

# **Briefing for the Public Petitions Committee**

### Petition Number: PE01592

Main Petitioner: Shaheen McQuade

Subject: Group B Strep Information and Testing

Calls on the Scottish Parliament to urge the Scottish Government to ensure all pregnant women receive information about Group B Strep and are given the option to be tested; and to set aside funding to find more reliable methods of testing.

# Background

### Group B strep

<u>Group B Streptococcus (GBS)</u> or 'strep B' is one of many bacteria that can be present in people's bodies. GBS usually <u>live harmlessly</u> inside the digestive system and in some women's reproductive systems. <u>Streptococcal</u> infections are any type of infection caused by the streptococcus ("strep") group of bacteria and infections vary in severity from mild throat infections to life-threatening infections of the blood or organs. For example <u>strep B</u> can sometimes cause <u>urinary tract infections (UTIs)</u>, skin infections, bone infections, blood infections and pneumonia, particularly in vulnerable people, such as the elderly and those with diabetes. It can also affect new born babies.

# Strep B in pregnancy

It is estimated that around one in every four pregnant <u>women</u> have strep B bacteria in their reproductive or digestive system and there is a small <u>risk</u> that GBS can pass to the baby during childbirth. Most babies <u>exposed</u> to strep B will be unaffected, but around 1 in every 2,000 <u>babies</u> can become infected.

Most babies who become <u>infected</u> will be treated successfully and will make a full recovery, however there is a chance they could die as a result of complications such as meningitis. <u>One in 10 babies</u> born with GBS will die from the infection and is estimated that around 340 babies in the UK will develop GBS infection over a year. As new born babies have a poorly

developed immune system, <u>strep B bacteria</u> can quickly spread through their body, and can cause serious infections such as meningitis and pneumonia. Some <u>babies</u> who survive are left with permanent problems, such as hearing loss, vision loss, and problems with memory and concentration. One-in-five babies who survive the infection will be affected permanently. A strep B infection during pregnancy can also <u>cause</u> miscarriage or stillbirth, but this is rare.

The symptoms of a strep B infection in a new born baby usually develop within the first few hours or days of giving birth. If a baby develops GBS infection less than seven days after birth, it is known as <u>early-onset group B</u> <u>streptococcus (EOGBS) infection</u>. Most babies who become infected develop symptoms within 12 hours of birth. Every year in the UK of the 680,000 births a year, around <u>340 babies</u> will develop early-onset GBS (EOGBS) infection. <u>Late-onset GBS infection</u> develops seven or more days after a baby is born. This is not usually associated with pregnancy. In such instances it is likely that the baby concerned became infected after the birth.

### Current UK strategy for screening for Strep B in pregnant women

In the UK, pregnant women are <u>not routinely offered testing for group B strep</u>, unlike in many other developed countries. Group B strep will sometimes be <u>detected</u> when other tests are taken for example, from a urine sample, or from a vaginal or rectal swab. However, often it is not detected, not least because the standard <u>'non-specific' tests</u> widely used within the NHS to detect group B strep carriage were not developed to find it.

In 2012, after a review of antenatal screening for group B streptococcus, the <u>UK National Screening Committee</u> (NSC) and the <u>Royal College of</u> <u>Obstetricians & Gynaecologists</u> did not recommend routine screening of all pregnant women for GBS. This is because the <u>review</u> found that there was insufficient evidence to demonstrate that the benefits to be gained from screening all pregnant women and treating those carrying the organism with intravenous antibiotics during labour would outweigh the harms. The UK National Screening for group B streptococcus in 2016. The UK NSC is an <u>independent expert advisory group</u>, which advises ministers and the NHS in the four UK countries about all aspects of screening and supports implementation of screening programmes.

Current UK policy uses a <u>'risk factor' approach</u> to determine which new born babies are likely to be at-risk of developing GBS infection. Risk factors include carrying GBS bacteria during their current pregnancy, high temperature during labour, labour starting or waters breaking prematurely and having previously had a baby infected with GBS. This risk-based strategy was introduced in the UK in 2003.

