



Public Health  
England

Protecting and improving the nation's health

**Enriched culture medium test for  
group B streptococcus infection**  
Position paper

Archived December 2017

## About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England  
Wellington House  
133-155 Waterloo Road  
London SE1 8UG  
Tel: 020 7654 8000  
[www.gov.uk/phe](http://www.gov.uk/phe)  
Twitter: @PHE\_uk  
Facebook: [www.facebook.com/PublicHealthEngland](http://www.facebook.com/PublicHealthEngland)

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# Contents

About Public Health England	2
Purpose	4
Foreword	4
Background	5
Group B Streptococcus	6
Maternal GBS carriage	6
Infant GBS disease	7
Treatment	7
Summary of guidelines	8
UK National Screening Committee ( UK NSC)	8
UK Standards for Microbiology Investigation	8
NICE	8
Royal College of Obstetricians and Gynaecologists	9
Clinical scenarios and current guidance	10
Current testing	10
Clinical scenarios	10
Next steps	13
Conclusion	14
References	15

Archived December 2017

## Purpose

This paper sets out the reasoning behind Public Health England's position that the use of enriched culture medium to detect group B streptococcus does not have a place within current accepted clinical guidance and therefore its decision not to introduce the test within PHE's regional laboratories.

It follows the related publication:

'Enriched culture medium testing for group B streptococcus is not recommended within current clinical guidance: a briefing note from PHE'

This paper has been developed by PHE and has been shared with the Royal College of Obstetricians and Gynaecologists, the National Institute for Health and Care Excellence, NHS England, the Royal College of Midwives and Group B Strep Support for comment.

## Foreword

Public Health England has now looked in depth at whether there are any circumstances in which the ECM test could be applied within the current standard of care, as recommended in the Royal College of Obstetricians and Gynaecologists' guidelines, 'The Prevention of Early-onset Neonatal Group B Streptococcal Disease'. This work has concluded that there are no clinical indications for testing women using ECM methods as recommended within current guidance. However, studies into the use of tests for GBS carriage in pregnancy are currently being considered by research funding agencies and, if conducted, will cast more light on this complicated area.

PHE takes the matter of GBS very seriously and, together with its partners, continues to work hard to improve the situation. The RCOG is undertaking an audit to ensure its most recent guidelines are followed, while PHE is monitoring the evolving situation in vaccine development. In addition, a national study of GBS infection in babies is taking place which will provide important information on risk factors and prevalence of infection. This information will be used to inform research into this complicated area including the development of new diagnostic tests.

Professor Paul Cosford  
Medical Director and Director for Health Protection, Public Health England

## Background

In 2012 the UK National Screening Committee (UK NSC) recommended that screening for group B streptococcus (GBS) in pregnancy should not be offered.<sup>2</sup>

The charity Group B Strep Support (GBSS) subsequently raised a number of concerns about the availability and quality of GBS testing in specific circumstances in UK laboratories with the Chief Medical Officer and Under Secretary of State for Health, in December 2012.

In response to this meeting, the Chief Medical Officer asked the Health Protection Agency, now Public Health England (PHE), to make recommendations for the introduction of a more accurate test for GBS carriage using an enriched culture medium (ECM), and to make this test available in its regional laboratories when there was a clinical indication for testing.

PHE therefore undertook a piece of work with clinical organisations, including the Royal College of Obstetricians and Gynaecologists (RCOG), the Royal College of Midwives (RCM) and NHS England, to determine in which circumstances the ECM test could be used.

Responsibility for guidance on the management of clinical scenarios rests with the RCOG and National Institute for Health and Care Excellence (NICE). The detailed guidance is provided in the RCOG Green-top guideline no. 36, 'Prevention of Early-onset Neonatal Group B Streptococcal Disease' (2012),<sup>3</sup> and the NICE Clinical Guidelines 149, 'Antibiotics for Early Onset Neonatal Infection' (2012),<sup>4</sup> relevant sections of which are outlined in this paper.

This work, which is set out in the following paper, concluded that within current clinical guidance from the key professional bodies, there are no clinical indications that would require the ECM test.

PHE therefore decided not to provide this test in its regional laboratories.

