.8 g 6-hourly, 3 g then 1.2 g 6-hourly, 2.4 g then 1.2 g 3-hourly) | 3 | 2.6 | 22 | 12.9 [†] |

*One protocol in the first audit did not recommend benzylpenicillin

[†]Other dosage not specified in first audit

3.4.7 Characteristics of the protocols

The majority of providers (91.1%, n = 112/123) submitted a written protocol specifically for preventing EOGBS. A further eight providers submitted a written protocol on early-onset neonatal infections, including GBS, while another three providers submitted protocols on other conditions, such as prelabour rupture of membranes at term or preterm prelabour rupture of membranes, but where management of maternal GBS was specifically addressed.

Almost all protocols stated the month and year of publication (95.9%, n = 118/123), with the publication year ranging from 2004 to 2014. The next review date was stated in 87.0% of protocols compared with 68.4% of protocols in the first audit.⁵ These protocols included 18 documents where the year of the next review was before the year that the audit took place, i.e. before 2014. The version number of the current protocol was stated in 90 protocols (73.2%), which included the first version of 12 protocols. Less than a third of protocols (30.1%, n = 37/123) contained evidence that they were reviewed at least every 3 years. A further 42.3% of protocols were intended to be reviewed at least every 3 years, as determined by the number of years between publication date and next review date or information stated in the protocol (n = 52/123).

3.4.8 Citation of clinical evidence

Four protocols did not contain any references to other published material (3.3%, n = 123). A greater proportion of protocols cited publications compared with the first audit when it was found that 21 protocols did not provide evidence to support recommendations made (12.3%, n = 171).⁵ Over a third of protocols (35.8%, n = 44/123) did not cite any locally developed guidelines related to preventive care for EOGBS. The ten most frequently cited national guidelines are shown in Table 7 along with results from the first audit, where available.

Over half of reviewed protocols (55.3%) cited the first edition of the RCOG Green-top Guideline on preventing EOGBS (2003) despite the document being superseded by the second edition in 2012. Furthermore, some protocols (15.4%) still cited publications from the Public Health Laboratory Service (PHLS) Group B Streptococcus Working Group, even though these recommendations were superseded by the RCOG Green-top Guideline, and all of these 19 protocols were published after the first version of the RCOG guideline. Yet compared with the first audit, far fewer protocols cited PHLS material (37.4% in first audit versus 15.4% in current audit). A minority of protocols (5.7%) cited the 1996 edition of the Centers for Disease Control and Prevention (CDC) guideline even though it had been updated in 2002 (cited in 9.8% of protocols). Both versions of the CDC guideline were cited by a smaller proportion of protocols in the current audit than in the first audit.⁵ The most recent version of the CDC guideline was published in 2010 but this version was not cited by any of the reviewed protocols.³⁰

Compared with the first audit, material from Group B Strep Support (GBSS), a UK charity, was cited by a greater proportion of protocols (28.7% in first audit versus 34.1% in current audit).⁵ In fact, GBSS was referenced almost twice as often as the report from the first audit published

| Table 7 | Ten nationa | l guidelines | most frequently | cited compared | with the first audit |
|---------|-------------|--------------|-----------------|----------------|----------------------|
|---------|-------------|--------------|-----------------|----------------|----------------------|

| Guideline | Current audit, | n=123 | First audit, <i>n</i> = 171 | |
|--|----------------|-------|-----------------------------|-------|
| | Protocols (n) | % | Protocols (n) | % |
| RCOG. Green-top Guideline No. 36. Prevention of Early Onset Group B Streptococcal Disease (2003) | 68 | 55.3 | 111 | 64.9 |
| RCOG. Green-top Guideline No. 36. Prevention of Early- onset Group B Streptococcal Disease (2012) | 43 | 35.0 | - | - |
| NICE. Clinical Guideline 55. Intrapartum Care: Care of Healthy Women and Their Babies during Childbirth (2007) | 25 | 20.3 | - | - |
| NICE. Clinical Guideline 149. Antibiotics for Early-Onset Neonatal Infection (2012) | 22 | 17.9 | - | - |
| PHLS. Interim "Good Practice" Recommendations for the Prevention of Early Onset Neonatal GBS Infection in the UK (2000, 2001 and 2002) | 19 | 15.4 | 64 | 37.4* |
| CDC. Guidelines for the Prevention of Perinatal Group B Streptococcal Disease (2002) | 12 | 9.8 | 27 | 15.8 |
| NICE. Clinical Guideline 62. Antenatal Care for Uncomplicated Pregnancies (2008) | 11 | 8.9 | - | - |
| CDC. Guidelines for the Prevention of Perinatal Group B Streptococcal Disease (1996) | 7 | 5.7 | 15 | 8.8 |
| NICE. Clinical Guideline 6. Antenatal Care: Routine Care for Healthy Pregnant Women (2003) | 7 | 5.7 | - | - |
| NICE. Clinical Guideline 70. Induction of Labour (2008) | 6 | 4.9 | - | - |

*2001 publication reported in first audit

CDC = Centers for Disease Control and Prevention; NICE = National Institute for Health and Care Excellence;

PHLS = Public Health Laboratory Service; RCOG = Royal College of Obstetricians and Gynaecologists

by the RCOG in 2007 (34.1% GBSS material versus 17.1% RCOG report, 2007). The Oracle I study (Kenyon et al., 2001) investigated neonatal outcomes associated with antibiotic treatment for preterm, prelabour rupture of membranes.³¹ This study was referenced by 10.6% of protocols, which was a slight reduction from 13.5% of protocols reviewed in the first audit.⁵ The Oracle II study (Kenyon et al., 2001) investigated neonatal outcomes associated with antibiotic treatment for spontaneous preterm labour.³² This study was only cited by 2.4% of protocols compared with 9.9% of protocols in the first audit.⁵

3.5 Summary

All providers should produce protocols that reflect national recommendations but are also locally relevant based on the needs and demands of the local population. This national review of 123 protocols on preventing EOGBS developed by NHS providers across the UK had three aims: to determine whether the quality of locally produced protocols has improved since the first review; assess local guidelines on testing for GBS colonisation in pregnant women; and to examine local recommendations on offering IAP against EOGBS.

3.5.1 Quality of the protocols

We found that most protocols (95.9%) recorded the date of publication and a next review date was stated in a larger proportion of protocols than in the first audit. However, not all aspects of protocol quality assessed in this review have improved since the first audit. Although guidelines should be reviewed at least every 3 years, only 30.1% of protocols showed evidence of this action.²⁹ The majority of protocols provided supporting evidence for recommendations but there was a wide range of national guidelines cited, including obsolete publications from PHLS and superseded guidance from the RCOG and NICE being included in a minority of protocols.

