ROYAL ACADEMY OF ENGINEERING

Innovation in **medical technologies**

Summary of a meeting held on Wednesday 19 June 2013
at the Royal Academy of Engineering

November 2013
ISBN: 978-1-909327-04-7
www.raeng.org.uk/MedTech

Royal Academy of Engineering
Prince Philip House
3 Carlton House Terrace
London SW1Y 5DG

Tel: 020 7766 0600
Fax: 020 7930 1549
www.raeng.org.uk

Registered Charity Number: 293074

Photo: Elan microprocessor ankle and KX06 hydraulic knee
© Chas. A. Blatchford and Sons Ltd

Innovation in medical technologies

Summary of a meeting held on Wednesday 19 June 2013
at the Royal Academy of Engineering

Contents

Foreword

The Royal Academy of Engineering has run a series of seminars to highlight the opportunities and challenges in innovation in engineering sectors that have potential for growth and global reach. On 19 June 2013, a half-day conference on *Innovation in medical technologies* brought together engineers and business leaders from the medical devices, biomedical engineering and related sectors to discuss issues, innovations and trends in medical technology.

Medical technologies cover a very wide span of disciplines and industries and are at the interface of medicine, biology and engineering. They include technologies and devices used by medical practitioners in disease diagnosis and treatment; in the development of tissue engineering and synthetic biology; and in broader innovations that are opening up new ways to deliver healthcare. Technology development and research in diverse areas from nanotechnology to telecommunications have significant implications in the delivery and the effectiveness of medical technologies.

The conference heard presentations from academics, industrialists, innovators, health practitioners and administrators. This report seeks to highlight some of the issues raised and to contribute to further the discussion of innovation in the medical technology sector, both within the Royal Academy of Engineering and beyond.

The medical technology sector in the UK has a turnover of around £16 billion, and employs around 70,000 people in 3,000 companies

1. The UK medical technology sector

Medicine, surgery and healthcare are increasingly reliant on engineering professionals working alongside the medical and healthcare professions. Engineering plays a crucial role in bringing advances in medical devices, surgical techniques and synthetic biology. The United Kingdom holds a leading position in many of these areas, as well as in related sectors such as pharmaceuticals.

The medical technology sector in the UK has a turnover of around £16 billion, and employs around 70,000 people in 3,000 companies, with the large majority of these companies being SMEs (small- to medium-sized enterprises). The sector has proved to be resilient in the face of the global recession of recent years, and medical and healthcare equipment budgets have largely been protected in public sector spending cuts.

The UK has a long record of invention and innovation in medical devices and technologies, though as in other sectors the follow-through into commercialisation and profitable exploitation has been less certain. UK engineers pioneered ideas in diagnostic equipment such as computerised tomography and magnetic resonance imaging, though the leading suppliers of equipment are now largely multinational groups with their origins outside the UK. The UK government, through the Departments of Health and of Business, Innovation and Skills, and through the research councils and the Technology Strategy Board, have sought to strengthen the innovation 'pipeline' from basic research through to exploitation. Government has also proactively promoted UK excellence in medical engineering worldwide.

In research, the medical technologies sector has benefited from the strength of the UK academic base and the close ties between universities and hospitals. Unlike other major economies such as the US, the UK has a relatively unified and homogeneous health service, and this potentially offers significant benefits in trialling and introducing new technologies and systems.

> One of the benefits of the new Centres of Excellence in Medical Engineering has been to facilitate the exchange of research between engineers and clinical departments

2. The medical technologies innovation ecosystem

Medical technologies use science and engineering to improve the diagnosis, management and treatment of disease. This definition was offered by Professor Lionel Tarassenko CBE FREng FMedSci, Professor of Electrical Engineering at the Institute of Biomedical Engineering at the University of Oxford, who gave the keynote address at the Royal Academy of Engineering conference. Professor Tarassenko identified five discrete groups that contributed to the ecosystem of innovation in this area.

