The Academy of Medical Sciences

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Accelerating access to medical innovation: a research agenda for innovation science

Summary report of a workshop held on 13 June 2017, supported by the Medical Research Council and the National Institute for Health Research

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MRC Medical Research Council

NHS
National Institute for Health Research

The National Institute for Health Research

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The Centre for the Advancement of Sustainable Medical Innovation

CASMI is the Centre for the Advancement of Sustainable Medical Innovation, a partnership between Oxford University and UCL, created to develop new models for medical innovation. The centre aims to address the issues that have led to current failures in the translation of basic bioscience into affordable and widely adopted new treatments.
By bringing together a broad range of academic disciplines and other stakeholders, including patient groups, industry, regulators, policy-makers and clinicians, CASMI will tackle the problem at a systemic level, designing socially and economically sustainable solutions that are acceptable to all.

The Academy of Medical Sciences

The Academy of Medical Sciences is the independent body in the UK representing the diversity of medical science. Our mission is to promote medical science and its translation into benefits for society. The Academy's elected Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service. We work with them to promote excellence, influence policy to improve health and wealth, nurture the next generation of medical researchers, link academia, industry and the NHS, seize international opportunities and encourage dialogue about the medical sciences.

The Academy of Medical Sciences' FORUM

The Academy's FORUM was established in 2003 to recognise the role of industry in medical research, and to catalyse connections across industry, academia and the NHS. Since then, a range of FORUM activities and events have brought together researchers, research funders and research users from across academia, industry, government, and the charity, healthcare and regulatory sectors. The FORUM network helps address our strategic challenge 'To harness our expertise and convening power to tackle the biggest scientific and health challenges and opportunities facing our society' as set in our Strategy 2017-21. We are grateful for the support provided by the members and are keen to encourage more organisations to take part. If you would like further information on the FORUM or becoming a member, please contact forum@acmedsci.ac.uk.

All web references were accessed in July 2017

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Executive Summary

The UK has an international reputation for excellence in biomedical and health research. However, translation, uptake and adoption of medical innovation in the NHS is slow due to challenges along the innovation pathway. These challenges are compounded by rising demands for sustainability and affordability in the NHS and the changing paradigm of healthcare delivery. To maintain the UK's excellence in medical science and support the entirety of the research and innovation pathway from early scientific development through to patient access, there is a need to identify the key barriers to accessing medical innovation and find new ways to overcome them.

On 13 June 2017, the Academy of Medical Sciences and the Centre for the Advancement of Sustainable Medical Innovation, supported by the Medical Research Council and the National Institute for Health Research, held a FORUM workshop on 'Accelerating access to medical innovation: a research agenda for innovation science'. Participants focused on innovation at three levels: innovation and the individual; the value proposition of innovation; and a systems approach to innovation. After identifying the challenges to the uptake and adoption of research and innovation at each of these levels, participants posed a series of research questions as part of a research agenda for innovation science that would help to address these challenges and drive better access. The key themes of discussion were:

- The importance of a **multidisciplinary approach** to innovation that incorporates a breadth of disciplines including biomedical, economic and social sciences. It is essential to consider the **social context** in which an innovation is used, including developing a better **understanding of the behaviour and motivations** of individuals involved in areas such as patient adherence and prescribing practices.
- **Involvement of different stakeholders** at various points in the innovation pathway, and the optimal models for this engagement and 'co-design' across patients, the public, commissioners, regulators and clinicians. This included discussions around designing innovation based on a real understanding of 'need' rather than ill-informed assumptions.
- Allowing for **individual needs in a population setting** and achieving an appropriate balance between personalisation or tailoring of innovation and broader applicability. This also includes considering differing local or regional environments alongside demographics and political context.
- Building a **strong evidence base for innovations,** whether around relevance, utility, applicability, economics, behaviour or impact, to encourage uptake and adoption.

- Considering the **value of innovation in the context of needs**, such as affordability challenges in the NHS, and incorporating these needs into the early design of innovation.
- Investigating a **broader definition of value** beyond direct health outcomes to incorporate wider measures such as social values and the downstream benefits of an innovation potentially outside of the healthcare system. For example, changing complex care pathways can unlock 'value' in many different places. The **weighting or balance of these different values** must also be agreed.
- The need for robust **evaluation of innovations and innovation pathways** to enable iteration and improvement of innovation and for demonstration of impact to create a compelling case for adoption across different stakeholders, potentially through piloting in small areas – often termed as 'commissioning through evaluation'.
- **Incentivising system change** for uptake and adoption of innovation, including establishing clear accountability for such change and encouraging leadership and early adopters.
- Finally, it was noted that **data underpin all of these discussions** and is central to much of the research agenda. There is an urgent need to better integrate and use the large volume of data held in the NHS and make these data more easily accessible for research to ensure future access to medical innovation and support general research and innovation processes.

Building a research agenda for innovation science: setting the scene

Whilst notable challenges remain around access to medical innovation, there are also significant opportunities for accelerating adoption and overcoming these barriers through creating a clear research agenda for innovation science. This would complement the steps to addressing some of these challenges outlined in the Accelerated Access Review and the Life Sciences Industrial Strategy, which can be used to drive progress in this area through fostering collective working across the life sciences ecosystem.[1,2]

Therefore on 13 June 2017, the Academy of Medical Sciences and the Centre for the Advancement of Sustainable Medical Innovation (CASMI) held a workshop, supported by the Medical Research Council and the National Institute for Health Research, examining ways to accelerate access to medical innovation. This aimed to build a research agenda for innovation science that will drive the uptake and adoption of innovation, focusing on three particular areas for innovation science: innovation and the individual; creating a value proposition for innovation; and a systems approach. The workshop brought together stakeholders from across the research and innovation ecosystem to discuss ways forward and identify the key research questions that will help to drive uptake and adoption in the UK.

[1] Accelerated Access Review (2016). www.gov.uk/government/uploads/system/uploads/attachment_data/file/565072/AAR_final.pdf
[2] Life Sciences Industrial Strategy: A report to the Government from the life sciences sector (2017). www.gov.uk/government/uploads/system/uploads/attachment_data/file/640696/life-sciences-industrial-strategy.pdf

A research agenda for innovation science – presentation

Professor Sir John Bell GBE FRS HonFREng FMedSci, Regius Professor of Medicine, University of Oxford and Co-Chair, Centre for the Advancement of Sustainable Medical Innovation, outlined the need for research into new ways of evaluating, testing and translating medical innovations into the NHS. He stressed that in a resource-limited healthcare system, the need for innovative and cost-effective approaches to healthcare is greater than ever. However, despite the UK's world-leading research base, the NHS is still slow to adopt innovation. Sir John described how a new, systematic approach is required to identify the unmet needs in the NHS and facilitate the accelerated development of innovations to meet those needs. The implementation of the recommendations within the Accelerated Access Review (AAR) will help to provide a supportive framework for assessing impact, value and outcomes.[3]

Sir John also described industry and academia as key partners for the NHS in accelerating access to innovation. The Life Sciences Industrial Strategy can help to foster an environment where NHS-industry engagement is mutually beneficial to reduce costs in the healthcare system and improve standards of care.[4] Finally, he emphasised the huge potential for using health data in the NHS, which will be integral to accelerated pathways of innovation.

