

# A study of cellular counting to determine minimum thresholds for adequacy for liquid-based cervical cytology using a survey and counting protocol

Henry C Kitchener,<sup>1\*</sup> Matthew Gittins,<sup>2</sup> Mina Desai,<sup>3</sup>  
John HF Smith,<sup>4</sup> Gary Cook,<sup>5</sup> Chris Roberts<sup>2</sup>  
and Lesley Turnbull<sup>6</sup>

<sup>1</sup>Institute of Cancer Sciences, St. Mary's Hospital, University of Manchester, Manchester, UK

<sup>2</sup>Institute of Population Health, University of Manchester, Manchester, UK

<sup>3</sup>Cytology Department, Clinical Sciences Building, Central Manchester University Hospitals NHS Foundation Trust, Manchester, UK

<sup>4</sup>Department of Histology and Cytology, Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK

<sup>5</sup>Stepping Hill Hospital, Stockport NHS Foundation Trust, Stockport, UK

<sup>6</sup>Liverpool Women's Hospital, Liverpool, UK

\*Corresponding author

**Declared competing interests of authors:** Dr John HF Smith reports grants from the Health Technology Assessment programme, during the conduct of the study; personal fees, accommodation and travel expenses from BD (Becton Dickinson) Europe Speaker Bureau, BD Asia-Pacific Speaker Bureau, outside the submitted work. Dr Mina Desai has received travel money and accommodation paid for by BD company to lecture on the Scientific Symposium in Sweden and India. Professor Henry C Kitchener is the chairperson of the Advisory Committee for Cervical Screening, but all views are reported here are those of the author and not of Public Health England.

Published March 2015

DOI: 10.3310/hta19220

## Plain English summary

### Minimum thresholds for adequacy for LBC

Health Technology Assessment 2015; Vol. 19: No. 22

DOI: 10.3310/hta19220

NIHR Journals Library [www.journalslibrary.nihr.ac.uk](http://www.journalslibrary.nihr.ac.uk)

## Plain English summary

The introduction of liquid-based cytology, using the commercial SurePath™ (SP; BD Diagnostics, Burlington, NC, USA) and ThinPrep™ (TP; Hologic, Inc., Bedford, MA, USA) systems, to the UK Cervical Screening Programme has resulted in the proportion of inadequate slides falling from 7–8% to 1–2%. There is uncertainty regarding the minimum number of cells needed within these preparations to provide a reliable reading because an important reason for inadequate slides is insufficient cells.

This study, which was performed between 2008 and 2011 using routinely obtained cervical screening samples, sought to address this uncertainty by means of (1) surveying current laboratory practice; (2) assessing the reliability (between experienced readers) of counting the number of cells on a slide; (3) evaluating the relationship between cell counts and the grade of cellular abnormalities reported across a range of laboratories; and (4) evaluating the effect of cell dilution on the reliability of reporting.

The participating laboratories reported variable practice in defining an adequate cell count and cell counting protocol. When a pre-specified cell counting protocol was adhered to, counting was moderately/strongly reproducible. The currently reported 'inadequate' slides cover a wide range of cellularity, but the data indicate that minimum adequate cellular counts for the SP and TP systems of 15,000 and 5000, respectively, appear appropriate in terms of excluding slides suitable for reading below these counts, as detection rates fell in samples below these levels of cellularity.

It can be reasonably concluded that a standardised cell counting protocol would be valuable, setting a minimum adequate cellular count at 15,000 for the SP system and 5000 for the TP system.

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/](http://www.publicationethics.org/)).

Editorial contact: [nihredit@southampton.ac.uk](mailto:nihredit@southampton.ac.uk)

The full HTA archive is freely available to view online at [www.journalslibrary.nihr.ac.uk/hta](http://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](http://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 05/41/02. The contractual start date was in October 2007. The draft report began editorial review in May 2014 and was accepted for publication in August 2014. 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 Kitchener *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](http://www.journalslibrary.nihr.ac.uk)), produced by Prepress Projects Ltd, Perth, Scotland ([www.prepress-projects.co.uk](http://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](http://www.journalslibrary.nihr.ac.uk/about/editors)

**Editorial contact:** [nihredit@southampton.ac.uk](mailto:nihredit@southampton.ac.uk)