## Group B streptococcus

Group B streptococcus (GBS, *Streptococcus agalactiae*), is a Gram positive bacterium found primarily in the gastrointestinal and genital tract. It usually causes no harm to the carrier but in infants, pregnant women, women who have recently given birth, and older adults, GBS can cause invasive disease.<sup>5</sup>

As GBS can colonise the vagina, it can be passed on to the baby during labour. Not all babies born to GBS colonised women will be colonised, and not all that are colonised will go on to develop invasive GBS disease.<sup>6</sup>

Invasive GBS disease in newborn infants before seven days of age is generally referred to as early onset GBS (EOGBS), although this term is sometimes used to refer to GBS disease occurring in the first 48 hours of life. EOGBS is usually thought to be due to mother to baby (vertical) transmission. GBS disease occurring from seven days up to three months of age is referred to as late onset GBS (LOGBS).<sup>7</sup>

Infection in babies with GBS can result in superficial skin infections, or systemic infections such as pneumonia, septicaemia or meningitis. Most cases of GBS resolve without long term effects; however it can be fatal, with mortality rates higher in preterm babies.<sup>8</sup>

### Maternal GBS carriage

The reported UK carriage rate of GBS among pregnant women varies between studies: a rate of 21% was found in one recent UK based rapid test study<sup>9</sup> while 26% was found in another UK study.<sup>10</sup> The evidence that supports NICE Clinical Guideline 149 (full version): 'Antibiotics for early-onset neonatal infection (2012)', did not find any evidence that maternal GBS carriage was useful for the prediction of early onset infection.<sup>11</sup>

This guideline also recommends that where invasive GBS infection has occurred in a previous baby, or maternal colonisation detected incidentally in the current pregnancy, intrapartum antibiotic prophylaxis (IAP) should be offered, and these risk factors should be used in the clinical assessment of individual newborn babies.<sup>11</sup>

Individual studies on the routine screening of women for GBS at 35–37 weeks report a broad range of results. These include the following:<sup>12,13</sup>

- 13–40% of women testing positive will no longer be carriers at term
- 4–10% of women testing negative will be carriers at term

Systematic reviews<sup>14,15</sup> of women screened at 35–37 weeks report that:

- 24–30% of women testing positive will no longer be carriers at term
- 5–6% of women testing negative will be carriers at term

The UK National Screening Committee (UK NSC) recommended in 2012 that screening for GBS in pregnancy should not be offered.<sup>16</sup> Screening recommendations are due to be re-evaluated in 2015/16.

## Infant GBS disease

The British Paediatric Surveillance Unit (BPSU) national surveillance study in 2001 remains the most comprehensive study of infant GBS in the UK. This reported an overall rate of culture proven cases of 0.48/1,000 or 377/794,000 live births.<sup>17</sup> The *Health Protection Report* gave the rate of early onset GBS as 0.38/1,000 live births in 2013 for England, Wales and Northern Ireland.<sup>18</sup>

In the BPSU study 37% of affected babies were preterm. From this study the rate in term babies would be approximately 0.33/1000 live term births. A health technology assessment (HTA) systematic review of UK studies found that 40.4% of cases of early onset GBS were premature.<sup>19</sup>

Direct comparisons with other countries should be treated with caution. However, recently published data from the USA report an EOGBS rate of approximately 0.21/1,000 term births.<sup>20</sup> A report from one region in Italy found that the rate in term women was 0.24/1,000 live births.<sup>21</sup>

The BPSU study reported an overall mortality rate of 10.6% for early onset GBS. There were a total of 38 deaths of which 23 were premature infants.<sup>22</sup>

## Treatment

NICE and the RCOG recommend that IAP should be administered in certain scenarios, including the incidental detection of GBS during pregnancy. This is usually in the form of high dose intravenous benzylpenicillin. There have been no confirmed cases of penicillin-resistant GBS isolates in the United Kingdom to date.<sup>23</sup> However, there have been reports from the Far East and United States describing the emergence of clinical GBS isolates with reduced susceptibility to penicillin.<sup>24,25,26,27</sup>

Clindamycin is the alternative first-line agent for penicillin-allergic patients. Levels of both clindamycin and erythromycin-resistant GBS isolates increased in the period 1991–2010, with resistance to erythromycin increasing markedly from 2.5% in 1991 to 15% in 2010.<sup>28</sup>

The high level of clindamycin resistance has severe implications for treatment options for penicillin-allergic patients, in particular where treatment is given empirically.