The five are:

The academic community

Long-term collaboration between academia and technology development has been enhanced through the establishment of four UK Centres of Excellence in Medical Engineering under the auspices of the Wellcome Trust and the Engineering and Physical Sciences Research Council (EPSRC). The four centres, at Imperial College London, King's College London, the University of Leeds and the University of Oxford, have different focuses within the research they are undertaking. King's College, for example, has spun out a technology SME in applying CT imaging in the diagnosis of aortic aneurysms, while a spinout from the Oxford centre, Oxehealth, is aiming to use tablet computers and Skype in personal healthcare monitoring.

Healthcare professionals

One of the benefits of the new Centres of Excellence in Medical Engineering has been to facilitate the exchange of research between engineers and clinical departments, and Professor Tarassenko explained how the involvement of the Wellcome Trust was helpful in breaking down barriers and raising engineers' credibility with their clinical colleagues. Partnership between engineers and clinicians is perhaps particularly crucial in the extension of healthcare systems into developing countries, where medical services could take advantage not just of low-cost equipment but also of new types of connectivity provided by wireless infrastructure.

Patients

New technologies and new models of deployment bring the patient into the process as an active participant. The increased use of self-diagnosis and self-monitoring systems demands that users' input is available from the outset of design, and the availability of information online means that patients are increasingly well-informed about their conditions and the treatments that are getting.

Industry

The medical technologies industry is a vibrant one but, said Professor Tarassenko, "it is very much an SME sector, with SMEs often being the route to technologically disruptive innovation". Large companies tend to concentrate on innovation in their existing product ranges. If smaller companies are more adventurous in terms of innovation, then there are also problems: Professor Tarassenko described it as, "more difficult for ideas from small firms to go through the necessary clinical trials."

Administrators and regulators

The regulatory system is the fifth part of Professor Tarassenko's innovation 'ecosystem' and the system is, he says, "designed for pharmaceuticals and doesn't really fit medical devices". Pharmaceuticals tend to be developed by very large companies over many years with significant funding to run trials. Medical devices, by contrast, are often developed by smaller firms with shorter development horizons and a 'monolithic' regulatory system is a significant factor in the so-called 'valley of death' between innovation and the commercialisation of products. Providers of venture capital and other forms of finance also expect faster returns than the regulatory system often allows. The UK is, however, well-placed to overcome some of these difficulties: the unified National Health Service offered a potential venue for speeding up the process of conducting clinical trials.

3. Innovations in technology

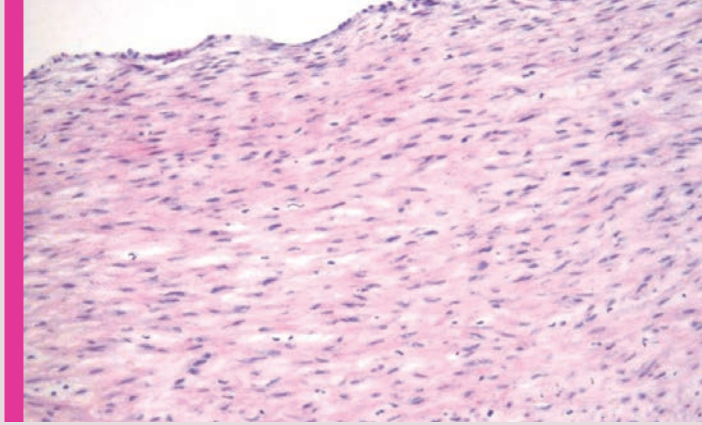
Biomedical engineering and medical technologies cover a very wide span of engineering innovation, and the conference focused on three categories.

The first is the use of engineering to regenerate new body material using biological building blocks that nature already provides.

The second is the engineering of synthetic replacements for body parts that are beyond repair using non-biological materials but increasingly interfacing with patient biology.

And the third is the engineering of systems that enable medical professionals to interact with the human body with accuracy and repeatability that is beyond human scope and increasingly at the level of individual cells.

Photo: Regeneration of dCELL® Vascular Patch biological scaffold with host cells (animal study) © iMBE



TISSUE ENGINEERING: TECHNOLOGY REGENERATING THE BODY

> This kind of tissue engineering potentially opens the door to a whole range of reconstructive and replacement surgery in applications that could solve life-threatening conditions

Tissue engineering, says Professor John Fisher CBE FREng FMedSci, very much illustrates the point that "to do transformational research you can't do it quickly or cheaply". Professor Fisher, in collaboration with Professor Eileen Ingham, is leading research at the University of Leeds on the creation of innovative 'scaffolds' that will form a potential basis for tissue regeneration.

The technique starts with tissue taken from a donor – human or animal – from which the cells are then removed to leave a scaffold that contains no cells. The scaffold is then repopulated with the patient's own cells and can be integrated as new tissue into the patient's body. The tissue thus created takes on the function of the tissue that formed the scaffold – so ligament remains as ligament, and a heart valve would still be a heart valve – but it is populated by the patient's own cells, and is mechanically and biologically compatible with the patient's own body and immune system.

So, for example, Professor Fisher sees potential applications in terms of repairing and replacing damaged tissue in young people's heart valves and then enabling them to grow as normal, since the replacement tissue will grow and change as they mature. Some of the work is currently in pre-clinical trial while other techniques have been commercialised and adopted clinically.

This kind of tissue engineering is, he says, a 'platform technology': it potentially opens the door to a whole range of reconstructive and replacement surgery in applications that could solve life-threatening conditions, such as vascular tears, down to 'wear and tear' conditions such as knee meniscus repair. Professor Fisher explained that some body parts wear out within a person's healthy lifespan: "The concept of 50 active years after the age of 50 indicates a vast market need."

"Our wish is that certain events in the Paralympics won't exist in 15 to 20 years' time" – and that's because there will be no difference in capability between athletes with and without prostheses

Photo: Orion microprocessor knee

PROSTHETIC ENGINEERING: TECHNOLOGY RE-ENABLING THE BODY

Prosthetics is the branch of engineering that constructs artificial replacements for body parts that have been removed through surgery, accident or disease and at the crude level of wooden or tin legs it is one of the oldest medical technology disciplines. But new technologies used in modelling and design, advanced materials and new forms of construction have changed the technology of prosthetics unrecognisably in the past 20 years. "They have created demand and expectation for further development", says Professor Saeed Zahedi OBE FREng, Technical Director of the world-leading UK prosthetic manufacturer Blatchford.

As with patients wanting to remain active into old age, so people with prosthetic limbs fitted want to be able to do everything they could before – and perhaps more. "Our wish," said Professor Zahedi, "is that certain events in the Paralympics won't exist in 15 to 20 years' time" – and that's because there will be no difference in capability between athletes with and without prostheses. Because of advances in life-saving surgery that enable people to survive what would formerly have been fatal events, it's not realistic to think that demand is going to be less.

Developments in recent years have radically enhanced and altered understanding of the physics of movement and of the interaction between the different elements of the limb, and now new sensors, controls and materials effectively mimic the actions of muscles. The quest for the next period is to integrate these elements and to go further in terms of customising to the individual, with all the variations in terms of residual anatomy and ability that that implies.

Work at Leeds had demonstrated huge potential for robotic repeatability to be used in rehabilitation work – for stroke victims and others recovering from surgery

SURGICAL ENGINEERING: TECHNOLOGY WORKING ON THE BODY

The record of robotics in surgery is a patchy one, said Professor Guang-Zhong Yang FREng, Director of Imaging and Robotics at the Institute of Biomedical Engineering at Imperial College London. "The current technology has tended to be a case of engineering looking for surgical applications, rather than meeting a demand from the surgeons," he said. So sectors such as urology have seen fast take-up of robotic aids to surgery, but other areas such as cardio-thoracic have been much slower.

Where there has been demand from the surgeon, it has come in areas where the advantages of minimal incisions and minimally invasive surgery are known, where there are elements of repeatability and where robotic dexterity can perform procedures that a surgeon's hand would struggle to do. Adding new senses such as vision would help adoption, and the utility of robots to do difficult tasks such as eye surgery was winning converts. It was unwise to expect fast change, Professor Yang said, as other surgical devices had barely changed in a century: aside from regulatory requirements, there was remaining conservatism within the sector.

However, surgery is just one of the applications for robotics in medicine. Work at Leeds, for example, had demonstrated huge potential for robotic repeatability to be used in rehabilitation work – for stroke victims and others recovering from surgery. And as digitisation of biology proceeds, definitions of medical robots are changing: devices that are programmed to deliver drugs or other treatment precisely to individual cells are robots of an entirely new kind.

4. Innovations in markets

While the technology of medical devices and equipment is patently a significant driver in innovation, broader market changes affecting the funding of research, the global distribution of healthcare services and the methods and organisation of healthcare delivery are key aspects that also impact on the nature of developments in this area. Medical technology and healthcare provision are subject to business influences that shape the landscape of innovation. The Royal Academy of Engineering's *Innovation in medical technologies* conference considered three diverse factors that affect the appetite for and the uptake of new ideas.

Evidence demonstrated that smaller innovative companies did best when surrounded by similar firms

Government and research council schemes that back innovation have made medical technologies a priority sector, with a growing emphasis across many programmes on introducing technology into biology and medicine

FINANCE: FUNDING MECHANISMS AND BUSINESS MODELS

Innovation in the medical technologies sector in the UK is largely in the hands of small companies, SMEs, and the cost of researching and taking a new product through the regulatory process can be significant. Government and research council schemes that back innovation have made medical technologies a priority sector, with a growing emphasis across many programmes on introducing technology into biology and medicine. But this sector shares with many others the difficulty of taking research ideas through to commercial products: the so-called 'valley of death' in terms of technology readiness levels (TRLs)[1] between the early stage research at TRLs 1 to 3 and the deployment of a mature and market ready products at TRLs 7 to 9.

Andrew Elder, a surgeon turned financier, is the lead healthcare partner at the venture capital company Albion Ventures. Early stage finance, he said, was more difficult to find than money for established technologies and products, and the European venture capital market for medical technologies was only about 20–25% of the size of the US market. That meant that innovators looking to develop products for world markets should not confine their search for finance to local sources; indeed, there was evidence that US finance houses were looking more favourably on European regulatory systems such as CE marking as routes to market. In addition, in sectors such as medical technologies, venture capitalists are having to be increasingly patient to see their return: horizons had lengthened to perhaps seven years, instead of the three to five years previously demanded.

But Dr Elder also had specific advice for smaller companies seeking to use venture capital to finance innovation that could make them a more attractive proposition. Evidence demonstrated, he said, that smaller innovative companies did best when surrounded by similar firms: "Medical technology tends to cluster around academic institutions and in locations where there is proactive legislation promoting it, and it makes sense to locate in these clusters."

Business models were also important. Venture capital groups were looking for realism and for capital efficiency; innovators who had thought about the capital efficiency of their model and the match to likely funders, as well as their markets and the customers were more likely to attract funding. And although the funding horizons had lengthened, there is often merit in looking for quick ways to an initial, limited commercialisation of the product.

[1] Technology Readiness Levels (TRLs) are a technology management tool that provides a measurement to assess the maturity of evolving technology,

www.publications.parliament.uk/pa/cm201011/cmselect/cmsctech/619/61913.htm

Photo: A village-based healthcare 'ecosystem' utilising digital health technologies © The George Institute for Global Health

"The challenge for technology is not just at the high end, but also in terms of encouraging engineers to work on mechanisms to deliver frugal healthcare"

GLOBAL MARKETS AND ERODING DIFFERENCES

Innovation in medical technologies appears often to be about the development of sophisticated products and systems, but the global need is not exclusively in this direction. Professor Robyn Norton from the George Institute for Global Health advocates the 'frugal innovation' concept, which is needed, she said, "because the world's greatest single health challenge is how to provide healthcare to seven billion people, five billion of whom do not have reliable access to healthcare, and about half of those are people who will develop a serious disease before the age of 60".

Technology needs to provide some of the answers to the disparities in healthcare provision between rich and poorer countries because other options – training more doctors, for example – are long-term projects and expensive too. "The cost of medical care is very high in relation to the ability to pay," she said. The concept of frugal innovation, also known as Jugaad innovation, involves re-engineering devices and whole systems so that healthcare can be delivered at affordable cost. An example has been the project in India to use existing village community care structures to deliver healthcare: training local people to focus on cardiovascular disease, for example, costs 70% less than relying on medical practitioners for all the screening and treatment work.

That is frugal innovation in terms of systems, but there is scope too for low-cost innovation in technology. For example, the universal mobile phone is reinvented in another Indian project as a sensor for diagnostics, linking through existing networks into an infrastructure that connects individuals to a clinical decision system. Further innovation is needed for the diagnosis of different diseases and also for the delivery of treatment. "The challenge for technology is not just at the high end, but also in terms of encouraging engineers to work on mechanisms to deliver frugal healthcare," Professor Norton said.

The next generation, he says, will see blood pressure sensors as standard on phones and other devices

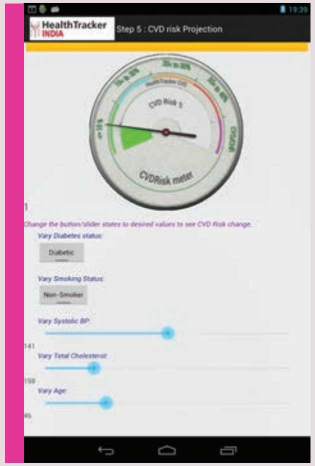


Image: Remote electronic sensors for mobile phones © The George Institute for Global Health

SELF-HELP AND DIFFERENT DELIVERY MECHANISMS

The technology changes that could deliver frugal innovation for those parts of the world where healthcare costs too much could also see a revolution in terms of provision in wealthier countries too, said Dr Chris Elliott MBE FREng, a former aerospace engineer and barrister, who is now a partner in a startup Swiss company developing micro-devices. Dr Elliott sees parallels between today's medical and healthcare systems and the changes that have happened in consumer electronics and computing over the past 50 years, where technologies that were huge, impenetrably complex, vastly expensive and only for the few have now become commonplace and universal.

"Health is very important to each of us, but although we spend a lot on consumer electronics, little or none of that spending is on electronics for health," he said. "So there's a potential revolution as medicine catches up and we change from being patients to being consumers."

The mechanism that Dr Elliott believes could bring this about is the same one that Professor Norton sees as delivering healthcare in less privileged places: the adaptation of the mobile phone to incorporate diagnostic sensors. The next generation, he says, will see blood pressure sensors as standard on phones and other devices. Functions that traditionally demanded the attention of a doctor would then be in the hands of the patient: "It takes the whole medical community into the consumer area of seeing medicine as an on-demand service."

5. Society and innovation

The concepts of self-diagnosis and home-based remote monitoring of conditions have major social implications. The technology that enables this potentially provides individuals with new levels of information about themselves and their conditions, but it does not necessarily equip them with the knowledge to make informed judgements. There are concerns that this could overload current healthcare systems and perhaps distort priorities through the clamour of the so-called 'worried well'. The idea of patients as 'customers' is not universally accepted, or even much liked.

But this is just one aspect of the broader changes that are in train. Underlying the whole of healthcare and medical technology innovation are other changes in society that influence the nature of demand and the responses that are required from engineers and medical and healthcare practitioners. The largest of these is the demographic change that has seen life expectancy increase everywhere, and not just in those countries that enjoy good medical services. And there are other linked societal changes: continuing population increase; the survivability of diseases formerly regarded as fatal; expectations of quality of life. Apparently tangential factors such as urbanisation and increased regulation also impact on the type of innovation that is wanted.

The aim of health technology horizon scanning is to systematically identify new and emerging technologies that have the potential to impact health, health services, and/or society; and which might be considered for health technology assessment. Horizon scanning can inform strategic priorities, help priorities research, inform guidance development and support innovation. It is a big task. Dr Alison Cook, Associate Director of the National Institute for Health Research (NIHR) Horizon Scanning Centre, is part of an academic unit

that is monitoring more than 250 medical technologies with the aim of identifying which innovations are close to reaching the market, in order to help those who will be affected to prepare for them. Examples of innovation that she sees within the next few years include the development of systems – in part putting together existing technologies – that could create an artificial pancreas to tackle type 1 diabetes, and work on visual prosthetics that could make artificial sight a reality. Further out, there is the potential for stem cell-based therapies to expand to the point where cells can be 'reprogrammed' to overcome faults.

