FORUM
Academy of Medical Sciences

Transforming healthcare through engineering and technology

Summary report of the 2018 FORUM Annual Lecture

The Academy of Medical Sciences

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The Academy of Medical Sciences

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Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows, or the Royal Academy of Engineering or its Fellows.

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Contents

Executive summary

Some of the most important and high-impact advances in medicine, such as keyhole surgery, capsule endoscopies and drug-eluting stents, have come from harnessing bioengineering and technology. The pace of advances in medical technologies (medtech), driven by improvements in AI and the use of data, is set to revolutionise the way that healthcare is delivered. Therefore, the Academy's 16th FORUM Annual Lecture, held on 5 September 2018, brought together a range of experts to discuss how engineering and technology is transforming healthcare.

In his keynote presentation, Dr Omar Ishrak, Chairman and Chief Executive Officer of Medtronic, described the three areas of technology innovation: 'continuous innovation, invention and market disruption'. All three approaches are essential to drive future growth and advance the standard of care that can lead to improved patient outcomes. He then set out his vision for a value-based healthcare system where positive patient outcomes, rather than service delivery, is rewarded. Lastly he explained that healthcare delivery should be restructured in order to better involve patients in the management of their health and chronic conditions.

Following Dr Ishrak's talk was a panel discussion, which explored how new technologies are increasingly impacting clinical practice and healthcare delivery, and how the UK can create a landscape which encourages these innovations and their utilisation within the NHS. Key points of discussion included:

- The **opportunities provided by new technologies**, including empowering patient-centred care, facilitating stratified medicine and supporting healthcare professionals.
- The **challenges of translating academic innovations into clinical impact**, and how to address them.
- The **importance of a robust evidence-base** of the benefits of new technologies in digital medicine and surgery, through randomised controlled trials (RCTs).
- The **benefits of a holistic, interdisciplinary approach** to bringing digital innovations into clinical practice.
- The **huge potential of the data** generated and held by the NHS, and the need for this potential to be realised by using it for research, improving individual care and for service planning and public health.
- The **importance of public and patient partnership** to ensure the trustworthiness of new innovations.

This meeting was convened as part of the Academy's FORUM programme, which was established in 2003 to recognise the role of industry in medical research and to catalyse connections across industry, academia and the NHS. We are grateful for the support provided by the members of this programme and are keen to encourage more organisations to take part. If you would like information on the benefits of becoming a FORUM member, please contact FORUM@acmedsci.ac.uk.

Innovate, invent, disrupt: the role of medical technology in transforming healthcare for the future

In his keynote presentation, Dr Omar Ishrak, Chairman and Chief Executive Officer of Medtronic, explained how bioengineering and technology can be used to transform healthcare. He described how three approaches to medtech development– 'continuous innovation, invention, and disruption' – can lead to pioneering technologies that improve the lives of patients. To truly put patients at the heart of healthcare and to create the right incentives in the system, he made the case for moving towards a value-based healthcare system, where all stakeholders are rewarded directly based on patient outcomes delivered. Finally, he demonstrated how, when coupled with the advent of new sources of data, medical technologies can help to resolve key challenges in care delivery for, and management of, chronic conditions.

Improving patient outcomes

Dr Ishrak introduced Medtronic's 'mission'; to '*contribute to human welfare by the application of biomedical engineering to alleviate pain, restore health and extend life*'. To fulfil this, he emphasised that collaborations between engineers and clinicians are required to create truly innovative technologies that solve major problems in healthcare. Medtronic was founded on this approach, leveraging the skills of a physician and engineer to develop a solution to an area of unmet clinical need, resulting in the first battery-operated (and therefore portable) pacemaker. Dr Ishrak explained that Medtronic has used this interdisciplinary approach to develop numerous innovations including further cardiac, vascular and diabetes therapies, as well as other restorative, minimally invasive interventions. More broadly, he extolled the virtues of such interdisciplinary approaches to medical research in addressing areas of unmet clinical need to improve patient outcomes.

The model for medtech development

Dr Ishrak explained that research and development in medtech falls into three categories:

- **Continuous innovation**, where the clinical effectiveness and economics of existing products are iteratively improved.
- **Invention** to develop technologies that offer a novel treatment option for patients.
- **Disruption** of existing markets, by developing technologies that are more effective than the current state of the art.

Importantly, all three of these approaches require a clinical problem to be defined that the technology will address. Doing this ensures that the resulting technology will improve clinical outcomes and fulfil a previously unmet need.

The continuous innovation of a technology through rapid and iterative development drives improvements that can translate to better patient outcomes or lower costs. As an example, Dr Ishrak cited the invention of transcatheter aortic valve replacement (TAVR) only a few years ago. Learning from the experience of many thousands of procedures, the TAVR was further improved to make the implant easier and further improve patient outcomes. With more insights, products are continuously innovated, such that the products of today are almost unrecognisable from the original product launched many iterations ago. This ability to continually innovate and iterate products is unique to medtech.