3.5.2 Testing for group B streptococcal colonisation in pregnant women

Most protocols (80.5%) stated that universal testing for GBS colonisation was not offered to pregnant women, in line with national guidance from the RCOG and the UK NSC, but 6.5% of protocols stated that selective (risk-based) testing for GBS colonisation was offered by the provider.^{4,22} A range of clinical indications for selective testing were stated but all stated indications included advice to use vaginal swabs (on their own or with other types of swabs).

3.5.3 Antibiotic prophylaxis against EOGBS

The three indications for GBS-specific IAP recommended by the RCOG were included in at least 95.9% of protocols. However, far fewer protocols advised offering GBS-specific IAP for the two other indications that feature in the RCOG guidelines (intrapartum pyrexia, 31.7% and chorioamnionitis, 14.6%). This finding is not surprising given that the RCOG recommends broad-spectrum IAP for these two indications, to include GBS cover.⁴

Although unsupported by the current edition of the RCOG guidelines, 21.1% of local protocols stated that two or more clinical indications must be present to offer IAP against EOGBS. These combinations contained many clinical scenarios that do not feature in the current RCOG guidance for GBS-specific IAP, such as preterm labour and prolonged rupture of membranes. This advice reflects guidance in the first edition of the RCOG guidelines which stated that the '... argument for prophylaxis becomes stronger in the presence of two or more risk factors.'³ Management of maternal requests for testing for GBS colonisation, requests for IAP and refusals of IAP were documented in a minority of protocols (4.9%, 4.9% and 14.6%, respectively). Most protocols (80.5%) stated the RCOG recommended firstline drug regimen against EOGBS. However, remaining discrepancies in guidance on the regimen of benzylpenicillin in some protocols might hinder the efficacy of prophylaxis.

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4 Review of written patient information on group B streptococcal disease

The General Medical Council (GMC) recommends that patients are provided with information that '... they want or need to know in a way they can understand^{26,33} Written patient information is typically presented in leaflet format (patient information leaflet, PIL). This material is widely used to improve patient awareness about conditions and diseases, and to support patients in their decisions about treatment and management. One example is the provision of patient information on medication, which has been compulsory in the UK since 1998.³⁴ For PILs to be of value to patients, they must be accurate and accessible.²⁶ This includes the provision of evidence-based and peer-reviewed material that is reviewed and updated regularly.^{34,35}

There is published guidance on developing PILs, such as the Information Standard certification programme for evidence-based health and care information for the public and brand guidelines for NHS communications (NHS Brands Guidelines).^{36,37} Despite these national guidelines, the quality of written information for patients is inconsistent and often poor.^{34,38} For example, PILs might not contain all the information that patients seek, there might be over-use of technical language or medical jargon, or text might be too small for comfortable reading.³⁴ These issues are further compounded by the wide range of organisations that provide PILs, extending beyond health providers to charities and patient groups. While breadth of information sources might enable patients to access material more easily, the quality of information provided by different organisations will be affected by the frequency of publication review, changes in clinical evidence and mapping to national guidelines (where available).

As part of the RCOG-led audit, the survey of NHS obstetric units found that patient information on GBS was available from three main sources in the UK: material developed by providers, the RCOG and GBSS.^{5,39,40}

4.1 Aim of the review of patient information

This review was intended to examine the range of written information that NHS hospitals in the UK provide to patients about neonatal GBS disease, and particularly early-onset GBS (EOGBS).

4.2 Sample of providers

Clinical Directors for maternity services in all eligible NHS hospitals in the UK (i.e. hospitals with an obstetric unit) were asked to submit all currently used patient information on GBS in February 2014. PILs were accepted in paper and electronic formats. Only PILs developed and published by providers (i.e. not developed by the RCOG, charities or other organisations) were eligible for individual review. These provider-developed PILs were individually assessed and compared with PILs on GBS infection published by the RCOG (2006, updated 2013) and GBSS on 'Group B Strep and pregnancy' (2010, updated 2012).^{39,40}

In addition, PILs submitted by providers were compared with corresponding obstetric unit survey responses from the provider, where available.⁵ The survey questions of interest were:

• Survey of obstetric units question 8. Which patients do you provide written information about GBS infection to?

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- Survey of obstetric units question 9. If you provide written information about GBS infection to SOME patients only, which patients do you provide the material to?
- Survey of obstetric units question 10. Do you give pregnant women written information about private testing for GBS colonisation?

(Source: RCOG, 2015.⁵)

4.2.1 Review process

A review of the literature was undertaken to inform the reviewing process. The topics of the review were identified from the literature review and discussion with the project group. Starting in July 2014, two members of the project group (MK and CT) independently reviewed each PIL using a standardised form in Microsoft Excel. Discrepancies in findings from the individual reviews were resolved by discussion and reassessment by MK and CT. PILs were assessed on their quality. This was determined by their appearance, readability, date of publication or review (whichever date was most recent) and clinical content. Readability was assessed using the Simplified Measure of Gobbledygook (SMOG) formula which takes into account the length of words and sentences to determine the reading level of written material.⁴¹ The higher the SMOG score, the more demanding the material is to read and understand.⁴¹ The SMOG test is one of the most commonly used measures of readability and has been widely used to assess patient information.⁴¹⁻⁴³

4.3 Results of the review of patient information

Patient information leaflets were received between February and May 2014, electronically or by post and were stored centrally at the RCOG. From 38 files submitted by providers, five files were excluded as they were templates of letters to patients about GBS infection (n=4) or information only on late-onset GBS disease (n=1). The remaining 33 leaflets were reviewed.

4.3.1 Publication information

Most of the provider-developed PILs (81.8%) stated the year of publication, which ranged from 2006 to 2013. The most frequently occurring year of publication of PILs with a known publication date was 2012 (29.6%, n=8/27), which is before the most recent review of the RCOG PIL (2013) and GBSS* PIL (2012). The majority of provider-developed leaflets with known publication date (72.7%) also stated the date of next review, but 48.2% of these PILs had a review date before the start of the audit, i.e. before February 2014 (n=27). Where both publication and review dates were provided (60.6%, n=20/33), the most frequently stated time interval between publication and review was 3 years (n=9/20), ranging from one year (n=2) to 6 years (n=1). The RCOG PIL is due for review in 2016 but no review date* was given for the GBSS PIL.

4.3.2 Appearance and readability of the leaflets

The PILs ranged from one to twelve pages in length, with an average of 5.9 pages per leaflet. The RCOG PIL was five pages long while the GBSS PIL was four pages long. Where leaflets were provided in original format (not photocopied or sent by email in greyscale), only a third of the PILs (30.3%) featured any colour (n = 10/30). Both RCOG and GBSS leaflets contained colour.