The National Institute of Clinical Excellence (NICE) has issued <u>guidance</u> on the prevention and treatment of early-onset infections in new born babies. Antibiotics given intravenously during labour can help to reduce the risk of a baby developing GBS. NICE guidance to the NHS identifies those women and babies who it is thought may benefit from intravenous antibiotics. NICE provides national guidance and advice to improve health and social care. The way NICE was established in legislation means that the guidance only covers England. However, NICE have agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland. Healthcare Improvement Scotland issue alerts to notify NHSScotland of the publication of NICE guidance and provide advice on its applicability to Scotland.

The Royal College of Obstetricians and Gynaecologists has also issued <u>guidance</u> about preventing early-onset neonatal GBS disease. These are consistent with the NICE guidance. For example, they recommend that women who have a high temperature in labour (above 38°C) should be offered broad-spectrum antibiotics to prevent GBS infection.

If <u>screening was introduced</u>, pregnant women would be offered the screening test as close as possible to the moment most babies are born, between the 35th and 37th week of their pregnancies.

### National screening programme for GBS

There is <u>conflicting evidence</u> and differing views about whether a national screening programme for GBS would be effective.

### Case for Screening

The charity <u>Group B Strep Support</u> continues to campaign for a GBS national screening programme. They feel that the 'risk factor' strategy seems to have had little, if any, <u>effect</u> on the rate of early-onset GBS infections in babies – the rate has not fallen. Furthermore, up to <u>40%</u> of babies who do become affected are born to mothers without any of the clinical risk factors, other than unknown GBS carriage within the mother. In Scotland, the rate is <u>0.47</u> cases per 1,000 births, compared with 0.36 in the UK. The UK National Screening Committee undertook a public consultation in 2012 on a national screening programme for group B strep. <u>212 written responses</u> were received and 207 were published on the NSC's website. Of these, 93% were in favour of introducing screening for group B strep in pregnancy and fewer than 4% were against.

The <u>Group B Strep Support</u> charity feel that the most cost-effective method is to test all low-risk mothers late in pregnancy and offer intravenous antibiotics in labour to those whose babies are at higher risk of GBS infection – those where GBS is found during their current pregnancy plus to those with other recognised risk factors.

The testing <u>programmes</u>, discussed above, have been adopted in many other European countries as well as in the US, Canada and Australia and found to be highly effective in terms of reducing early-onset GBS. For example in America guidelines were given to healthcare providers. These guidelines provided them with a choice of either offering women a screening test for GBS at 35-37 weeks of pregnancy or using a risk factor approach to determine which women should be offered intravenous antibiotics to minimise the risk of GBS infection in their new born baby. <u>Research</u> was undertaken on the two different approaches and it showed that a screening test was more effective than using risk factors alone to determine which women should be offered intravenous antibiotics in labour. In 2002 the American Centers for Disease Control and Prevention (CDCs) updated their guidelines recommending that all women should be offered a screening test. It was <u>shown</u> that the incidence of early-onset GBS fell further after the introduction of the CDC's universal screening guidelines and that this lower level has been maintained. In the US in 2014 the rate for early-onset GBS infection was <u>0.24</u> per 1,000 live births whereas in Scotland the rate was <u>0.44</u> per 1,000 live births.

<u>Group B Strep Support (GBSS)</u> wants to avoid preventable cases of group B strep infection in babies. They believe that every woman should be fully informed about group B strep and offered the opportunity to have a sensitive (ECM) test to detect GBS carriage late in pregnancy. The results of these tests can then be used to inform as to what further treatment may be needed, if any, to minimise the risk of GBS infection in the new born baby.

#### Case against Screening

Most <u>babies</u> born to women who carry the bacterium do not become infected. Other <u>concerns</u> include the possible effect on the new born babies' normal gut flora (healthy bacteria) and the risk of allergic reaction among the women receiving any treatment.