Accelerating access: the funders' perspective – presentation

Dr Louise Wood, Director of Science, Research and Evidence, Department of Health, described the NHS as a complex ecosystem involving many different systems, which can make adoption and diffusion of innovation difficult. It can also be challenging to predict the outcomes of innovation and there may be unforeseen barriers due to indirect or knock-on effects elsewhere in the system. She emphasised the need for innovation science – that is, the application of scientific methods to the practice of innovation – and a research agenda to support this. Such an agenda should include systematic observations; measurements and experimentation; formulation, testing and modification of hypotheses; and integration of knowledge to apply to endeavours. For example, the Massachusetts Institute of Technology (MIT) Lab for Innovation Science and Policy has established initiatives to drive innovation including: developing innovation metrics; policies to promote innovation such as visa schemes, intellectual property programmes and tax benefits; and innovation programmes to promote entrepreneurship.[5]

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[3] Accelerated Access Review (2016). *Accelerated Access Review: Final Report*
www.gov.uk/government/uploads/system/uploads/attachment_data/file/565072/AAR_final.pdf
[4] Life Sciences Industrial Strategy – A report to Government from the life sciences sector (2017).
www.gov.uk/government/uploads/system/uploads/attachment_data/file/640696/life-sciences-industrial-strategy.pdf
[5] https://innovation.mit.edu/research-policy/lab-innovation-science-policy/

Dr Wood outlined key areas to consider when discussing a research agenda for innovation science. Firstly, all relevant stakeholders must be engaged to both inform the debate and promote outcomes. This requires a multidisciplinary approach including social, economic and engineering sciences as well as basic and applied science, and stakeholders should apply a mix of methodologies to find the best approach. There are still questions around how we interpret, synthesise and value different evidence as it remains to be seen if some evidence sources are more useful or robust than others; an open mind is needed on new ways of generating evidence. Finally, Dr Wood discussed the importance of further research into scaling up innovation, the push and pull factors involved in access and the need for stakeholder championing. This research provides opportunities for accelerating access to innovation and enhancing the efficiency of the healthcare system in delivering improved health outcomes.

Innovation and the individual

Introduction

Participants discussed the behavioural and societal barriers to innovation that may occur at the level of the patient, clinician or organisation, and how innovation science can help to address some of these challenges. Opportunities and approaches for patient and public involvement (PPI) were also explored to increase engagement with, and uptake of, innovation and its relevance to individuals.

It was widely agreed that patient demand for innovation, termed 'patient-pull', is key to accelerating translation of innovation research. This might include patient groups or charities campaigning for access to new interventions or encouraging trial participation. The Cancer Drugs Fund was cited as an example of where patient demand ensured access to novel cancer treatments in the NHS that would not be available otherwise. Although this is a unique example, delegates suggested that the principle of a demand-led system could be applied for other innovations and advocated patient 'buy-in' as a means to encourage consideration of innovation by regulators and commissioners. Developing a way to measure pull factors, either quantitatively or qualitatively, could be an integral part of the early innovation process and could enable prediction of uptake and diffusion. PPI is also a valuable way to create early adopters and champions of new innovations amongst patients.

Medical innovation and the individual – presentation

Hilary Newiss, Chair of National Voices, opened by highlighting the importance of involving patients as active partners at the heart of the research and innovation process. PPI recognises patients as a core component of the research community, particularly in the development of medical and digital technology where patients themselves are emerging as great innovators. As

part of the AAR, a set of 'I-statements' were developed which identify four areas of importance for patients in accessing innovation:[6]

- Priorities of research – priorities for research and innovation should be set in partnership with patients and citizens. For example, many patients want to prioritise first-in-class over 'me-too' medications.
- Design of research – the voice and expertise of patients and citizens should be valued at every stage of research and innovation. Co-production of research was cited as a huge opportunity for developing evaluation and outcome criteria to better fit patient needs. For example, quality of life is increasingly important for patients compared with overall survival.
- Availability of, and access to, new treatments – decisions about the availability of new innovations should be made in partnership with patients and citizens. Patients desired transparency around risks and benefits of innovations.
- Shared decision-making – patients should be empowered to actively participate in the decision-making process which can enable them to take control of their personal health.

Ms Newiss summed up by emphasising the potential importance of 'patient-pull' in bringing new technologies through the innovation pathway. In the future, use of digital and electronic technologies combined with other PPI tools could significantly improve patient-centred care.

Personal preferences and social practice: the research agenda – presentation

Professor Rob Horne, Professor of Behavioural Medicine, University College London, described the cycle of medical innovation and outlined two key areas where he felt improvements could accelerate the development and adoption of innovation. Firstly, addressing the challenges in achieving widespread uptake, adoption and patient adherence, and secondly, the failure to feedback insight from user experience into the research and innovation process – or 'reverse translation'.

He explained how differences in stakeholder behaviour have led to a 'behavioural gap' where uptake and adoption of innovation is assumed but often fails to meet expectations. For example, an innovation may be supported by a large evidence base but the translation of the evidence into 'real-world' benefit is often conditional on behaviour at several levels: individuals such as patients and clinicians; organisations, for example the NHS; and systems or society as a whole. He used the example of medication to illustrate this, citing a World Health Organisation estimate that approximately 50% of medicines prescribed for long-term health conditions are not taken as advised.[7] The reasons for this are complex but at the level of the individual, adherence (or

[6] National Voices and Accelerated Access (2016). *Involving patients and citizens: I statements for research and innovation.* www.nationalvoices.org.uk/sites/default/files/public/publications/involving_patients_and_service_users_-_i_statements_for_research_and_innovation_oct_2016_0.pdf
[7] World Health Organisation (2003). *Adherence to long-term therapies: evidence for action.* www.who.int/chp/knowledge/publications/adherence_full_report.pdf?ua=1

engagement with a medical innovation) can be considered primarily as being a product of two factors: motivation and ability.

He summarised research showing that non-adherence is often related to patients' beliefs about their illness and treatment, particularly how they evaluate necessity for the treatment relative to concerns about the negative effects of taking it.[8] These beliefs often arise from 'common-sense' understandings of the illness and treatment (or innovation) that shape individual assessment of whether engagement is a good idea. They may be more strongly influenced by the views and 'stories' of individuals (family members or even Internet bloggers) than by scientific evidence.[9,10] This may be even more prominent in preventative medicine where immediate benefits are not obvious and, in the case of genetics, patients may feel that there is little incentive to take medication if they consider themselves predisposed to becoming unwell anyway. Professor Horne also highlighted the importance of understanding clinician behaviour and how internal and external factors (such as organisational policy and culture) influence intrinsic motivation and ability to adopt innovations. He summarised by calling for more research into patient and public views of innovation and developing tools to support informed decision-making through communicating risks and benefits.[11]

Professor Horne argued that the high rates of non-adherence to medicines show us that engagement is not an automatic corollary of technological innovation. Rather, technologies require parallel innovation in behavioural science to understand how innovation will be viewed and used. The challenge is to develop innovations that are *'behaviourally intelligent'* and designed with stakeholder behaviour in mind to understand how the innovation will influence the motivation and ability of key stakeholders to engage.

Finally, he posed a series of challenges as research priorities:[12]

- How do we incentivise long-term adherence to preventative treatments?
- How do we convey scientific evidence in a form that is compatible with the way people actually make decisions about treatments?
- How do we personalise medicine at the psychosocial level as well as the biological level tailoring treatment to optimise engagement? - putting the person into personalised medicine
- How do we understand and overcome any negative effects of personalising on the basis of genetic factors (e.g. supporting 'patient' B who does not have the requisite gene to receive a treatment)?
- How can we systematically engage the public to renew the social contract for innovation, and support patients to convert evidence into common sense statements?

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[8] R Horne, *et al.* (2013). *Understanding patients' adherence-related beliefs about medicines prescribed for long-term conditions: a meta-analytic review of the Necessity-Concerns Framework*. PLoS One, 8(12), e80633.
[9] The Academy's report on 'Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines' has developed a series of recommendations on better communicating the risks and benefits of medicines to patients and the public.
[10] Academy of Medical Sciences (2017). *Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines*. https://acmedsci.ac.uk/file-download/44970096
[11] *Ibid.*
[12] R Horne (2017). *The Human Dimension: Putting the Person into Personalised Medicine*. The New Bioethics, **23(1)**, 38-48.

