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Innovation in Diagnostics and Healthcare: Improving bench to bedside processes for testing

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St Anne's College Oxford, November 11th 2011

Conference Organisers:

Centre for Monitoring and Diagnosis at the University of Oxford Department
of Primary Care Health Sciences, Technology Strategy Board, Diagnostics
Assessment Programme, National Institute for Health and Clinical Excellence,
British In-Vitro Diagnostics Association

Centre for Monitoring and Diagnosis (MaDOx)
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This report presents key findings from a meeting held at the University of Oxford on November 11th, 2011. The meeting was convened as an outcome of the Development and implementation of new diagnostic processes and technologies in primary care programme, funded by the National Institute for Health Research's (NIHR) Programme Grants for Applied Research, and received financial support from the NIHR, the National Institute for Health and Clinical Excellence, the Technology Strategy Board and the British In-Vitro Diagnostics Association. The meeting brought together leading experts from the diagnostics industry, academic researchers, and technology assessment bodies with the aim of devising a joint strategy to improve the translation of new diagnostic tests from research and development settings at the industry level, to front-line clinical use in the NHS. The aim of the meeting was to address three key questions: How can the generation of evidence for diagnostic tests be improved? How can we facilitate this process? and what studies are essential before introduction of tests into clinical practice?

The detailed programme and presenters are listed at the end of this report.

Foreword

Diagnostics have an increasing role to play in healthcare but having the right evidence to support technology is essential to allow innovation and widespread diffusion of new tests. So it is timely that the stakeholders for diagnostics took the initiative to widen the debate about the type of evidence appropriate to enable the wide spread use of diagnostics.

Last year Sir David Nicholson, Chief Executive of the NHS, asked me to lead a review into the adoption and diffusion of innovation in the NHS on his behalf. His report, *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS* sets out a delivery agenda for spreading innovation at pace and scale throughout the NHS.



Sir Ian Carruthers,
Chief Executive,
NHS South of England
& Chairman, Innovation,
Health & Wealth
Implementation Board

It sets out the actions we must now take to make innovation and its spread central to what we do. They are designed as an integrated set of measures that together will support the NHS in achieving a systematic and profound change in the way it operates. Many of the recommendations in *Innovation Health and Wealth* such as the alignment of financial incentives, building greater collaboration between industry, academia and the NHS and creating the systematic delivery mechanism for the spread of innovation will provide a platform to support the findings in *Innovation in Diagnostics: Improving Bench to Bedside Processes for Testing*.

I am pleased to introduce this publication, as implementing its findings and conclusions will bring great benefit to patients, the NHS and local communities.

Sir Ian Carruthers



■ The importance of diagnostic tests for health care in the UK and medical technology industry:

- Tests are involved across the board in almost all areas of health care – ruling in or ruling out particular conditions, monitoring people with established disease, screening asymptomatic people for disease.
- Nearly three quarters of all clinical decisions are made based on the results of standardised diagnostic tests (e.g. blood results, imaging results)
- UK is the 5th largest market for in vitro diagnostics in Europe
- The UK medical technology industry consists of over 3,000 companies with a combined turnover of £15bn

Introduction

There are numerous issues driving healthcare change within a framework that aims to improve quality, reduce risk and contain costs; ultimately offering better value to patients, purchasers and providers. So, whilst patients are demanding better access to care and better outcomes, commissioners and providers are looking at different ways of delivering care. This is set against a backcloth of rising healthcare demand, including substantial increases in the elderly population and those with long term conditions.



Drivers of diagnostic technology innovation and adoption:

- 1 Rapid and significant advances in test technologies
- 2 Increases in numbers of tests performed
- 3 Pressure from patients and carers for more accurate and rapid diagnoses

Diagnostic tests include a vast array of devices and technologies including blood tests, imaging devices, physiological markers, microbiology, pathology and genomic tests used in a variety of settings across healthcare sectors.

Three main shifts in health care are directly affecting the adoption and dissemination of new diagnostic technology. The first is the rapid and significant technological advances in tests and electronic devices. Tests which were previously only available in laboratory or hospital settings are now readily available as bedside “point of care” tests, or even for self-testing by patients. Secondly, there has been a marked increase in the number of tests performed, which partly reflects increased availability, but also expanded indications for monitoring of chronic diseases and targeting treatment. This includes new indications for screening and identification of earlier markers of disease. Thirdly, there are growing pressures from patients, clinicians, and health care commissioners who expect more rapid and more accurate diagnoses.

Translation of new diagnostic tests from research and development settings to clinical settings is hampered by a lack of clarity about what research evidence is required by stakeholders involved in the approval, adoption and reimbursement of new tests. At the same time, clinicians feel technological advances do not always match their needs.

Key stakeholders in this area include patients, primary care clinicians, pathologists and radiologists, diagnostic research methodologists, diagnostic technology industry, device regulatory agencies, and those responsible for funding (or commissioning) health care services (including health insurance carriers in some countries). The risk for patients and health care providers is failure (or delays) in adopting diagnostic innovations which could directly improve care. For the diagnostics industry, failure in transition of a new test from “bench to bedside” may result in decreased return on investment, a lack of future investment in the technology, and driving innovation into other markets.

This report presents the key findings from a meeting held at St Anne’s College Oxford in November 2011, hosted by the Centre for Monitoring and Diagnosis at the University of Oxford, the British In-Vitro Diagnostic Association, National Institute for Health and Clinical Excellence, and the Technology Strategy Board. We brought together leading experts from the diagnostics industry, academia, and technology assessment bodies with the aim of devising a joint strategy to improve the “bench to bedside” translation of new diagnostic tests from research and development settings at the industry level, to front-line clinical use in the NHS.

Dr Matthew Thompson

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Current challenges for diagnostic innovation

Regulation

In contrast to the European Medicines Agency which evaluates pharmaceutical products, there is currently no single European institution which evaluates diagnostic tests. This leads to a situation where companies need to present different evidence to European countries before market introduction. Moreover, requirements may vary within countries according to the nature of the test or the reviewer responsible for the evaluation. This lack of predictability hampers a standardised approach to generating evidence and the subsequent process of evaluation not only for regulatory approval, but also for impact analysis.

For the majority of diagnostic tests, the only formal evidence required for introduction on the European market is CE marking. In the USA it is FDA approval. The majority of diagnostic tests are classified as class II devices for CE regulation and therefore there is no formal requirement for evidence to demonstrate clinical utility, impact on health outcomes, or cost effectiveness. The exception to this situation is for tests that are included in national screening programmes.

Evidence generation

The evidence for clinical utility of diagnostic tests available in the peer-reviewed literature is typically poor, which limits the ability to recommend new tests in clinical practice guidelines. The majority of published research deals with the association between the test and the pathology of the disease, and the technical performance of the test, or involves poorly designed (or performed) studies which may not adequately fulfill quality standards for studies of diagnostic tests.

Clinical needs

There is not always a clear link between new tests brought to the market (supply) and clinical needs (demand). Development of new tests is often driven by technological possibilities rather than clinical problems. Although it is clear that the clinical utility of a new device may not yet be apparent in the design phase, many clinicians feel that the developers of new tests do not sufficiently address their day-to-day diagnostic problems or put them in context.

Commissioning

Purchasing and delivery of tests is typically undertaken according to a commodity, or fee-for-service, business model, often with little appreciation of the overall care pathway. Delivery is organised and budgeted as an independent “silo”, and incentives may exist to perform as many tests as possible, to maximise profit. As a direct consequence, there is little perceived linkage between availability of a test and improved health outcomes, whilst there is a widely held perception of both over-requesting of tests by clinicians, as well as underutilisation of tests.

Adoption

There are a number of barriers which reduce the speed of adoption of new diagnostic tests in the National Health Service (NHS). The pattern of uptake of new tests is variable across the UK, but widespread adoption typically takes about ten years. Moreover, the innovation and benefits claimed for a new test – such as changes in practice, improved outcomes and associated disinvestment in old tests and practices – are not always achieved in reality. The primary reasons for the slow speed of adoption is the poor understanding of the clinical need, the low quality of the evidence and the lack of understanding of the impact on care pathways and patient outcomes. As a consequence, the business case for new tests is often poor and the implementation strategy invariably absent or flawed – with limited commitment to changes in clinical practice and resource utilisation. In addition to slow adoption, these same issues give rise to highly variable patterns of adoption, with evidence of both under- and over-request of tests.

Regulation of In Vitro Diagnostics

In vitro diagnostics (IVDs) are one particular group of diagnostics. They are regulated differently from pharmaceuticals, and despite efforts to introduce a common worldwide regulatory framework under the Global Harmonisation taskforce, this is still years away from becoming a reality. Most significant global markets (outwith the US or EU) now have regulations in place including China, Japan, Brazil, Canada and Australia. Countries which do not have national regulation usually require either Food and Drugs Administration (FDA) or EU compliance.

Since 2003, IVDs in Europe have been subject to compliance with the Medical Device In Vitro Diagnostic Directive of the European Union. Countries in the European Economic Area also use the IVD Directive to form their regulations. This has had to be transposed into Member State law in each country, and in the UK is part of the Consumer Protection Act. The IVD Directive does not require evidence on the utility or effectiveness of an IVD, but tests must meet any product claims for technical specifications stated by the manufacturer. The IVD Directive is currently under review, and is likely to become an EU regulation rather than a directive, and may require evidence of clinical utility and effectiveness. The new regulation will probably not come into effect before 2017; the first draft version is likely to be available by the late autumn 2012.

In the United States IVDs are regulated by the FDA under two mechanisms: either 510(k) pre-market notification or pre-market approval (PMA). A 510(k) application can be made where the IVD can be shown to have at least equivalent

performance to existing tests/technology. As with the IVD Directive, such tests only need to prove technical claims made. PMA approval is required for high risk IVDs and for first to market tests or technology where a de novo exemption has not been agreed by the FDA. While this is much more rigorous in terms of the clinical performance data required than the 510(k) process, it still assesses the technical aspects of the test rather than clinical utility or outcome data. In addition, FDA approval is granted for use in a particular medical condition.

There are concerns, both in Europe and the United States, that some in vitro tests are being used without the required regulatory approval. It is the responsibility of those that “manufacture” and/or “use” these non-certificated tests to ensure that the requisite reagents have been prepared and validated to the standard expected by the regulations and regulatory authorities applicable in that country (i.e. the Consumer Protection Act, and the Medicines and Healthcare products Regulatory Agency in the UK).

References:

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2. MHRA guidance: <http://www.mhra.gov.uk/Howweregulate/Devices/InVitroDiagnosticMedicalDevicesDirective/index.htm>
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Current needs

Three key questions for diagnostic innovation:

- 1 How can we improve the generation of evidence for diagnostic tests?
- 2 How can we facilitate the generation of evidence with industry?
- 3 What studies are absolutely essential before introduction in clinical practice?

Improving the link between clinical needs and development of new tests by industry

Recent NHS reviews have highlighted that diagnostic services (e.g. pathology, radiology) are rarely involved in the strategic planning of services. For example, when Hereceptin was approved by NICE for treatment of women with HER2 positive breast cancer, there was little consideration given initially of the need for tests for Her-2/neu testing which is necessary to establish which patients are eligible for the treatment. As a consequence there were difficulties obtaining regulatory approval for this diagnostic test, and also there was no funding made available for providing the pathology services to deliver the test.

On the other hand, some tests are marketed without a clear clinical need. Examples include a rapid point of care test for syphilis, which is little used because clinicians usually want to test for several sexually transmitted infections at the same time, rather than just for syphilis alone.

Improving the level of engagement between industry developers of diagnostic tests, and clinicians who use diagnostic tests at an early stage is not only important, but essential for rapid deployment of new tests across a number of settings.

Diagnostic tests targeting unmet clinical needs are expected to have the greatest clinical impact, increase the likelihood they are adopted in the health service, and provide greatest return on investment. Identifying unmet needs at the outset increases the justification for investment in research and

development by industry (as well as NHS and other research funders), and allows prioritisation of new test development. Developers and researchers should also consider trends that may change the clinical need and market; for example the introduction of a vaccine could drastically reduce the need for a diagnostic technology.

Understanding the place of a new diagnostic technology in the clinical pathway for a given condition highlights the most appropriate uses of a new test. This may include replacing an existing test, as a triage test to direct the need for additional tests, or as an add-on test performed after the current diagnostic workup to further stratify patients. Understanding the role of a new test highlights its impact on existing diagnostic test pathways, and resource utilisation, and may identify places where disinvestment in existing diagnostics may be possible.

Clinicians knowledgeable in individual clinical areas understand where diagnostic problems currently exist in clinical pathways and the ways in which new diagnostic tests would improve clinical outcomes (emphasising clinical utility rather than less clinically relevant and process outcomes). However, the diagnostic challenges may vary not only from one centre to another across the UK as well as between countries, so that care should be taken in defining new test requirements.

Equally, engaging with patient or carer representatives or disease advocacy groups can sometimes identify unmet needs and difficulties in existing NHS pathways and services for particular patient groups (e.g. housebound elderly), or disease areas (e.g. patients with diabetes). These can be used to prioritise needs and identify essential characteristics of diagnostic tests that may not be apparent to test developers.

Therefore, an essential starting point in improving diagnostic test development and adoption is more effective communication between clinicians and diagnostic test developers. This engagement can occur at national levels (e.g. in response to Department of Health priorities) or at regional or local levels (e.g. in response to local commissioners). However, with the planned increased devolution of strategic decision making in NHS care to local commissioning groups, it may be more difficult to communicate strategic objectives to industry, and points to the need for a central or co-ordinated forum to facilitate this.



Engaging research funders, academic institutions, NHS bodies

There is currently too little communication between the diagnostic industry and the major bodies who commission research in the UK (e.g. National Institute of Health Research, Wellcome Trust, Medical Research Council), and also the academic and NHS organisations who conduct much of the research. Although there are notable exceptions, to a large extent these sectors tend to operate in isolation.

This can lead to lack of awareness among industry of NHS research funds that may be available to fund clinical research at various stages of new test development. Given the relatively poor return on investment for many diagnostic tests, the opportunity to access funds from UK research bodies may help to offset research and development costs borne by industry.

In addition, there is often a lack of funds for implementation research that is so vital in understanding the role of the test in the clinical pathway. Such research is vital to improve the understanding of the role of the test but also its subsequent uptake. Implementation research of this nature is relatively cheap to undertake given the right infrastructure is in place.

The lack of awareness of sources of funding is compounded by lack of skills and opportunities to engage with and collaborate with academic and health services partners in seeking research funds. Conversely, relatively few academic groups are experienced in conducting diagnostic research, and academic clinical researchers may have difficulties in finding appropriate industry groups who are developing new diagnostic tests and who are interested in collaborating on clinical studies.

Disconnect between industry, the major funders, and clinical researchers involved in research on diagnostic tests is currently hampering diagnostic test development.

■ **Recommendation 1:** Early engagement is needed between clinicians (and patients) and the diagnostics industries in order to identify current (and where possible future) needs for testing. This will prioritise clinical conditions and health service areas where new tests are likely to have greatest clinical impact and steer research and development

■ **Recommendation 2:** Understanding where a new diagnostic test lies within the clinical pathway for a particular clinical condition requires closer interaction between clinicians and diagnostic test developers. This will clarify intended uses of the new diagnostic test, identify opportunities for disinvestment in existing pathways, and options for reimbursement.

■ **Recommendation 3:** Initiate a group or forum to facilitate improved communication between research funding bodies, diagnostics industry, academic researchers, and NHS bodies, to improve access to UK funding bodies' existing mechanisms to support R&D, and facilitate funding and operationalising of clinical studies.

Reducing financial barriers to evidence generation

There are several financial disincentives among both industry and research funders to invest in generating research evidence for new diagnostic tests, including demonstrating the cost effectiveness of new tests.

For the diagnostic technology industry, the return on investment for diagnostics is lower, and the rapidity of change in technology is higher than for new pharmaceuticals. This leads to pressures to minimise research evidence generation to the minimum necessary for regulatory approval, whilst maximising market share irrespective of clinical outcomes.

For the NHS, assessing the cost effectiveness of new tests (e.g. one that replaces an existing test) is essential. The financial impacts of new tests need to consider potential savings in other more costly services. In some cases this may involve more accurate targeting of treatments and improved patient outcomes. In others it may result in reductions in need for referrals or more costly tests. For example introduction of a point of care test for B-Natriuretic peptide (a biochemical marker of heart failure) in primary care could reduce the need to refer patients to cardiology services for a more costly echocardiography test to determine whether heart failure is present. This might allow disinvestment in some services (echocardiography in this case). Conversely however, introduction of some new diagnostic tests can lead to recategorising previously healthy patients as 'diseased', and lead to higher treatment costs. Since most diagnostic services operate on a fee-for-service model, where there is no link between reimbursement and impact on outcome, it can be difficult for industry to estimate the likely financial impact of adopting a new test, further reducing incentives to invest in new tests.

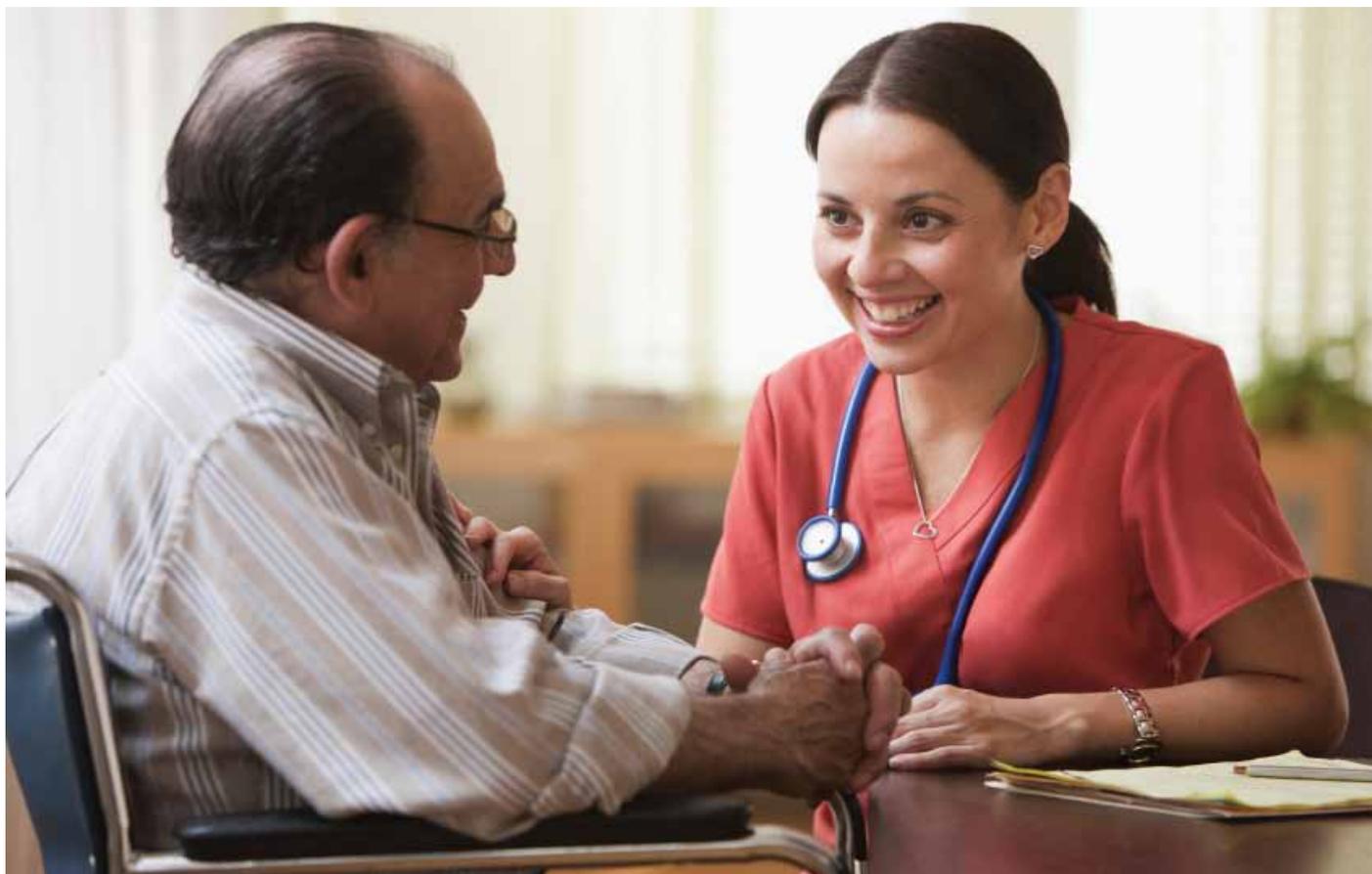
In order to fully understand and quantify the impacts of introducing of new tests, it is necessary to develop sophisticated cost effectiveness models. Such models can also be used to derive evidence on the transfer of savings, and the potential for disinvestment following the introduction of a new test. This is increasingly important within the current climate of constraints on health care expenditure. Cost effectiveness models need to be developed that take account of the spectrum of care, dispensing with the "silo" approach of assessing costs, and looking for impacts on costs along the entire clinical pathway.

