

Uncertainties

Should all pregnant women be offered testing for group B streptococcus?

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This is one of a series of occasional articles that highlight areas of practice where management lacks convincing supporting evidence. The series advisers are Sera Tort, clinical editor, and Nai Ming Lai, clinical editor. You can read more about how to prepare and submit an Education article on our Instructions for Authors pages: <https://www.bmj.com/about-bmj/resources-authors/article-types>

Box start

What you need to know

- Many countries have guidelines that recommend universal testing for group B streptococcus (GBS) in late pregnancy so that women who are colonised with GBS receive intrapartum antibiotic prophylaxis to prevent newborn GBS infection
- Observational studies suggest that routine testing in pregnancy reduces the risk of early onset GBS in newborns compared with offering antibiotics to women with risk factors for GBS transmission, or no testing. However, those observational studies have a moderate to critical risk of bias, and no randomised trials of routine testing versus a risk factor based approach have taken place
- Routine testing could result in a large number of women receiving antibiotics unnecessarily, resulting in potential harms of widespread antibiotic use at individual and population levels
- Offer testing for GBS carriage to pregnant women as per local guidelines, and where that guidance is lacking, discuss with the woman the risks and benefits of testing, as well as how the test result could affect her delivery

Box end

Introducing routine testing for group B streptococcus (GBS) for all women in late pregnancy would likely reduce cases of early onset infection in their newborns, but might also increase the number of women given antibiotics during labour.

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One in five pregnant women carries GBS in the gut or genital tract, and more than half of them will pass it to their child during pregnancy, labour (most commonly), or after birth.¹ Most babies exposed to maternal GBS remain well, but 1 in 1750 newborns in the UK and Republic of Ireland develops early onset GBS infection, mostly pneumonia and sepsis. Each year in the UK about 40 babies die from GBS infection, and one in 14 of the survivors has a long term disability.¹ Babies born preterm are at higher risk of serious infection and death.²

Low quality evidence shows that giving antibiotic prophylaxis to women known to be colonised with GBS during labour (intrapartum antibiotic prophylaxis, or IAP) reduces the incidence of early onset GBS infection in newborns. A Cochrane review of three randomised controlled trials (500 women, 488 babies) found that, compared with no treatment, giving antibiotic prophylaxis in labour to pregnant women known to be colonised with GBS was associated with a reduction in the incidence of early onset neonatal GBS infection (risk ratio (RR) 0.17, 95% confidence interval (CI) 0.04 to 0.74, risk difference -0.4, 95% CI -0.07 to -0.01), although all trials were at a high risk of bias. No differences in the incidence of late onset infection or infection from other organisms were observed.³

Two strategies are commonly used to identify which pregnant women need antibiotic prophylaxis to reduce early onset neonatal GBS infection. One approach is routine testing for GBS colonisation in all pregnant women, and the other is based on risk factors to determine which women should be offered antibiotics in labour.

Many countries, including the US and 34 others, test all women for GBS in late pregnancy and offer women who test positive antibiotic prophylaxis during labour (table 1).⁴ Maternal GBS testing typically involves microbiological culture of a vaginal-rectal swab at 35-37 weeks' gestation (fig 1). The rationale for universal testing is that it identifies nearly all pregnant women with GBS colonisation at the time of testing. The downsides are that colonisation status may change between the time of testing and the time of birth, and maternal GBS colonisation alone does not mean that a baby will develop GBS infection.

Table 1 Recommendations from national guidelines regarding GBS testing in pregnancy⁴

Country	Policy on GBS testing in pregnancy	Recommended test
US ⁵	All pregnant women offered testing for GBS colonisation at 36-37 completed weeks of pregnancy, unless IAP indicated for GBS bacteriuria or previous baby affected by GBS infection	Vaginal-rectal swab and enriched culture medium testing
UK ⁶	Only pregnant women with GBS detected from a swab or sample taken from the mother in a previous pregnancy offered GBS testing at 35-37 weeks' gestation. Routine testing not recommended	Vaginal-rectal swab and enriched culture medium testing

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Canada ⁷	All pregnant women offered testing for GBS colonisation at 35-37 weeks	Vaginal-rectal swab and enriched culture medium testing
Australia ⁸	Offer either routine antenatal testing for GBS colonisation or a risk factor-based approach to prevention	Vaginal-rectal swab and culture testing (type of culture test not specified)
China	No national guidance ⁹	
World Health Organization recommendation for low-to-middle income countries ¹⁰	Intrapartum antibiotic prophylaxis (IAP) to women with GBS colonisation is recommended. No recommendation on testing for colonisation	