Patient and public involvement with innovation

PPI has the potential to greatly improve patient engagement with the healthcare system, and could lead to increased participation in trials, greater empowerment for patients in management of personal health and data, and enhanced knowledge and understanding to enable patients to make informed decisions.

Defining the patient

Participants expressed the need for clear distinction between lay patients, patient experts, patients' families and the public, to understand the different opinions, needs and opportunities of these groups. This enables engagement to be tailored to maximise its relevance for each of these stakeholders and ensure that the outputs are fit-for-purpose.

Alongside patients, public perception of innovations was also highlighted as important for driving translation of innovation in the NHS. Examples of where public perception could be key include areas that have differing levels of public understanding and acceptance such as regenerative medicine, stem cell treatments and gene therapies. These public views need to come from an informed position and should be placed in the correct social context, which may change over time.

Incorporating patient needs through co-design

It was agreed that co-design of innovations with patients is critical to ensuring uptake and some participants expressed concern that patient opinions were not always incorporated into the early stages of therapeutic development. The historical focus on 'me-too' drugs (a drug that is very similar to a therapy that is already available, both structurally and by mechanism of action) was referenced as an illustration of this where many patients might prefer that research was focused on areas of high unmet need. In addition, defining outcomes and endpoints at the early stages of study design is essential to guiding decision-making for an intervention, and such outcomes can be co-designed with patients and clinicians to ensure that they are relevant to their needs.[13] In other cases such as digital patient decision-aids, there is better involvement of patients early in development to ensure that technology is optimised to meet their needs. One participant gave the example of Apple iPad health apps, which have been adjusted to meet the needs of different populations to allow more effective interaction with the app, such as larger icons for older patients who may have difficulty typing. These cases demonstrate the co-design is not only important for content (or aims) of the health app itself, but also for its method of operation. Innovation is unlikely to meet the needs of an entire population without considering different stakeholder requirements such as age or mobility of patients. It was stressed that it is important for PPI to feel like a two-way exchange that benefits the patients as well as the innovators.

Iteration of technologies based on user feedback is an important component of the innovation cycle to ensure continual improvement and early use by patients and clinicians. This cycle allows unforeseen challenges to be overcome before they emerge as issues and compromise the effectiveness of an innovation in a real world setting. An example of this technology improvement is the development of an app for diabetes patients that issues reminders for checking blood glucose levels. Patients with chronic diabetes found constant reminders intrusive, but women with gestational diabetes found it helpful as they were not used to checking these levels and had the added incentive of rigorously doing so to protect their babies. This feedback on individual preferences helped designers to refine the app for different users.

However, even when innovations reflect patient wants and needs, there can be challenges around scale up and implementation. Therefore the patient perspective is not only key for co-design of innovation, but also for commissioning decisions and healthcare delivery in a transparent manner. This is demonstrated by a study showing that women with HER2 positive cancer preferred receiving Herceptin subcutaneously in the community rather than intravenously in hospital, but this was not adopted more widely due to inflexibility of healthcare budgets.[14]

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[13] The Academy held a workshop on 3 July on endpoints in oncology clinical trials, which explored the role of PPI in selecting appropriate endpoints. The meeting report of this workshop will be available on the Academy website once published.

[14] Tjalma A, Huizing M & Papadimitriou K (2017). *The smooth and bumpy road of trastuzumab administration: from intravenous (IV) in a hospital to subcutaneous (SC) at home.* Facts Views Vis Obgyn. **9(1)**, 51-55.

The evidence base for PPI

PPI in research and innovation was agreed to be very important but delegates debated the *optimal* level of PPI at different stages of the research process. It was felt that innovation may not require PPI or co-design along the whole pathway and should not be seen as a *'panacea'*; instead, innovators should consider where it can be most beneficial to ensure maximum relevance and utility by using this tool to best effect, without inhibiting innovation. This will vary depending on the technology. Therefore further research is needed to create a robust evidence base for the most effective methods of co-design and PPI in different settings and where it is most helpful along the research pathway, to ensure that it can be employed most efficiently to complement and accelerate innovation. For this research it was felt that focus groups, whilst useful, are not systematic in their approach and that patient needs, wants and engagement would vary across disease areas and demographics. Health surveys already exist for many disease areas and these could be enhanced to include additional opportunities for feedback on PPI as a relatively low-cost way to begin to gather evidence. However, this engagement and more generally can be low or biased and awareness is needed to assess and mitigate sources of bias and error and ensure that groups are representative of the target population.

Delegates suggested that PPI could become an integral, routine part of care to provide an opportunity for patients to engage with their health, provide input into innovation processes and receive peer support. This could improve health outcomes and ensure greater relevance and impact of medical innovations. In addition, it is expected that technological advances will make it cheaper and easier for patients to engage with clinicians and self-monitor health. However, although there is significant opportunity to maximise these routes of engagement, participants also cautioned of the need to consider the risks. For example, digital access to data can support remote consultation but this ease and scale of access to clinicians could create further workload for the clinician. Additionally, there are issues around accuracy and robustness of data from self-monitoring and reporting.

Innovation in a social context: behavioural science

It is vital to build an understanding of the behaviour of individuals and their interaction with all aspects of the healthcare system. 50% of patients with chronic medical conditions poorly adhere to medication and understanding the reasons for this low adherence is important to maximise the effectiveness of medicines and improve treatment outcomes.[15] Adherence issues extend to all disease areas and reasons can include poor communication or limited understanding of the benefits and risks of treatment, a lack of motivation to take medicines routinely, and side effects. It was noted that poor adherence is often hidden from clinicians because patients may feel that they will be judged. Although these views may be unfounded, this demonstrates the important role of clinicians in also understanding and managing adherence. The exact benefits of improving adherence have not been widely defined but are likely substantial, both in terms of health outcomes and cost-savings. Therefore robust research that supports prediction of patient behaviour is needed, including impact of external influences. In addition, preventative medicine – one of the major pillars of the NHS Five Year Forward View – comes across further behavioural obstacles as it may be difficult to convince a person who considers themselves healthy to take a medication for preventative reasons, requiring better communication of the benefits of therapy and the risks of not taking a treatment.

Participants suggested that improved access to healthcare and better communication, understanding and empowerment for patients could significantly improve engagement to tackle areas such as non-adherence. Patient concerns around sharing health data were also cited as a barrier to engagement, which could again be addressed in part through better communication. For example, reassurance and transparency around where and how data might be used allows patients to make informed decisions around sharing health data. This is essential to ensuring the collection of high-quality, robust longitudinal data for research that is not compromised by missing datasets.

Improving the evidence base

Delegates noted that there are significant challenges to generating evidence on individual behaviour. For example,

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[15] World Health Organisation (2003). *Adherence to long-term therapies: evidence for action.* www.who.int/chp/knowledge/publications/adherence_full_report.pdf?ua=1

although it is generally agreed that improving adherence likely maximises the effectiveness of interventions and improves health outcomes, studies to demonstrate this with meaningful results require large populations similar to the original trial size for the intervention. It is also unclear if adherence initiatives for one intervention will work for another, potentially requiring new studies for each intervention. Such studies may be difficult to justify if there is only marginal improvement in health outcomes with better adherence, even if they are clinically significant or notable at a population level.

The behaviour of clinicians and other health staff is also an important area for research as they play a central role in ensuring effective adoption and diffusion of interventions. It was suggested that personal opinions, training and setting can impact a healthcare professional's view of an innovation regardless of its proven effectiveness or advantages. Clinical champions and early adopters are therefore vital to ensure peer adoption, and this 'bottom-up' approach through peer diffusion may be more effective than a 'top-down' approach.