Many experts, such as the UK National Screening Committee and the Royal College of Obstetricians & Gynaecologists, believe that a <u>screening</u> <u>programme would do more harm than good</u>. Currently there are <u>limitations</u> with the tests and the treatment, as well as aspects of the condition, that mean it is not at all clear that screening would be of benefit overall. Identifying women who are GBS carriers in order <u>to treat them all with antibiotics</u> during labour would result in many thousands of women and babies being treated in order to prevent a very small number of serious infections.

There are <u>concerns</u> about using antibiotics on this scale given by this method. Around 150,000 women each year would receive the drugs during labour by an intravenous (IV) route, i.e. through a tube into a vein. If antibiotics are <u>used too widely</u>, bacteria may become resistant to antibiotics in the future. The <u>use of antibiotics in labour</u> is the subject of increasing concern amongst health practitioners such as midwives and obstetricians and gynaecologists. The <u>current GBS test</u> is not always accurate and could therefore lead to many thousands of women being offered antibiotics they did not need.

Most of the deaths and long term problems from GBS are in babies who would not be <u>helped</u> by screening. For example premature babies are born before screening would take place (screening usually takes place at 35-37 weeks of pregnancy) and are often affected by other conditions which increase the risk of ill health. It is <u>estimated</u> that around 65% of deaths from

GBS are found among these babies. GBS causing illness after seven days of life (late-onset GBS) cannot be prevented by screening programmes and most long term disability is caused by this type of GBS. The test can only tell if a woman is carrying GBS not if their unborn baby will become unwell.

The NSC found that the current UK rate of early-onset GBS is <u>comparable</u> to that in countries in which screening is recommended. They also found that the ability of <u>screening</u> to significantly impact on mortality and long term morbidity caused by GBS is uncertain.

# Testing

Testing is <u>presently</u> the only way to identify whether a woman is carrying GBS however there are issues with the current tests. For example the tests usually used to detect group B strep carriage in pregnant women (when any tests are used) were not designed for the purpose. They are <u>'general purpose'</u> tests. A better test is available, designed specifically for the detection of group B streptococcus carriage (<u>UK SMI B58</u>) but it is rarely available for health professionals to request for pregnant women in their care. <u>Enriched culture medium (or ECM) testing</u> is the 'gold standard' method for detecting group B strep as described by <u>Public Health England's UK Standards for Microbiology Investigations B 58</u>. However ECM tests are not yet widely available within the NHS although they are available privately (and cost approximately £35). However, it is still <u>not useful for screening</u> as the likelihood of identifying which babies would be affected by early-onset GBS (EOGBS) infection is very low.

Testing <u>cannot accurately predict</u> which mothers will or will not have GBS by the time they go into labour. Around 25% of women whose tests would say they have GBS will actually be clear by the time they give birth. Around 5% of women's tests that came back clear would be carrying GBS by the time they go into labour. For this reason the current test i.e. 'general purpose' test is not useful for screening.

### **Future research**

The National Screening Committee commissioned <u>a study</u> comparing the different approaches to preventing early onset GBS infection in babies. These approaches include the current high risk management strategy used in the UK, and potential screening strategies used elsewhere. The outcome will inform the next policy review due in 2016.

The Meningitis Research Foundation is <u>researching</u> a vaccination for pregnant women to protect unborn babies from the Group strep B infection.

### Healthcare staff

<u>Healthcare staff</u> are expected to follow professional guidance from their respective royal colleges, such as the Royal College of Obstetricians and Gynaecologists (RCOG) Green top Guideline Number 36 <u>Group B</u> <u>Streptococcal Disease, Early-onset (EOGBS)</u> which was published in July 2012. The RCOG conducted an audit, commissioned by the UK NSC, examining current practice in preventing early-onset neonatal GBS disease. The first of the two reports from the audit was <u>published</u> in March 2015 and looked at how national guidelines are currently being implemented and identifies areas for improvement in order to reduce the number of neonatal infections due to GBS. The <u>second report</u>, which is due to be published early in 2016, will focus on patient information on GBS, hospital protocols on preventing EOGBS, a survey of practice in midwifery-led units, and the influence of patient risk factors on practice.