Fig 1 Microbiological culture for GBS colonisation, with a two stage enrichment culture as the recommended method

In contrast, the UK National Screening Committee recommends against routine universal testing for maternal GBS colonisation. The potential harms from intrapartum antibiotics at an individual level (maternal adverse effects, childhood diseases linked to disruption of the microbiome) and at a population level (antimicrobial resistance) are unclear. Evidence consistently shows short term intestinal microbiota changes in infants born to mothers receiving prophylactic antibiotics in labour.¹¹ Gut dysbiosis may increase the risk of metabolic and autoimmune conditions, as seen experimentally in animal models.¹² The Royal College of Obstetricians and Gynaecologists recommends targeting the offer of antibiotic prophylaxis in labour to women who have risk factors for GBS transmission (box 1).⁶

And yet, an observational study in the UK and Republic of Ireland (including 794 037 live births in 2000 and 914 132 live births in 2014) reported a rise in the incidence of early onset GBS infections from 0.48/1000 births in 2000 to 0.57/1000 births in 2014-15,^{13 14} despite the introduction of a national risk factor based prevention strategy in 2003. Over roughly the same time period in the US, where routine late third trimester testing was adopted in 2002, surveillance studies (encompassing 629 912 live births in 2002 and ~200 000 livebirths in 2014) showed that the incidence of early onset GBS infection rates had decreased from 0.5 per 1000 live births in 1998-1999 to 0.22 in 2014.^{15 16}

Uncertainty remains as to whether routine testing for GBS colonisation in late pregnancy or a risk factor based strategy for administering IAP strikes the best balance between preventing GBS transmission and the potential harms of antibiotic use.

Box start

Box 1 Maternal risk factors known to increase the chance of a baby developing early onset GBS infection

- Preterm birth

- The mother has previously had a baby affected by GBS infection
- The mother has a fever or other signs of maternal infection during labour
- GBS detected from a vaginal or rectal swab or a urine sample taken from the mother during the current pregnancy
- Ruptured amniotic membranes more than 24 hours before the baby is born

However, not all of these risk factors prompt the offer of IAP in the UK. As per the 2017 guideline from the Royal College of Obstetrics and Gynaecology, the presence of any one of the following risk factors prompts the offer of IAP:

- Preterm labour
- The woman has previously had a baby affected by GBS infection
- Maternal fever or other signs of maternal infection during labour
- GBS detected from a swab or sample taken from the mother during the current pregnancy (eg from a urine culture to investigate urinary symptoms or where a woman has chosen to test outside the NHS)
- GBS detected from a swab or sample taken from the mother in a previous pregnancy (in this situation, the mother should be offered the option of testing for GBS carriage using a GBS specific test with IAP offered if the result is positive, or being offered IAP without testing)

Although the mother's waters breaking more than 24 hours before the baby is born is recognised as a risk factor for early onset GBS infection, current guidelines do not recommend the automatic offer of IAP in this situation

Box end

What is the evidence of uncertainty?

Many observational studies have compared routine testing for GBS with a strategy based on risk factors, but no randomised controlled trials of universal routine testing have been conducted.

Three systematic reviews of observational studies completed in 2019-2020 (11 million, 600 000 and 9828 live births, respectively) indicate that routine testing more than halved the risk of early onset GBS infection in newborns compared with risk factor-directed antibiotic prophylaxis in labour. Similar numbers of women received antibiotics with either approach. Table 2 lists findings from these reviews.¹⁷⁻¹⁹ No difference was seen in early onset GBS infection rates between risk-factor directed protocols for giving IAP compared to no consistent IAP protocol.¹⁷ Studies included in the systematic reviews were retrospective in design and noted substantial variations between testing protocols (timing of testing, site sampled, method of testing) and baseline rates of early onset GBS infections.