Individual vs. population science

Innovation science at a local, national and global level

Participants recognised the importance of understanding the wider 'setting' for innovations including the environment surrounding adoption and differing stakeholder behaviour at a regional, national and global level. When considering stratification at an individual level, participants recognised the need for tailored population-based solutions and potential adaptation of innovation to consider local determinants. For example, when a single medicine is marketed globally, the way it is prescribed, administered or monitored may vary both geographically and based on local demographics such as age and ethnicity. Therefore development may need to reflect local environments, which has multiple potential benefits including improved adherence and patient engagement with personal health. Stratification at a local level could be enabled by peer or community support, flexibility in prescribing practices, adaption of monitoring technologies and flexible clinical decision-making models. Alignment between innovators, regulators and commissioners could help to create flexibility for adapting innovation to local systems/populations. However, delegates stressed that stratification must be evidence-based to prevent unnecessary adaptation which does not improve health outcomes or system efficiencies.

Participants debated the extent to which innovation can, and should, be tailored to an individual and the appropriate level of disaggregation to reflect individual needs. There is often disparity between individual and population perspectives and public attitudes or social context may not be of relevance to an individual patient, and so a balance is needed. It was suggested that most innovation can be personalised through consultation and shared decision-making so that the innovation itself remains the same but there is flexibility in the way in which it is used, reflecting the local context and personal factors. [16]

Shared decision-making

One notable opportunity for innovation is empowerment of patients through informed decision-making aimed at enabling a patient to access and understand personal health data, treatment options and associated risks. This allows patients to make joint healthcare decisions with clinicians and so tailors care at an individual level. Shared decision-making is becoming an integral part of NHS care and pilot programmes such as the Health Foundation's Making Good Decisions in Collaboration (MAGIC) have shown it to be beneficial to increasing patients' engagement with their healthcare.[17] Although some patient decision-aids are recommended by NICE, shared decision-making is still not a routine part of care across the country.

[16] Academy of Medical Sciences (2016). *Health economics for stratified medicine*. https://acmedsci.ac.uk/file-download/61141574
[17] The Health Foundation (2013). *The MAGIC programme: evaluation*. www.health.org.uk/sites/health/files/TheMagicProgrammeEvaluation.pdf

Key research questions

Delegates proposed the following areas as key parts of a research agenda:

- What are the factors underlying 'patient pull', how can these be measured, and how can we use them systematically to drive adoption?
- What is the best model for PPI? ie. What is the appropriate level, at what stages of the innovation pathway should this occur and how can it be effectively implemented.
- Who is the individual in the system and how can we define them?
- How can we assess individual perspectives (patient, clinician, commissioner etc) and apply these within a wider framework at a population level?
- What are the key factors for clinicians that lead to uptake of innovation and how can we use these to accelerate access?
- What are the best ways of gathering and using patient data for innovation?
- What are the behavioural motivations for different individuals and can we use these as part of a multidisciplinary approach to enact positive change? E.g. better understanding prescribing practices, patient adherence.

The value proposition for innovation

Introduction

Participants discussed the importance of developing appropriate measures of value for innovation, the challenges to realising value, and the need for innovators to work alongside commissioners to address gaps and areas of need and improve health outcomes. In particular, there was discussion around incorporating a broader definition of value and different stakeholder perspectives into assessment, and how commissioners can work alongside innovators to ensure that innovations offer the best value for money and drive adoption.

Affordability and commissioning – presentation

Challenges of the UK healthcare system

Mr Richard Murray, Director of Policy, The King's Fund, summarised the challenging financial environment within the NHS, which creates issues around the affordability of innovation. He noted that many NHS Trusts already rely on central funding or exceptional financial support, have had to draw upon previous surpluses, and are increasingly concerned about their ability to meet financial targets.

Mr Murray described some of the different NHS measures aimed at driving uptake of innovation and improving efficiencies and cost reduction. For example, at a commissioning level, Sustainability and Transformation Plans (STPs) are now moving from the planning stages to delivery and will enable providers and local authorities to drive change alongside commissioners. The new models of care introduced through the NHS Vanguards also provide a mechanism for enabling innovation by coordinating different providers across the system. In addition, Accountable Care Systems, an evolution of STPs, will assemble healthcare

organisations into a single integrated system, to work together to improve efficiency and outcomes. Finally, Mr Murray described the risks of using special financial measures, which threaten devolution by bringing funding decisions back to commissioners in a centralised, capped expenditure process that may challenge local discretionary ability to choose value for money over cost reductions.

The value proposition of innovation

With these financial pressures, Mr Murray observed that healthcare providers have become adept at cost reduction and so cost-saving innovations have better traction with the healthcare community. A move towards 'value for money' innovation such as complicated system changes or new models of care, which can lead to new operational challenges, is thus more complex and will take time. However, he noted the important potential long-term benefits of these new structures in facilitating uptake and adoption of innovation and addressing some of the existing barriers, and flagged the valuable role of the AAR and some of the new models for innovation.

The value of innovation – presentation

Professor Karl Claxton, Professor of Economics, University of York, argued that the real problem NHS patients face in accessing innovative medicines, and that manufacturers face in getting market access and an early return on investments, has been the discrepancy between the prices charged and how much the NHS can afford to pay for the benefits that new medicines offer without damaging health outcomes overall.[18] He stated that NICE has for many years undertaken evidence-based and accountable assessments of the additional benefits that innovative drugs might offer, by taking account of all the evidence to try and assess the longer run effects on survival and quality of life, using comparable summary measures such as Quality Adjusted Life Years (QALYs).[19] Professor Claxton asserted that how much can the NHS afford to pay for the benefits of innovation depends on what health could have been gained elsewhere if the additional resources required had been available to offer effective treatments for other patients. He explained that there is now some evidence about what the scale of these health opportunity costs might be across the NHS. Some recent estimates of the effect of changes in NHS expenditure on the health of all NHS patients suggest that every £13,000 of NHS resources adds one QALY to the lives of NHS patients.[20]

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[18] Claxton K (2016). *Pharmaceutical Pricing: Early Access, The Cancer Drugs Fund and the Role of NICE*. Centre for Health Economics Policy & Research Briefing, University of York. www.york.ac.uk/media/che/documents/policybriefing/Drug_prices.pdf

[19] The QALY is used as an economic assessment of the expected quality and quantity of life that a particular treatment gives. One QALY is defined as one year in perfect health; consequently a patient suffering with morbidity for one year would contribute to less than one QALY. Different levels of morbidity and quality of life have different weightings in their impact on the QALY measurement, with a quality of life weighting ranging from 0 to 1. The expected cost per QALY is used a metric for comparing the economic value of one treatment against another. As an example, a treatment costing £10,000 that extends life for 6 months in perfect health and one costing £10,000 that extends life for 12 months with significant morbidity could both have a QALY of £20,000, meaning that they are equivalent in terms of cost per health outcomes.

[20] K Claxton, *et al*. (2015). *Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technol Assess*. **19(14)**, 1-503.