The provider-developed PILs contained an average of 20.7 words per sentence (n=33). The SMOG scores of provider-developed PILs ranged from 16.2 to 19.5, with an average score of 17.9. This compared to SMOG scores of 17.9 for the RCOG PIL and 19.0 for the GBSS PIL. Less than half of the PILs stated that the material was available in alternative formats or languages (42.4%, n=33). Where alternative formats were available, large or easy-read print were most frequently offered (n=11/14), followed by audio (n=7/14) and braille (n=7/14). Neither the leaflets produced by the RCOG or GBSS stated that the information was available in alternative formats or languages.

^{*}The GBSS PIL has since been reviewed.

4.3.3 Content of the patient information leaflets

Less than a quarter of provider-developed PILs (21.2%) contained a summary of key points from the leaflet although both the RCOG and GBSS PILs contained a summary. Less than half of the PILs (42.4%) referenced clinical evidence or national guidelines. The most frequently cited evidence was the first edition of the RCOG Green-top Guideline on 'Prevention of early onset neonatal Group B Streptococcal Disease' published in 2003 (57.1%, n=8/14). The RCOG PIL cited the updated RCOG Green-top Guideline (2012) and referred to a list of sources of evidence on the RCOG website. The GBSS PIL cited RCOG recommendations but did not provide a specific reference, and instead referred to references on the GBSS website.

Most provider-developed PILs (90.9%) suggested alternative sources of information and support for patients, as shown in Table 8 (n=30/33). Among these PILs, midwife was the most frequently cited contact for additional information (70.0%, n=21/30) followed by GBSS (53.3%, n=16/30) and doctor (43.3%, n=13/30). Three leaflets listed websites that no longer exist. The RCOG leaflet identified the midwife and doctor caring for the patient as sources of information and listed two websites for further information (the UK National Screening Committee and NHS Choices). The GBSS leaflet identified the patient's midwife and obstetrician as sources of information, and referred readers to the GBSS website as well.

| Table 8 | Other sources | of information | for women | (multiple answers | allowed), $n = 30$ |
|---------|---------------|----------------|-----------|-------------------|--------------------|
|---------|---------------|----------------|-----------|-------------------|--------------------|

| Leaflets (n) |
|--------------|
| 21 |
| 16 |
| 13 |
| 8 |
| 7 |
| 6 |
| ö |
| |

*Birth centre or delivery suite, antenatal clinic, maternity centre, labour ward or postnatal ward.

**Includes UK National Screening Committee, National Institute for Health and Care Excellence (NICE) and NHS Direct.

4.3.4 Information about group B streptococcal colonisation

The intended audience was defined in 39.4% of PILs and also in the RCOG and GBSS leaflets. All the provider-developed PILs defined GBS colonisation and stated that it was usually harmless or occurs without symptoms (n=33), as did the RCOG and GBSS PILs. All except one leaflet provided an estimate of GBS colonisation (97.0%, n=32/33). Where an estimate was provided, the majority of these PILs stated that GBS is present in the vagina of at least one in four women (71.9%, n=32). Half of PILs also reported that one-third of people carry GBS (50.0%, n=32). The RCOG PIL stated that GBS bacteria was '... found in the vagina and bowel of about 2 in 10 women in the UK ...', while the GBSS PIL stated that '... up to one in every three adults carries GBS in the gut and up to one in four women in the vagina'.^{39,40}

4.3.5 Diagnosis of group B streptococcal colonisation in pregnant women

Most PILs (75.8%) stated the type(s) of sample(s) taken to test for GBS colonisation in pregnant women but fewer PILs (21.2%) stated when these tests would be performed, and none of the leaflets specified a gestational age range for testing (n = 33). The most frequently reported sample type was urine (92.0%, n = 25), followed by vaginal (88.0%, n = 25), rectal (20.0%, n = 25) and unspecified swab (12.0%, n = 25). The RCOG leaflet stated that GBS bacteria could be detected (or inferred) by swabs or in urine, but the PIL did not state when tests would be carried out or the gestational age

range for testing. The GBSS leaflet stated that GBS could be detected (or inferred) by swabs or in urine. The leaflet also described and recommended testing using enriched culture medium (ECM), with swabs from the vagina and rectum. The GBSS PIL reported that ECM was available privately and from a few NHS trusts. It also stated that testing for GBS colonisation should occur between 35 and 37 weeks of gestation.

4.3.6 Group B streptococcal infection in babies

All but three provider-developed PILs (90.9%) provided an estimate of the incidence of GBS infection in babies up to 7 days old (n=30/33). However, the two most frequently cited estimates varied substantially from one in 1000 babies (n=15) to one in 2000 babies (n=11). The remaining four PILs reported incidences of one in 500 babies, one in 1000 to 2000 babies, a third of babies or half of babies born to mothers with confirmed GBS colonisation during pregnancy, respectively. The RCOG leaflet stated that EOGBS affects one in 2000 babies while the GBSS leaflet stated an incidence of one in 1000 babies. Almost all leaflets (93.9%) stated at least one risk factor for GBS infection in newborn babies (n=31/33). Table 9 shows that the most frequently stated risk factor among the PILs was previous baby with EOGBS infection (90.3%, n=28/31). The table also shows that the RCOG and GBSS leaflets stated almost the same risk factors as each other and the provider-developed PILs.

| Risk factor | Provider leaflets (n) | RCOG leaflet | GBSS leaflet |
|--|--------------------------|-----------------|-----------------|
| Previous baby with GBS infection | 28 | \checkmark | \checkmark |
| Preterm labour | 25 | \checkmark | \checkmark |
| Pyrexia in labour | 24 | \checkmark | \checkmark |
| GBS positive, urine specimen | 23 | \checkmark | \checkmark |
| Prolonged rupture of membranes | 23 | \checkmark | \checkmark |
| GBS positive, vaginal specimen | 20 | \checkmark | \checkmark |
| GBS positive, rectal specimen | 8 | \checkmark | \checkmark |
| Preterm rupture of membranes | 6 | | \checkmark |
| GBS carrier (unspecified) | 5 | | |
| Chorioamnionitis, suspected infection, bacterial infection within 24 hours of birth, GBS positive (cervical specimen), GBS positive on swab, GBS urine infection in pregnancy, multiple births and one baby has suspected infection, GBS positive in previous pregnancy, preterm prolonged rupture of membranes, small for gestational age | <5 | √* | |

Table 9 Risk factors for early-onset group B streptococcal disease stated in provider-developed leaflets (multiple answers allowed, n=31) and RCOG and GBSS leaflets

*Suspected infection of unknown cause

Most PILs (81.8%) stated at least one sign or symptom of GBS infection (n = 27/33) and a wide range of signs and symptoms were described. The ten most frequently stated signs and symptoms in the provider-developed leaflets are shown in Table 10. The RCOG and GBSS leaflets included almost all of these ten signs and symptoms.

