

# Diagnosics Forum 2014 Report

*Changing the landscape of adoption of diagnostics*

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This report presents the key findings from the third UK Diagnostics Forum held at the University of Oxford on 18–19 March 2014, supported by Innovate UK (previously Technology Strategy Board), the British In-Vitro Diagnostics Association (BIVDA), the National Institute for Health and Care Excellence (NICE), and the National Institute for Health Research Diagnostic Evidence Co-operative Oxford at Oxford NHS Foundation Trust.

The UK Diagnostics Forum brings together leading experts from the UK diagnostics industry, clinicians, academic researchers, health economists, NICE, NIHR and Innovate UK.



# Diagnostic tests in the NHS

Diagnostic tests are central to many activities in healthcare. Labelling a patient with a certain condition explains that person's symptoms and offers prognostic information. It directs patients to treatment and further tests can be used to monitor a person's health. The demand for diagnostic services has increased over the past decade and the expectation is that it will increase even further: people are not only living longer, but also with (several) long-term conditions that require monitoring; technological advances make tests more available and more accurate; doctors become increasingly reliant on diagnostic information.

In 2012, the DH brought together leaders in diagnostic services to propose a vision for diagnostic services in 2020 and beyond (Department of Health – Diagnostic Services in 2020 and beyond: Visioning for the future v1.9 Dec 2012). In their report, they put the service user at the heart of service design, delivery and evaluation, based on three principles:

1. Availability and access to information should be improved, supporting patients in self-management
2. Widespread innovation should be accelerated
3. Pathways should be redesigned to support patients to manage their conditions, and to improve access to services

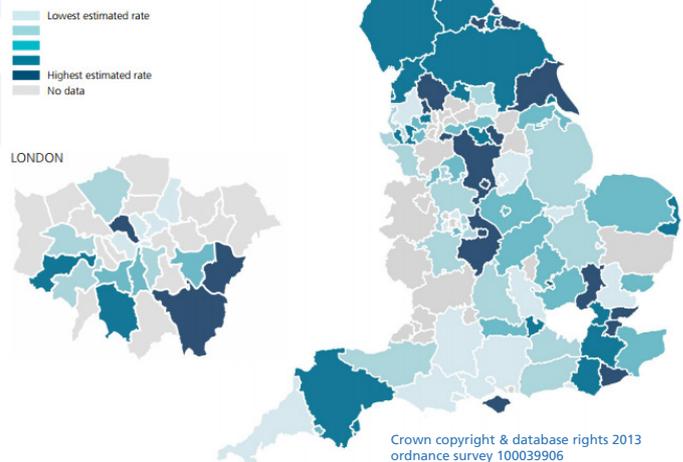
The NHS Atlas of Variation in Diagnostic Services published in November 2013 revealed a magnitude of variation in diagnostic test usage that was far greater than that seen for treatment. Although there will always be some variation because the needs of populations differ, variation may also be due to the fact that the evidence base for diagnostic tests is less strong than for treatment, clinicians sometimes perform diagnostic tests to be safe, and the diagnostic process is less well integrated in care pathways.

Typically diagnostic tests take at least ten years to be widely disseminated in routine clinical care, and some are adopted more in some areas than in others. Brain natriuretic peptide (BNP) has been recommended by NICE in patients with suspected heart failure since 2003. It has the potential to reduce the need for echocardiography by ruling out heart failure in primary care. Echocardiography services have difficulties coping with current demands, leading to long waiting times for patients and subsequent delays in treatment. Yet the uptake of BNP has been slow and patchy. In 2012, there was a 297-fold variation on the number of BNP tests performed annually between local health areas.

**Map 51:** Estimated annual rate of use for brain natriuretic peptide (BNP or NTproBNP) tests ordered by GPs per practice population by PCT

2012<sup>1</sup>

Domain 1: Preventing people from dying prematurely



*Reproduced from the NHS Atlas of Variation in Diagnostics Services with kind permission from Public Health England and NHS Right Care.*

This is not particularly different from what has been documented for healthcare innovation in general, with evidence-based findings to take an average of 17 years to reach routine clinical practice (Balas et al, 2000). Barriers to uptake and development of innovation in the NHS include budget constraints, the lack of national strategies and financial incentives, insufficient training, patchy procurement, a culture that is resistant to change, lack of clinical engagement, a failure to evaluate the impact of new innovations after implementation and consequential decision to stop doing things that are made redundant by the innovation.

Managing redundant resource utilisation can be challenging, for example, in the case where length of stay in hospital is reduced, or clinic visits saved.