Professor Claxton suggested that this research shows that increasing expenditure on the NHS appears to be much better value than implied by thresholds NICE actually uses (£30,000 and up to £50,000 per QALY in some circumstances). However, he claimed that it also means that, on average, when NICE approves a new drug it does more 'harm' than good to population health because the health lost elsewhere in the NHS due to the additional costs exceeds the benefits gained.[21] In his view, this meant that without addressing the question of price, accelerating and widening access by approving new drugs more quickly – and with lower evidential standards – will just increase the net harm to the rest of the NHS and undermine the evidence base for clinical practice. He argued that the difficulty is that global prices for new drugs are generally unaffordable for the NHS, primarily because they are set by the US market. In addition, he suggested that the NHS is in the difficult position of either allowing unaffordable innovations to harm health outcomes overall, or denying patients access to new drugs which may benefit them. In his view, Professor Claxton determined that there is a solution that has been available for some time but only now are all the elements required in place, and that all that is needed is to link NICE appraisal to the type of national rebate agreement that was negotiated in 2014 as part of the current Pharmaceutical Price Regulation Scheme. He claimed that this would mean that rebates paid by manufacturers at a national level would reflect the discrepancy between the global prices charged for their portfolio of products and how much the NHS can afford to pay for the benefits they provide. In return, local prescribers could be reimbursed by the Department of Health at the prices they actually face, which he considered would ensure early uptake of innovation without harm to other services and NHS patients.

Building a system which recognises value

Affordability

Affordability is a key driver of adoption in a resource-limited system such as the NHS where siloed, yearly budgets have limited flexibility for investment in long-term cost-effective innovations. Thus for an innovation to receive widespread uptake, the economics of implementation are as important as the evidence for improved health outcomes and other benefits. It was cautioned that in the current system, an innovation that improves health outcomes or is deemed cost-effective may still struggle to be adopted if there are issues of affordability. Technologies should fit with system needs and so participants proposed that affordability must be considered early in the innovation process to enable innovators to predict and ensure uptake and adoption. Innovators could even consider *'designing for price'* by assessing affordability, undertaking an economic analysis of expected costs of implementation and other factors, and then anticipating savings by predicting direct cost savings and also system efficiencies and savings from improved health outcomes. In addition, there is a need for a culture change in the healthcare system to better recognise the benefits of cost-effectiveness and downstream long-term health and efficiency gains. The metrics for success placed on NHS Trusts need to be reviewed so that they reflect these gains. Participants were interested in the evaluation of, and learnings from, the NHS Innovation Accelerator, which aims to demonstrate the benefits of innovations piloted in the NHS and facilitate uptake.[22]

One delegate suggested that the healthcare system is primarily set up for novel (and often relatively expensive) innovations but that opportunities also lie in 'not-for-profit' innovation such as repurposing existing treatments that are proven to have efficacy in management of other diseases, such as use of anti-malarials in cancer treatment. When using

[21] Claxton K, *et al.* (2015). *Causes for concern: is NICE failing to uphold its responsibilities to all NHS patients?* Health Econ. **24(1)**, 1-7.
[22] www.england.nhs.uk/ourwork/innovation/nia/

therapies outside of their licensed indications, the manufacturer is currently responsible for applying for each new indication. However, there may be cases where there is little economic incentive for manufacturers to apply for a new indication or too much accountability on prescribers for using a medicine off-label, but there is value for the healthcare system. Therefore different pathways to support controlled repurposing could be considered such as public funding to enable healthcare providers to explore different opportunities, building capabilities for high-quality data collection on outcomes with off-label use, and support for prescribers to use treatments more flexibly in this way. It was even suggested that regulators could pursue licensing for new indications without initiation by the manufacturer.

Metrics for commissioning

Participants emphasised that commissioning decisions should consider the balance between the evidence base and the social context of an innovation. It was emphasised that QALYs take these factors into account to some extent and act as a benchmark for affordability of innovations. For example, NICE typically only considers interventions that meet a limit of £20,000 per QALY. However, one participant noted that research suggests that £13,000 per QALY provides the NHS with 'value for money'. For QALYs below this value, on average the economic benefits derived from improved health outcomes outweigh the cost of the intervention whereas above this value, the costs may exceed the benefits. Economic value calculated by QALYs is not the only factor that influences whether an intervention is recommended, as other factors are also incorporated. As a result, it was argued that the 'soft target' of £20,000 per QALY is often exceeded by NICE such as in rare diseases or areas of high unmet need, with patient demands and other considerations factored into decisions around commissioning. However, participants also recognised the importance of competition in driving innovation and that 'me too' drugs – which may offer little improvement in health outcomes – are still needed if they provide significant cost savings. It was stressed that flexibility in commissioning decisions for interventions exceeding £20,000 must be underpinned by transparency of how these decisions are made, with assurances that the appraisals are done fairly and not at the cost of other innovations.

A wider definition of value

Value beyond direct health benefit

Participants highlighted the importance of involving the breadth of stakeholders in discussions around value including those beyond the health sector. Impact and economic gains of transformative innovations can extend beyond direct health outcomes, including avoidance of health complications and societal/cultural benefits such as ability to contribute to the economy, reduced reliance on carer support and decreased use of public services. Innovations which change entire care pathways can have a huge value proposition where they also release 'value' elsewhere and create headroom. There is a need to overcome the different budget and operational siloes between relevant Government departments in addition to the Department of Health such as the Department of Work and Pensions, the Department for Business, Energy and Industrial Strategy and the Home Office, who may also have an interest in the wider benefits of an innovation. Economic and reimbursement models should consider these wider benefits and social factors outside of direct health outcomes, which may drive adoption of innovation. NICE appraisal should already consider the wider economic gains for improving health, however, it was widely agreed that further research into methods of assessing different benefits such as social factors and incorporating them into commissioning decisions is needed.[23,24] Elements of value may also differ across global healthcare systems and markets, and so the value proposition of an innovation must meet the necessary criteria of the healthcare system and payer, and not assume success based on uptake elsewhere. Fostering a culture of innovation will be key to delivering value for the healthcare system.

Decision-making on value and access

Consideration needs to be given to the weighting of social factors in comparison with other measures and transparency around this balance is needed. Participants discussed the potential role of citizen's juries in communicating social values and deciding the balance of different costs and health conditions against one another. However, it was argued that NHS

[23] Academy of Medical Sciences (2017). *Health economics for stratified medicine.* https://acmedsci.ac.uk/file-download/61141574
[24] Academy of Medical Sciences (2015). *Stratified, personalised of P4 medicine: a new direction for placing the patient at the centre of healthcare and health education.* https://acmedsci.ac.uk/file-download/38266-56e6d483e1d21.pdf

expenditure needs to be founded on scientific, systematic methods for decision-making which can be accountable and re-reviewed. Although social values are complex, weighting of these different measures would allow them to be included in models of value.

Generating evidence on value

Delegates raised the issue of areas where economic impact, and other value metrics, of an innovation are poorly defined. This includes areas such as rare diseases where patient populations may be so small that analysing the value of an innovation is difficult without a large randomised controlled trial. Similarly, highly disruptive innovations that may significantly alter a care pathway or drive dramatic improvements in health outcomes may have unclear value due to limited precedent or uncertainties around system change. One example given was the development of potentially curative regenerative medicines. In these cases, the best available model must be used to assess value but these models should be adaptive and use real world evidence to iteratively improve future assessment. Delegates agreed the need for new methods of generating evidence on the economic and health impacts of innovation.

Key research questions

Delegates proposed the following areas as key parts of a research agenda:

- How do you define value - what other metrics of value for innovation should be considered?
- What methodologies are needed to assess and incorporate new measures of value into evaluative models?
- In particular, how can societal views be incorporated into value measures and decision-making and what is the appropriate weighting/balance for these views? What is the effectiveness of citizen's juries in this decision-making process?
- How can we better map where value and downstream benefits are released in complex systems?
- In addition, how can we better address lost opportunities in the system such as drug repurposing, in a system which incentivises some innovations but not others.
- Is there value in incorporating societal values into value assessment and if so how could these be achieved and where would the biases lie?
- How can metrics of value be communicated between regulators, commissioners and industry to ensure they are incorporated early into the innovation cycle?

