

Group B Strep Support
Preventing life-threatening group B Strep
infection in newborn babies

Screening will save newborn lives:
A case for the introduction of routine
screening for group B streptococcus
in late pregnancy



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Medical panel

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Foreword

Life-threatening group B Strep infections in newborn babies can usually be prevented. A simple and inexpensive test in the later stages of pregnancy can detect the bacteria, allowing treatment to be given to the mother during labour so preventing infection in the newborn baby. I'd like to see every pregnant woman in the UK offered a sensitive test for GBS on the NHS – this test is a routine part of antenatal care in many countries including Australia, Canada, Spain and the USA.

This report makes the simple case that the current system of only treating women identified through 'risk factors' is ineffective. While the number of GBS infections in newborn babies continues to rise in the UK, it has fallen dramatically in countries where routine screening has been introduced.

The UK National Screening Committee is currently reviewing the evidence for routine testing and I hope that this time the evidence from around the world will convince them that a national screening programme is the most effective way to prevent the pain and suffering caused by unnecessary group B Strep infection in newborn babies.

Every year, large numbers of babies are affected by life threatening group B Streptococcal infection. Whilst most recover, some are stillborn, more die in the first weeks of life and others suffer lifelong disability.

Group B Strep, known as GBS or Strep B, is Britain's most frequent cause of severe early-onset (0–6 days of life) infection in babies¹. Most GBS infection in babies is early onset and these infections are highly preventable.

Prevention methods are not currently available for late-onset (after age 6 days) GBS infection and this report therefore focuses on those of early-onset only.

A simple maternal GBS screening programme could identify women carrying the potentially lethal bacteria and those women, and others known to be at higher risk, could be offered antibiotics in labour to minimise the risk of GBS infection in their newborn babies. Many countries have already recognised the scale of the problem, and have introduced screening programmes, including Australia, Argentina, Belgium, Canada, Czech Republic, France, Germany, Hong Kong, Italy, Kenya, Poland, Spain, Slovenia, Switzerland and the USA.

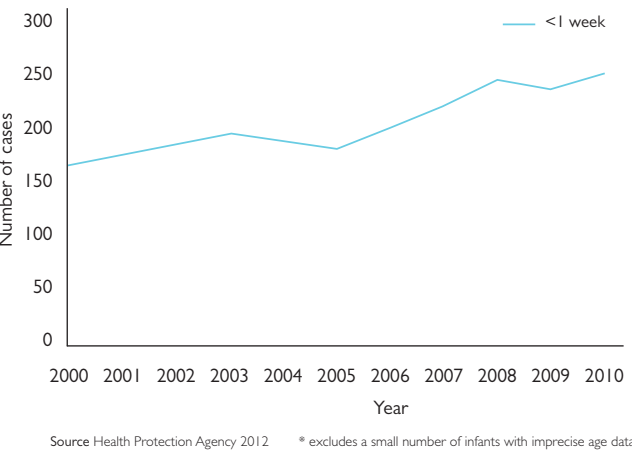
As a result of these screening programmes, the number of GBS infections in newborn babies has fallen significantly – in the USA by over 80%,⁶ in Spain by 86%,⁷ in Australia by 82%⁸ and in France by 71%⁹. In the UK, routine screening for GBS is not offered and the incidence is increasing (see graphs).

Since 2003, the number of voluntarily reported culture-proven GBS infections in newborn babies has risen by 32% to 302 cases in England, Wales and Northern Ireland in 2010². Even with the best medical care, about one in ten babies with GBS infection die¹ and, although most survivors recover fully, up to half of those who recover from GBS meningitis suffer long-term problems. If current trends continue, the number of GBS infections and resultant deaths and disabilities among newborn babies will double within the next three decades.

Many obstetricians, paediatricians and midwives are concerned that Britain is out of sync with much of the rest of the developed world. Approximately one in four people in Britain are likely carriers of the GBS bacteria, which produces no symptoms – the first many parents hear of group B Strep is when their baby is fighting for its life in the Special Care Baby Unit.

