

Continuous low-dose antibiotic prophylaxis to prevent urinary tract infection in adults who perform clean intermittent self-catheterisation: the AnTIC RCT

Robert Pickard,^{1*†} Thomas Chadwick,²
Yemi Oluboyede,² Catherine Brennand,³
Alexander von Wilamowitz-Moellendorff,³
Doreen McClurg,⁴ Jennifer Wilkinson,³ Laura Ternent,²
Holly Fisher,² Katherine Walton,⁵ Elaine McColl,²
Luke Vale,² Ruth Wood,³ Mohamed Abdel-Fattah,⁶
Paul Hilton,⁷ Mandy Fader,⁸ Simon Harrison,⁹
James Larcombe,¹⁰ Paul Little,¹¹ Anthony Timoney,¹²
James N'Dow,⁶ Heather Armstrong,¹³ Nicola Morris,¹²
Kerry Walker⁴ and Nikesh Thiruchelvam¹⁴

¹Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK

²Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK

³Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK

⁴Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian University, Glasgow, UK

⁵Department of Microbiology, Newcastle upon Tyne Hospitals NHS Foundation Trust, Freeman Hospital, Newcastle upon Tyne, UK

⁶Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK

⁷Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, UK

⁸Health Sciences, University of Southampton, Southampton, UK

⁹Department of Urology, Mid-Yorkshire Hospitals NHS Trust, Pinderfields Hospital, Wakefield, UK

¹⁰Skerne Medical Centre, Sedgefield, UK

¹¹Primary Care and Population Sciences, University of Southampton, Southampton, UK

¹²Bristol Urological Institute, North Bristol NHS Trust, Bristol, UK

¹³Patient representative, no affiliation

¹⁴Department of Urology, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

*Corresponding author robert.pickard@newcastle.ac.uk

†Chief investigator

Declared competing interests of authors: Robert Pickard reports grants from the National Institute for Health Research (NIHR) during the conduct of the study. Thomas Chadwick reports grants from the NIHR Health Technology Assessment (HTA) programme during the conduct of the study and outside the submitted work. Katherine Walton reports grants from NIHR during the conduct of the study. Elaine McColl reports grants from the NIHR HTA programme during the conduct of the study and from the NIHR Journals Library outside the submitted work. From 2013 to 2016 she was an editor for the NIHR Programme Grants for Applied Research (PGfAR) series, with a fee paid to her employing organisation. Luke Vale reports that he is a member of the NIHR HTA Clinical Evaluation and Trials panel and is co-director of NIHR Research Design Service North East. Mohamed Abdel-Fattah reports grants from Bard Medical UK (Crawley, UK), Astellas Pharma Inc. (Tokyo, Japan), Coloplast (Humblebæk, Denmark), Pfizer Inc. (New York, NY, USA), Advanced Medical Solutions [(AMS) Winsford, UK] and Ethicon Inc. (Somerville, NJ, USA) outside the submitted work and is a member of the HTA Interventional Procedures panel. Paul Hilton reports a grant from the NIHR HTA programme during the conduct of the study and grants from the William Harker Foundation and Wellbeing of Women outside the submitted work. He was a member of the National Institute for Health and Care Excellence (NICE) Interventional Procedures Advisory Committee (2002–7), NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)-HTA Therapeutic Procedures Panel (2007–8) and NETSCC-HTA Clinical Evaluations and Trials Prioritisation Group (2008–10). He chaired the NICE development group for clinical guideline on urinary incontinence in women (2004–7). Mandy Fader reports grants from NIHR (reference number RP-PG-0610-10078) and from the Small Business Research Initiative grant outside the submitted work. Simon Harrison reports grants from the NIHR HTA programme (reference number 11/72/01) during the conduct of the study. James Larcombe reports grants from the NIHR HTA programme during the conduct of the study and is a member of the HTA Elective and Emergency Specialist Care panel. Paul Little reports that he is director of PGfAR and editor-in-chief of the PGfAR publication in the NIHR Journals Library. James N'Dow is a member of the HTA General Board. Nikesh Thiruchelvam reports grants from Astellas, non-financial support from Astellas and personal fees from Coloplast outside the submitted work.

Published May 2018

DOI: 10.3310/hta22240

Plain English summary

The AnTIC RCT

Health Technology Assessment 2018; Vol. 22: No. 24

DOI: 10.3310/hta22240

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

Plain English summary

People who have trouble emptying their bladders naturally often use a fine tube (catheter) inserted through the urine channel (urethra) into the bladder to drain urine 3–5 times a day. This is called clean intermittent self-catheterisation (CISC). About one-third of people who use CISC suffer frequent urinary tract infections (UTIs) that require antibiotic treatment. The repeated use of antibiotics may cause side effects and result in bacteria becoming resistant to antibiotics.

This trial was conducted to find out whether or not taking a daily low dose of antibiotic (prophylaxis) over 12 months was better than not taking prophylaxis in reducing the rate of infection for people carrying out CISC who suffer from repeated UTIs.

A total of 404 people took part in the trial. They were divided into two groups: 203 people took prophylaxis and 201 people did not. To make a fair comparison, people were put into the two groups at random using a computer program. We followed those who took part for 12 months and counted how many UTIs they suffered.

We found that people taking prophylaxis had half as many UTIs as those who did not use prophylaxis. The use of prophylaxis seemed worthwhile to patients and the NHS, with few side effects and only a small additional cost. Taking prophylaxis did not seem to improve overall well-being. This appeared to be because participants felt that UTI, although unpleasant, was not as bad as other health problems that they had to deal with. The main drawback was that infecting bacteria were more likely to develop resistance to antibiotics in people taking prophylaxis, making it more difficult to treat infection in those individuals and threatening public health. These results will help patients using CISC who suffer from repeated UTIs to decide whether or not taking prophylaxis is right for them.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the 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@nhr.ac.uk

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

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 11/72/01. The contractual start date was in September 2013. The draft report began editorial review in August 2017 and was accepted for publication in January 2018. 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.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Pickard *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. 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.nhr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Health Technology Assessment Editor-in-Chief

Professor Hywel Williams Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

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

NIHR Journals Library Editors

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

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

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

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

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

Professor Geoffrey Meads Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, 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 Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

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

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, 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: journals.library@nihr.ac.uk