A systems level approach to innovation

Introduction

Participants assessed the prospects for enacting change on the complex healthcare system in the UK, where services and organisations are involved in a diverse network which can lead to challenges around responsibility, resource and leadership. They also discussed the need for the NHS itself to 'pull' innovations into the system by identifying and embracing high value innovations, and initiating and championing programmes of positive change.

Adoption and diffusion of innovation in the NHS – presentation

Professor Mark Emberton, FMedSci, Professor of Interventional Oncology and Honorary Consultant Urological Surgeon, University College London, presented a case study of trialling and adoption of a new diagnostic pathway for prostate cancer. This pathway uses advances in the detection and management of prostate cancer to improve patient experience and outcomes through initial stratification of patients, and employment of Magnetic Resonance Imaging (MRI) to identify tumours and direct where biopsies are made. Compared with the traditional one-size-fits-all approach for biopsies, this technique increases both the precision and sensitivity for detecting prostate cancer, and has reduced the number of patients suffering undesirable consequences of surgery through more specific selection of patients to undergo surgery.

However, there have been notable inequities in adoption and diffusion of this new care pathway across the UK. London-based centres are more likely to offer the new model than outside London and there was a ten year gap between demonstration of the benefits of this approach and adoption. Professor Emberton noted that despite initial research published in 2006 showing the advantages of the new care pathway over current practice, evidence generation and

widespread adoption is only now driving routine clinical use of this novel technique.[25]

Further to this, there may also be disparities in quality of implementation arising from the need for new skills and knowledge in the area as the procedure, despite being more effective, is more complicated to perform. Therefore training will be a key component to driving uptake. Despite robust evidence for the care pathway there still remain barriers to widespread use, such as it being mentioned in NICE guidelines as a treatment option rather than recommended. Finally, Professor Emberton questioned the best approach to proving the cost-effectiveness of a new technique, and whether commissioners should wait for the full complement of research to adopt or whether such evidence can be generated during implementation through an iterative process.

A systems approach to innovation – presentation

Professor John Clarkson FREng, Director, Cambridge Engineering Design Centre, University of Cambridge, outlined the role of engineering processes in improving healthcare systems and driving better quality through system design. The NHS and wider healthcare infrastructure is a complex system, and so a systems-wide approach is necessary to ensure that any potential system failures are mitigated. He explained that systems change needs careful design to ensure that the correct 'problems' are addressed and needs met, as changes and errors may lead to patient harm. Each element of the system should be considered, including how they perform and interact with one another as well as the different key stakeholders operating within the system.

Professor Clarkson explored the benefits of risk-thinking – the forward planning of exceptional circumstances to reduce the risk of accidents or failures in the future. He cited two examples of where careful planning could reduce risk of error. Firstly, when inserting a central venous catheter, despite generally being a low-risk procedure it was found that physicians who were interrupted at a certain point during the procedure may forget whether the guidewire used to aid insertion is in or out of the patient, resulting in complications. Improvements to the equipment design and the process surrounding its use could greatly reduce the likelihood of such errors occurring. Secondly, infusion pumps lack standardisation, with multiple different approaches to their set-up procedures arising from different manufacturers. This can lead to errors in operation, arising again from poor equipment design where designers did not fully appreciate how users might interact with the pump.

[25] Villers, *et al.* (2007). *Dynamic contrast-enhanced MRI for preoperative identification of localised prostate cancer* J Urol **6(8)**, 525-532.

In another example, patients with rheumatoid arthritis were prescribed methotrexate in child-proof containers, which are likely to be difficult to open, resulting in the potential for non-adherence, or coping mechanisms such as removing all tablets from the container and storing them without their original labels, which could also compromise safety. There are also examples of where different dosages of the same medication were packaged similarly, potentially causing confusion and over or under-dosing by the patient. These errors arise from notable design flaws that do not appropriately consider the end user. Therefore Professor Clarkson highlighted the importance of four key factors of a systems approach to improve the operation of the healthcare system: design; risk; systems; and people that sit at the core of this process.

Finally, Professor Clarkson summarised the findings of a series of workshops held jointly by the Royal Academy of Engineering and the Academy of Medical Sciences on 'A systems approach to healthcare'. These included:

- Importance of iteration before implementation with multiple rounds of testing and improvement before implementation.
- Design is an exploratory process and designers must adapt to feedback and new findings.
- Risk management must be proactive, where risk is mitigated or eliminated before an incident occurs and not retrospectively.

Driving systems change

It was agreed that objectives and incentives must be aligned to drive system change across all key stakeholders including patients, healthcare professionals, commissioners and general managers. This requires a full understanding of the benefits (and limitations) of innovation, as well as consideration of its potential impact on the different parts of the health system and patient pathways. For example, with the introduction of aortic stents in vascular surgery, vascular surgeons either moved to other parts of the healthcare system or re-trained so that the speciality both devolved *and* evolved overnight to accommodate these experts elsewhere in the system.

Accountability for system change

A key theme over the course of the day was lack of clarity around the responsibility and accountability for instigating change in the healthcare system. This may be, in part, due to new medical innovations blurring the boundaries between existing areas of responsibility. For example, if a new medical innovation requires staff re-training, the responsibility for initiating and financing this training is not clear. Similarly, if a significant change in care pathways is needed, the responsibility for change and where the funding for this comes from is confusing. Delegates felt that decision-making in this way is easier at a local level, which could provide the best route for evaluation and piloting of changes that would otherwise not be possible or practical to initiate at a national level. In addition, it was proposed that responsibility needs to be established for different areas of change, and a separate body may be required to facilitate and incentivise wider diffusion. STPs and AHSNs will play a key role in creating accountability and facilitating this change, but a further level of granularity will be needed that goes beyond these structures. Overall, it will be essential to evaluate the outcomes of system change to gauge effectiveness and future learnings.

There was also concern that regulatory criteria for accessing new innovations may be too strict and that the regulatory infrastructure may benefit from having greater flexibility to allow iterative product development with continued generation of real world evidence to support product use and accelerate access. It was recognised that this should not compromise the efficiency of the regulatory system in protecting patient and public safety.

Finally, it was suggested that there is a risk-averse or cautious research culture for innovation in the UK due to the potential high costs, lengthy timescales and high risk associated with innovation. It was therefore deemed important that sufficient research capacity is focused on addressing only key research questions for the healthcare system to reduce some of the burden of accountability amongst research funders.

Incentivising change

In addition to end-users being adequately informed and trained, further incentives may be required to achieve rapid diffusion of an innovation through the system. At the scale of whole Trusts or institutions, these incentives could be target-related or financial, and at an individual level could comprise appraisal or performance review processes. In addition, funding and other commitments need to be stable and reflect the length of time for diffusion of an innovation. Although early adopters are vital to adoption and diffusion of innovation, they have few incentives and associated rewards for doing so. Programmes that provide financial support, such as the Global Digital Excellence program that gives additional funding to digitally advanced Trusts, were felt to be a key driver for establishing champions of change. Such funding could be linked to the number of 'early adopted' innovations and pilots that are taken through to completion, and not based on the success of the innovation itself, which would help to de-risk adoption. However, delegates warned against creating too many new initiatives where solutions may already exist. This was stressed as especially pertinent in a system that is target-driven, to prevent exploitation of targets and their associated rewards rather than choosing the best path for positive change.

Overall, participants called for further research into what these incentives might look like and how individuals and organisations respond to them, as an important component of understanding system pull and change. Delegates envisioned then creating a 'toolbox' using this research that could be tailored to each innovation to target incentives and maximise the potential for system pull.