In 2009, the NHS Institute for Innovation and Improvement summarized the main barriers to adoption:

- lack of communication: between healthcare sectors, between research and healthcare
- financial matters, such as budget restraints, budget silos, and research funding
- lack of evidence, including no good quality evidence and the wrong type of evidence
- time constraints: lag in research and publication of research, rushed adoption processes, lack of staff time to absorb innovation
- role of facilitators and champions: can be both facilitating or hindering
- staff training and education: to be considered throughout the adoption process
- staff resistance: reluctance to change, perceived negative impact on workflow
- technology itself, especially user friendliness
- infrastructure, including lack of space
- workforce shortage
- lack of leadership and management commitment.

*Source: Organisational and Behavioural Barriers to Medical Technology Adoption, NHS Institute for Innovation and Improvement, September 2009.*

# How can we overcome current barriers?

Barrier/problem	Potential solution
Clinical needs are not met	Engage with clinicians and healthcare providers early in the development process
A patient journey for one diagnostic problem may span several care settings involving multiple budget silos.	Commission the patient journey and not the service
Evidence requirements are high in relation to the expected return on investment	<p>Make the evidence gathering process more efficient by using routine data and practice based research</p> <p>Agree on shared standards for evaluation</p> <p>Simplify access to clinical and methodological expertise, e.g. DECs and AHSNs</p>
Classic economic analyses do not take all aspects of diagnostic test evaluation into account	<p>Develop specific methods to include other aspects such as patient experience/satisfaction, adherence to test results and pathways, timing effects and interpretation issues.</p>



# Evidence requirements vary between stakeholders

Before introducing a new diagnostic test in routine clinical practice, we need to understand its value to patients, to healthcare providers and healthcare commissioners to estimate the resources that will be required to adopt the new test compared to current practice and estimate any benefits to these stakeholders as well as to the wider society. This will require evidence to persuade different stakeholders along the way, including clinicians, commissioners and guideline developers.

Understanding the value of new diagnostic tests includes more than simply the acquisition cost of the test, and will help service managers, commissioners and local authorities understand the impact of introducing these new tests. Value may have a different meaning depending on the perspective of whoever is evaluating it: patients may attach a different meaning to value than providers, commissioners or society at large. Elements of value include core benefits, such as improved symptoms and wider elements of value, such as non-health benefits for caregivers. In order to be able to evaluate a diagnostic test's value, evidence is typically required on the clinical validity, clinical utility, cost-effectiveness, budget impact and impact on clinical pathway.

Box 1: key objectives for evidence gathering	
1. Clinical validity	Is the test accurate and reliable?
2. Clinical utility	Does the test have an impact on patient outcome?
3. Cost-effectiveness	Is the test worth its money?
4. Budget impact	How much will it cost, is there opportunity for disinvestment elsewhere and who is going to pay?

One of the major challenges in the field of evidence requirements for diagnostic test innovation is that a test may be used in a number of different ways, as well as in a range of care pathways and in different clinical settings. For example, HbA1c has been used to monitor diabetes treatment but is now also recommended for diagnosis. C-reactive protein may be used in primary care to rule out serious infections but may also be used in secondary care to decide to stop antibiotic treatment for patients hospitalised with pneumonia.

Recommendations:

- Identify the unmet clinical needs and the potential clinical utilities, e.g. screening, diagnosis, treatment and/or monitoring.
- Identify the care pathway(s) relevant to the diagnostic test.
- Consider early stage modelling to explore health and cost benefits.
- Identify possible benefits, harms and change in practice that might result from using the test.
- Identify the stakeholders who will be impacted by the introduction of the the test.
- Identify the investment and disinvestment decisions at a stakeholder level.

# Evidence requirements for NICE

NICE aims to improve outcomes for people using the NHS and other public health and social care services by producing evidence-based guidance and advice, developing quality standards and performance metrics for those providing and commissioning services and providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care. New diagnostics tests can be notified to NICE through the Medical Technologies Evaluation Programme (MTEP) for an evaluation selection and routing decision. This provides a single point of contact for evaluation of diagnostic tests, matching the value proposition of the new diagnostic to the most appropriate evaluation methodology.

Medical Technologies Evaluation Programme (MTEP)	Diagnostics Assessment Programme (DAP)
<p>Produces guidance on single, simple (i.e. the test is clinically non-inferior but may not provide extra health benefits) diagnostic topics.</p>	<p>Produces guidance on diagnostic tests and technologies that may have the potential to improve health outcomes in the following situations:</p> <ul style="list-style-type: none"> <li>a) where impact on clinical practice and/or costs to the NHS is not clear because of the complexity of the diagnostic or care pathway</li> <li>b) where introduction may be associated with an overall increase in cost to the NHS</li> <li>c) where meaningful assessment needs to consider multiple tests or technologies.</li> </ul>
<p>The guidance includes a summary on the test's diagnostic accuracy, clinical effectiveness and cost consequences analysis. MTEP also undertakes research commissioning for all medical technology programmes at NICE.</p>	<p>It evaluates diagnostic accuracy, clinical effectiveness and cost effectiveness (cost utility analysis) and produces guidance with adoption or research recommendations and is supported by independent external assessment groups.</p>
<p>Evidence is submitted by the sponsor, including a systematic review and economic model to support the case for adoption. The evidence should demonstrate equivalent or superior clinical performance and NHS cost savings, compared with current practice.</p>	<p>The programme sends out structured information request but there is no sponsor submission. Evidence includes a systematic review, modelling patient outcomes, costs and cost effectiveness, calculated in cost per QALY which requires evidence throughout the care pathway including treatment. When direct evidence is not available, a linked evidence approach is used that combines evidence on diagnostic accuracy with evidence on treatment efficacy.</p>

