# Non-invasive testing for early detection of neovascular macular degeneration in unaffected second eyes of older adults: EDNA diagnostic accuracy study

Katie Banister,[1] Jonathan A Cook,[2]
Graham Scotland,[1,3] Augusto Azuara-Blanco,[4]
Beatriz Goulão,[1] Heinrich Heimann,[5]
Rodolfo Hernández,[3] Ruth Hogg,[4]
Charlotte Kennedy,[3] Sobha Sivaprasad,[6]
Craig Ramsay[1] and Usha Chakravarthy[4*]
on behalf of the EDNA study group

[1]Health Services Research Unit, University of Aberdeen, Aberdeen, UK
[2]Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK
[3]Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
[4]Centre for Public Health, Queen's University Belfast, Belfast, UK
[5]Liverpool University Hospitals NHS Foundation Trust, Liverpool, UK
[6]National Institute for Health Research Moorfields Biomedical Research Centre, Moorfields Eye Hospital NHS Foundation Trust, London, UK

*Corresponding author u.chakravarthy@qub.ac.uk

**Declared competing interests of authors:** Usha Chakravarthy received funding from Novartis (Basel, Switzerland) relating to the FASBAT study, which is an externally led (University of York, York) add-on to the EDNA study. Augusto Azuara-Blanco contributed to the Health Technology Assessment (HTA) Prioritisation Committees A (out of hospital; 2019–20) and B (in hospital; 2020 to present). Jonathan A Cook was a member of the HTA Efficient Study Designs and End-of-Life Care and Add-on Studies Boards (2014–16). Ruth Hogg contributes to an Advisory Board for Roche (Basel, Switzerland). Sobha Sivaprasad reports Honoraria for Advisory Board Attendance for Novartis, Bayer (Leverkusen, Germany), Allergan Inc. (Dublin, Ireland). Sobha Sivaprasad also reports grants from an investigator-initiated study from Allergan Inc.; a clinical research fellow salary from Bayer; Principal Investigator commercially sponsored studies from Novartis, Bayer and Allergan; advisory board attendance from Boehringer and Roche; a research grant from Boehringer; speaker fees and non-financial support from a research grant from Optos (Dunfermline, UK); and membership of the HTA Commissioning Committee (2017–present). Craig Ramsay is a Member of the National Institute for Health Research (NIHR) HTA General Board (2017–present). Usha Chakravarthy reports travel expenses for NIHR topic selection panel membership; advisory board fees (Alimera Sciences; Roche), Chair of International DMC for Trials (Bayer), consultation fees for research studies (Apellis); speaker fees (Novartis), membership of HTA IP Panel (2013–18) and HTA Prioritisation Committee B (2013–19).

Published January 2022
DOI: 10.3310/VLFL1739

# Plain English summary

## EDNA diagnostic accuracy study

Health Technology Assessment 2022; Vol. 26: No. 8
DOI: 10.3310/VLFL1739

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

# Plain English summary

Wet age-related macular degeneration is the leading cause of sight loss in older people. It is diagnosed using fundus fluorescein angiography, which involves photographing the retina after the injection of a dye into a vein in the arm, which may result in allergic reactions.

Many people with wet age-related macular degeneration in one eye will also develop it in their second eye. To avoid regular fundus fluorescein angiography, non-invasive tests are used to routinely monitor for wet age-related macular degeneration in the second eye of patients with wet age-related macular degeneration already in one eye.

We studied five commonly used and easily performed non-invasive tests to see which best detected the onset of wet age-related macular degeneration.

The five tests were:

- self-report of vision
- self-completion of an Amsler chart
- a standard sight test
- examination of the retina by a specialist
- optical coherence tomography, which is a non-invasive scan of the central retina.

If any tests suggested wet age-related macular degeneration, fundus fluorescein angiography was performed to compare results.

In total, 552 hospital eye clinic patients who had wet age-related macular degeneration in only one eye took part. Over a 3-year period, wet age-related macular degeneration developed in the second eye in 145 people (26%), of whom 120 had undergone fundus fluorescein angiography. In 25 people with wet age-related macular degeneration, fundus fluorescein angiography was not carried out for safety reasons or because the patient did not want to undergo it.

Of all the tests, only optical coherence tomography was good at detecting wet age-related macular degeneration correctly (92% sensitivity) and at detecting those who did not have wet age-related macular degeneration (88% specificity). All other tests either did not detect wet age-related macular degeneration consistently when it occurred or gave a false positive result when it had not occurred. This study confirmed that optical coherence tomography detected wet age-related macular degeneration correctly in the second eye of people with wet age-related macular degeneration in their first eye, and may offer cost saving for the NHS.

# 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 12/142/07. The contractual start date was in January 2015. The draft report began editorial review in September 2020 and was accepted for publication in April 2021. 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).