

A rapid intrapartum test for group B *Streptococcus* to reduce antibiotic usage in mothers with risk factors: the GBS2 cluster RCT

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Declared competing interests of authors: Jane Plumb is the chief executive of Group B Strep Support (Haywards Heath, UK), a charity working to stop group B streptococcal infections in babies. She is the vice chairperson of Women's Network within the Royal College of Obstetricians and Gynaecologists (London, UK). She received support from Cepheid (Maurens-Scopont, France) to attend an academic conference in 2016, from Pfizer Inc. (Pfizer Inc., New York, NY, USA) to attend a summit for vaccine advocacy stakeholders in the USA in 2019 and from i-CONSENT (Valencia, Spain) to attend workshops in London in 2018 and Brussels in 2019, regarding consent for vaccine trials. She was a member of the Department of Health and Social Care Research Prioritisation Expert Group in 2016. Jane Plumb (2019–present) and Jim Gray (2018–2020) are members of the National Institute for Health and Care

Excellence's Guideline Update Committee for Neonatal Infection: Antibiotics for Prevention and Treatment (August 2018, guideline to be published 2021). Jim Gray was a member of the National Institute for Health and Care's Diagnostics Advisory Committee (August–November 2010) that produced *Rapid Tests for Group A Streptococcal Infections in People With a Sore Throat* (DG38) in 2019 (which included an assessment of the Cepheid GeneXpert Xpert® Xpress Strep A test). Jane Daniels, Jane Plumb and Jim Gray are grant holders for Health Technology Assessment (HTA) programme 17/86/06 (GBS3), a cluster randomised trial of routine screening for group B *Streptococcus*. Jane Daniels and Jane Plumb are grant applicants for a study to determine a serocorrelate of immune protection against group B *Streptococcus* (MRC MR/T030925/1). Jane Daniels is a member of the National Institute for Health Research (NIHR) Clinical Trials Unit Standing Advisory Committee (2016–present). Jonathan Deeks was on various NIHR panels between 2008 and 2017 [i.e. the HTA Efficient Study Designs 2 (2015–16), HTA End of Life Care and Add-on Studies (2015–16), HTA Medical Tests Methods Group (2015–17), HTA Primary Care Themed Call Board 2013–14, Pre-Exposure Prophylaxis Impact Review Panel (2017), HTA Funding Committee Policy Group (2011–16) and the HTA Commissioning Committee (2011–16)]. Michael Millar was a member of the NIHR Funding Committee for Antimicrobial Resistance Studies (2014–15), the NIHR Board for Hospital Infections (2006–7), the Economic and Social Research Council Antimicrobial Resistance Board (2016–17) and of the NIHR HTA Diagnostic and Screening panel (2008–15).

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Plain English summary

The GBS2 cluster RCT

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Plain English summary

What is the problem?

Group B *Streptococcus* is a common bacterium found in the vagina and intestines of approximately one in four women. Group B *Streptococcus* may be passed to the baby around birth and cause severe infection. In the UK, women are offered antibiotics in labour to protect their baby from group B *Streptococcus* infection when specific risk factors are present. Most women with risk factors do not carry group B *Streptococcus* and their babies are unnecessarily exposed to antibiotics. Most women carrying group B *Streptococcus* do not have risk factors and so will not be offered antibiotics to protect their babies.

What did we plan to do?

We planned to find out if, for women with risk factors, a 'rapid test' in labour resulted in fewer women receiving antibiotics compared with 'usual care'. We also wanted to establish if the test correctly identified if mothers were carrying group B *Streptococcus*, helped reduce infections in babies and represented value for money.

What did we find?

We involved 1627 women (1700 babies) from 20 hospitals randomly allocated to rapid test or usual care. Using the 'rapid test' did not reduce antibiotics provided to mothers (41% in rapid test units and 36% in usual-care units). The test correctly identified 86% of women carrying group B *Streptococcus*, 89% of those who did not and failed to provide a result in 14% of women. A rapid test policy resulted in 13% fewer babies receiving antibiotics. The rapid test generated no cost savings when only the mothers' care was considered, but there was potential for reduced costs when including the newborns' hospital stay.

What does this mean?

The rapid test is accurate; however, using it for women with risk factors for their baby developing group B *Streptococcus* infection does not reduce antibiotic usage in mothers, although it does in babies. Value for money is uncertain and depends on what costs are included.

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This report

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