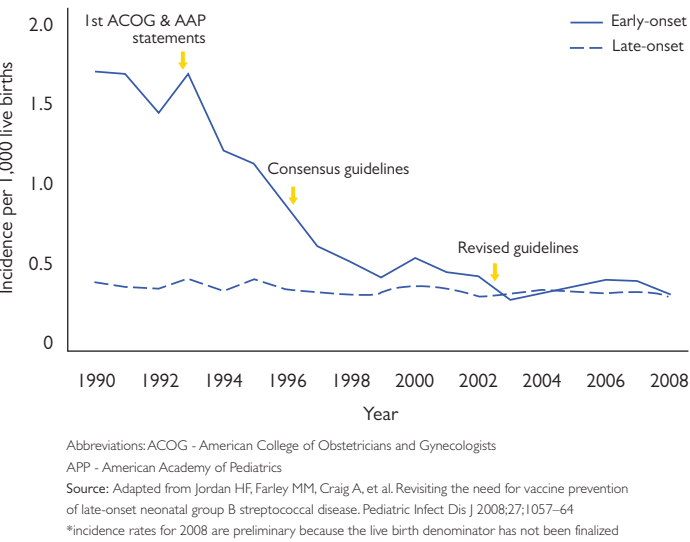
The UK National Screening Committee, which has twice decided against recommending screening to reduce infection, disability and death from GBS, is currently reviewing the latest evidence. Their review for public consultation is to be published shortly and, in the light of the compelling

Laboratory reports of early onset (0–6days) GBS bacteraemia in infants*: England & Wales, 2000–2010



National decline of GBS infection in the USA⁶

Incidence of early- and late-onset invasive group B streptococcal (GBS) disease
Active Bacterial Core surveillance areas, 1990–2008, and activities for prevention of GBS disease



evidence from other countries of the success of screening programmes, should recommend the introduction of GBS screening for the UK.

Within the last five years, four reports^{10–13} have been commissioned through the Government's Health Technology Assessment Programme, the Medical Research Council and other healthcare research agencies, to establish how to combat preventable GBS infection in newborn babies. All have found screening to be more cost effective than risk-based prevention and recommended that steps to introduce screening should be explored. So far their findings have been ignored.



While in opposition the Prime Minister David Cameron tabled three parliamentary motions calling for better prevention of these devastating infections in newborn babies, but as yet GBS screening is not routinely available to pregnant women.

This report looks at the implications of the increase in GBS infection in newborn babies. It outlines the case for the introduction of a national screening programme, it looks at the existing recommendations for a 'risk factor' approach to group B Strep prevention, and the hopes for a vaccine that will one day prevent the misery of child death being visited on too many parents every year.



Chief executive of GBSS Jane Plumb MBE and
Professor Philip Steer Chair of GBSS Medical Panel

GBS is the most common cause of life-threatening infection in newborn babies, causing death and disability

- GBS infections in newborn babies continue to rise in the United Kingdom
- GBS infections in newborn babies have fallen substantially in countries which routinely screen

Group B Strep Support would like to see

- Sensitive GBS testing offered by the NHS to all pregnant women
- All pregnant women given information about GBS as part of routine antenatal care
- Intravenous antibiotics offered during labour to all women with identified risk factors (including GBS carriage detected by testing)

Isabel

“Isabel was born in March 2003 with early onset GBS infection which resulted in her being quadriplegic, blind and suffering from cerebral palsy.

The impact on the family of managing Isabel’s daily needs is considerable. Our other children are often restricted in what they can do as we need to be home to look after Isabel. Holidays and trips are few and far between as there is little available for blind and disabled children and getting access to beaches and rugby pitches requires a specialist wheelchair that we don’t currently have. We constantly worry that our other two children feel neglected. The other day our daughter Zoe asked if she could change sisters and her little brother Leo firmly believes that Isabel will learn to walk soon.

What shocked me most was that while I was pregnant with my second and third children the midwives told me that GBS was nothing to worry about even though I had Isabel in a wheelchair next to me.

GBS is a serious infection that can have devastating consequences. I believe everything possible should be done to make people aware of GBS infection and reduce its harm by providing screening and treatment when needed.”



What is group B Streptococcus?

Group B Streptococcus is a bacterium carried harmlessly in the vagina of approximately 21% of pregnant women in the UK¹⁴.

It usually only becomes a problem if a baby is exposed to it around the time of labour as the immune systems of newborn infants are less able to fight off its potentially damaging effects. If GBS gets into the bloodstream or lungs of a newborn baby, it can cause septicaemia and pneumonia, each of which can be fatal and is expensive to treat. Most GBS infections in babies develop within the first hours and days of life but, less commonly, it can develop up to age three months. Then it is more likely to cause meningitis, which can be fatal or cause a range of lifelong disabilities including blindness, deafness, speech problems or learning impairments.

It is not clear how many babies’ deaths and disabilities from group B Strep infections are excluded from official statistics because babies are rapidly treated on symptoms alone before a diagnosis is made, or because a baby is stillborn due to GBS infection and the cause of the infection is never investigated.

In the UK, anything up to 88,000 babies a year are colonised with GBS at birth. In 2003, it was estimated that 340 babies¹⁵ a year in the UK developed GBS infection aged 0–6 days, with varying degrees of severity and 39 died from their infection, although subsequent research shows that the true current incidence could be three times greater³. A study in a major London hospital found an incidence of proven GBS infection of 1.1 per 1,000 live births, but this increased to 3.6 per 1,000 live births when it included probable cases – one case in every 277 babies born³. UK wide, this would mean around 2,500 newborn babies requiring treatment, even though many may never be formally identified as infected with GBS.

In the UK as a whole, about one in seven of all newborn babies requires some extra hospital care, which can cost £1,200 or more a day depending on how much intensive nursing they need. Removing the GBS cases would not only save money but also free up many intensive care cots for other sick babies.

A growing problem

The number of GBS infections in newborn babies is rising substantially in Britain.

The Health Protection Agency, the independent body that protects the health and well-being of the population and collects data on disease, found a 35% increase in the number of voluntarily reported culture-proven cases of GBS infection in babies aged 0–6 days between 2004 and 2008 alone². Although the rate of increase has slowed, the trend is still upwards. In other reports, the Health Protection Agency acknowledges that since “systems rely on voluntary reporting... the dataset is often incomplete.”

The GBSS charity’s medical advisory panel, led by Professor Philip Steer, emeritus professor of obstetrics and gynaecology at Imperial College, London, note that despite the recommendation for risk factor screening made in 2003 by the Royal College of Obstetricians and Gynaecologists, this rise is now causing an estimated 34 deaths in newborn babies each year, apart from costing additional millions of pounds in hospital and other ongoing care costs for the babies affected, some of whom survive with major disabilities.

“The total burden, including the deaths, is probably about 1,000 cases a year,” Professor Steer says. “About 4% of affected babies suffer long-term damage, but reliable data on the number of survivors with long-term problems are hard to come by. Given there are three probable cases for every confirmed diagnosis, the total burden is likely to be substantial.”

GBS also causes stillbirth, and contributes to Britain’s alarmingly high number of babies who die in the womb. A study published last year by *The Lancet* showed Britain is one of the poorest performing countries in tackling stillbirth¹⁶. Its analysis found Britain came 33rd in a league table of 35 similarly developed countries, with 4,000 babies dying in the final weeks of pregnancy. As only a minority undergo post-mortems, for many the cause of death is never explained.

Prematurity is a recognised risk factor for GBS infection as preterm babies are particularly vulnerable with their less developed immune systems. The number of premature babies born in the UK is increasing year on year. Normal pregnancy lasts 37–42 weeks, but 8% of babies are born before then, itself a risk factor for disability.

What is currently done to prevent GBS infections in the UK?

UK guidelines on how to prevent GBS infection in newborn babies were first widely circulated by the Royal College of Obstetricians and Gynaecologists (RCOG) in 2003¹⁵. These call upon health professionals to be alert to risk factors and either give or consider giving antibiotics to the pregnant woman in labour where recognised risk factors exist.

Risk factors for GBS infection

Each of the risk factors shown below increases the risk of GBS infection in a newborn baby:

- Mother has previously had a GBS infected baby
- Mother has been identified during the current pregnancy as a GBS carrier, or GBS has been found in her urine
- Labour starts or membranes rupture (waters break) before 37 weeks of pregnancy (i.e. preterm)
- Where the waters break more than 18 hours before delivery
- Where the mother has a temperature of 37.8°C or higher.

Carrying GBS during pregnancy is recognised as an important risk factor for GBS infection in a newborn baby, yet women are rarely told about group B Strep by their health professionals and even more rarely offered testing for it.

When tests are offered within the NHS, the methods used are not sensitive enough, only finding 50% of the women carrying GBS, so up to half of the carriers are not detected. The ‘gold standard’ GBS test, the enrichment culture medium (ECM) test, used widely in other countries and described by the Health Protection Agency’s National Standard Method¹⁷ has not generally been made available on the NHS.

The RCOG guidelines seem to have made little impact in the nine years since they appeared, despite RCOG’s 2007 audit reporting that “The practice reported by midwives and obstetricians is in broad agreement with the risk-based IAP strategy described in the RCOG Green-top guideline.”¹⁸. The level of knowledge about GBS among health professionals caring for expectant parents is poor.¹⁹ It may be that part of the problem with this risk-based strategy is that it is too complex – to be effective, any strategy needs to be both easy to understand and easy to implement.