■ **Recommendation 4:** Research studies on new diagnostic tests need to include health economic modelling of the costs of introducing a new test, taking into account downstream consequences (and potential for disinvestment). A central organisation could provide access to health economic expertise for the UK, including health care costs, health service needs and priorities related to diagnostics, and facilities for modelling.

Increasing the speed of dissemination and adoption to new diagnostic tests

The length of time currently taken to achieve widespread adoption of a new test in the NHS is estimated at 10 years. Some of the reasons for this, such as poor understanding of the clinical need and the lack of understanding of the impact on the care pathway and patient outcomes have already been mentioned. In other cases it may be due to lack of awareness of diagnostic problems in certain clinical areas, or lack of training among health care staff. However, these can contribute to poor business cases for new diagnostics, and an implementation strategy that may be flawed, with limited commitment to changes in clinical practice and resource utilisation. These also lead to highly variable patterns of adoption, with evidence of both under- and over request of new tests. Employing the key elements of commissioning for the use of diagnostic tests offers the opportunity to monitor appropriate utilisation of tests – taking a whole care pathway approach rather than simply the number of tests requested. In addition it offers the opportunity to address issues of clinical safety and more targeted post-launch surveillance.

■ **Recommendation 5:** The implementation strategy for a new diagnostic test needs to involve a structured business plan, including performance management following introduction. This is likely to involve working with commissioners, specialists and GPs.



Developing an evidence ‘toolkit’ for diagnostic test research

A lack of consensus about how much evidence is sufficient for regulatory approval and adoption in the NHS leads to uncertainty for industry. This contrasts with the well accepted model used for new pharmaceuticals which guides evidence generation for regulatory submission and adoption.

The most important issues where there is currently uncertainty in the diagnostic industry is the extent to which evidence is required on clinical utility (rather than clinical validity), effects on patient outcomes, and less direct outcomes of diagnostic tests. For example, does a company which is attempting to market a new rapid point of care test to detect troponins (a biochemical marker for myocardial damage) in patients presenting to the Emergency Department with chest pain need to show that it reduces hospital admission rates, or is it sufficient to show correlation of the new rapid test with the existing laboratory test?