Table 2 Systematic reviews of observational studies of routine testing, risk factor directed intrapartum antibiotic prophylaxis, or no policy

Review	Comparison	Outcome	Number of studies (heterogeneity)	Relative Risk (95% confidence interval)	Interpretation/limitations
Hasperhoven 2020 (17 studies, 11 million babies) ¹⁷	Universal screening versus risk based policy	Early onset GBS infection*	10 (low)	0.43 (0.32 to 0.56)	Routine testing was associated with a reduction in cases of early onset GBS infection compared with a risk factor approach, while risk factor approaches could not show a significant benefit over no policy. The authors acknowledge substantial variations between testing protocols and baseline rates of early onset GBS infections
	Risk based policy versus no policy	Early onset GBS infection*	7 (high)	0.86 (0.61 to 1.20)	
	Universal screening versus no policy	Early onset GBS infection*	4 (high)	0.31 (0.11 to 0.84)	
Li 2020 (18 studies, 604 869 babies) ¹⁸	Universal screening versus risk based screening	Early onset GBS infection†	18 (moderate)	0.45 (0.34 to 0.59)	Routine testing was associated with a reduction in cases of early onset GBS infection compared to a risk factor approach. Included studies used a retrospective design without parallel control and their quality was at a moderate to high level
Da Silva 2019 (2 studies, 9828 women) ¹⁹	Universal screening versus no policy/ risk-based screening	Neonatal infection‡	2 (none)	0.39 (0.17 to 0.91)	Routine testing was associated with a reduction in cases of early onset GBS infection compared with no policy. Limited number of included studies

*Positive GBS culture from normally sterile site, <7 days of age

†Positive GBS culture from normally sterile site, or clinically defined sepsis or meningitis <7 days of age

‡Not defined

A 2016 modelling study commissioned by the UK National Screening Committee suggested that antenatal microbiological testing would correctly predict early onset GBS infection in around 2 of every 1000 pregnant women who tested positive for GBS colonisation,¹ meaning that 998 might have unnecessary antibiotics. Their further modelling suggested the proportion of women in labour receiving antibiotics would increase from 4.3% under a risk factor approach to 17.8% with routine testing. Routine testing would result in 1675-1854 additional women receiving IAP to prevent one neonate having early onset GBS infection.²⁰ The model's input parameters have subsequently been called into question, as the risk factor strategy emerged with an early onset GBS infection rate of 0.49/1000 live births, which is lower than what surveillance data suggest (0.57/1000).^{2 20}

Without randomised controlled trial evidence, there is ongoing uncertainty regarding the balance of advantages and disadvantages of universal antenatal GBS testing compared to risk factor based strategies to identify pregnant women who should receive IAP to prevent GBS transmission to their babies.

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Is ongoing research likely to provide relevant evidence?

For the first time a randomised controlled trial comparing routine testing versus a risk factor based approach has been funded. The GBS3 trial (ISRCTN49639731) is a cluster randomised trial involving 320 000 women from up to 80 UK maternity units. It will determine the clinical and cost effectiveness of routine testing (160 000 women), compared with the current risk factor directed IAP strategy (160 000 women). There will also be a sub-randomisation to compare the testing strategies of antenatal enriched culture (80 000 women) at 35-37 weeks against intrapartum rapid testing (80 000 women). Recruitment has been delayed because of the covid-19 pandemic and will take two years. Simultaneous qualitative research will explore the factors that affect the adoption or uptake of either testing method, and a parallel economic evaluation will be undertaken. This RCT is likely to provide high quality evidence of the efficacy and cost effectiveness of IAP directed by universal testing compared with a risk factor based approach for preventing early onset neonatal GBS infection.

A separate UK based randomised trial compares the current practice of offering IAP to pregnant women with risk factors for GBS transmission without testing them with a strategy of offering these women intrapartum GBS testing, giving IAP only to women who test positive for GBS colonisation. This study will report its results in 2021 (ISRCTN74746075). No other trials are ongoing in this area from a search of ClinicalTrials.gov and ISRCTN registries performed on 9 March 2021 (box 2). Any maternal testing or risk factor based prevention strategy can—at best—identify women at risk of transmitting GBS to their babies. None can definitively predict which babies will develop GBS infection.

What should we do in light of the uncertainty?

We recommend following existing guidelines that support either an institutional or national antenatal testing programme, or a risk factor based strategy. Patients may have questions about GBS testing and prophylaxis. Explain to women the potential advantages and disadvantages of routine testing for GBS (advantage: observational studies reporting a reduction in cases of newborn GBS infection; disadvantage: a large number of women requiring antibiotics in labour to prevent a small number of infections; the implications of widespread use of antibiotics; the implications of knowledge of colonisation status on choice of birth location). Discuss their risk factors (box 1) and the testing options available to enable women to make informed and supported decision about their care. Offer intrapartum

antibiotic prophylaxis to women who are in preterm labour, have an intrapartum fever, where GBS has been detected in this or a previous pregnancy, or who have had a previous baby with GBS infection.⁶