There is evidence that the guideline’s implementation has not been ideal: a study published just over two years ago¹



Adam

Adam was born in March 2011 at Royal Shrewsbury Hospital after a completely normal pregnancy with no indications that anything would be wrong. The morning after his birth (Saturday), Adam was grunting and not feeding. Staff quickly realised that something was wrong and he was taken to the Neonatal Unit where he stopped breathing and was put on a ventilator and brain monitor and fed with intravenous solutions. He was given antibiotics to combat the most common infant illnesses until a diagnosis could be confirmed. Adam became so ill that he was not expected to live. Hospital staff battled around the clock to save his life and by Sunday group B Strep Meningitis was confirmed.

For the first week, Adam's life was in danger but slowly he started to improve and by day seven, he was removed from the ventilator. He began to recover in tiny steps and after 23 days he was discharged from hospital. His parents were warned that possible complications included brain damage, epilepsy, cerebral palsy, paralysis, amputations, blindness, hearing loss and learning difficulties.

Adam now has impaired hearing and has been diagnosed with Auditory Dyssynchrony, meaning he may be able to hear sounds but the sound is scrambled and his ability to hear at all could fade in and out.

Despite the challenge and the difficulty, Adam's parents feel truly blessed to have their 'little miracle' alive and kicking when it was originally believed he wouldn't survive. Thankfully, Adam is a survivor, yet his life is now marked by disability.

All this could have been averted – a sensitive GBS test for the mother late in pregnancy would almost definitely have found GBS and, with antibiotics from the start of labour, Adam could have been protected.

The final irony is that Adam's mother is Canadian and in Canada sensitive testing for GBS is routine, as it is in many other western countries, including the USA, France, Germany, Italy, Slovenia, Czech Republic, Argentina, Australia and Spain.

If Adam had been born in his mother's home country all the suffering could have been avoided.

investigated 48 cases of GBS infection in newborn babies between 2004 and 2007 from eight UK neonatal units. 67% of the mothers had one or more known GBS risk factors, and the authors reported that between 50% and 80% of the infections in the babies could have been prevented had health professionals followed existing guidelines to give antibiotics when risk factors were identified. Of the women with recognised risk factors, only six (21%) received the correct antibiotics during labour. Four more mothers were prescribed the wrong antibiotics. Recent studies from other countries have shown no risk factors to be present in even higher proportions of newborn babies developing GBS infection (57%²⁰ to 78%²¹).

There is little evidence that the guidelines have brought about more recent improvements. "I have seen cases where senior doctors have used completely the wrong antibiotics, and haven't even thought of screening women for the infection," said Alison Bedford Russell, a senior consultant neonatologist at Birmingham Women's Hospital, who regularly has to treat tiny babies with undiagnosed GBS infection, fighting for their lives. "The UK is now very much behind the rest of the world on this."

Whilst there are real concerns about using antibiotics inappropriately and promoting antibiotic resistance by over-use, studies in the US have shown these fears have not been realised except when broad spectrum²², rather than the recommended narrow spectrum, antibiotics were used against GBS infection in newborn babies. Likewise, concerns about the antibiotics causing major allergic reactions, with potentially devastating effects for both the mother and her baby, have largely been allayed²³.

An updated version of the RCOG guideline is due out this summer. It is expected to reiterate the existing risk-based recommendations. Given the poor level of knowledge about GBS among health professionals caring for expectant parents,¹⁹ without greater input by the NHS and hospital trust management in enforcing their use, there is little prospect they will make a significant difference.

The case for screening

Many more cases of GBS infection in newborn babies can be prevented by routine screening (which identifies women actually carrying GBS) rather than using the current system of risk-factors (many women have risk factors but don't actually carry GBS), although the proportion of women offered antibiotics in labour would be similar¹³. In addition, at least a third of newborn babies with GBS infection are born to mothers with no recognised risk factors^{1; 20; 21}.

Risk-based programmes, because of their complexity, have a lower adherence than screening programmes. The evidence from countries which do screen shows dramatic falls in the incidence of GBS infection in newborn babies whereas the UK incidence is rising.

Testing pregnant women for GBS carriage involves swabs being taken from the low vagina and rectum at 35–37 weeks of pregnancy and growing the bacteria using enriched culture techniques, which can take up to three days. The swabs can be taken by the pregnant woman herself, or by her health professionals, and there are no risks associated with the test. In countries which screen for GBS, mothers who go into labour before the test result is available are routinely offered antibiotics in labour based on risk factors, such as prematurity or fever in labour.

A 2007 Health Technology Assessment study commissioned by the Government estimated that £67m could be saved were GBS detection optimised¹¹. That figure is likely to be a huge under-estimate because of rising healthcare costs.