By contrast, inventive and disruptive developments offer new treatment options for patients and clinicians, and create opportunities for new standards of care. In 2009, the invention of the first retrievable stents, which could clear blood clots in the brains of patients experiencing an acute ischemic stroke, fulfilled an area of high unmet clinical need and created a new care pathway.[1] However, as inventive technologies disrupt care pathways, they will require a robust evidence base to demonstrate their safety and efficacy for use in clinical practice. This evidence is key to ensuring that the interventions improve patient outcomes, have appropriate safety profiles and are a worthwhile investment for health services.[2] Generating this evidence can take a significant amount of time and investment. For example, the clinical evidence for the retrievable stent was generated over six years, resulting in five New England Journal of Medicine publications; the new evidence enabled the technology to be incorporated into NICE guidelines for the treatment of acute ischemic stroke.[3]

Similarly, disruptive innovation can create new clinical pathways in what might be considered a ‘mature market’. For example, in 2016, after 60 years of continuous innovation, a new, disruptive innovation for pacemakers was developed: the first leadless single chamber pacemaker. This innovation dramatically reduced the size of the technology by 90%, and reduced major complications and risk of hospitalisation by nearly 50%.[4] Dr Ishrak described how further advances, in areas such as battery technology, data science, novel materials, robotics, artificial intelligence (AI) and miniaturisation, will inevitably supersede the current generation of medtech. Upcoming technologies that might cause such disruptive innovation include: injectable pacemakers, negating the need for surgery; expandable transcatheter

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[1] Slee E, Cam A & Shrivastava S (2010). *A novel device for the revascularization in acute ischemic stroke patients.* Interv Neuroradiol **16(3)**, 306-308
[2] 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
[3] National Institute for Health and Care Excellence (2015). *Mechanical clot retrieval for treating acute ischaemic stroke*. https://www.nice.org.uk/guidance/ipg548/documents/interventional-procedure-consultation-document
[4] Duray GZ *et al.* (2017). *Long-term performance of a transcatheter pacing system: 12-month results from the Micra Transcatheter Pacing Study.* Heart Rhythm **14(5)**; 702-709

valves for all four valves in the heart as a less invasive way to treat damaged or disease valves; and intelligent capsule endoscopies, using AI to interpret images in real time.

Value-based healthcare

The economic case

Today, most healthcare systems are based around a 'fee' for a product or service. Dr Ishrak argued that for a technology company, this means that revenue is based on a provider purchasing a technology which is tied to a 'promise' or prediction – supported by credible clinical evidence – to change outcomes. However, he highlighted that this means there is no financial accountability for *actual* health outcomes and so the technology is paid for irrespective of whether it works in practice, or causes unforeseen side effects, for example. He outlined a vision of a shift towards a value-based healthcare system, where costs are based on the value delivered to the patient or healthcare system, and defined value as '*the health outcomes achieved that matter to patients, relative to the cost of achieving these outcomes*'.

It was argued that such a value-based system would better incentivise the development of interventions to improve patient outcomes, making the industry more patient-centred. A fee-for-service healthcare system without such accountability could be unsustainable in the long-term and does not encourage effective disease prevention or disease escalation strategies. However, better linking costs to the value delivered is a challenging system to implement. To reward value, 'desirable' patient outcomes must be clearly defined and measurable. This is easier in the traditional model of episodic care management, where a patient has an acute episode and then recovers. Outcomes are easier to measure in episodic care, because they are clearly defined—they are based on the recovery process as well as the result of the clinical intervention. In addition, there is ensured accountability with the physician for the progress of recovery from an acute episode.

This may be challenging for chronic conditions, which may be complex and incurable, or when multiple providers are managing the care of an individual, thereby making it difficult to assign responsibility for the patient outcomes and their associated economic value. As such, a value-based approach might first be realised in conditions where the patient population that will benefit from the intervention can be clearly defined. This will prevent the use of value-based interventions in patients who are unlikely to benefit, which reduces waste and also potential harm. However, identifying such patient groups is in many cases challenging due to the lack of comprehensive patient health data, the complexity of disease and the diversity of patients.

Stratification to promote prevention

Historically, healthcare has been focused on treating acute conditions, measuring outcomes such as symptom recovery. However, prevention (and early diagnosis) of disease, and the ongoing management of long-term conditions, are becomingly increasingly recognised as important for developing a sustainable healthcare system that maximises quality of life, and so these areas are now being prioritised by UK Research & Innovation and the NHS.[5,6]

[5] https://www.ukri.org/innovation/industrial-strategy-challenge-fund/from-data-to-early-diagnosis-and-precision-medicine/

[6] Department of Health and Social Care and Matt Hancock (2018). *Matt Hancock: my priorities for the health and social care system*. https://www.gov.uk/government/speeches/matt-hancock-my-priorities-for-the-health-and-social-care-system

Achieving a value-based system that encourages technologies for early diagnosis, prevention and chronic care will be challenging. For prevention, generating evidence for a technology and determining its value will be challenging without the appropriate biomarkers, monitoring technologies or predictive tools.

For chronic care, Dr Ishrak explained that while many health interventions focus on the management of disorders in isolation, we are seeing increasing proportions of patients with multiple conditions (an area explored in the Academy of Medical Sciences' recent report on multimorbidity).[7] Identifying the numerous variables that determine patient outcomes in these circumstances is highly complex. It requires not only the stratification of patient populations based on their risk for developing conditions, but further stratification to determine who would benefit most from specific devices/interventions.