# Summary of guidelines

## UK National Screening Committee ( UK NSC)

The UK NSC advises ministers and the NHS in the four UK countries about all aspects of screening and supports implementation of screening programmes. Using research evidence, pilot programmes and economic evaluation, it assesses the evidence for programmes against a set of internationally recognised criteria covering the condition, the test, the treatment options, and the effectiveness and acceptability of the screening programme.

Assessing programmes in this way is intended to ensure that they do more good than harm at a reasonable cost. The UK NSC also sets up practical mechanisms to oversee the introduction of new programmes in the English NHS and monitors their effectiveness and quality.

The UK NSC Policy on GBS screening in pregnancy review was completed in November 2012, and the next review is due in 2015/16. The policy<sup>29</sup> concluded that a “*systematic population screening programme is not recommended*”.

As such, GBS screening tests, including the ECM test, should not be offered to women at 35–37 weeks.

## UK Standards for Microbiology Investigations

These documents provide a standardised method for culture where clinicians decide to investigate specific patients with conditions considered to confer a high risk of infection. The high risk clinical scenarios in which investigation may be relevant are dependent on individual clinical risk assessment.

With reference to GBS testing, SMI B58<sup>30</sup> is currently being updated; in line with other national guidance it does not recommend antenatal screening.

## NICE

NICE clinical guideline 62: Antenatal Care<sup>31</sup> states, “Pregnant women should not be offered routine antenatal screening for group B streptococcus because evidence of its clinical and cost effectiveness remains uncertain.”

NICE clinical guideline 149: Antibiotics for early-onset neonatal infection<sup>32</sup> states, “Further research is needed to evaluate the clinical and cost effectiveness of routine antenatal

screening for group B streptococcus combined with intrapartum antibiotic prophylaxis in women identified as carriers.”

## Royal College of Obstetricians and Gynaecologists

The RCOG’s clinical ‘Green-top Guideline No. 36’: The Prevention of Early-onset Neonatal Group B Streptococcal Disease (2<sup>nd</sup> edition, July 2012) <sup>33</sup> states that:

“There have been no studies addressing whether routine screening has had any impact on all-cause mortality. Antenatal screening and treatment may carry disadvantages for the mother and baby. These include anaphylaxis, increased medicalisation of labour and the neonatal period, and possible infection with antibiotic-resistant organisms, particularly when broad-spectrum antibiotics such as amoxicillin are used for prophylaxis. The UK National Screening Committee examined the issues of strategies for the prevention of EOGBS disease in November 2008 and recommended that routine screening using bacteriological culture or near-patient testing techniques should not be introduced into UK practice.

RCOG guidance on the management of a range of clinical scenarios is described in the next section.

These guidelines from key professional organisations do not identify any clinical situations in which testing specifically for GBS has been shown to be of value. Therefore, within existing guidance, no scenarios where the ECM test would add benefit have been identified.

Archived December 2017

## Clinical scenarios and current guidance

### Current testing

The current form of testing, where there are vaginal or urinary symptoms in pregnancy, is a quality assured culture method<sup>34</sup> that will detect GBS and other pathogens from appropriate samples.

Although the ECM test may be more sensitive for the detection of GBS than the current method for the investigation of genital tract specimens, it may not detect and may even suppress other organisms. This is because ECM involves selective enrichment for GBS which would suppress growth of other potential pathogens. Therefore the ECM method may be inferior to the current quality assured culture method for this purpose, and the current method is better at detecting a greater range of pathogens.

Use of the ECM in addition to the current test, where there are maternal symptoms, could potentially detect additional cases of GBS carriage. However these are likely to be cases of lower GBS bacterial load, and the clinical significance or implications for the neonate of detecting of GBS carriage in this circumstance has not been determined.

### Clinical scenarios

The following table presents clinical scenarios, the management guidance from RCOG and NICE, and whether there are indications for vaginal / rectal swabs to be processed using an ECM to detect maternal GBS carriage.

