The relative clinical effectiveness and cost-effectiveness of three contrasting approaches to partner notification for curable sexually transmitted infections: a cluster randomised trial in primary care

Jackie A Cassell, 1* Julie Dodds, 2,3 Claudia Estcourt, 4 Carrie Llewellyn, 1 Stefania Lanza, 1 John Richens, 3 Helen Smith, 1 Merle Symonds, 4 Andrew Copas, 3 Tracy Roberts, 5 Kate Walters, 3 Peter White, 6,7 Catherine Lowndes, 8 Hema Mistry, 5 Melcior Rossello-Roig, 5 Hilary Smith 1 and Greta Rait 2

Declared competing interests of authors: none

¹Division of Primary Care and Public Health, Brighton and Sussex Medical School, Falmer, Brighton, UK

²Medical Research Council, General Practice Research Framework, London, UK ³Research Department of Primary Care and Population Health, UCL and Medical

Research Council General Practice Research Framework, London, UK

⁴BICMS, Barts and The London School of Medicine and Dentistry, Queen Mary College, University of London, London, UK

⁵Health Economics Unit, School of Health and Population Science, University of Birmingham, UK

⁶MRC Centre for Outbreak Analysis and Modelling and NIHR Health Protection Research Unit in Modelling Methodology, Department of Infectious Disease Epidemiology, School of Public Health, Imperial College London, London, UK

⁷Modelling and Economics Unit, Centre for Infectious Disease Surveillance and Control, Public Health England, London, UK

⁸STI Section, Centre for Infectious Disease Surveillance and Control, Public Health England, London, UK

^{*}Corresponding author

Scientific summary

Approaches to partner notification for curable STIs

Health Technology Assessment 2015; Vol. 19: No. 5

DOI: 10.3310/hta19050

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

Scientific summary

Background

Partner notification (PN) is the process of providing support for, informing and treating sexual partners to individuals who have been diagnosed with sexually transmitted infections (STIs). It is traditionally undertaken by specialist sexual health services, and may involve informing a partner on a patient's behalf, with consent. With an increasing proportion of STIs diagnosed in general practice and other community settings, there is a growing need to understand the best way to provide PN for people diagnosed with a STI in this setting. We sought to undertake a randomised controlled trial (RCT) to evaluate the effectiveness and cost-effectiveness of different methods of PN in primary care.

Objectives

- 1. To standardise, appropriately for the primary care setting, three contemporary and evidence-based models of PN for STIs (patient referral, provider referral and contract referral).
- 2. To compare the clinical effectiveness of these three models.
- 3. To compare the cost-effectiveness of these three models.
- 4. To enhance the efficiency of the trial through mathematical modelling of the potential impact of each modality of PN on outcomes for different types of partner (main, casual and ex-partners) and for men who have sex with men.
- 5. To determine the acceptability to patients of each approach to PN, and to identify means for improving PN rates for 'highly connected' partnerships.
- 6. To provide comprehensive, definitive evidence for policy-makers and public health practitioners on the implementation of clinically effective and cost-effective PN for patients diagnosed with STIs in the primary care setting.

Design

Cluster randomised controlled trial.

Setting

General practices in England (66 practices proposed) and, within these, patients tested for and diagnosed in that setting with genital chlamydia or other bacterial STIs, with a target of 934 individual participants diagnosed with an STI.

Interventions

Three different approaches to PN: patient referral alone, or the additional offer of either provider referral or contract referral.

Main outcome measures

- 1. Number of main partners per index patient treated for chlamydia and/or gonorrhoea/non-specific urethritis/pelvic inflammatory disease.
- 2. Proportion of index patients testing negative for the relevant STI at 3 months.

Results

In phase 1 we piloted the processes of the RCT as proposed above. Testing rates for chlamydia were far lower than expected in response to our initial strategy for recruitment which used a mailshot inviting young people aged 16–24 years to attend the practice for a chlamydia test, alongside opportunistic testing.

In phase 2 we identified strategies aimed at improving recruitment within general practice through a process of literature review, practice consultation and wider data analysis.

In phase 3 we implemented these changes, but they were not effective in improving recruitment to the extent necessary to scale up the trial.

Phase 4 was a feasibility pilot of intensive recruitment. This succeeded in generating chlamydia tests in general practice.

Economic evaluation was not possible because of recruitment failure; cost comparisons with other care pathways and the costs of intensive recruitment are presented.

We were not able to scale up the trial, which was concluded at pilot stage, and are not able to answer the original research questions.

It was not possible to standardise provider and contract referral separately, and we present results of qualitative work aimed at optimising these interventions for future research.

Conclusions

External recruitment may be required to facilitate the recruitment of young people to research in general practice, especially in sensitive areas, because of specific barriers experienced by general practice staff. Costs and feasibility conditions need to be taken into account.

Partner notification interventions for bacterial STIs may not be clearly separable into the three categories of patient, provider and contract referral. Future research is needed to operationalise the approaches of provider and contract PN if future trials are to provide generalisable information.

Given the highly distributed pattern of chlamydia and other STI testing among general practice surgeries, future research in this field should take into account the fact that PN interventions need to be suitable for very occasional delivery.

Trial registration

This trial is registered as ISRCTN24160819.

Funding

Funding for this study was provided by the Health Technology Assessment programme.

HTA/HTA TAR

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

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

Editorial contact: nihredit@southampton.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

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 07/43/01. The contractual start date was in January 2010. The draft report began editorial review in June 2013 and was accepted for publication in November 2013. 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. 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.

© Queen's Printer and Controller of HMSO 2015. This work was produced by Cassell et al. under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

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

Editor-in-Chief of *Health Technology Assessment* and NIHR Journals Library

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Health Sciences Research, Faculty of Education, University of Winchester, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk