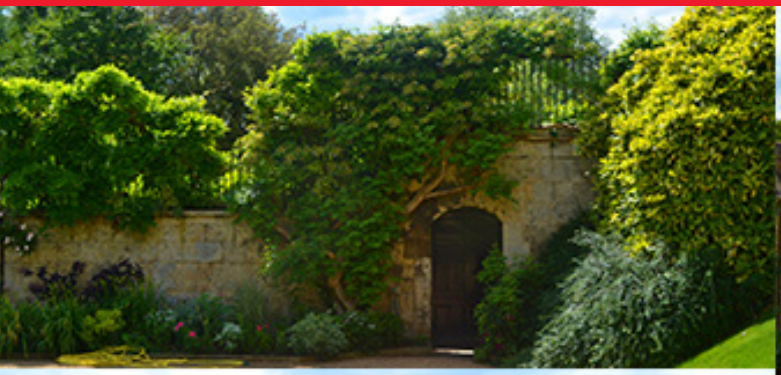
Diagnostic
Evidence Co-operative
Oxford

National Institute for
Health Research

Diagnostic Evidence Workshop




1-2 October 2015 Worcester College, Oxford

Welcome

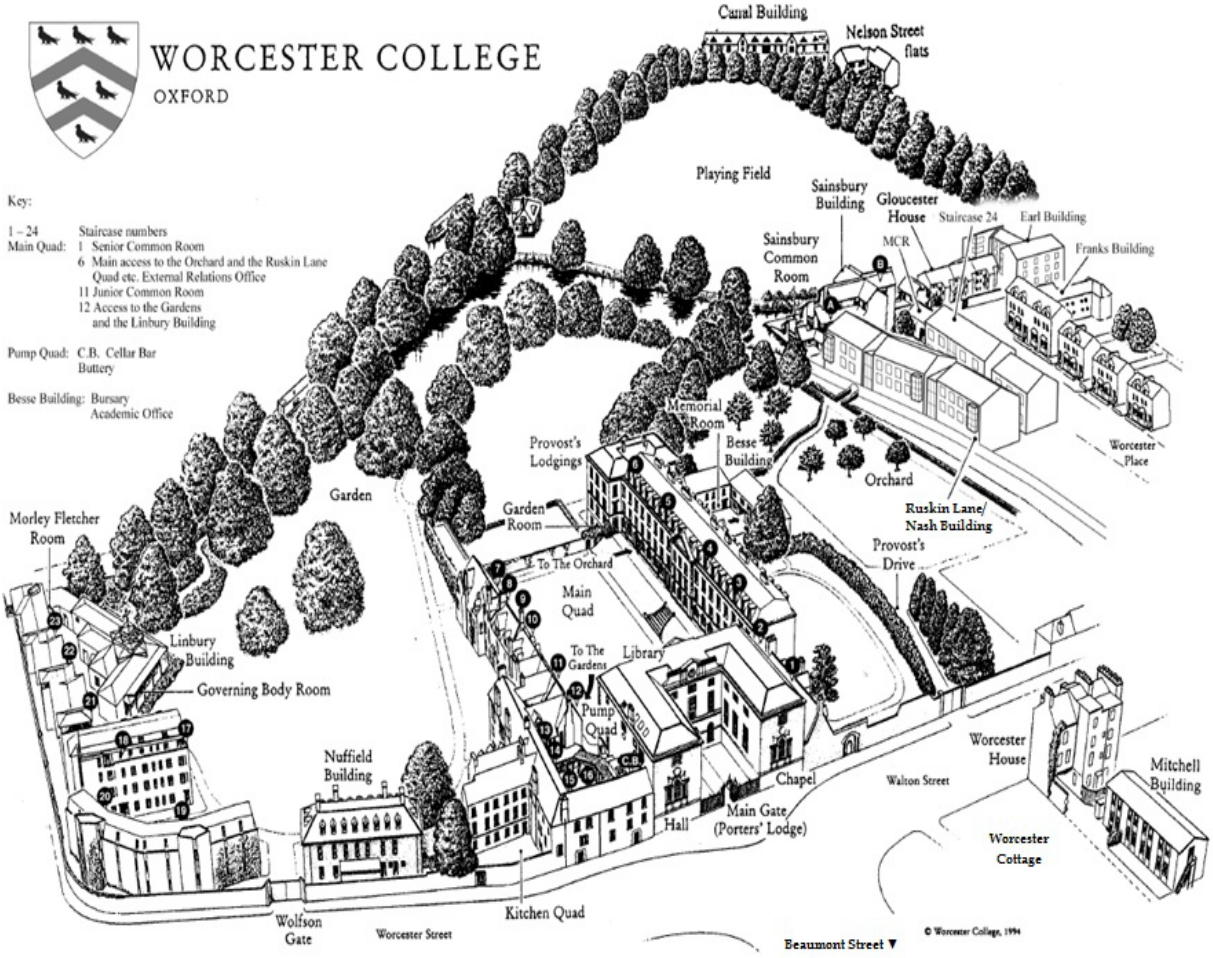
Welcome to the **second NIHR DEC Oxford Diagnostic Evidence Workshop**