Most PILs (81.8%) stated at least one complication of GBS infection (n=27/33). The two most frequently stated complications were death (n=18/27) and unspecified serious illness (n=10/27). The RCOG leaflet stated that disability and death could result from the infection while the GBSS leaflet stated that GBS was associated with septicaemia, pneumonia and meningitis, and might result in 'long-term problems' or death.

Table 10 Ten most frequently stated signs and symptoms of group B streptococcal infection in provider-developed leaflets (multiple answers apply, n=27) and RCOG and GBSS leaflets

| Signs and symptoms of group B streptococcal infection | Provider leaflets (n) | RCOG leaflet | GBSS leaflet |
|---|--------------------------|-----------------|-----------------|
| Altered temperature | 26 | \checkmark | \checkmark |
| Irritable, listless, jitteriness, fretful or not settling | 24 | \checkmark | \checkmark |
| Poor feeding | 24 | \checkmark | \checkmark |
| Altered breathing | 22 | \checkmark | \checkmark |
| Sleepy, drowsy, lethargic or unresponsive | 20 | \checkmark | \checkmark |
| Vocalisation (shrill or moaning cry, whimpering or grunting) | 20 | \checkmark | \checkmark |
| Altered heart rate | 17 | \checkmark | \checkmark |
| Low blood pressure/blood sugar | 16 | \checkmark | \checkmark |
| Floppiness | 14 | \checkmark | |
| Change in skin colour/complexion (including jaundice, $n = 1$) | 9 | | |

4.3.7 Antibiotic prophylaxis

Most provider-developed PILs (93.9%) stated at least one of the clinical indications for IAP published in the RCOG Green-top Guideline (2012) (n=31/33).⁴ The number of indications stated in the PILs ranged from two indications (19.4%, n=6/31) to all five indications (9.7%, n=3/31). The RCOG and GBSS PILs both stated all five indications reported in the RCOG Green-top Guideline (2012). Table II also shows that chorioamnionitis was not stated as an indication for IAP in most PILs.

Table 11 RCOG clinical indications for intrapartum antibiotic prophylaxis stated in providerdeveloped leaflets (multiple answers allowed, n=31)

| RCOG clinical indication for intrapartum antibiotic prophylaxis | Provider leaflets (n) | RCOG leaflet | GBSS leaflet |
|---|--------------------------|-----------------|--------------|
| Previous baby with invasive GBS infection* | 27 | \checkmark | ✓ |
| GBS bacteriuria in the current pregnancy* | 28 | \checkmark | \checkmark |
| Vaginal swab positive for GBS in current pregnancy* | 24 | \checkmark | \checkmark |
| Pyrexia (above 38 °C) in labour** | 23 | \checkmark | \checkmark |
| Chorioamnionitis** | 4 | \checkmark | ✓ |

RCOG Green-top Guideline (2012) recommends:

*GBS-specific cover.

** Broad-spectrum IAP with GBS cover.4

Unlike the RCOG leaflet, the GBSS PIL recommended that women with any risk factors (Table 9) should be offered IAP. All provider-developed PILs reported that IAP was offered for suspected or confirmed GBS colonisation during pregnancy (n=33) but only 48.5% of PILs reported that penicillin or benzylpenicillin would be offered, including I4 leaflets that specified IV administration. Approximately half of PILs (48.5%) stated that an alternative drug to penicillin would be offered to women who were allergic to penicillin (n=16/33). Of these leaflets, I0 did not specify the alternative antibiotic while the remaining six leaflets stated clindamycin (including one leaflet that also stated erythromycin). The RCOG and GBSS leaflets stated that IV penicillin was the firstline drug, with broad-spectrum antibiotics offered for suspected infection of unknown cause during labour. The RCOG PIL stated that an alternative antibiotic (not specified) would be offered if women were allergic to penicillin while the GBSS leaflet stated that clindamycin should be offered if an alternative to penicillin while the GBSS leaflet stated that clindamycin should be offered as an alternative to penicillin.

All provider-developed PILs and the RCOG and GBSS PILs stated that IAP would be offered during labour, but only 54.6% of the provider-developed leaflets referred to the frequency of

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antibiotic administration (n=33). Even fewer PILs stated a minimum time before delivery for IAP to be administered (30.3%, n=10/33). The RCOG PIL stated that IAP should be started as soon as possible after labour begins, with further doses (unspecified number) offered until delivery. The GBSS PIL stated that IAP should be started immediately at the start of labour and cited the RCOG recommendation for antibiotics to be given at least 2 hours before delivery, but the leaflet suggested that for optimal therapeutic effect, antibiotics should be given at least 4 hours before delivery.

Approximately half of provider-developed leaflets (51.5%) stated at least one potential risk (or side-effect) of IAP (n=33). The most frequently stated potential side-effect of antibiotics was allergic reaction (n=11/17), followed by antibiotic resistance (n=6), diarrhoea (n=6), nausea (n=6) and vaginal thrush (n=1). Six leaflets stated that research has indicated an association between antibiotic use early in life and increased risk of asthma or other allergies (n=6). The RCOG leaflet also stated these potential side effects except vaginal thrush. The GBSS leaflet did not state any potential side effects from the use of antibiotics but it did advise readers to discuss the risks of using antibiotics with their health professional, and to notify the health professional if they are allergic to penicillin or any other antibiotic. Only a minority of PILs (18.2%) stated any benefits of IAP (n=33). The RCOG leaflet stated that antibiotics could be life-saving for babies with GBS infection while the GBSS leaflet stated that up to 90% of cases of EOGBS could be prevented by providing IAP to certain groups of women.

Over a third of PILs (39.4%) indicated that IAP would be provided in hospital (n = 13/33). Some of these leaflets further advised that home birth (n = 5) and delivery in some midwife-led units (n = 2) might not be possible if IV antibiotics were required, which was also stated in the RCOG leaflet. The GBSS leaflet did not mention any potential restrictions on choice of delivery setting if IAP was required.

Completed obstetric unit surveys were available for all 33 providers that submitted patient information to the audit. For all except three providers, survey responses were received from more than one participant (n=30/33). There were conflicting reports in eight of these 30 sets of survey responses:

- One participant stated that a PIL was unavailable but at least one other participant stated that a PIL was provided to some patients (n=3/8 sets of survey responses).
- One or more participants stated that a PIL was provided to all patients but the other participant(s) stated that a PIL was provided to some patients only (n=5/8 sets of survey responses).