BOX start**Box 2 Search strategy**

We searched PubMed in March 2021 using the terms “Group B streptococcus” OR “GBS” AND “screen” OR “screening” OR “test” OR “testing” OR “risk factor” NOT “Guillain-Barré syndrome”, filtered on “systematic review” OR “meta-analysis” OR “randomised controlled trial” and limited to publications since May 2015. This yielded 60 results, including three systematic reviews of screening for GBS from 2019 to 2020^{13 14 20} and one diagnostic test accuracy review of molecular testing methods, which was included in this article.¹² The 2016 review of the National Screening Committee criteria and outputs from the British Perinatal Surveillance Unit provided further information.^{1 2 18}

Box end

Box start**Recommendations for future research**

Further research is needed to identify the strains of GBS most likely to cause early onset GBS infection, so that we can better target antibiotics to the women that really need them and refine the testing methods to detect them.

Two main testing options exist: first, microbiological culture at 35-37 weeks’ gestation, which takes about 48 hours for a result¹⁹ and second, rapid tests, which utilise a polymerase chain reaction assay to give a real time result. The disadvantage of the vaginal-rectal culture test is that colonisation status may change between sampling and childbirth, and sample degradation may adversely affect culture detection rates. On the other hand, antenatal testing gives women the opportunity to consider their choice of location for birth based on the results, which should be known before labour starts.

Rapid GBS tests have the potential advantage of testing women in labour on the maternity unit, meaning that colonisation status at the time of birth can be determined, even for women presenting in preterm labour. Manufacturers of the only commercially available, low complexity rapid GBS test cite sensitivity and specificity as high as 92% and 95%, respectively (Xpert GBS, Cepheid, Sunnyvale, USA). A study to determine the accuracy of the rapid GBS test when used as a point-of-care test by midwives has been completed and will be published in 2021 (NIHR HTA 13/82/04). A qualitative study alongside GBS3 is planned to determine women’s knowledge, attitudes, and acceptability of GBS testing, including the different types of testing.

However, further research is needed to determine whether rapid tests could further reduce rates of neonatal GBS infection in practice compared with culture based testing. Rapid tests may not allow sufficient time for the antibiotics to work for women with fast labours, despite the rapid test turnaround.

The direct costs of antenatal testing are approximately half those of rapid testing, although there are no current data on the wider healthcare and societal costs of either.²¹

Finally, greater understanding of the maternal and neonatal immunological response to GBS will identify optimal vaccine targets, which would reduce the need for testing.

Box end

Box start**What expectant parents need to know**

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- Group B streptococcus (GBS) is a bacterium present in the vagina or lower gut of approximately 1 in 5 pregnant women
- Approximately one baby in every 1750 will develop a GBS infection within seven days of birth. Most recover, but each year in the UK about 40 babies die, and 1 in 14 of the survivors has a long term disability
- Countries have adopted various approaches to identify women whose babies are at risk of newborn infection and provide preventive antibiotics. In the US, Canada, and Australia, women are routinely tested for GBS in late pregnancy. In the UK, New Zealand, and South Africa women are not routinely tested, but those with risk factors for their baby developing an infection are identified. In most African countries, no guidance is offered
- Where women are routinely tested for GBS, if the test is positive, the woman will be offered antibiotics
- Current UK practice is to offer antibiotics if the woman has risk factors for her baby developing the infection
- Routine testing is not currently recommended in the UK because no randomised controlled trial has directly compared testing and risk based strategies, nor has value for money been demonstrated. Non-randomised studies have reported reduced infections from routine testing and many countries offer testing to all women in late pregnancy
- Both routine testing and risk factor based approaches result in giving many women antibiotics whose babies never go on to develop infection
- Research is underway to determine how testing strategies compare with a risk factor based approach

Box end

Box start

Education into practice

Think about the last time you talked to a pregnant woman about GBS. How confident did you feel answering her questions? How might you engage with women on this subject next time? How do you present GBS testing to women? Do you offer women a choice? What risks and benefits of testing might you discuss?

Box end

Box start

How patients were involved in the creation of this article

Jane Plumb of Group B Strep Support, who is integral to the GBS3 trial, recruited new and expectant parents to review an earlier version of this article. As a result of their input we re-wrote the section on what expectant parents need to know to make the language more understandable. Throughout the whole article, the disadvantages of testing methods were discussed.

Box end

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Contributorship statement and guarantor: KW and JD planned the work. KW wrote the first draft of the work. All authors reviewed and edited the first draft. All authors agreed the final manuscript. KW and JD are guarantors of the paper and accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Provenance and peer review: commissioned; externally peer reviewed.

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