Evaluating systems change

The importance of reviewing and evaluating systems change to effect truly beneficial systems reform and identify key learnings was recognised, taking into consideration a broader definition of value and downstream effects including outside of the NHS. Systems modelling needs to be able to simulate/test an environment first before integration, and the NHS Vanguards are an exemplar of piloting projects for intervention at a systems level. In addition to improvement, evaluation is critical for incentivising change through demonstrating the benefit of innovation. It was suggested that interest in evaluation could be built by establishing a commitment to adopt innovation – otherwise termed *'a view to purchasing'* – if certain data or outcomes were generated. The importance of involving the research community to develop robust methodologies and evidence synthesis approaches for this evaluation was agreed and it was proposed that new incentives such as this will foster engagement with this community.

Creating NHS pull

Alongside creating a 'push' for innovation into the NHS, participants advocated increased NHS 'pull' and the need to develop a better understanding of these pull factors. This will enable innovation to be developed based on needs. Some participants argued that the current research agenda may focus too much on the push rather than the pull factors where the latter are key to understanding the unmet needs of patients and the healthcare system, and so central for driving uptake and adoption of innovation.

Scale-up of innovation

Delegates commented that the success of an innovation often depends on the social context in which it is used. Even where innovations have been free, offered significant cost-savings or proved successful through a pilot scheme, some have performed poorly when implemented in the wider healthcare system. This may be due to differences in the social context for an innovation that were not accounted for, or a breakdown in the systems that help it to run efficiently on a small scale when it is escalated to a national level. An innovation that takes a 'one size fits all' approach and does not

allow for the flexibility of the differences between healthcare centres and subsystems is more likely to encounter barriers to adoption. Therefore it was proposed as key to examine social context as part of innovation pathways and where products may need to be adapted to local systems, as well as the value of people in scale up of innovation.

With a large, complex system such as the NHS, issues with implementation can be difficult to predict. Robust methodologies for determining and predicting social context for innovations need to be developed so that it can be accounted for in early development, monitoring post-launch and incorporated into continuous improvement processes.

Using the NHS as a test bed for innovation

Delegates agreed that the NHS is in a unique position to trial and enact new innovations compared to other health systems worldwide where, for example, disruptive innovation that reduces cost may directly threaten the income of a service or clinician, potentially resulting in a reluctance to trial and uptake new innovations. In the NHS, however, cost-saving innovations are far more desirable and so centres are likely to be more willing to trial and implement them.

Building capacity and capability

Delegates agreed that a key driver for pulling innovations into the NHS is ensuring that healthcare staff are aware of the benefits of the innovation and sufficiently informed and trained to promote its use. Innovation requires an interdisciplinary approach as it is likely to increasingly obscure professional boundaries and may even cause superseding of some specialisms, which can retrain or evolve in the system as necessary. Training was seen as particularly key in areas where an innovation involves new in its delivery methods, requires cross-disciplinary cooperation or aims to supersede an established care pathway. Education and training can foster an understanding of the benefits and need for new innovations and how to implement them, as well as creating buy-in from healthcare professionals. For example, participants referenced one of the recent National Innovation Accelerator products, a non-injectable arterial cannula, which, despite being available free on the NHS is still not widely used due to resistance from anaesthetists.

Where there is a lack of responsibility for driving systems change, championship and leadership from different stakeholders within the healthcare system can create an 'NHS pull' to facilitate uptake and adoption, whether clinicians, commissioners or regulators.

Key research questions

Delegates proposed the following areas as key parts of a research agenda:

- What are the factors behind 'NHS pull' (including behavioural and cultural factors) and how can these be better utilised to accelerate access to innovation?
- What are the general barriers to uptake and adoption of innovation in the healthcare system and how can these be addressed?
- Where does responsibility lie for system improvement?
- What are the incentives for system change and improvement across different stakeholders, and how can these be used to drive uptake of innovation?
- What new models of evaluation can be developed (particularly for complex system change such as care pathways) and how can continued evaluation be incentivised?
- Where can the regulatory framework facilitate access to innovation and what are the changes that need to be made?
- What are the opportunities for using healthcare/patient data and what should be done in the short, medium and long-term?

Conclusion

There is a need to better understand the major challenges that face the development, translation, uptake and adoption of innovations, to accelerate access to medical innovation in the NHS. Professor Sir John Tooke FMedSci, Co-Chair, Centre for the Advancement of Sustainable Medical Innovation, summarised the importance of 'innovation science' in helping to address some of these challenges and elucidate new ways of ensuring access to innovative research. Innovation science — that is, the understanding of what makes a 'good' innovation, why and where innovation succeeds and fails, and what drives the uptake and use of an innovation —is an important and emerging field in a healthcare ecosystem which is slow to enable access to innovation. Innovation science must be a shared, cross-sector and multidisciplinary endeavour with innovators working alongside funders, regulators, patients, commissioners and clinicians to promote uptake, adoption and diffusion.

Firstly, Sir John noted the need for a more patient-centred approach but also recognised that the pursuit of innovation demands a thorough understanding of the limitations of co-design. It is key to understand the optimal role of the patient and citizen in this process, what works best for PPI and engagement with other stakeholders, and how best practice can be spread to extract the most value from innovations. Within this, there is also an awareness that society is not uniform and so there remains a question around the level of stratification that should be applied to an innovation with regard to individual behaviours, beliefs and needs, against consideration of wider populations. He noted that in terms of behaviour change, a combination of capacity, capability, opportunity and motivation is fundamental to accelerating access, and that these are issues which impact on healthcare professionals and researchers as well as system users. Finally, Sir John emphasised the benefits of an engineering systems approach to some of the barriers faced, and that there is a need to balance design, risk and a systems approach with people at the centre, taking a socio-technical approach to innovation science.

Annex I: Agenda

09.00-09.30	**Registration and Refreshments**
09.30-09.40	**Welcome** Professor Sir John Tooke FMedSci, Professor of Medicine, University College London and Co-Chair, Centre for the Advancement of Sustainable Medical Innovation
09.35-09.50	**Energising progress in medical innovation** Professor Sir John Bell GBE FRS HonFREng FMedSci, Regius Professor of Medicine, University of Oxford and Co-Chair, Centre for the Advancement of Sustainable Medical Innovation
Innovation and the individual	
09.50-10.05	**Medical innovation and the individual** Ms Hilary Newiss, Chair, National Voices
10.05-10.20	**Personal preferences and social practice: the research agenda** Respondent: Professor Rob Horne, Professor of Behavioural Medicine, University College London
10.20-11.10	**Panel discussion: innovation and the individual** *How can the research community move to address barriers to innovation at an individual level – where are the research opportunities?* • Professor Andrew Hattersley FRS FMedSci, Professor of Molecular Medicine, University of Exeter • Professor Rob Horne, Professor of Behavioural Medicine, University College London • Ms Hilary Newiss, Chair, National Voices • Professor Lionel Tarassenko CBE FREng FMedSci, Head of Department of Electrical Engineering, University of Oxford
11.10-11.40	**Tea and coffee**
Creating a value proposition for medical innovation	
11.40-11.55	**Innovation in the context of affordability and commissioning** Mr Richard Murray, Director of Policy, The King's Fund
11.55-12.10	**The value of innovation** Respondent: Professor Karl Claxton, Professor of Economics, University of York
12.10-13.00	**Panel discussion: a value proposition for medical innovation** *How can medical innovation create and support a compelling value proposition to drive access so that we become a world-leading hub for adoption of innovation – what does this value proposition look like for different stakeholders?* • Professor Karl Claxton, Professor of Economics, University of York • Dr Rob Cook, Deputy Director – Bazian, National Institute for Health Research Dissemination Centre • Professor Jonathan Knowles FMedSci, Chairman of the Board, Immunocore Ltd • Mr Richard Murray, Director of Policy, The King's Fund • Dr Harpreet Sood, Associate Chief Clinical Information Officer, NHS England
13.00-13.40	**Lunch**
A healthcare systems approach to medical innovation	
13.40-13.55	**Adoption and diffusion of innovation in the NHS** Professor Mark Emberton FMedSci, Professor of Interventional Oncology and Honorary Consultant Urological Surgeon, University College London
13.55-14.10	**A systems approach to medical innovation** Professor John Clarkson FREng, Director, Cambridge Engineering Design Centre
14.10-15.00	**Panel discussion: how can we invoke system change?** *What can, and should be addressed at a system level by the research community, and where do national initiatives such as AAR and the Industrial Strategy fit with this?* • Professor John Clarkson FREng, Director, Cambridge Engineering Design Centre • Professor Mark Emberton FMedSci, Professor of Interventional Oncology and Honorary Consultant Urological Surgeon, University College London