Technology to enhance chronic care

Whilst acute care is overseen and managed by clinicians, chronic care is more patient-focused, and delivered in primary care and home settings rather than hospitals. A move to focus on chronic care will require patients to be more involved in decision-making and management of their health. For this to happen, patients will need to have better access to tailored information. The Academy of Medical Sciences, through its recent report on *'Our data-driven future in healthcare: People and partnerships at the heart of health related technologies',* highlights the need for mechanisms to effectively communicate and engage with patients about the technologies involved in their care.[8] Engagement with patients to put them at the heart of decision-making and product design will be vital.

Achieving a data-enabled future

The effective use of data is essential to enabling early diagnosis and prevention, stratification of patients, assessment of health outcomes and patient self-management. In the future, Dr Ishrak predicted that an integrated device management system, managed by the patient, will collect clinical, behavioural and sensor-based data to provide a complete picture of a patient's health. Predictive algorithms and outcome measures could then be used to give personalised and actionable health insights.

Conclusion

Dr Ishrak concluded that through combining digital technology and traditional medicine, both medical technologies and engineering will be at the centre of improving patient outcomes and standardising care. As our understanding of the human body is still rapidly evolving, our potential to invent, innovate and disrupt in healthcare is seemingly endless. This will be increasingly underpinned by data, analytics and collaboration across disciplines. Moreover, an understanding of the global market and specific healthcare challenges is needed to tailor these technologies to more local needs. Finally, for the benefits of medtech to be fully realised, both clinical and economic value must be created in a system that prioritises patient outcomes at its heart.

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[7] Academy of Medical Sciences (2018). *Multimorbidity: a priority for global health research*. https://acmedsci.ac.uk/file-download/82222577

[8] Academy of Medical Sciences (2018). *Our data-driven future in healthcare: People and partnerships at the heart of health related technologies* https://acmedsci.ac.uk/file-download/74634438

How can we realise the potential of medtech in the UK?

The panel discussed the ways in which engineering and technology are being, and will be, used to improve care delivery and patient outcomes. A key driver behind this is the increasing ability to capture and make effective use of data. This will power technologies that improve and personalise patient care, and empower patients to take more responsibility for, and a more holistic approach to, their health. The UK must encourage an agile and innovative landscape where cross-disciplinary research is encouraged and the NHS can capitalise on innovative medical technologies for health benefit.

Introduction

The panel members, whose expertise crosses the life sciences and engineering sectors, discussed the ways in which engineering and technology might impact patient care and health, and the steps needed to realise these benefits. Those that participated in the panel discussion, chaired by Professor Sir Robert Lechler PMedSci, were:

- Dr Omar Ishrak, Chairman and Chief Executive Officer, Medtronic
- Professor Alison Noble OBE FRS FREng, Professor of Biomedical Engineering, University of Oxford
- Professor Sebastien Ourselin, Head of the School of Biomedical Engineering & Imaging Sciences, King's College London
- Professor Lionel Tarassenko CBE FREng FMedSci, Chair in Electrical Engineering, University of Oxford
- Professor Chris Taylor OBE FREng, Professor of Medical Biophysics and Professor of Computer Science, University of Manchester

New models of care

The panel presented several examples of where medtech is already being used to augment healthcare, for example, to support existing clinical pathways by making them faster, safer and more efficient. Professor Ourselin described EpiNav, an electrode guidance system for

surgical interventions in epileptic patients.[9] It is thought to improve patient safety during the surgery and reduces a four hour surgery to 15 minutes. Similarly, Professor Noble explained that artificial intelligence (AI) can remove human variability in the recording of antenatal ultrasound images. In her example, algorithms can automate and so standardise image capture to overcome variabilities in the skills of the sonographer. However, the panel also recognised that human clinical experience can be a huge asset to support the development of technologies. For example, Professor Noble cited an example where a machine learning algorithm was trained through eye tracking of expert sonographers, enabling the algorithm to learn to interpret images in the same way as a human expert. Once trained, this algorithm can speed up the interpretation of images. In addition to digital algorithms being a key driver of these developments, improvements in engineering are resulting in the miniaturisation of technologies, enabling the development of point of care devices and tools that are smaller, cheaper and portable.

Empowering patients and clinicians

Medtech such as smartphone apps can promote patient-centred care and self-management of conditions. Professor Tarassenko described the GDm-Health app for self-management of gestational diabetes. Patients use the app to annotate blood glucose data with meals, medication doses and other comments; review personalised data screens that allow them to link food intake to blood glucose levels; and to receive real-time advice at home from a hospital diabetic team.[10] This technology also allows diabetes midwives, registrars and consultants to view blood glucose results in real-time, institute an intervention between clinic visits, and adjust medication according to the individual needs of patients.

AI-driven technologies could also empower clinicians in areas that are isolated, rural or lacking essential equipment, such as some low and middle-income countries. As an example, Professor Noble explained that machine learning algorithms have been developed and trained to analyse antenatal ultrasounds. This has the potential to allow a non-expert sonographer, taking a simple scan, to assess key metrics such as foetal age, presentation and biometry by allowing an algorithm to interpret the image.

The importance of interdisciplinary collaboration

Professor Noble described how cooperation between engineers and clinicians can drive successful development and implementation of medical technologies. First, a specific problem that can be solved by a technology needs to be identified, requiring clinicians to outline the challenges they face and then engineers to propose how technologies might solve them. Secondly, engineers and clinicians need to work together to ensure that the resulting technology is relevant, meets clinical need and demonstrably solves the problem that it is intended to address. Finally, Professor Noble noted that clinical expertise and interpretation varies, and so a technology needs to be flexible enough to incorporate this and defer interpretations to clinicians where appropriate.

