

Cepheid UK Ltd – Written evidence (PRT0064)

Introduction

Preterm birth, defined as the delivery of the baby before 37 weeks of gestation, is a worldwide health issue as it is involved in up to 80% of all neonatal deaths.ⁱ Preterm births occur mainly spontaneously, around one third are due to voluntary initiation of delivery by physicians.ⁱⁱ Infections are the leading causes of spontaneous preterm births and group B Streptococcus plays a key role.ⁱⁱⁱ

About Group B streptococcus (GBS) and its impact on pre-terms

GBS is a common bacterium which is present in around 20-40% of adults in the UK. It is not usually harmful to the adults who carry it; however, it can impact the health of newborn babies if they are infected around the time of birth. This is known as an early-onset GBS infection.^{iv}

Around 1 in every 1,750 newborn babies in the UK are diagnosed with an early-onset GBS infection.^v Early-onset GBS can cause sepsis, pneumonia and meningitis and, on average, leads to two babies dying and three surviving with long-term physical or mental disabilities each month.^{vi} That means that tragically each year around 24 babies die from early-onset GBS and 36 are left with long-term disabilities.^{vii}

Pre-term babies are more likely to be impacted by the harms of GBS than newborns.^{viii} Preterm babies are at greater risk of developing GBS than full-term babies and are more likely to become unwell with a GBS infection.^{ix} The case fatality rate of GBS is between 20% to 30% in pre-terms, compared to 2% to 3% in a full-term infant.^x In addition, GBS can cause premature delivery and is a major cause of death of delivering women globally.^{xi} Studies have shown a consistently observed increase in risk of preterm birth, ranging from 20% to 80%, in women with maternal GBS infection.^{xii,xiii}

The current diagnosis and treatment pathway for GBS

Most cases of early-onset GBS are preventable, but most cases are not being prevented.^{xiv}

Currently, GBS is detected during pregnancy using a vaginal or rectal swab, or a urine test.^{xv} These tests typically happen three-to-five weeks before the anticipated delivery date,^{xvi} meaning there is no guarantee that a woman who was positive will still be so at the time of her birth, or vice versa.^{xvii} However, these tests are not routine and are only given to women judged to be at high risk, meaning cases of GBS can go undetected.^{xviii}

If GBS is detected before birth, then treating or managing the baby's risk of GBS (preventing early-onset) relies on antibiotics. Women with a positive GBS test result should be offered antibiotics through a drip during labour, as should women who have previously had a baby who was diagnosed with a GBS infection.^{xix}

If GBS is found or developed following birth, the standard course of treatment of newborns, including pre-terms, is antibiotics. ^{xx} Early-onset GBS can make newborns severely ill and, due to the conditions it goes on to cause, newborns including pre-terms may need to be treated in intensive care to support their recovery, with some sadly going on to die or develop life-changing physical or mental disabilities.^{xxi}

Supporting GBS harm-reduction in pre-terms

With both GBS being a risk factor of pre-term births and a major cause of ill health and mortality in pre-term babies, we believe that there is a case for a greater focus on improved prevention and management policies to reduce the impact on pre-term babies.

Current guidelines developed by the Royal College of Obstetricians and Gynaecologists (RCoG) designed to prevent and support the management of early-onset GBS^{xxii} are not being consistently implemented within England. A report by the patient group *Group B Strep Support (GBSS)* in 2021 found that:^{xxiii}

Around 20% of Trusts had not updated their local guidelines since the RCoG guidance was published in 2017.

Over half (51%) of Trusts did not give all pregnant women information on GBS, contradicting RCoG guidance.

Two-thirds (66%) of Trusts are using the wrong swab test to try and detect GBS in a pregnant woman, and only 13% of Trusts are following the right laboratory methodology for processing the tests.

The information uncovered points to extensive variation within the comprehensiveness of services provided by the NHS according to guidelines, potentially resulting in outcome differences depending upon where newborns and mothers accessed care.

Supporting neonatal and follow-up care

Although the vast majority of newborns who develop an early-onset GBS infection will make a full recovery, the impact of early-onset GBS can be extremely distressing for newborns and families, with pre-term babies having a heightened risk of developing a GBS infection.