During the next two days we will provide you with the latest information on what evidence is needed to obtain regulatory approval, how NICE evaluates new diagnostic technology and how to collect evidence to support adoption in routine clinical practice. In addition we will teach you about different study designs including quality assessment and where to look for funding opportunities.

We are very fortunate to have several speakers from our NIHR Diagnostic Evidence Co-operative (DEC) but also from other key organisations such as NICE, MHRA, NOCRI and the CPRD database.

We look forward to working with you!

Map


WORCESTER COLLEGE
OXFORD
Key:
1 – 24 Staircase numbers
Main Quad: 1 Senior Common Room
6 Main access to the Orchard and the Ruskin Lane Quad etc. External Relations Office
11 Junior Common Room
12 Access to the Gardens and the Linbury Building
Pump Quad: C.B. Cellar Bar
Buttery
Besse Building: Bursary
Academic Office
Canal Building
Nelson Street flats
Playing Field
Sainsbury Building
Gloucester House
Staircase 24
Earl Building
Sainsbury Common Room
MCR
Franks Building
Memorial Room
Provost's Lodgings
Besse Building
Worcester Place
Orchard
Ruskin Lane/ Nash Building
Provost's Drive
Garden
Morley Fletcher Room
Garden Room
To The Orchard
Main Quad
Linbury Building
Governing Body Room
To The Gardens
Library
Pump Quad
Nuffield Building
Chapel
Hall
Main Gate (Porters' Lodge)
Walton Street
Worcester House
Mitchell Building
Worcester Cottage
Wolfson Gate
Worcester Street
Kitchen Quad
Beaumont Street
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Programme
Thursday 1 October

Time	Title	Speaker/tutor	Location
9.00–9.40	**Registration and welcome**		**Linbury foyer**
9.40–10.20	Tests as part of a clinical pathway	Dr Ann Van den Bruel	Linbury room
10.20–11.00	Aligning research and development with clinical needs	Dr Philip Turner	Linbury room
11.00–11.30	**Tea/coffee break**		**Linbury foyer**
11.30–12.30	Different forms of evidence for different types of questions	Dr Ann Van den Bruel	Linbury room
12.30–13.30	**Lunch**		**Linbury foyer**
13.30–15.00	Workshop: How to avoid low quality studies	Dr Annette Pluddemann and Dr Ann Van den Bruel	Linbury room
15.00–15.30	**Tea/coffee break**		**Linbury foyer**
15.30–17.00	Workshop: Searching for existing evidence to support regulatory approval and other purposes	Dr Nia Roberts	Linbury room
17.00–19.30	Free time		
19.30–21.30	**Three course dinner**		**Dining hall**

Abstracts Thursday 1 October

9.40–10.20: Tests as part of a clinical pathway • Dr Ann Van den Bruel

Diagnostic tests are at the heart of clinical activity, and they are used for a variety of purposes including diagnosis, monitoring or screening. They are seldom used in isolation, but rather are one element of a larger clinical pathway. In this first session, we will set the scene for the next two days: the different roles of diagnostic tests, how tests can influence pathways, and why it is important to evaluate tests in their specific pathway.

10.20–11.00: Aligning research and development with clinical needs • Dr Philip Turner

A vast array of diagnostic tests are currently available with many more in development. With increasing expectations on healthcare providers in terms of care delivery coupled with tightening budget constraints (particularly in state-provided health services such as the NHS), healthcare commissioners have an increasingly difficult task to balance delivery and budget. This issue is not only a conundrum for commissioners, but also for those in diagnostics research and development. During the session we will examine some examples of methods which have been used to assess clinical need. We will use an example from UK primary care to illustrate one method in more detail.

11.30–12.30: Different forms of evidence for different types of questions • Dr Ann Van den Bruel

In this session, we will explore the different types of questions that could be asked when developing a new diagnostic test.These questions may range from classic accuracy to impact and costs. A variety of study designs may be used to answer these questions, and some designs may provide stronger evidence than others. Using real-life examples, we will discuss the different options and their effects on the confidence we have in the results.