Clinical scenario	Clinical guidelines/comment	Indication for ECM?
Previous baby affected by GBS	RCOG <sup>35</sup> guidance recommends that intra-partum antibiotic prophylaxis (IAP) 'should be offered to women with a previous baby with neonatal GBS disease.... Vaginal or rectal swabs are not helpful, as IAP would be recommended even if these swabs were negative for GBS.'	No IAP is indicated within current guidance
Carriage in a previous pregnancy	RCOG <sup>36</sup> states that, 'current evidence does not support screening for GBS or the administration of IAP to women in whom GBS carriage was detected in a previous pregnancy'. NICE's Guideline Development Group (GDG) <sup>37</sup> states, 'The group concluded that although there is a	No Current guidance recommends testing should not be offered. RCOG guidance is

	<p>higher likelihood of carriage in a subsequent pregnancy this does not constitute a risk factor for the baby and that the woman should be informed and reassured that the management of her current pregnancy and birth of the baby will not be affected by the detection of GBS colonisation in a previous pregnancy.'</p>	<p>clear on this.</p>
<p>Elective caesarean section</p>	<p>RCOG guidance<sup>38</sup> recommends that, 'Antibiotic prophylaxis specific for GBS is not required for women undergoing planned caesarean section in the absence of labour and with intact membranes. Women undergoing planned caesarean delivery in the absence of labour or membrane rupture do not require antibiotic prophylaxis for GBS, regardless of GBS colonisation status. The risk of neonatal EOGBS disease is extremely low in this circumstance.'                      NICE Caesarean section guideline<sup>39</sup> recommends that antibiotics to prevent overall infectious morbidity should be administered prior to surgical incision. Antibiotics 'effective against endometritis, urinary tract and wound infections' in the mother should be used.</p>	<p>No IAP specific for GBS is not indicated within current guidance regardless of colonisation status.</p>
<p>Preterm delivery</p>	<p>Offering the ECM in scenarios involving spontaneous delivery earlier than 37 weeks is impractical for the purpose of managing the delivery. The earliest a positive result of an ECM test could be available is after 40 hours. A negative result would take about 60 hours.                      RCOG guidance recommends that, 'Women presenting in established preterm labour with intact membranes with no other risk factors for GBS should not routinely be offered IAP unless they are known to be colonised with GBS.'<sup>40</sup></p>	<p>No                      A GBS nucleic acid detection test could give a definitive result within two hours and may be of value. Research in this area is being considered by the HTA.</p>
<p>Premature pre-labour rupture of membranes (PPROM)</p>	<p>For preterm women, RCOG guidance recommends routine antibiotic prophylaxis; if GBS colonisation is known, the antibiotic chosen should offer appropriate cover.<sup>41</sup>                      The value and practicality of ECM testing in women in this group has not been evaluated and is not recommended within current guidance.                      The earliest a positive result of an ECM test could be available is after 40 hours. A negative result would take about 60 hours.</p>	<p>No.                      A GBS nucleic acid detection test could give a definitive result within two hours and may be of value. Research in this area is being considered by the HTA.</p>

<p>Prolonged rupture of membranes at term</p>	<p>Offering the ECM in clinical scenarios involving PROM at term is impractical for the purposes of managing the labour. The earliest a positive result of an ECM test could be available is after 40 hours. A negative result would take about 60 hrs.</p> <p>For term women, RCOG guidance refers to the NICE guidance. The NICE Intrapartum care guideline<sup>42</sup> recommends that: 'If there are no signs of infection in the woman, antibiotics should not be given to either the woman or the baby, even if the membranes have been ruptured for over 24 hours.</p> <p>If there is evidence of infection in the woman, a full course of broad-spectrum intravenous antibiotics should be prescribed.'</p>	<p>No IAP is indicated within current guidance if there is evidence of infection.</p>
<p>Pyrexia in labour (&gt;38<sup>0</sup>)</p>	<p>Use of the ECM for clinical management during labour is impractical. The earliest a positive result of an ECM test could be available is after 40 hours. A negative result would take about 60 hours.</p> <p>RCOG guidance<sup>43</sup> recommends, 'IAP should be offered to women who are pyrexial in labour (&gt;38°C). Women who are pyrexial in labour should be offered broad-spectrum antibiotics including an antibiotic for prevention of neonatal EOGBS disease.'</p>	<p>No IAP is indicated within current guidance</p>
<p>Presentation with signs and symptoms of vaginal infection during pregnancy</p>	<p>RCOG guidance recommends that, 'IAP should be offered if GBS is detected on a vaginal swab in the current pregnancy. Vaginal swabs should not be taken during pregnancy unless there is a clinical indication to do so.'<sup>44</sup></p> <p>The function of testing in this context is to explore a range of potential causes of infection. The value and practicality of ECM testing at 35–37 weeks in addition to this has not been evaluated and is outside current guidance.</p>	<p>No The value and practicality of ECM testing, instead of or in addition to current testing, has not been evaluated</p>
<p>Presentation with signs and symptoms of urinary infection in pregnancy</p>	<p>RCOG guidance<sup>45</sup> recommends that, 'Clinicians should offer IAP to women with GBS bacteriuria identified during the current pregnancy.'</p> <p>Urinary samples may be taken during screening for asymptomatic bacteriuria or due to signs or symptoms of a urinary infection. As in above scenario.</p>	<p>No The value and practicality of ECM testing, instead of or in addition to current testing, has not been evaluated.</p>