The intended audience of the PIL was only stated in three out of the eight leaflets for these providers (Table 12).

Table 12 Availability of patient information and intended audience, results from obstetric unit surveywhere there were conflicting responses from participants of the same provider

| Obstetric unit survey responses | Patient information leaflet, intended audience | Sets of responses (n) |
|---|--|--------------------------|
| No patient information available (response 1), patients with GBS only (response 2) | Women who are pregnant or planning on being pregnant | I |
| All patients (response 1), patients with GBS only or patients with at least one RCOG clinical indication for IAP (response 2) | Women who are pregnant and with confirmed GBS colonisation | 2 |

Among the 33 providers with eligible PILs for review, one or more participants of the obstetric unit survey from two providers reported that written information on private testing for GBS colonisation during pregnancy was provided to patients in their respective unit. In the corresponding PILs for the two providers, only one leaflet mentioned private testing by stating that it was not recommended.

4.4 Summary

This review investigated the range and quality of written patient information on GBS provided by NHS hospitals in England. We found that most provider-developed PILs contained information about GBS colonisation during pregnancy, early-onset GBS, testing for GBS colonisation and IAP. Where corresponding survey responses and PIL were available, the intended audience of the PIL that was stated in the two sources did not match for 26.7% of units. This discrepancy indicates that some staff working in obstetric units may not be aware of patient information available. Each unit should ensure that all staff are aware of PILs, and be familiar with their intended audiences and the contents of the leaflets.

4.4.1 Quality of written patient information

Patient information should contain short blocks of text using patient-friendly language, with complex information broken down to improve comprehension.^{37,44} PILs should also be simple to navigate, especially for readers with poor health literacy.^{37,44} Yet all of the reviewed PILs, including the RCOG and GBSS leaflets, had poor readability. Less than half of PILs (42.4%) cited clinical evidence or national guidelines and 18.2% of provider-developed PILs did not provide the year of publication. Almost half of PILs (48.2%) with recorded dates stated a review date before the start of this audit. A minority of leaflets (9.1%) cited obsolete websites as sources of additional information. These findings suggest that some patients are not receiving up-to-date information underpinned by clinical evidence and national policy.

4.4.2 Risk factors for EOGBS

Almost all of the provider-developed leaflets stated an estimated incidence of GBS but the stated numbers and groups of people affected by GBS (i.e. women or all adults) varied between leaflets. Overall, the provider-developed, RCOG and GBSS leaflets were consistent in reporting of risk factors for GBS infection as well as signs and symptoms of GBS infection in newborn babies. Unlike the majority of provider-developed PILs and the RCOG leaflet which described morbidity and mortality associated with GBS infection in general terms, the GBSS leaflet also stated specific conditions associated with GBS infection (septicaemia, pneumonia and meningitis). While most units use PILs developed by the RCOG (36.8%) or GBSS (37.5%) as reported in the survey of obstetric units,⁵ it is essential that all PILs, including those developed by providers, provide consistent information across common topics.

4.4.3 Testing for group B streptococcal colonisation in pregnant women

Most PILs (75.8%) reflected the description in the RCOG leaflet that GBS colonisation during pregnancy could be detected (or inferred) by swabs or in urine. In contrast, the GBSS leaflet provided additional information on testing using enriched culture medium (ECM), which is predominantly conducted by private laboratories and is not endorsed by the RCOG or the UK NSC.

4.4.4 Antibiotic prophylaxis

While the RCOG and GBSS leaflets both stated all five clinical indications for IAP from the RCOG Green-top Guideline, only 9.7% of the provider-developed PILs included all indications. However, the majority of provider-developed PILs (at least 77.4%) stated the three indications for GBS-specific IAP. Less than half of provider-developed PILs (48.5%) stated that the recommended firstline drug for GBS-specific IAP is penicillin or benzylpenicillin. Although patient information should avoid over-use of medical terminology, drug names should be stated where there is a standard drug regimen.

It is recommended that potential side effects of care should be included in patient information, nevertheless only approximately half of the provider-developed leaflets (51.5%) did so and the RCOG leaflet stated at least one potential side-effect of IAP.^{37,44,45} Only 18.2% of PILs stated any benefits of IAP. The implications of IAP on choices of location for delivery were mentioned

in the RCOG leaflet but only in very few of the provider-developed leaflets and not at all in the GBSS leaflet.

The review of PILs found inconsistencies in a number of areas that should be addressed in future revisions of existing patient information on GBS, and when developing new material for patients. The areas where consistency of reporting in leaflets could be improved are: estimates of GBS colonisation in women; incidence of early-onset GBS infection; outcomes of EOGBS; risk factors for EOGBS; clinical reasons for offering IAP; methods for assessing GBS colonisation; name of the firstline antibiotic; potential side effects from IAP; web sources for further information (including future prospects) and implications of IAP on women's choices for delivery.

²⁶ 5 Conclusions

5.1 Findings

This second and final report of the audit features the results from the survey of midwife-led units; review of local protocols for preventing EOGBS; and review of patient information on GBS infection. Our key findings are as follows:

Survey of midwife-led units

- Interpretation of the survey results should be made with consideration of the relatively low participation rate: 50.6% of eligible units.
- A substantial proportion of participating units (38.2%) reported that they accept women in labour who have confirmed GBS colonisation.
- GBS-specific IV antibiotics were reported to be available in almost all (91.2%) of the units where women with confirmed GBS colonisation were reported to be accepted.
- In a third of participating units where survey responses and admissions criteria were received (33.3%) reported practice on whether women with current GBS colonisation were accepted for delivery did not fully reflect the admissions policy.

Review of local protocols

- Contrary to national guidelines, a small proportion of protocols (6.5%) stated that selective (risk-based) testing for GBS colonisation was offered to pregnant women.
- There were some discrepancies in the definitions of clinical indications for IAP (e.g. minimum temperature for fever during labour) and in the recommended benzylpenicillin regimen for GBS-specific IAP.
- Evidence that the protocol was updated at least every 3 years was present in less than a third of protocols (30.1%).
- Where there was evidence of regular review, local guidance adhered closely to national guidelines. However, publications referenced by some protocols were outdated and/or obsolete.