In addition there is uncertainty about the differing evidence requirements when a new test is replacing an existing test or is a new technology, and evidence requirements for particular patient subgroups.

Numerous frameworks have been proposed to assess the evidence for new diagnostic tests, and can be used to highlight evidence gaps in the process of moving from test development to test adoption. (see Box). Most are based on a model for the evaluation of imaging tests from the 1970s. These typically involve 4 steps: analytic validity, clinical validity, clinical utility, and cost effectiveness and other effects on health care outcomes. However, although several similar frameworks have been proposed by diagnostic researchers, few are widely known among test developers. They do not identify the research steps that are needed along the path from bench to bedside, and mostly imply a linear process for development, rather than the cyclical process that occurs in reality.

Another major area of uncertainty is the research designs needed at each of the steps. These include, knowing when

a randomized trial is needed or when other types of study design are sufficient; whether the research methods used depend on the type of diagnostic device; and when evidence needs to be generated for effects of tests on patient outcomes and service changes rather than changes in analytic sensitivity or specificity etc. Moreover, in some cases, benefit to the end users is not always apparent until full adoption of the test occurs.

Given the relatively poor return on investment and rapid changes in diagnostic tests, there is a need to consider ways to improve the efficiency of evidence generation. One important issue is the generalizability of diagnostic test evidence. For example, evidence for some tests may need to be country-specific or even region-specific, but evidence for some tests may be directly relevant across multiple countries, therefore providing good value for research investment. All too often however, industry and health technology assessment agencies are forced to repeat studies to generate the appropriate evidence.

At a European level, EUnetHTA brings together 34 organizations from the EU Member States, Accession Countries and EEA to develop reliable, timely, transparent and transferable information to contribute to health technology assessments in European countries. Other efficient solutions could include the use of stored samples, “piggy backing” on top of other funded trials or studies in order to gain access to data while minimizing additional research costs, and collecting individual patient data which can provide additional evidence on subgroups.

Given the importance of cost effectiveness, the diagnostics industry and the NHS require more efficient ways of performing cost effectiveness modelling. There is currently no single “one stop shop” central organisation or repository which could provide access to a central database of health care costs, health service needs and priorities, and diagnostic costs, access to modelling (e.g. modelling for point of care test cost effectiveness), and resources to help develop evidence for a business in certain areas of diagnostics.

Frameworks for diagnostic tests

Shared components of frameworks which propose a chain of phases used to evaluate the evidence for new tests:

Analytic validity:

How well new assay performs in laboratory setting (technical efficacy etc)

Clinical Validity:

Accuracy of test to diagnose outcome of interest in clinical settings

Clinical Utility:

Effects on clinical decision making, and patient outcomes

Other effects:

Cost effectiveness
Ethical, legal or societal implications

Recommendation 6: Develop a ‘diagnostic research toolkit’ as a collaboration between academic researchers and industry, which would identify a pragmatic framework which can be used by multiple stakeholders (e.g. industry, regulators, HTA bodies, funders or commissioners) to assess where a new test lies in the pathway from development to dissemination. It would also clarify the research methods needed to address particular evidence gaps, and the most appropriate and efficient study designs needed at each stage.



Summary of recommendations and next steps

The conference identified six recommendations which were considered key for improving the pathway from development of new diagnostics tests to their dissemination:

1 Early engagement is needed between clinicians (and patients) and the diagnostics industries in order to identify current, and where possible future, needs for testing. This will prioritise clinical conditions and health service areas where new tests are likely to have greatest clinical impact and steer research and development

2 Mapping where a new diagnostic test lies within the clinical pathway for a particular clinical condition requires closer interaction between clinicians and diagnostic test developers. Mapping the clinical pathway will clarify intended uses of the new diagnostic test; identify opportunities for disinvestment in existing pathways, and options for reimbursement.