The <u>RCOG and the Royal College of Midwives</u> are also currently working to develop educational materials for health professionals, to include details on the appropriate testing methodology, sample site selection and culture methods for GBS carriage in pregnant women.

### **Scottish Government Action**

On screening issues the Scottish Government is advised by the UK National Screening Committee, (NSC), an independent expert advisory group which advises ministers and the NHS in the four UK countries about all aspects of screening. The Scottish Government is not bound by the advice of the NSC but it accepted the outcome of the review in November 2012 which recommended that a national screening programme for GBS should not be introduced. The NHS in Scotland is following that advice.

The <u>Scottish Government</u> is represented at the NSC meetings and is actively involved in all discussions the NSC has regarding group B streptococcus.

The <u>Scottish Government</u> funds NHS Health Scotland to develop and publish Ready, Steady, Baby booklet, which is a guide to pregnancy which is given to all pregnant women at their first booking appointment with a midwife. The current edition of Ready, Steady, Baby booklet contains information on group B streptococcus. This section is currently being reviewed and the revised section is due to be published at the end of January 2016.

### **Scottish Parliament Action**

On 21 February 2014, Jackie Watt lodged a <u>petition</u> calling on the Scottish Parliament to urge the Scottish Government to introduce new guidelines advising that all expectant mothers are given information about Strep B and are either screened for Strep B as a matter of routine or given information on where to go if they wish to be tested privately. The Public Petitions Committee agreed to <u>close the petition on 26 May 2015</u> on the basis that over the next 18 months the Scottish Government will consult with the petitioner when redrafting the GBS section of Ready, Steady, Baby booklet and the UK National Screening Committee will review the evidence on group B streptococcus. SPICe produced a <u>petition briefing</u> on pregnant women and Group B Strep in February 2014.

The issue of Group B streptococcus has been raised in the Parliament. For example there was a PQ on group B streptococcus awareness, which was <u>discussed</u> in Parliament on 31 March 2015.

### Motion S4M-12723: Margaret McDougall, West Scotland, Scottish Labour, Date Lodged: 18/03/2015

That the Parliament notes with concern what it understands is the lack of public awareness regarding group B streptococcus (GBS) and the effects that it can have on newborn babies; understands that, in the UK, GBS infects over 500 babies every year and that 340 will develop early-onset GBS infection and one in 10 of them will die; believes that the incidence of early-onset GBS infection in England, Wales and Northern Ireland has remained unchanged since prevention strategies were first introduced in 2003 and that, in Scotland, it has increased from 0.21 per 1,000 live births in 2000 to 0.47 in 2012; understands that many countries, including the USA, Canada, Germany and Spain, offer routine testing for GBS at 35 to 37 weeks of pregnancy; notes that, although the Royal College of Obstetricians and Gynaecologists does not recommend routine testing, the Scottish Government is not bound by this approach, and notes calls for the Scottish Government to introduce guidelines so that hospitals in the west of Scotland and beyond provide expectant mothers with information regarding GBS and either offer routine testing or provide information on how testing can be accessed privately.

In response the Scottish Government stated that "estimates suggest that between 13,000 and 49,000 women each year whose tests would say that they have group B streptococcus would be clear of the virus by the time they give birth" and that "17,000 to 25,000 women in the UK would need to be treated with antibiotics each year to prevent one death from group B streptococcus. This is approximately one in 30 pregnant women."

The Official Report from this debate can be found here.

Louise Rennick Senior Researcher 18 December 2015 SPICe research specialists are not able to discuss the content of petition briefings with petitioners or other members of the public. However if you have any comments on any petition briefing you can email us at <a href="mailto:spice@scottish.parliament.uk">spice@scottish.parliament.uk</a>

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