Professor Ourselin described how an interdisciplinary approach to innovation is similarly essential to combine the fields of engineering, technology and medicine for new surgical

[9] http://cmictig.cs.ucl.ac.uk/research/igs/epilepsy
[10] https://ouhbsp.oxnet.nhs.uk/gdm/

interventions. Engineers face significant challenges when attempting to translate their academic research into clinical development. These include issues around funding and infrastructure; a poor understanding of how the technology would translate into practice; and/or a lack of expertise in clinical standards and the level of evidence required. However, many of these challenges can be overcome through closer interdisciplinary working.

As an example, Professor Ourselin cited a case study at Guys and St Thomas' hospital, where a holistic approach that embeds clinicians and engineers in shared spaces is improving the success of surgical interventions by bringing together their expertise. He also emphasised the need for engineers to work across domains, branching out from traditional engineering specialisms into the fields of biological sensors, tissue engineering, robotics and software. The ultimate aim of this interdisciplinary approach is to move towards an 'enhanced operating theatre' where medtech, in the form of sensors, analytics and surgical aids can support the surgical team and improve efficiency and patient outcomes.

In addition, Professor Ourselin felt that a more robust and nurturing infrastructure to encourage surgical innovation is needed. Unlike in medicine, there is no internationally agreed evaluation pathway for assessing surgical innovations. The 'IDEAL' framework and recommendations were set up in 2009 to provide this, and are increasingly being used.[11] A more agile Quality Management System, with streamlined translation of research ideas into clinically usable technologies, whilst upholding patient safety, would be useful. Importantly, there needs to be system integration, where various expertise in areas such as clinical trials, good manufacturing practices and regulation, are brought together to support the translation of technology. This interdisciplinary working could be encouraged within the NHS through its large, embedded workforce of clinical engineers and technologists. A member of the audience noted that there is already a professional career route for clinical engineers and technologists within the NHS, but the panel agreed that there still needs to be a culture change for the role of engineers to be fully understood and for them to be fully embedded in both research and clinical practice.

Data as a driver for change

The benefits of medtech are often underpinned by the capture, linkage and use of data. From health and social care records, genomics, patient-recorded experiences, shopping and financial transactions, to the environment, the potential sources of data are ubiquitous. Professor Taylor described how combining existing and new data sources may provide new insights into the management of chronic health conditions, which are collectively responsible for 70% of the NHS budget.[12] For example, a patient with chronic obstructive pulmonary disease (COPD) may be able to record biomarkers, environmental factors and patient-reported outcomes, which, when combined, will give clinicians a more holistic picture of their disease. In addition, there is the opportunity to link prescribing details with outcomes to understand the effectiveness of medicines and allow treatment to be better tailored. The possible contributions to healthcare of areas such as real world evidence, the regulation of

[11] Hirst *et al.*, 2018. *No surgical innovation without evaluation: evolution and further development of the IDEAL framework and recommendations*. Ann Surg. **269(2)**, 211-220

[12] Department of Health and Social Care (2011). *Improving the health and well-being of people with long term conditions.* https://www.yearofcare.co.uk/sites/default/files/pdfs/dh_improving%20the%20h&wb%20of%20people%20with%20LTCs.pdf

health apps and improving the collection and utilisation of clinical data, are topics that the Academy of Medical Sciences has previously explored.[13,14,15]

Real world data to support interventions in mental health

Professor Taylor considered the use of real world data – data collected during routine care and outside of clinical settings – to be one area that could be transformational in some therapy areas, such as mental health. He explained that mental health problems are generally poorly understood, resulting in a lack of effective treatments for common, long-term conditions that are both damaging to individuals and expensive to manage. He considered the revolution in AI, combined with real world data collection, to be a major opportunity for their prevention and management. In his view, real-time, real world data will inform research to better understand mental health, including identifying patterns which could provide an early warning of patient deterioration, informing more timely intervention and developing better strategies to manage conditions. However, there are significant challenges, including the technical ability of AI in understanding human behaviour and emotions, and its ability to make reliable predictions from unreliable and complex data. An audience member asked how national scale behavioural interventions, both in mental health and beyond, might be implemented, and the panel agreed that we need better understanding of human behaviour to understand how effective interventions would be before implementation.

Personalised medicine

Data will also facilitate a stratified or personalised approach to medicine, enabling more targeted and effective treatments.[16] Through machine learning algorithms, populations can be stratified early into risk levels in order to tailor interventions. Professor Tarassenko used gestational diabetes as an example where data analytics of pregnant women could inform health interventions such as medication (for those at high risk) or management through diet (for those at lower risk). Maternal and neonatal outcomes can also be predicted by antenatal data (such as age, BMI, blood glucose levels and medication data). The risk of, and time to, developing Type II Diabetes may be predicted by an algorithm analysing blood glucose measurements coupled to foetal size compared to gestational age. The panel discussed how stratifying patients would enable individualised care and also inform disease prevention strategies, an area of increasing priority for the NHS.[17] This stratified medicine approach is an area of focus for the Academy of Medical Sciences and the FORUM programme.[18,19]

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[13] The Academy of Medical Sciences (2014). *Health apps: regulation and quality control*. https://www.raeng.org.uk/publications/reports/health-apps-regulation-and-quality-control
[14] The Academy of Medical Sciences (2015). *Real world evidence.* https://acmedsci.ac.uk/viewFile/56cab22108cf9.pdf
[15] Academy of Medical Sciences (2018). *Our data-driven future in healthcare: people and partnerships at the heart of health related technologies.* https://acmedsci.ac.uk/file-download/74634438
[16] Academy of Medical Sciences (2013). *Realising the potential of stratified medicine*. https://acmedsci.ac.uk/file-download/34525-51e915f9f09fb.pdf
[17] Department of Health and Social Care and Matt Hancock (2018). *Matt Hancock: my priorities for the health and social care system*. https://www.gov.uk/government/speeches/matt-hancock-my-priorities-for-the-health-and-social-care-system
[18] Academy of Medical Sciences (2013). *Realising the potential of stratified medicine*. https://acmedsci.ac.uk/file-download/34525-51e915f9f09fb.pdf
[19] Academy of Medical Sciences (2015). *Stratified, personalised or 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

Obtaining value from data

The effectiveness of medtech depends on the quality of data, with *the 'garbage in, garbage out'* principle being especially true in the case of AI algorithms. In cases where data are collected with human input, either by a patient or healthcare professional, there is a risk that they will be of variable quality. This applies to technologies used outside of the clinic such as apps and home monitoring devices, but equally to the clinical data inputted into a patient's electronic health record (EHR) by healthcare professionals. For medtech to truly empower patients to manage their own health, they will need to take responsibility for the quality of data they collect and contribute. The panel noted that where poor quality data lead to clinical errors there must be clear lines of accountability.

A key point raised by the panel is that to obtain value from data, the public need to trust that it is being used appropriately. One aspect of this is the 'circle of trust' – a balance between linking data geographically whilst still retaining local trust. For example, the public may be more accepting of data linked at a city or regional level, but less so at a national level. The appropriate level of linkage that maintains trust whilst also allowing data to be used effectively is an area where more research is needed.

The data held by the NHS is of huge value to researchers from both academia and industry seeking to develop innovative technologies. In response to a question from the audience on how we place value on NHS-held health data, Professor Tarassenko described this data as a 'sovereign asset', adding that companies can analyse data and perform trials on the technology developed from the data, but the NHS does not 'give it away'. He described how different benefit-sharing models might allow the NHS to benefit from enabling access to data for innovation. For example, the model used by Sensyne Health involves partner NHS Trusts that have contributed data receiving an equity of £5 million. The NHS now owns 10% of Sensyne Health and receives royalties.[20]

However, Professors Taylor and Ourselin noted that questions remain over who 'owns' NHS data and that in some circumstances the public are increasingly feeling that patients should have ownership over the data about them. This was supported by a comment from an audience member, who asked how we obtain value from data where patients might believe that the data about them should be in their control. Professor Tarassenko countered that public dialogue studies have found that people are happy for their data, in anonymised form, to be used for greater societal purposes; adding that the National data opt-out programme also enables the public to withhold their primary care data from research and planning purposes.[21,22] This is an issue that the Academy of Medical Sciences has been, and is, actively involved in exploring.[23,24] Public dialogue recently commissioned by the Academy, as part of its report *'Our data-driven future in healthcare: People and partnerships at the heart of health related technologies'*, showed that the public are supportive of data being used for improving care and for wider social benefits in line with the ethos of the NHS.

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[20] https://oxfordbrc.nihr.ac.uk/ground-breaking-digital-health-deal-agreed-with-drayson-technologies/
[21] https://digital.nhs.uk/services/national-data-opt-out-programme
[22] Ipsos MORI (2016). *The one-way mirror: public attitudes to commercial access to health data.* https://wellcome.ac.uk/sites/default/files/public-attitudes-to-commercial-access-to-health-data-wellcome-mar16.pdf
[23] The Academy of Medical Sciences (2006). *Personal data for public good: using health information in medical research.* https://acmedsci.ac.uk/file-download/34792-Personal.pdf
[24] Academy of Medical Sciences (2018). *Our data-driven future in healthcare: people and partnerships at the heart of health related technologies.* https://acmedsci.ac.uk/file-download/74634438

Challenges for evidence generation

Conducting RCTs and generating evidence in medtech and digital health

Before technology is integrated into clinical pathways, its efficacy and safety need to be demonstrated. The 'gold-standard' of evidence in medicine is the randomised controlled trial (RCT), which is not as commonly used in digital medicine or surgery compared to traditional medicine development.[25] Professor Ourselin explained that in surgery, a limited number of trials are undertaken and a limited amount of evidence exists to prove beneficial outcomes. Resulting deficiencies of the evidence-base and the relative lack of surgical innovation may mean that effective interventions take longer to be developed and implemented. In contrast, Professor Tarassenko argued that in a digital setting RCTs should be easier to implement. However, there are issues with conducting RCTs for digital tools. For example, digital tools can be iteratively and rapidly updated, so evaluations of one version may cease to be relevant for a future tool. In addition, RCTs for digital tools may encounter challenges around maintaining blinding of control and intervention groups. Finally, there may be significant costs involved when achieving useful sample sizes over a long period of time.

Professor Tarassenko described a case study where a digital intervention was successfully trialled in an RCT of the GDm-Health app in gestational diabetes. The intervention was first tested independently at the Royal Berkshire Hospital for six months. This allowed an evidence base to be gathered, demonstrating a 26% reduction in clinic visits compared to those receiving standard care, and a 50% reduction in the time spent by diabetes midwives on clerical and administrative tasks. Following these initial results, an RCT of GDm-Health was undertaken, which showed increased self-monitoring and fewer preterm and caesarean births.[26] In addition, Professor Ourselin described how surgical RCTs are beginning to become more commonplace. He stated that EpiNav is currently undergoing the first neurosurgical RCT.[27] Professor Ourselin stated that although it is expensive and difficult to undertake RCTs, a robust evidence base for interventions is essential for determining their value and maintaining trustworthiness of the technologies. Achieving this robust evidence base can be challenging, however.

In some cases, algorithms have been shown to (at least) equal human performance in interpreting images.[28,29,30] However, translating this into clinical practice is not simple due to the lack of large datasets – on which the accuracy of the machine learning algorithms depend for their training. Professor Noble's research, for instance, has been heavily influenced by the INTERGROWTH-21st study, which gathered large ultrasound datasets from clinical sites around the world and produced optimal growth charts of foetal development.[31]

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[25] The Lancet (2018). *Is digital medicine different?* https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(18)31562-9.pdf
[26] Mackillop *et al.*, (2018). *Comparing the efficacy of a mobile phone-based blood glucose management system with standard clinic care in women with gestational diabetes: randomized controlled trial.* JMIR mHealth **20:6(3)**, e71
[27] https://www.ucl.ac.uk/news/2017/oct/first-randomised-control-trial-nhnn-test-effectiveness-robot-guiding-electrode-placement
[28] Dodge S and Karam L (2017). *A study and comparison of human and deep learning recognition performance under visual distortions*. arXiv preprint arXiv:1705.02498.
[29] He K *et al.*, (2015). *Delving deep into rectifiers: surpassing human-level performance on imagenet classification*. In Proceedings of the IEEE international conference on computer vision, pages 1026–1034.
[30] Rajpurkar P *et al.*, (2017). *CheXNet: Radiologist-level pneumonia detection on chest X-rays with deep learning*. arXiv preprint arXiv:1711.05225.
[31] https://intergrowth21.tghn.org/standards-tools/

Adoption of technologies in the NHS

Responding to a question from the Chair, Dr Ishrak noted that the UK is an attractive place for investment by medtech companies thanks to its world leading academic research environment. However, in response to a question from an audience member, Dr Ishrak noted that adoption of technologies into the NHS is challenging, as although there is a single regulatory framework, the NHS has many separate commissioning and evaluation structures. Professor Tarassenko explained how this challenging environment can be navigated. He described the roll-out of the GDm-Health app in the NHS, which was one of the first apps in the NHS Digital library of apps and has now been deployed in three NHS Trusts and used by 1700 women. He stated that an additional dozen Trusts are scheduled to deploy the app before the end of 2019, showing that widening adoption is possible where the technology has a sufficient evidence base. Scaling up promising medtech from academia may also be challenging if there is not sufficient evidence to achieve commercial or venture capitalist investment. The panel felt that it is important for institutions to provide good support and funding to help scale up promising innovations.

Public and patient partnership

Public consent is an essential component for the successful use of new medical technologies. Where personal and sensitive data are involved, they should be handled ethically, respecting the privacy and confidentiality of patients. This is especially critical as any examples of data misuse will damage public trust in the NHS as a steward of patient data. Transparency over data use will be crucial in maintaining and building trustworthiness.

Professor Taylor also raised a number of issues that developers of medtech will need to address for it to be trustworthy. This includes an expectation that technologies will be inclusive regardless of demographics, personal circumstances and the level of digital literacy. Technologies also need to be distributed fairly across the NHS, providing fair access to all, and aiming to empower patients to have more responsibility in their health and care decisions. Patients should also retain choice, and be able to make non-recommended choices which may lead to sub-optimal health, without their decision affecting their access to healthcare. A key step to meeting these criteria will be to include patients and the public in the development and creation of medtech to ensure that it meets their needs and does so in an acceptable way.

The panel called for further research into how medtech might disrupt or change healthcare. For example, medtech has the potential to impact the interactions and relationships between patients and their healthcare professionals, for example by automating processes or replacing face to face appointments with digital or telehealth alternatives. More understanding is needed of the wider impact of these changes and subsequently incorporated into the assessment of a technology.

In response to a question from an audience member, the panel also highlighted the need for industry and the public sector to invest in cybersecurity in order to protect patient data. They also pointed out that dialogue is essential in helping to inform the public about the potential benefits and risks of using data in healthcare and research.

Conclusion

In his closing statement, Professor Sir Robert Lechler PMedSci summarised by saying that it is clear that the opportunities for engineering and technology to positively impact healthcare are growing, and the pace of change is likely to increase over the coming years. The ability of medtech to transform patient pathways is inspiring, but to effectively harness its potential we need to consider and prepare for the logistical and practical implications (such as adoption), the impact on existing pathways, and training needs. Similarly, the value-based approach to healthcare that medtech is pioneering could pave the way for similar innovations in the pharmaceutical and biotechnology sectors, where progress has been slower.