	• Professor Gary Ford CBE FMedSci, Chief Executive, Oxford Academic Health Science Network • Dr Mair Powell, Expert Clinical Assessor, Medicines and Healthcare products Regulatory Agency • Dr Louise Wood, Director of Science, Research and Evidence, Department of Health
15.00-15.30	**Tea and coffee**
A research agenda for innovation science	
15.30-15.40	**Accelerating access: the funders' perspective** Dr Louise Wood, Director of Science, Research and Evidence, Department of Health
15.40-16.40	**A research agenda for medical innovation** *Participants will split into four break-out groups to explore the key research opportunities from each session of the meeting, to build a straw man research 'roadmap' for accelerating access using novel perspectives and approaches.*
16.40-16.55	**Feedback and conclusions** Participants to feedback on key areas for the research agenda, for discussion with the audience.
16.55-17.00	**Closing remarks** Professor Sir John Tooke FMedSci, Professor of Medicine, University College London and Co-Chair, Centre for the Advancement of Sustainable Medical Innovation
17.00	**Close followed by networking drinks reception**

Annex II: Participants list

Chair

Professor Sir John Tooke FMedSci, Professor of Medicine, University College London and Co-Chair, Centre for the Advancement of Sustainable Medical Innovation

Speakers

Professor Sir John Bell GBE FRS HonFREng FMedSci, Regius Professor of Medicine, University of Oxford and Co-Chair, Centre for the Advancement of Sustainable Medical Innovation
Professor John Clarkson FREng, Director, Cambridge Engineering Design Centre
Professor Karl Claxton, Professor of Economics, University of York
Professor Mark Emberton FMedSci, Professor of Interventional Oncology and Honorary Consultant Urological Surgeon, University College London
Professor Rob Horne, Professor of Behavioural Medicine, University College London
Mr Richard Murray, Director of Policy, The King's Fund
Ms Hilary Newiss, Chair, National Voices
Dr Louise Wood Director of Science, Research and Evidence, Department of Health

Panellists

Dr Rob Cook, Deputy Director - Bazian, National Institute for Health Research Dissemination Centre
Professor Gary Ford CBE FMedSci, Chief Executive, Oxford Academic Health Science Network
Professor Andrew Hattersley FRS FMedSci, Professor of Molecular Medicine, University of Exeter
Professor Jonathan Knowles FMedSci, Executive Chairman, Immunocore
Dr Mair Powell, Expert Clinical Assessor, Medicines and Healthcare products Regulatory Agency
Dr Harpreet Sood, Associate Chief Clinical Information Officer, NHS England
Professor Lionel Tarassenko CBE FREng FMedSci, Professor of Electrical Engineering, University of Oxford

Participants

Dr Christiane Abouzeid, Head of Regulatory Affairs, BioIndustry Association
Dr Virginia Acha, Executive Director, Research, Medical and Innovation, Association of the British Pharmaceutical Industry
Professor Eric Alton FMedSci, Professor of Respiratory Medicine and Gene Therapy, Imperial College London
Dr Nigel Banister, Chief Executive Officer, Science Developments
Professor Rachel Batterham, Professor of Obesity, Diabetes and Endocrinology, University College London
Professor Phil Beales, Professor of Medical and Molecular Genetics, University College London
Miss Mita Brahmbhatt, Programme Manager, NIHR Brain Injury Healthcare Technology Co-operative
Dr Mike Capaldi, Commercialisation Director, Edinburgh Bioquarter
Ms Charlotte Casebourne, Founding Director, New Medicine Partners
Ms Victoria Charlton, PhD Student Department of Global Health and Social Medicine, King's College London
Mr Warren Cowell, National Market Access Policy Lead, Health Economics, Market Access & Reimbursement, Janssen
Mr Tony Davis, Commercial Director, West Midlands AHSN
Mr Jim Dawton, Director, Impeller Ventures
Dr Stuart Dollow, Founder, Vermilion Life Sciences
Dr James Duffy, NIHR Doctoral Fellow, University of Oxford
Dr Mark Duman, Non-Executive Director, Patient Information Forum
Professor David Edwards FMedSci, Professor of Paediatrics and Neonatal Medicine, King's College London
Dr Michael England, Director of Medical Affairs, Hospital and Speciality Medicine, Merck, Sharp and Dohme
Dr Christopher Exeter, Director, International Strategy Group, UnitedHealth Group

Professor Dame Lesley Fallowfield FMedSci, Professor of Psycho Oncology, University of Sussex
Ms Hilary Fanning, Deputy Director, of Delivery and Director, of Research Development & Innovation, University Hospitals Birmingham
Professor Mathias Gautel FMedSci, Professor of Molecular Cardiology, King's College London
Ms Joanne Goddard, Senior Portfolio Manager, Economic and Social Research Council
Dr Fiona Godlee, Editor-in-Chief, BMJ
Professor Liam Grover, Professor of Biomaterials Science, University of Birmingham
Dr Christina Guindy, Head of Research, Royal Academy of Engineering
Ms Jenny Hargrave, Director of Service Innovation and Evaluation, British Heart Foundation
Dr Kirsty Henderson, Policy Adviser, Cancer Research UK
Dr Sarah Homer, Medical Assessor, Paediatric Unit, Medicines and Healthcare products Regulatory Agency
Mr Tim Horton, Associate Director, (Insight & Analysis), Improvement Team, The Health Foundation
Professor Alun Hughes, Professor of Cardiovascular Physiology and Pharmacology, University College London
Dr Peter Jarritt, Deputy Director, NIHR Brain Injury Healthcare Technology Co-operative
Dr Aaron Jenkins, Senior EBM Manager, Pfizer
Dr Anthony Johnson, VP and Head of Early Clinical Development, AstraZeneca
Dr Jonathan Jones, Senior Medical Director – Northern Europe, Vertex Pharmaceuticals
Dr Louise Jones, Head of Translational Research, Medical Research Council
Ms Susan Kay, Executive Director, Dunhill Medical Trust
Dr Lindsay Keir, Acting Head of Clinical Research & Physiological Sciences, Wellcome Trust
Dr Zisis Kozlakidis, ICONIC Project Manager; UCL Innovation Fellow, University College London
Professor Sanjeev Krishna FMedSci, Professor of Molecular Parasitology and Medicine St George's, University of London
Ms Karen Livingstone, National Director, SBRI & Director of Partnerships & Industry Engagement, Eastern AHSN
Mr Joseph Lu, Director – Longevity Science, Legal & General
Ms Jacqueline Mallender, Partner for Public Policy, Optimity Advisors
Dr Nick McNally, Director of Research Support, Joint Research Office, University College London
Dr Christine McNamee, Network Manager, Pharmacogenetics & Stratified Medicine, University of Liverpool
Mr Robert Meadowcroft, Chief Executive, Muscular Dystrophy UK
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