## Next steps

With regard to the future, several candidate GBS vaccines are under development and wider population-based studies for safety and efficacy in high prevalence areas such as South Africa are planned. Although development and licensing may take several years, PHE is already planning studies to inform a potential introduction if marketing approval is granted.

The Department of Health, PHE, the RCOG and the National Institute for Health Research Health Technology Assessment (NIHR HTA) are also working together on a number of areas:

PHE is undertaking enhanced surveillance of infant disease in 2014/15 in partnership with St George's Hospital, the British Paediatric Surveillance Unit and national public health bodies across the UK and Ireland to assess disease incidence, associated mortality and frequency of established risk factors. PHE will monitor developments in GBS vaccines and are currently collaborating on a grant-funded study led by Cambridge University to assess the potential impact of a maternal immunisation programme. They are also seeking research funding to identify any genetic differences in GBS carriage strains compared to those causing infant disease as a means to develop a more specific screening test.

The RCOG in partnership with the London School of Hygiene and Tropical Medicine have appointed a clinical research fellow to carry out an audit across the UK. It aims to provide feedback and advice to all participating trusts about how they can further improve the adherence of their policies to the RCOG's guideline on the prevention of neonatal group B streptococcal disease. The UK NSC Secretariat is continually engaged with the RCOG regarding this.

The NIHR HTA programme is seeking to commission a study to provide evidence on whether intrapartum testing in some groups at high risk enables more timely identification of women with GBS carriage so as to target antibiotic use. A study of this type would focus on pregnant women at high risk of having an affected baby, with reference to the risk factors identified in the guidance from the RCOG. If conducted, this will cast more light on this complicated area. Applications for this work have been submitted, and PHE has engaged in consultations and promoted this research.

## Conclusion

Public Health England has now looked in depth at whether there are any circumstances in which the ECM test could be applied within the current standard of care, as recommended in the Royal College of Obstetricians and Gynaecologists guidelines on the 'Prevention of Early-onset Neonatal Group B Streptococcal Disease'. This work has concluded that, within current guidance, there are no clinical indications for testing women using ECM methods.

There are logistical and clinical issues concerning the use of ECM tests in high risk clinical circumstances in pregnancy. An ECM test result would not alter management in some scenarios; for example IAP is offered to women with a previously affected baby or pyrexia in labour even if swabs are negative for GBS.

ECM tests are not intended for use during labour and, in some of the clinical scenarios described, the ECM test would not be sufficiently timely to alter the management of labour as the test takes a minimum of 40 hours to process in the laboratory. It takes 60 hours to produce a negative result. As such the test would be impractical in women with prelabour rupture of the membranes at term. The value and practicality of an ECM test for women with preterm prelabour rupture of the membranes has not been evaluated. A GBS nucleic acid detection test could give a result within two hours in high risk clinical circumstances. Research in this area is being considered by the HTA.

Current non-selective testing in symptomatic women, where there are signs and symptoms of vaginal or urine infections, is for a range of possible organisms, some of which may be suppressed by the ECM test. ECM tests are not intended for use in these circumstances and could be an inferior test for this purpose. The value and practical application of an additional ECM test has not been evaluated.

Offering the test to low risk women at 35–37 weeks is not recommended by the UK National Screening Committee, NICE or RCOG.

There are no clinical indications for testing women specifically for GBS under current guidance, and therefore ECM methods are not recommended.

On this basis PHE laboratories do not currently provide the ECM test.

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Archived December 2011