Review of written patient information

- Over half of the patient information leaflets, PILs, (57.6%) did not reference any clinical evidence or national guidelines.
- Reviewed PILs, including the leaflets produced by the RCOG and GBSS, had poor readability (e.g. long blocks of text and complex word structures).
- All PILs, including the leaflets produced by the RCOG and GBSS, were generally consistent in their reporting of risk factors for GBS infection, signs of GBS infection in newborn babies and detection (or inference) of GBS colonisation during pregnancy by swabs or urine. However, the GBSS leaflet provided additional information on testing using enriched culture medium (ECM) which is predominantly conducted by private laboratories and is not endorsed by the RCOG or Public Health England (PHE).
- Most provider-developed leaflets (at least 77.4%) stated the three clinical indications for GBSspecific IAP that are recommended by the RCOG.

5.2 Strengths and limitations of the audit components

This audit benefitted from a multi-method approach to provide a comprehensive understanding of current practice and policy on preventing EOGBS in the UK. Our pragmatic methodology reduced the burden of data collection on hospital staff and was logistically more efficient to implement than a conventional patient-level audit.

In recognition of the increasing number of women giving birth in settings other than the obstetric unit, our survey of midwife-led units highlighted the importance of including this care setting in future studies into preventive care for EOGBS. Our survey had a low participation rate of 50.6% of eligible units which will need to be improved in order to produce a better picture of care and local policies in MLUs. We also received far fewer sets of admission criteria than survey responses so investigation of the coherence between reported practice and policy was limited. As with our assessment of obstetric units, this survey provided a snapshot of reported practice in MLUs but its scope did not extend to in-depth examination of practice which is needed to provide context for the results. Improvements to, and the standardisation of, care requires understanding gained from such investigations.

We reviewed the protocols on preventing EOGBS from 78.9% of eligible NHS providers and therefore it is reasonable to consider that our findings were representative of local policies in the UK. Provider-developed PILs on GBS were reported to be used by 15 units in the survey of obstetric units published in the first report, yet we received 33 eligible PILs for review.⁵ This indicates that not all staff are aware of available PILs in their obstetric unit but also demonstrates that many units produce their own written material for patients.

5.3 Gaps in knowledge

Through the different audit components, we aimed to provide a comprehensive picture of current clinical practice and local policy on preventing EOGBS across maternity services in the UK. Nevertheless, there are a number of topics that we were unable to address within the scope of our work. Firstly, our focus was on the prevention of EOGBS in intrapartum care but the management of neonates with suspected or confirmed EOGBS also needs to be evaluated to ensure the provision of appropriate and good-quality care across the care continuum. Secondly, the implications of antibiotic resistance must be considered in the next reviews of national and local policies in terms of the types of antibiotics that are recommended and the groups of women for whom they are recommended. This is important given that GBS resistance to the drug (clindamycin) recommended for GBS-specific IAP in women who are allergic to penicillin is increasing. Thirdly, to support women to make decisions about their maternity care, much more understanding is needed about the relationships between informed choices on delivery location, availability of GBS-specific IAP, maternal refusals and requests for IAP and clinical decision making. This is especially important for women at high risk of transmitting GBS to their newborn baby, to reduce the occurrence of EOGBS.

5.4 **Recommendations**

- I National guidelines should be updated to reflect the findings from this audit, the forthcoming review of screening by the UK NSC and the forthcoming results from the recent national GBS surveillance study. The revision of national guidelines should address the care of women who are considering or plan to give birth in locations besides an obstetric unit.
- 2 National guidelines should be applied to all NHS trusts to reduce future deviations in local practice and policy. Local protocols should be reviewed at least every 3 years to ensure they are fit for purpose and that they reflect current national guidance. The last review date should be recorded on the current protocol and the recording of the last review date should be monitored in national audits.

- 3 Future studies on preventive care for EOGBS should address care provided in midwife-led units as this audit found that pregnant women with risk factors for EOGBS are accepted for delivery in these units.
- 4 Admission criteria and practice in midwife-led units should be informed by national guidelines on preventing EOGBS, including the availability of GBS-specific IV antibiotics.
- 5 A nationally produced patient information leaflet should be used locally by all NHS trusts. The material should reflect the findings from this audit, the forthcoming review of screening by the UK NSC and the forthcoming results from the recent national GBS surveillance study. The leaflet should be accessible to patients with low literacy.

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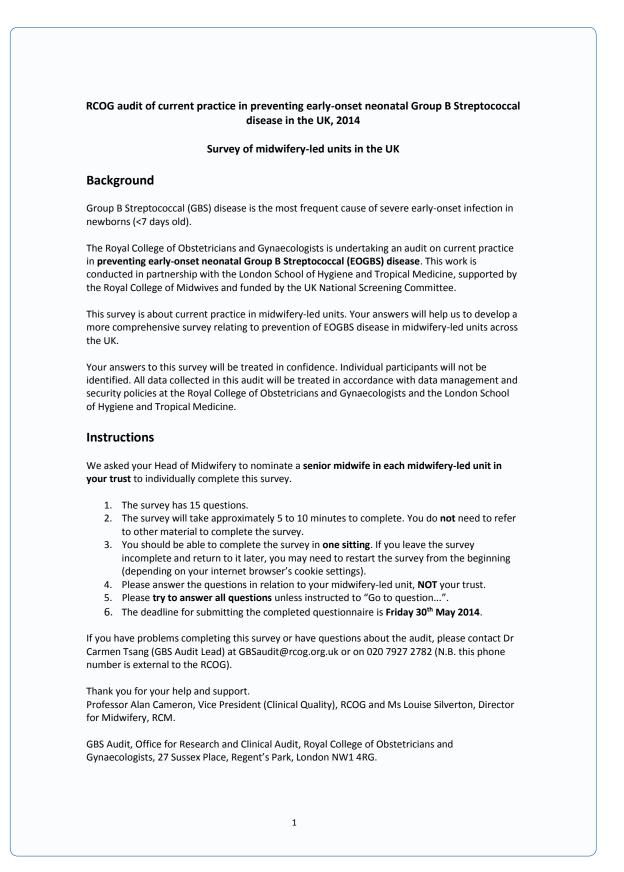
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Appendix I