The treatment regime involves prompt aggressive intravenous antibiotic therapy and potentially intensive care, the result of which can be distressing for both newborns and their families.^{xxiv}

The infections that group B Strep most commonly causes in newborn babies are sepsis (infection of the blood and other tissues), pneumonia (infection in the lungs), and meningitis (infection of the fluid and lining

around the brain) which can severely impact the health and wellbeing of babies and may require life-long support.^{xxv}

In the small cases where an infection results in stillbirth or an infant death, there is a need for families to be supported with appropriate follow-up care and bereavement support.

Recommendations

To support the improved health and well-being of pre-terms and their families, we recommend the following policies:

1. Any strategy which focuses on reducing the number of babies who are delivered prematurely or on improving the health and well-being of pre-term babies should incorporate a focus on GBS, given the link to pre-term births and the increased risk factors of pre-terms of developing GBS infection.
2. NHS England should commission a national audit of maternity units against compliance with RCoG and NICE clinical guidance on the prevention and management of GBS, with recommendations designed to reduce the variation of care currently experienced in NHS services.
3. NHS England and the Department of Health and Social Care should adopt mandatory recording and reporting of GBS in England to enable a better understanding of the impact of GBS on pre-term babies, with the view to informing improved policies to support better care and outcomes, a system which has been in place in Northern Ireland since 2013.^{xxvi}
4. NHS England should review its maternity training programmes to include a greater focus on preventing the harm caused to pre-term babies by GBS, and additionally review the extent to which NHS Trusts routinely provide the correct information to parents to support informed decision-making and improved awareness.

5. Additional consideration should be made by NHS England as to the appropriate level of access to post-natal support provided to families whose newborns have been impacted by early-onset GBS.

About Cepheid UK

Cepheid is a leading molecular diagnostic company that is dedicated to improving healthcare by pioneering molecular diagnostics that combine speed, accuracy, and flexibility. As a committed partner of the NHS, we deliver approximately two million tests to patients each year.

We are a part of Danaher Corporation, a leading global life sciences and diagnostic innovator, with a sizeable footprint across the UK.

Cepheid's GeneXpert® System allows frontline staff to deliver laboratory quality rapid PCR testing from the patient bedside within under an hour, with minimal training and within the confines of the existing health and social care estate due to the use of automation and its variable size.

A total of 31 UKCA and CE marked in vitro diagnostics (IVD) Xpert® tests can be performed from the one platform, allowing providers to accurately and quickly test a range of condition areas including respiratory infections, blood virology, women's and sexual health, TB and emerging infectious diseases, healthcare-associated infectious diseases, oncology, and human genetics – from hospital emergency department and wards, to primary care, and community settings. As part of this portfolio, we produce PCR gold-standard bedside tests for Group B streptococcus.

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ⁱⁱ Chen X, et al. *Iatrogenic vs. spontaneous preterm birth: A retrospective study of neonatal outcome among very preterm infants*. March 2021

ⁱⁱⁱ Lamont RF. *Advances in the Prevention of Infection-Related Preterm Birth*. November 2015.

^{iv} Royal College of Obstetricians and Gynaecologists, *Group B Streptococcus (GBS) in pregnancy and newborn babies*, December 2017

^v Royal College of Obstetricians and Gynaecologists, *Group B Streptococcus (GBS) in pregnancy and newborn*

babies, December 2017

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- xi Kurian, N., et al, *Mechanisms of group B Streptococcus-mediated preterm birth: lessons learnt from animal models*
- xii Bianchi-Jassir, et al. *Preterm Birth Associated With Group B Streptococcus Maternal Colonization Worldwide: Systematic Review and Meta-analyses*. November 2017.
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- xxii Royal College of Obstetricians and Gynaecologists, *Prevention of Early-onset Group B Streptococcal Disease (Green-top Guideline No. 36)*, 13 September 2017.
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- xxvi Department of Health, Social Services and Public Safety, *Mandatory reporting of confirmed cases of Group B Streptococcus (GBS) infection in babies*, March 2013