It is also clear that innovation needs to become more patient-centred. This could be achieved by designing interventions and technologies that fulfil their needs through co-creation, and by developing technologies that empower patients to manage their own health and care. He concluded that the ability of both medtech and digital tech to acquire and harness new data sources in powerful new ways brings with it huge opportunities but also risks. A balanced approach that protects confidential data whilst also allowing it to be usefully used will be essential to retain trust and confidence.

Annex I - Agenda

Wednesday 5 September 2018, 14.30-17.15
Royal Academy of Engineering, Prince Philip House, 3 Carlton House Terrace, London, SW1Y 5DG

14.30-15.00	**Registration and refreshments**
15.00-15.15	**Welcome and introduction** Professor Sir Robert Lechler PMedSci, President, Academy of Medical Sciences & Professor Serena Best CBE FREng, Chair of the Panel for Biomedical Engineering, Royal Academy of Engineering
15.15-15.50	**Keynote** Dr Omar Ishrak, Chairman and Chief Executive Officer, Medtronic
15.50-17.10	**Panel discussion: 'Transforming healthcare through engineering and technology'** *Chaired by Professor Sir Robert Lechler PMedSci, President, Academy of Medical Sciences* • **Dr Omar Ishrak**, Chairman and Chief Executive Officer, Medtronic • **Professor Alison Noble OBE FRS FREng**, Professor of Biomedical Engineering, University of Oxford • **Professor Sebastien Ourselin**, Head of the School of Biomedical Engineering & Imaging Sciences, King's College London • **Professor Lionel Tarassenko CBE FREng FMedSci**, Chair in Electrical Engineering, University of Oxford • **Professor Chris Taylor OBE FREng**, Professor of Medical Biophysics and Professor of Computer Science, University of Manchester
17.10-17.15	**Closing comments from the President of the Academy of Medical Sciences** Professor Sir Robert Lechler PMedSci, President, Academy of Medical Sciences
17.15-18.30	**Drinks reception**

Annex II - Attendee list

Co-Chairs
Professor Sir Robert Lechler PMedSci, President, Academy of Medical Sciences
Professor Serena Best CBE FREng, Chair of the Panel for Biomedical Engineering, Royal Academy of Engineering

Keynote speaker
Dr Omar Ishrak, Chairman and Chief Executive Officer, Medtronic

Panellists
Professor Alison Noble OBE FRS FREng, Professor of Biomedical Engineering, University of Oxford
Professor Sebastien Ourselin, Head of the School of Biomedical Engineering & Imaging Sciences, King's College London
Professor Lionel Tarassenko CBE FREng FMedSci, Chair in Electrical Engineering, University of Oxford
Professor Chris Taylor OBE FREng, Professor of Medical Biophysics and Professor of Computer Science, University of Manchester

Attendees
Professor David Adams FMedSci, Pro-Vice Chancellor and Head of College of Medical and Dental Sciences and Professor of Hepatology, University of Birmingham
Dr Kate Adcock, Director of Research and Innovation, Muscular Dystrophy UK
Miss Jessica Agyemang
Mr Mirza Ali
Dr Carolina Arevalo, Head of Operations, Public Health England
Dr Maryam Atakhorrami, Head of Business Innovation and Intelligence Group, University College London
Professor Tipu Aziz FMedSci, Professor of Neurosurgery, University of Oxford
Dr Sue Bailey, Strategic Partnership and Early Asset Director, Bristol-Myers Squibb
Dr Adrian Baker, Policy Manager, British Heart Foundation
Ms Carol Bewick, Head of Member Engagement and Communications, Association of Medical Research Charities
Mr Amit Bose, Chief Engineer, Quanta Fluid Solutions
Ms Silvia Bottaro, Forum Policy Officer, Federation of the European Academies of Medicine
Mr Philip Brading, Chief Executive Officer, UCLH Foundation Trust
Dr Emma Brunton, Research Associate, Newcastle University
Professor Clive Buckberry, Chief Technology Officer, Quanta Fluid Solutions
Dr Magda Bujar, Project Manager, Centre for Innovation in Regulatory Science
Dr Andy Clempson, Senior Research Policy Manager, Association of Medical Research Charities
Mr Clive Collett, HRA Ethics Guidance & Strategy Manager, Health Research Authority
Dr Dimitra Darambara, Team Leader, Multimodality Molecular Imaging, Institute of Cancer Research
Professor Adrian Davis
Ms Annie Dhillon, Regulatory Affairs Manager – Clinical Investigations and Evaluation, Medicines and Healthcare products Regulatory Agency