3 Initiate a forum to facilitate improved communication between research funding bodies, diagnostics industry, academic researchers, and NHS bodies, to improve access to UK funding bodies' existing mechanisms to support R&D, and facilitate funding and operationalising of clinical studies.

4 Research studies on new diagnostic tests need to include health economic modelling of the costs from introducing a new test, taking into account downstream consequences (and potential for disinvestment). A central organisation could provide access to health economic expertise for the UK, including health care costs, health service needs and priorities related to diagnostics, and facilities for modelling.

5 Implementation strategies for new diagnostic tests require a structured business plan, including performance management following introduction. This is likely to involve working with commissioners, specialists and GPs.

6 Develop a 'diagnostic research toolkit' as a collaboration between academic researchers and industry, which would identify a pragmatic framework which can be used by multiple stakeholders (e.g. industry, regulators, HTA bodies, funders or commissioners) to assess where a new test lies in the pathway from development to dissemination. It would also clarify the research methods needed to address particular evidence gaps, and the most appropriate and efficient study designs needed at each stage.

Next steps



This report will be disseminated widely to stakeholders in this area, including key leaders in the Department of Health, National Institute for Health and Clinical Excellence (NICE), the Technology Strategy Board (TSB), the British In-Vitro Diagnostics Association (BIVDA), industry groups, commissioners, diagnostic researchers, and all conference attendees. Based on the response, we propose setting up a steering group comprised of key stakeholders from these groups, which will lead further discussion and prioritise implementation of the conference recommendations.

We propose three ways to take forward the Conference recommendations:

1 Set up a UK 'Diagnostics Forum'

An ongoing 'Diagnostics Forum' could act as a catalyst to develop a strategy to continue dialogue between stakeholders. One of the main priorities will be to explore ways to improve integration of clinical input into the prioritisation and development of new diagnostic tests (Recommendations 1 & 2). The forum could also explore the feasibility of setting up an epidemiology network similar to the FDA's Medical Device Epidemiology Network Initiative (MDEpiNet), to facilitate the sharing of data on diagnostic test use and performance in different NHS settings.

In addition, the steering group will seek funding to develop a more robust approach to needs assessment, and to conduct rapid needs assessments across key clinical areas. This could include working with relevant Royal Colleges and across health care sectors to identify unmet needs, and also identifying diagnostic gaps identified in NICE guidelines and commissioning quality standards. The group will also seek funding to support a Horizon Scanning system for new and emerging diagnostic technologies to provide rapid assessment and highlight critical steps needed for industry, research, and implementation.

2 Develop a diagnostic toolkit

There is clearly a pressing need to bridge a gap that exists in terms of evidence requirements for new diagnostic tests between developers of new tests on the one hand, and on the other the various organisations who 'assess' new tests including regulators, NICE and commissioners of diagnostic services. Academic researchers sit in the middle between these groups, but need to develop a clearer approach to identifying what types of evidence are required for each of these bodies in the UK, and the transferability of this evidence across borders.

We therefore propose developing a diagnostic evidence toolkit. (Recommendation 6) The toolkit will propose a common approach to understanding the evidence needed at each step from test development to adoption, including what evidence is needed, what study designs are appropriate, which research designs are most efficient, and which translate between countries and different settings etc. Funding to support the development of the toolkit will be identified from existing NIHR research methodology calls.

3 Improve the financial incentives

The combination of continued pressures on NHS funding on the one hand, and central support for encouraging the development of the medical technology industry in the UK highlights the need to develop a more sophisticated understanding of the potential financial impacts of the introduction of new diagnostic tests. This includes where necessary disinvestment in existing tests and other health care resources.

This means that we need to find ways to facilitate research and health economic modelling that are directly applicable to the UK. This could include generic modelling tools, a central source of UK health care costs etc that could be used by diagnostic researchers and industry partners. (Recommendation 4). This in turn will help the diagnostics industry develop better business cases for implementation of new tests (Recommendation 5).

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