Survey of midwife-led units



| Sı | urvey of midwifery-led units |
|----|---|
| | About you |
| | 1. What is your job title/role? a. Midwife b. Other Please specify: |
| | 2. What band are you employed at? Data will be anonymised, individual participants will not be identified. |
| | About your midwifery-led unit |
| | 3. What is the name of the NHS hospital trust which your midwifery-led unit is part of? |
| | 4. What is the name of your midwifery-led unit? |
| | 5. How would you best describe your midwifery-led unit? a. Alongside midwifery-led unit (AMU)* |
| | *Care for women with straightforward pregnancies during labour and birth, led by midwives. AMUs are situ the same hospital or the same site as an obstetric unit, with access to obstetric, neonatal or anaesthetic car site. If obstetric care is required, transfer is usually by trolley, bed or wheelchair to the obstetric unit. |
| | b. Freestanding midwifery-led unit (FMU)** |
| | **Care for women with straightforward pregnancies during labour and birth, led by midwives. FMUs are no situated in a hospital or site with an obstetric unit or neonatal unit. Diagnostic and treatment medical servic including obstetric, neonatal and anaesthetic care, are not available immediately. General Practitioners ma be involved in care. If obstetric, neonatal or anaesthetic care is required, transfer is usually by car or ambulo Definitions of AMUs and FMUs adapted from Rowe. Birthplace terms and definitions: consensus process. Birthplace in England research programme. Final report part 2. NIHR Service Delivery and Organisation programme; 2011. |
| | 6. Which of the following services are provided in your midwifery-led unit (select all that apply): a. Antenatal care b. Intrapartum care c. Postpartum care |
| | 7. You do not need any additional information to answer this question. If you do not know the act number of women, please give an estimated number. |
| | How many women gave birth in your midwifery-led unit (all births) between 1 st January and 31 st December 2013? |
| | a. Actual number b. Estimated number (to nearest 50 women) |

| About the women | | | |
|---|---|--|--|
| 8. In your midwifery-led unit, do neonatal GBS infection? | you accept women for care in labour who had a previous baby with | | |
| a. Yes | | | |
| b. No | | | |
| c. Don't know | | | |
| 9. In your midwifery-led unit, do | you accept women for care in labour who were identified with GBS | | |
| carriage in a previous pregnancy or outside of pregnancy? | | | |
| a. Yes | | | |
| b. No | | | |
| c. Don't know | | | |
| 10. In your midwifery-led unit, do | o you accept women for care in labour with identified GBS carriage in | | |
| their current pregnancy? | | | |
| a. Yes | | | |
| b. No c. Don't know | | | |
| | uon't know", please go to question 12 | | |
| | | | |
| | o you accept women for care in labour with GBS carriage in their | | |
| | tified from the listed specimen(s)? (select all that apply) | | |
| a. Urine culture | | | |
| b. Vaginal swab c. Rectal swab | | | |
| d. Other | Please specify: | | |
| | | | |
| | a woman develops fever (>38°C) during labour, can she continue to | | |
| give birth in your unit? a. Yes | | | |
| b. No | | | |
| c. Don't know | | | |
| | | | |
| | o you accept women for care in labour with chorioamnionitis? | | |
| a. Yes | | | |
| b. No c. Don't know | | | |
| C. DOIL KNOW | | | |
| 14. In your midwifery-led unit, do you administer intravenous antibiotics in labour (i.e. intrapartum | | | |
| | st early-onset neonatal Group B Streptococcal (EOGBS) disease? | | |
| a. Yes | | | |
| b. No | | | |
| c. Don't know | | | |
| 15. Please provide comments abo | out this survey in the space below. | | |
| | | | |
| Thank you for completing the sur | wey. We are grateful for your help and support on this audit | | |
| Thank you for completing the su | rvey. We are grateful for your help and support on this audit. | | |

Your answers to this survey will be treated in confidence. Individual participants will not be identified. Results of the audit will be published in late 2014. If you have any questions about this survey or the audit, please contact Dr Carmen Tsang (GBS Audit Lead), GBSaudit@rcog.org.uk or 020 7927 2782 (N.B. this phone number is external to the RCOG). GBS Audit, Office for Research and Clinical Audit, Royal College of Obstetricians and Gynaecologists, 27 Sussex Place, Regent's Park, London NW1 4RG.

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Appendix 2

List of participating providers

Providers are listed by their status at the time of the audit. The list does not reflect provider changes since February 2014. For example, Barnet and Chase Farm Hospitals NHS Trust merged with Royal Free London NHS Foundation Trust in July 2014. The list shows the providers that submitted data to one or more components of the audit.

Abertawe Bro Morgannwg University Health Board Airedale NHS Foundation Trust Aneurin Bevan University Health Board Ashford and St Peter's Hospitals NHS Foundation Trust Barnet and Chase Farm Hospitals NHS Trust Barnsley Hospital NHS Foundation Trust Barts Health NHS Trust Basildon and Thurrock University Hospitals NHS Foundation Trust Bedford Hospital NHS Trust Belfast Health and Social Care Trust Betsi Cadwaladr University Health Board Birmingham Women's NHS Foundation Trust Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust **Bolton NHS Foundation Trust** Bradford Teaching Hospitals NHS Foundation Trust Brighton and Sussex University Hospitals NHS Trust Buckinghamshire Healthcare NHS Trust Calderdale and Huddersfield NHS Foundation Trust Cambridge University Hospitals NHS foundation Trust Cardiff & Vale University Health Board Central Manchester University Hospitals NHS Foundation Trust Chelsea and Westminster Hospital NHS Foundation Trust Chesterfield Royal Hospital NHS Foundation Trust City Hospitals Sunderland NHS Foundation Trust Colchester Hospital University NHS Foundation Trust Countess of Chester Hospital NHS Foundation Trust County Durham and Darlington NHS Foundation Trust Croydon Health Services NHS Trust Cwm Taf University Health Board Dartford and Gravesham NHS Trust Doncaster and Bassetlaw Hospitals NHS Foundation Trust Ealing Hospital NHS Trust East and North Hertfordshire NHS Trust East Cheshire NHS Trust East Kent Hospitals University NHS Foundation Trust East Lancashire Hospitals NHS Trust East Sussex Healthcare NHS Trust Epsom and St Helier University Hospitals NHS Trust Frimley Park Hospital NHS Foundation Trust Gateshead Health NHS Foundation Trust George Eliot Hospital NHS Trust Gloucestershire Hospitals NHS Foundation Trust Great Western Hospitals NHS Foundation Trust