Dr Kevin Doughty, Visiting Professor of Digital Transformation of Care Services, University of Cumbria
Miss Ella Dulake, Student
Mr Gordon Duncan, Director, Harwell Campus
Sir Christopher Edwards
Ms Sue Farrington, Chair, Patient Information Forum
Dr Patrick Finlay, Chief Executive Officer, Institute of Measurement and Control.
Mr Alan Finnerty, Technology Development Manager, Medovate
Dr Shaun Fitzgerald FREng, Director, The Royal Institution of Great Britain
Professor Rebecca Fitzgerald FMedSci, MRC Programme Leader at the MRC Cancer Unit, University of Cambridge
Dr Norman Freshney, Health and Scientific Research Strategy Consultant, Freshney Consulting
Mr Martin Gadsden, Programme Manager, Japan Agency for Medical Research and Development
Mr Daniel Gill, Associate, Wellcome Trust
Ms Ellen Goodman, Communications, Royal Academy of Engineering
Dr Alexander Green, Spaulding Senior Lecturer of Neurosurgery, University of Oxford
Professor Liam Grover, Professor of Biomaterials Science, University of Birmingham
Professor Neva Haites OBE FMedSci, Vice Principal, University of Aberdeen
Dr Shahid Hanif, Head of Health Data & Outcomes, Association of the British Pharmaceutical Industry
Mr Tom Hardie, Improvement Fellow, Health Foundation
Dr Margaret Hartnett, Director of Research, GBG Plc
Professor Anthony Holland CBE FMedSci, Chair in the Psychiatry of Learning Disabilities, University of Cambridge
Ms Sophia Jaikaran, Communications & Engagement Officer, Kings College London
Ms Hannah Jones, Research Project Manager, Newcastle University
Eur Ing David Kent, Past Master, Institute of Measurement and Control
Dr Jeff Kipling, Freelance Science Policy and External Scientific Affairs Executive,
Mr Nick Kirby, Managing Director, Shelford Group
Ms Katie Konyn, Communications Manager, King's College London
Dr Uwe Krueger, Senior Managing Director, Temasek
Dr Rick Kuntz, Senior Vice President, Chief Medical and Scientific Officer, Medtronic
Dr Sabrina Lamour, Associate, The Wellcome Trust
Mr James Lawford Davies, Partner, Hempsons
Dr Maximillian Lee
Professor Gillian Leng CBE, Director of Health and Social care and Deputy Chief Executive, National Institute for Health and Care Excellence
Dr Louise Leong Medical Research Council
Mr Graham Lewington, Science Project Manager, Colliers International
Peter Lewis
Dr Tom Lillie, Vice President, Oncology Global Medical Affairs, MSD
Mr David Mabwa, PhD Researcher, University of Nottingham
Mr Andrew Mackenzie, Head of Policy and Communications, Physiological Society
Dr Mirren Mandalia, Senior Director, New Ventures & Transactions, Medical Devices, JNJ Innovation
Dr Helen Meese, Healthcare and medtech Policy & Public Affairs Consultant, The Care Machine Ltd.
Dr Anthony Metcalfe, Senior Fellow in Medical Technology, University of Birmingham
Ms Emma Moberly, Strategy Development Adviser, Wellcome Trust
Professor Michael James (Jim) Norton, Non-Executive Director, Coventry University
Dr Stephen Oakeshott, Head of Innovative Technologies Medical Research Council

Dr Lanre Olatomiwa, Postdoc Researcher, Loughborough University
Professor Raymond Oliver, Director, BioDesign Studio-Lab, Northumbria University
Dr Emil Olsen, Clinical Research Fellow, Royal Veterinary College
Mr Panagiotis Pardalidis, Medical Student
Mr Ethan Park
Sir John Pattison FMedSci, Emeritus Professor of Medical Microbiology, University College London
Mr James Peach, Precision Medicines Lead, Medicines Discovery Catapult
Mr Erlick Pereira, Consultant Neurosurgeon, St George's University Hospitals NHS Foundation Trust
Professor John Pickard FMedSci, Professor (Emeritus) of Neurosurgery, University of Cambridge
Mr David Pitney, Chartered Engineer
Mr Shiron Rajendran, Graduate
Professor Jeremy Ramsden, Professor of Nanotechnology, University of Buckingham
Mr Johnny Reed
Dr Duncan Richards, Head of Translational Medicine Future Pipeline Discovery and Director of Clinical Unit Cambridge, GlaxoSmithKline
Dr Christopher Rowe, Lead Technologist, Stratified Medicine Innovation Platform, Innovate UK
Mr Neville Sankey, Director, THIN GUIDES
Professor Julia Schnabel, Professor, Kings College London
Mr David Seivwright, Briefing Officer, Office for Life Sciences
Dr Tim Shuttleworth, Clinical Technologies Portfolio Manager, Engineering and Physical Sciences Research Council
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Professor Peter Smith CBE FMedSci, Professor of Tropical Epidemiology, London School of Hygiene and Tropical Medicine
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Mr Kris Wadia, Chief Executive Officer, Advisory
Dr George Wang, Senior Associate, Parexel
Geoff Watts
Dr Xian Weng Jiang, Principal Scientist, Orphidia
Dr John Williams, Managing Director, Birmingham Health Partners
Dr Matthew Wintle, Managing Director, Zestmedica
Professor Jeremy Wyatt, Professor of Digital Healthcare and Director, University of Southampton
Dr Ben Yarnall, Early Diagnosis Manager (Evidence and Research), Cancer Research UK
Mr Elias Zapantis, Programme Manager, MedCity
Dr Justine Zhang, Academic Clinical Fellow, Imperial College London,
Emma Moberly, Strategy Development Adviser, Wellcome
Fatima Suleyman

Professor Serena Best, Professor of Materials Science, University of Cambridge
Mrs Mandy Chessell, Distinguished Engineer, IBM
Mr Peter Ellingworth, Chief Executive, Association of British Healthcare Industries
Dr Melanie Lee CBE FMedSci, Chief Scientific Officer, BTG International
Mrs Angela McFarlane, Market Development Director, IQVIA
Professor Fiona Watt FRS FMedSci, Executive Chair of the Medical Research Council, and Director of the Centre for Stem Cells & Regenerative Medicine, King's College London

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