In 2010, health economists at the University of Birmingham published a study estimating that introducing universal GBS screening for pregnant mothers at 35–37 weeks of pregnancy would save £633,000 for every baby death avoided and £45,000 per disease avoided¹². There are insufficient data to assess the lifetime costs for babies left with disabilities, but these will be significant. Four recent UK reports^{10–13} have concluded that screening would be more cost effective than risk-based prevention.

Screening would be welcomed by expectant mothers

A survey in 2011 of 1,000 women aged 20–35²⁴ found that 92% would welcome the opportunity for pregnant women to be screened for group B Strep in the later stages of pregnancy and believe this should be offered to women routinely.

In addition, 92% believe that information on group B Strep should be given to all pregnant women yet almost 50% of them had no idea what GBS is (and of those who had heard of it, only 20% knew what it was).

Furthermore, 95% believe antibiotics should be offered in labour to women with group B Strep and that they themselves would definitely, or probably, accept the offer (89%).

Sadly, all too often parents only find out when tragedy strikes.

Princess Elizabeth Hospital, Guernsey

The Princess Elizabeth Hospital in Guernsey is the only hospital in the whole of the British Isles that has implemented the screening strategy used elsewhere in the developed world for GBS prevention. The procedure was introduced nearly 20 years ago after a local study found almost three babies per 1,000 were born with the condition – five times more than government figures suggested. "We have now virtually eliminated the infection," said Dr Bryan Lean, a senior paediatrician at the hospital. "I believe all hospitals should do surveys of their own to establish levels of local GBS risk, and then decide for themselves if screening is a waste of money."



"I'm not used to being applauded by obstetricians, but when I presented our GBS results at a national conference, I was greeted by wild applause."

Since the introduction of screening, there have been just two GBS cases in Guernsey. One was in a baby born to a woman who refused screening, and the other was a premature baby born with GBS before the mother had been screened.

Is more research needed?

More research is always welcome when it sheds light on something not understood. However, further research, if required before introducing screening, would mean more avoidable deaths occur while more and better evidence is collected for what is already known: screening strategies are better than risk factor strategies at preventing group B Strep infections in newborn babies.

There is a perception that health professionals just aren't being given the tools they need to tackle these devastating infections and the failure to offer safe and effective tests, estimated to cost just £10.63 each in 2009,¹⁴ underlines this. The reasons for this are unclear, particularly against a backdrop of other countries seeing 80% falls in their incidence of early onset GBS disease following the introduction of preventative measures^{6–9} whilst the incidence in the UK is rising.

The prospects for a vaccine

Although there are at least eight different subgroups (or serotypes) of GBS causing infection in the UK, a vaccine against three of them (III, Ia and V) could prevent about 85% of cases²⁷. It could prevent GBS infections not only in newborn babies, but also the less common late-onset (occurring seven or more days after birth) infections, which are not prevented by antibiotics in labour, as well as maternal infections.

Such a vaccine has been developed by the pharmaceutical company Novartis, and has been trialled on 320 pregnant and non-pregnant women aged 18 to 40, in South Africa. The trial is deemed to have been successful and data from the trial is being analysed to determine the optimum dose to produce an antibody response, a process due for completion at the end of this year. Further large-scale trials in pregnant women will then be required before the product can be licensed, which could take a further three to five years, assuming all is well.

Rolling out an NHS vaccine programme could take a decade or more, so it is important that screening is introduced now to save more babies suffering these severe infections and dying in the meantime.

Conclusion

It is well recognised that GBS is causing avoidable severe infections in newborn babies, causing death and disability and that the incidence is rising in the UK. The existing Royal College of Obstetricians & Gynaecologists' guidelines, whilst a huge step forward in 2003, have been shown to have had little effect on the incidence of these devastating infections.

Ample evidence is available of the life-saving benefits of screening, from countries that are offering it. Evidence also suggests that this would save the NHS money.

In the light of this, GBSS is calling for:

- Pregnant women to be given information about GBS as part of routine antenatal care
- Sensitive GBS testing to be offered freely on the NHS to every pregnant woman whose newborn baby is at low risk of developing GBS infection
- Intravenous antibiotics to be offered during labour to all women with identified risk factors including those with GBS carriage detected by testing

Introducing these measures can prevent severe group B Strep infections in newborn babies which, in turn, saves lives, prevents disability, saves parents the debilitating grief caused by loss or damage to their child, and saves the health service millions of pounds.

With the UK National Screening Committee currently considering their position on GBS screening, the time for action is now.

Report prepared by Jane Plumb MBE

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