Guy's and St Thomas' NHS Foundation Trust Hampshire Hospitals NHS Foundation Trust Heart of England NHS Foundation Trust Heatherwood and Wexham Park Hospitals NHS Foundation Trust Hinchingbrooke Health Care NHS Trust Homerton University Hospital NHS Foundation Trust Hull and East Yorkshire Hospitals NHS Trust Hywel Dda University Health Board Imperial College Healthcare NHS Trust Isle of Man Government Isle of Wight NHS Trust James Paget University Hospitals NHS Foundation Trust King's College Hospital NHS Foundation Trust Kingston Hospital NHS Foundation Trust Lancashire Teaching Hospitals NHS Foundation Trust Leeds Teaching Hospitals NHS Trust Lewisham and Greenwich NHS Trust Liverpool Women's NHS Foundation Trust Luton and Dunstable University Hospital NHS Foundation Trust Maidstone and Tunbridge Wells NHS Trust Medway NHS Foundation Trust Mid Cheshire Hospitals NHS Foundation Trust Mid Essex Hospital Services NHS Trust Mid Staffordshire NHS Foundation Trust Milton Keynes Hospital NHS Foundation Trust NHS Ayrshire and Arran **NHS Borders** NHS Dumfries and Galloway NHS Fife NHS Forth Valley NHS Grampian NHS Highland NHS Lanarkshire NHS Lothian NHS Orkney NHS Tayside NHS Western Isles Norfolk and Norwich University Hospitals NHS Foundation Trust North Bristol NHS Trust North Middlesex University Hospital NHS Trust North Tees and Hartlepool NHS Foundation Trust Northampton General Hospital NHS Trust Northern Health and Social Care Trust Northern Lincolnshire and Goole NHS Foundation Trust Northumbria Healthcare NHS Foundation Trust Nottingham University Hospitals NHS Trust Oxford University Hospitals NHS Foundation Trust Peterborough and Stamford Hospitals NHS Foundation Trust Plymouth Hospitals NHS Trust Poole Hospital NHS Foundation Trust Portsmouth Hospitals NHS Trust Powys Teaching Health Board Royal Berkshire NHS Foundation Trust Royal Cornwall Hospitals NHS Trust

Royal Derby Hospitals NHS Foundation trust Royal Devon and Exeter NHS Foundation Trust Royal Free London NHS Foundation Trust Royal Surrey County NHS Foundation Trust Royal United Hospital Bath NHS Trust Salisbury NHS Foundation Trust Sheffield Teaching Hospitals NHS Foundation Trust Sherwood Forest Hospitals NHS Foundation Trust Shrewsbury and Telford Hospital NHS Trust South Devon Healthcare NHS Foundation trust South Tees Hospitals NHS Foundation Trust South Tyneside NHS Foundation Trust South Warwickshire NHS Foundation Trust Southend University Hospital NHS Foundation Trust Southern Health and Social Care Trust Southport and Ormskirk Hospital NHS Trust St George's Healthcare NHS Trust St Helens and Knowsley Hospitals NHS Trust Stockport NHS Foundation Trust Surrey and Sussex Healthcare NHS Trust Taunton and Somerset NHS Foundation Trust The Dudley Group NHS Foundation Trust The Hillingdon Hospitals NHS Foundation Trust The Ipswich Hospital NHS Trust The Mid Yorkshire Hospitals NHS Trust The Newcastle Upon Tyne Hospitals NHS Foundation Trust The Pennine Acute Hospitals NHS Trust The Princess Alexandra Hospital NHS Trust The Rotherham NHS Foundation Trust The Royal Wolverhampton NHS Trust United Lincolnshire Hospitals NHS Trust University College London Hospitals NHS Foundation Trust University Hospital of North Staffordshire NHS Trust University Hospital of South Manchester NHS Foundation Trust University Hospital Southampton NHS Foundation Trust University Hospitals Bristol NHS Foundation Trust University Hospitals Coventry and Warwickshire NHS Trust University Hospitals of Leicester NHS Trust University Hospitals of Morecambe Bay NHS Foundation Trust Walsall Healthcare NHS Trust Warrington and Halton Hospitals NHS Foundation Trust West Hertfordshire Hospitals NHS Trust West Middlesex University Hospital NHS Trust West Suffolk NHS Foundation Trust Western Health and Social Care Trust Western Sussex Hospitals NHS Foundation Trust Whittington Health Wirral University Teaching Hospital NHS Foundation Trust Worcestershire Acute Hospitals NHS Trust Wrightington, Wigan and Leigh NHS Foundation Trust Wye Valley NHS Trust Yeovil District Hospital NHS Foundation Trust York Teaching Hospital NHS Foundation Trust

Appendix 3

Guidance on managing requests to test for group B streptococcal disease colonisation during pregnancy

| Clinical scenario | Action recommended in the protocol(s) |
|---|--|
| Previous GBS colonisation | Protocol 1: Decision lies with consultant obstetrician Protocol 2: Decision lies with clinician and if agreed, a combined lower vaginal and rectal swab should be taken at 35–37 weeks of gestation |
| Previous GBS colonisation detected incidentally, without adverse pregnancy event or where baby did not have neonatal GBS disease | Protocol 1: Accept request but advise that there is a lack of clinical evidence on offering IAP if GBS colonisation is confirmed from testing |
| Any request for testing | Protocol 1: Advise that testing is not recommended but support requests for lower vaginal and rectal swabs to be taken which should be sent by the woman for private processing using ECM; also advise that the sensitivity of these tests are not published Protocol 2: Accept request and take (unspecified) swabs but woman is responsible for forwarding specimens for private processing using ECM Protocol 3: Advise that antenatal testing or treatment is not recommended in national guidelines but offer lower vaginal swab at 36 weeks of gestation |
| Requests for testing during third trimester | Protocol 1: Accept request but advise that this is not recommended in national guidelines |
| Private testing | Protocol 1: Advise that testing is not recommended and provide counselling by a midwife on potential risks of screening |

ECM = enriched culture medium; GBS = group B streptococcal disease; IAP = intrapartum antibiotic prophylaxis

Appendix 4

Guidance on managing requests for intrapartum antibiotic prophylaxis against early-onset neonatal group B streptococcal disease

| Clinical scenario | Additional information | Guidance |
|---|---|--|
| GBS colonisation in previous pregnancy or outside of pregnancy | Previous baby did not have neonatal GBS disease | Protocol 1: Accept request if consultant obstetrician agrees Protocol 2: Discuss with woman – offer testing at 35–37 weeks of gestation and offer IAP to those with positive test result |
| GBS colonisation in previous pregnancy or outside of pregnancy and requested testing for GBS in current pregnancy | Without adverse pregnancy event or where baby did not have neonatal GBS disease | Protocol 1: Accept request even if test result for GBS colonisation is negative, with informed consent (advise on effectiveness and potential risks of IAP) |
| GBS colonisation in previous pregnancy | | Protocol 1: Advise that IAP is not recommended in national guidelines but accept request by creating an individual care plan at woman's request Protocol 2: Accept request with informed consent |
| GBS colonisation previously or currently | | Protocol 1: Accept request with informed consent (discussion of risks and benefits of IAP) |
| Received IAP in previous pregnancy | | Protocol 1: Advise that there is no evidence to provide IAP without the presence of risk factors. Discussions may occur with the Community Midwife if the woman has previously received prophylaxis and counselling, or the woman may request a consultant appointment for further discussion |

IAP = intrapartum antibiotic prophylaxis