13.30–15.00: Workshop: How to avoid low quality studies • Dr Annette Pluddemann & Dr Ann Van den Bruel

This workshop consists of an introduction presenting the different forms of bias and variability of diagnostic accuracy studies. We will then put this into practice by reviewing existing studies and identifying possible sources of bias. Strategies to avoid such pitfalls, or how to deal with inevitable sources of bias, will be discussed.

15.30–17.00: Workshop: Searching for existing evidence to support regulatory approval and other purposes • Nia Roberts

This session will focus on identifying supplementary evidence to inform the pathway from regulatory approval to the adoption of diagnostic technologies by patients, clinicians and health systems. We will look at refining search methods and selecting appropriate resources for searching for studies on diagnostic accuracy, economic evaluation and process assessment. A point-of-care testing scenario will be used to illustrate how queries need to be formulated on different search engines to optimise results. Participants will then have an opportunity to develop their own questions and gain practical experience of using the different search engines.

Programme Friday 2 October

Time	Title	Speaker/tutor	Location
9.00–10.00	Basic statistics in diagnostic studies	Dr Jason Oke	Linbury room
10.00–11.00	Evidence for regulatory purposes: CE marking and European IVD Directive	Steve Lee	Linbury room
11.00–11.30	Tea/coffee break		Linbury foyer
11.30–12.30	Evidence for implementation in routine clinical practice - NICE evaluations	Dr Sarah Byron	Linbury room
12.30–13.30	Lunch		Dining hall
13.30–14.10	Possibilities of routinely available data	Dr Antonis Kousoulis	Linbury room
14.10–14.50	Using evidence to support the business case: the route to adoption	Professor Chris Price	Linbury room
14.50–15.20	Tea/coffee break		Linbury foyer
15.20–16.00	Funding for diagnostic test development / opportunities for collaboration with academia	Ravi Chana	Linbury room
16.00–16.15	Closing remarks	Dr Ann Van den Bruel	Linbury room

Abstracts *Friday 2 October*

9.00–10.00: Statistics for diagnostic medicine • Dr Jason Oke

Assessing the quality of the information provided by diagnostic tests and their practical value is challenging. Test performance is often summarised using specialised statistical terminology and is frequently misinterpreted by experts and laypeople alike. This workshop will introduce the most commonly used measures in diagnostic accuracy research and demonstrate how they can be calculated and interpreted from clinical data via interactive exercises.

10.00–11.00: Evidence for regulatory purposes: CE marking and European IVD Directive • Steve Lee

A brief summary of existing requirements for CE marking together with an update on the new requirements of the imminent IVD regulations.

11.30–12.30: Evidence for implementation in routine clinical practice - NICE evaluations • Dr Sarah Byron

This session will cover the general principles of health technology assessment and the meaning of cost effectiveness, what is meant by value from the perspective of NICE, and how the value proposition links to the need for specific evidence. It will also explain how NICE assesses medical diagnostic technologies, particularly the work of the Diagnostics Assessment Programme which focuses on evaluating the clinical and cost effectiveness of diagnostic technologies to ensure the rapid and consistent adoption of innovative and effective diagnostic technologies in the NHS. This will include covering the types of evidence considered during an evaluation and the important factors to consider.

13.30–14.10: Possibilities of routinely available data • Dr Antonis Kousoulis

Databases of Electronic Health Records (EHR) are fast becoming an extremely important research tool worldwide. Due to the structure of the NHS, UK records are a valuable resource of information. This session, drawing from the long experience of the Clinical Practice Research Datalink (CPRD), will go in depth describing how to define a diagnosis in EHR, and further exploring ways to validate these diagnoses. We will discuss what evidence is available in routinely collected healthcare records, how these fit with new biomarker adoption, and identify what are the advantages as well as the challenges and limitations of working with EHR data.

14.10–14.50: Using evidence to support the business case: the route to adoption • Professor Chris Price

Adoption of new biomarkers is the translation of invention into practice based on demonstrating a benefit to patients and other stakeholders. The benefit is defined within a framework of clinical and cost effectiveness. The starting point will be the unmet need which will typically derive from clinical practice and the formal mechanisms of strategic planning and quality improvement. Adoption is viewed from three perspectives, namely outcomes, processes and resources. The business case can be seen as the bridge between the generation of evidence that the unmet need has been satisfied, and the translation of this proof into practice. The business case begins with the statement of unmet need, placed in the context of current clinical practice and processes, and resource utilisation. The core of the case is translation of the critically appraised evidence of effectiveness by identifying how practice, processes and resource utilisation will change in order to achieve the proposed benefits (outcomes), as well as building the implementation process.