# Methods to make evidence gathering more efficient

Performing end-to-end studies for a diagnostic innovation is not always feasible: some conditions are diagnosed and managed in a variety of settings and pathways, there may be multiple treatment options leading to different outcomes depending on patient preferences and the outcome of interest (better health) may not become measurably different after a long follow-up of a large group of patients.

Through the use of modelling, we can understand the knock-on benefits and costs of new tests and their potential impact on pathways. In the current era of healthcare delivery, where process redesign is an important agenda item for most health economies across the world, it is important to understand the clinical, operational and economic perspectives of current practice and how innovation can contribute to each.

1. Obtain data and elicit expert opinion on disease progression or recurrence and test performance, as well as the processes of care.
2. Simulate patient cohort modelling disease progression and results of the monitoring tests based on evidence.
3. Simulate process redesign and resource utilisation.
4. Evaluate performance of alternative monitoring strategies.
5. Identify optimum strategies for further evaluation.

Many input variables are required for linked evidence of monitoring tests. For example modelling the impact of a new monitoring strategy for liver fibrosis, data are required on the condition's natural history (progression of fibrosis and variability at presentation, occurrence of liver related events), the new test's performance (measurement error and accuracy) and the effectiveness of subsequent treatment. The quality of each of these different data elements may vary in strength and, when more than one study is available for a particular data element, may even be contradictory. Routinely collected data such as electronic patient records or laboratory data may be a useful source of evidence as they will allow to better understand what is happening today and what might change after implementing a new test. Estimating the impact on patient outcomes may stretch the data too far, but it may prove very helpful in identifying the optimal strategies to be evaluated and predict the potential impact on outcomes.

Based on the results of modelling, the most promising test strategies may be evaluated in real life situations using Practice Based Research. Practice Based Research is research that is conducted in routine healthcare. It is the best setting for studying the processes of care and the manner in which diseases are diagnosed, treatments initiated and chronic conditions managed, linking bench discoveries to everyday effectiveness. It also allows barriers to implementation to be explored and addressed, including those from clinicians and patients. Importantly, patient outcomes are at the heart of any Practice Based Research study.

Finally, when a test strategy has been shown to have a positive impact on healthcare delivery and/or patient outcomes, a business case for providers (both in primary and secondary care) and commissioners needs to be developed. Considering budgets are compartmentalised, it is important to show the impact on all compartments in the healthcare delivery.

# NIHR infrastructure aimed at improving innovation in the NHS

“Our ambition must be for an NHS defined by its commitment to innovation demonstrated both in its support for research and its success in the rapid adoption and diffusion of the best transformative most innovative ideas, products and clinical practice”

Innovation Health and Wealth Accelerating the Adoption and Diffusion in the NHS  
DH 2011

In 2013, NIHR and DH set up new research infrastructure to support the development and adoption of clinically relevant innovation, including diagnostic tests. The goal is to transform research in the NHS, by increasing the volume of applied health research for the benefit of patients and the public and developing and supporting people who conduct and contribute to applied health research.

Unprecedented opportunity:	Unprecedented expectation:
Political drive	Delivering health gain
Clear national strategy	Delivering wealth gain
Supportive national structures	Harnessing the research potential of NHS
Alignment between major funders	Faster translation of basic research into applied research
Increased funding	Faster translation of applied research into patient benefit
Scientific advances across disciplines	Transforming public health through better evidence



# Funding streams for diagnostic test development and implementation

There are now a wide range of funding streams for diagnostic technologies. The list below provides some examples of available funding streams but is by no means comprehensive.

## **Efficacy and Mechanism Evaluation (EME)**

- Funded by NIHR and MRC.
- Sits between basic science and early clinical research and the more applied NIHR programmes.
- Actively supports the translational pull-through of promising innovations, with significant potential to benefit patients and the NHS in the medium to longer term, from early clinical studies into later phase evaluation.
- Funds science driven clinical efficacy studies to test interventions and provides the opportunity to explore disease or treatment mechanisms, which may in turn lead to improvements in health and patient care.
- Supports and encourages academics and clinicians to work with commercial organisations, in particular SMEs.

