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

Jane Daniels,[1] Emily F Dixon,[2] Alicia Gill,[2] Jon Bishop,[2] Maria D'Amico,[3] Khaled Ahmed,[2] Julie Dodds,[3] Kostas Tryposkiadis,[2] Mark Wilks,[4] Michael Millar,[4] Shahid Husain,[4] Jim Gray,[5] Angela Whiley,[4] Patrick V Moore,[2] Ruvimbo L Munetsi,[2] Karla Hemming,[2] Tracy Roberts,[2] Jane Plumb,[6] Jonathan Deeks,[2] Khalid S Khan[4] and Shakila Thangaratinam[7]* on behalf of the GBS2 Collaborative Group

[1]Nottingham Clinical Trials Unit, School of Medicine, University of Nottingham, Nottingham, UK
[2]Institute of Applied Health Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK
[3]Centre for Women's Health, Institute of Population Health Sciences, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, UK
[4]Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, UK
[5]Birmingham Women's and Children's NHS Foundation Trust, Birmingham, UK
[6]Group B Strep Support, Haywards Heath, UK
[7]Institute of Metabolism and System Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

*Corresponding author s.thangaratinam.1@bham.ac.uk

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).

Published February 2022
DOI: 10.3310/BICF1187

Plain English summary

The GBS2 cluster RCT

Health Technology Assessment 2022; Vol. 26: No. 12
DOI: 10.3310/BICF1187

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 13/82/04. The contractual start date was in May 2016. The draft report began editorial review in January 2020 and was accepted for publication in September 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).