15.20–16.00: Funding for diagnostic test development/opportunities for collaboration with academia and clinicians • Ravi Chana

Tutors

Dr Ann Van den Bruel, Associate Professor, Director of NIHR DEC Oxford

Ann has worked mainly on the diagnosis of serious infections in children, conducting a large-scale study in primary care to analyse the value of clinical features for this diagnosis. She looked at how laboratory tests can help and how parents and doctors view the diagnostic process when a child is admitted to hospital with a serious infection. The results of these studies have been used in several guidelines including one on feverish children by NICE.

Dr Annette Pluddemann, Director, Diagnostic Horizon Scan Programme, NIHR DEC Oxford

Annette's research aims to identify and assess the evidence for innovations in diagnostic technologies likely to have a significant impact in primary care, and disseminating this information to NHS bodies such as the Health Technology Assessment Programme and the NICE Diagnostics Assessment Programme. She is also the course director for the MSc in Evidence-Based Health Care, co-ordinator of the evidence-based diagnosis and screening module and a tutor for the Centre for Evidence-Based Medicine.

Dr Philip Turner, Researcher & Industry Liasion, NIHR DEC Oxford

Phil is the researcher within NIHR DEC Oxford who is responsible for liaising with members of the *in vitro* diagnostics industry and for facilitating interactions with the DEC advisory panel. He has a specific interest in IVDs which could be deployed in resource-limited settings.

Nia Roberts, Outreach Librarian, Bodleian Health Care Libraries

Nia contributes to the Horizon Scanning workstream at NIHR DEC Oxford. She collaborates with several research units and departments in the University of Oxford, contributing to systematic reviews and teaching literature searching and information management skills.

Professor Chris Price Visiting Professor in Clinical Biochemistry, Nuffield Department of Primary Care Health Sciences

Chris trained as a clinical biochemist and his early career was spent in the National Health Service. He was Professor of Clinical Biochemistry at the St Bartholomew's and Royal London School of Medicine and Dentistry from 1988 to 2001, and Director of Laboratory Medicine at the Barts and London NHS Trust from 1993 to 2001. From 2002 and 2005 he was Vice President of Outcomes Research in the Diagnostics Division of Bayer Health Care. He was Clinical Director of the Cumbria and Lancashire Pathology Commissioning Network between 2009 and 2011.

Tutors

Dr Jason Oke, Senior Statistical Researcher, Nuffield Department of Primary Care Health Sciences.

Jason's research interests include evaluating monitoring and screening programmes and overdiagnosis.

Antonis Kousoulis, Acting Head of Business Development at CPRD

Antonis qualified in medicine at the University of Athens, Greece, and has undertaken post-graduate degrees in public health at Imperial College London and at the London School of Hygiene and Tropical Medicine. He has been an investigator in various clinical research protocols and has published in peer-reviewed journals and presented extensively in scientific events.

Ravi Chana, Business Development Manager, NOCRI

Ravi's remit is to facilitate initial engagement between the life sciences industry and NIHR academic investigators, linking them together to form research collaborations and partnerships. He has a particular focus on NIHR medtech and diagnostic research, and has good connections to NIHR investigators/ centres that focus on medtech/diagnostic clinical research. He has worked closely with the NIHR Diagnostic Evidence Co-operatives (DECs) and the NIHR Healthcare Technology Co-operatives (HTCs).

Dr Sarah Byron, Technical Adviser, Diagnostics Assessment Programme, NICE

Sarah is the Technical Adviser for the Diagnostics Assessment programme at the National Institute for Health and Care Excellence (NICE). She has technical and scientific responsibility for the programme and the development of diagnostics guidance. Since joining NICE, Sarah has been involved in establishing and developing the two new programmes for assessing medical technologies: the Medical Technologies Evaluation programme and the Diagnostics Assessment programme. Sarah is also a member of the Equalities Expert Group and Research Advisory Group at NICE, in additional to participating in work with the European Network for Health Technology Assessment (EUnetHTA).

Steve Lee, MHRA

Chartered Scientist with 20 years of experience in biomedical sciences and regulation of *in vitro* diagnostic medical devices Chair of European Commission's IVD Working Group.

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5th UK Diagnostics Evidence Forum 2016

The next Forum is in the planning stages and will be held in Oxford during spring 2016. If you would like to attend, please email **dec@phc.ox.ac.uk** to join the mailing list.
www.oxford.dec.nihr.ac.uk/courses-and-events

A meeting of industry, academia and healthcare developing ways to facilitate the utilisation and adoption of innovative tests through good quality evidence.

If your company would be interested in sponsoring or exhibiting at the 2016 Forum, please contact: **dec@phc.ox.ac.uk**

UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF **PRIMARY CARE** HEALTH SCIENCES