## **Invention for Innovation (i4i)**

- Designed to translate med tech innovations into patient benefit for the NHS with end user pull.
- Moving technologies and devices towards investor readiness with de-risked, compelling propositions.
- “Valley of Death” - funding for novel innovations which are too early stage to be funded by venture capital or private equity.
- Mission-critical funding for collaborations: universities, clinicians and med tech industry (focus on SMEs).
- Strong commercial, clinical, technology development and regulatory experience within the funding panel.

## **Health Technology Assessment (HTA)**

Supports research that is immediately useful to clinical practice and NHS decision makers. There must be preliminary evidence but with uncertainty around its clinical and cost-effectiveness compared to the current best alternative.

## **Innovate UK – Biomedical Catalyst**

Joint with Medical Research Council (MRC), aimed at small and medium-sized commercial enterprises. Divided into three classes: feasibility, early-stage and late-stage.

## **Horizon 2020**

Several calls might be relevant for diagnostic test development. Relevant calls include the SME Instrument, Information and Communication Technologies, or the Personalising Health and Care call.



## Case study – point-of-care tests

Point-of-care tests are tests that can be used at the patient's bedside, in the doctor's surgery or in the patient's home.

Rather than having to send a sample to the laboratory and then wait for the result to come back, point-of-care tests provide an immediate result, sometimes within 5 minutes. Having the result available faster can potentially impact on clinical decision making, such as the decision to refer a patient from primary to secondary care, antibiotic prescribing or arranging additional testing.

For example, point-of-care testing devices for chlamydia and gonorrhoea provide results within 30 minutes to 2 hours rather than after 10 days. This allows at-risk patients to be tested and treated in one visit to the genito-urinary medicine (GUM) clinic instead of two visits, speed up time to appropriate treatment while avoiding inappropriate treatment, reducing potential transmission as well as patients "lost-to-follow up", and subsequently decrease the number of patients with acute symptomatic pelvic inflammatory disease.

Implementing point-of-care tests requires the management of:

- quality control
- education and training of those conducting the tests
- record keeping of the results
- support
- regulatory issues
- evaluations.

In secondary care, these issues have been tackled by appointing point-of-care testing co-ordinators, point-of-care testing committees and point-of-care teams. The requirement to have a point-of-care testing committee is now in the procurement guidelines of the Pathology Services Specification. In primary care, there are some examples of good practice depending on the workload of the local point-of-care testing co-ordinator, but generally more support is required. Patients may benefit from stronger links between primary and secondary care, more specific guidelines and regulatory requirements for point-of-care implementation and quality control and better purchasing decisions.

# The Precision Medicine Catapult

Innovate UK has created a number of technology and innovation centres called Catapults, which are designed to accelerate and simplify the path from research to commercial products in a number of industries. The latest Catapult is focusing on precision medicine, with the aim of making the UK the leading place worldwide to develop and launch new solutions in this space.

Precision medicine is defined as the application of diagnostic tests to select the most appropriate treatment for individual patients. It is already worth £14 billion in annual sales of new therapies and diagnostic tests worldwide, and is forecast to reach £50-60 billion by 2020. The Catapult will help industry by offering a critical mass of multidisciplinary expertise, infrastructure and services. The ultimate goal is to simplify and accelerate precision medicine product development, help create new companies and attract inward investment by large life sciences companies.

The Catapult will take precision medicine products in clinical settings testing, provide clinical, technical and regulatory expertise, create opportunities for collaboration nationally and internationally and will become a source of business expertise and knowledge.

# Forum speakers

**Dr Matthew Thompson, Prof Christopher Price, Dr Ann Van den Bruel, Prof Carl Heneghan, NIHR Diagnostic Evidence Co-operative Oxford, Oxford Health NHS Foundation Trust**

**Dr Penny Wilson, Innovate UK**

**Doris-Ann Williams, British In-Vitro Diagnostics Association**

**Tony Soteriou, Department of Health**

**Prof John Simpson, NIHR Diagnostic Evidence Co-operative Newcastle, Newcastle Upon Tyne Hospitals NHS Foundation Trust**

**Dr Michael Messenger, NIHR Diagnostic Evidence Co-operative Leeds, Leeds Teaching Hospitals NHS Trust**

**Prof George Hanna, NIHR Diagnostic Evidence Co-operative London, Imperial College London**

**David Horne, Alere Connected Health Limited**

**Ravi Chana, NIHR Office for Clinical Research Infrastructure**

**Prof Gary Ford, Oxford Academic Health Science Network**

**Prof Mehdi Tavakoli, Health Technology Knowledge Transfer**

**Simon Kimber, School of Healthcare Science, Manchester Metropolitan University**

**Dr Elisabeth Adams, School of Social and Community Medicine, University of Bristol**

**Prof Jon Deeks, Department of Public Health, University of Birmingham**

**Dr Sarah Byron, National Institute for Health and Care Excellence**

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