If this kind of technology horizon scanning is essentially an academic exercise, then the other constituencies identified as central to the medical technology innovation process by Professor Lionel Tarassenko in the keynote address also have their individual perspectives on future innovation directions:

→ From the medical practitioner viewpoint, Professor Shervanthi Homer-Vanniasinkam, Consultant Vascular Surgeon at the Leeds General Infirmary, is a specialist in regenerative medicine and identified that the next big challenge that requires innovation in her area was the expansion of regenerative techniques that are currently very restricted in application to more general use; an example is the use of allogeneic stem cell treatments and autologous stem cell therapy.

- From the patient viewpoint, Jeremy Taylor, chief executive of National Voices, the national coalition of health and social care charities in England, said that the current UK model of medical care was very much rooted in 20th century thinking, and that "technology with a human touch" such as personalised diagnostics by mobile phone might enable the centre of gravity in healthcare to shift away from hospitals and on to a different, less rigid structure in which people would be able to take greater control of their own health.

- From the industry perspective, Dr Chris Elliott saw several over-arching themes that future medical technologies might be expected to conform to. They include, inevitably, the requirement for cost to be squeezed out as far as possible to encourage wide adoption. But he believed it would be axiomatic that future technologies would be networked, with data from one application available for others. And he also saw a demand for a no-blame investigation of failures so that technology developers could learn from mistakes without fearing legal consequences.

- From the NHS scientific and educational perspective, Dr Chris Gibson, scientific director of the NHS South of England Central Region, said that routine use of genomics and genetic profiling information would enable medical and healthcare staff to introduce "stratified medicine" that aligns treatment to the predicted response in the patient. He sees new "big technology" systems still requiring the traditional structure of hospital beds, but also increasing their use of community-based technologies, such as wearable monitors. The changes, he believed, would demand more of the skills traditionally associated with engineers to be used in the NHS, on tasks ranging from bioinformatics to bring order to the data through to clinical engineering to set up the infrastructure for a more decentralised community-based health service.

personalised diagnostics by mobile phone might enable the centre of gravity in healthcare to shift away from hospitals and on to a different, less rigid structure in which people would be able to take greater control of their own health

6. Further information and reading

The *Innovation in medical technologies* event on 19 June 2013 was the fourth in a series of conferences held at the Royal Academy of Engineering on innovation in sectors that are important to UK engineering and that offer potential for growth locally and globally.

Further reading

Royal Academy of Engineering and Academy of Medical Sciences (2013).
Establishing high-level evidence for the safety and efficacy of medical devices and systems, Summary of a roundtable forum hosted by the Royal Academy of Engineering and The Academy of Medical Sciences

Mirsadree, S., Wilcox, H.E., Watterson, K.G., Kearney, J.N., Hunt, J., Fisher, J. and Ingham, E. (2007).
Biocompatibility of Acellular Human Pericardium, *Journal of Surgical Research*, 143:407–414

Knight, R.L., Wilcox, H.E., Korossis, S.A., Fisher, J. and Ingham, E. (2008).
The use of acellular matrices for the tissue engineering of cardiac valves, Proc. IMechE, Vol. 222 Part H: *J. Engineering in Medicine*, 129–143

Stapleton, T.W., Ingram, J., Katta, J., Knight, R., Korossis, S., Fisher, J. and Ingham, E. (2008).
Development and characterization of an acellular porcine medial meniscus for use in tissue engineering, *Tissue Eng Part A*, 14(4):505–518

Stapleton, T.W., Ingram, J., Fisher, J. and Ingham, E. (2011). Investigation of the Regenerative Capacity of an Acellular Porcine Medial Meniscus for Tissue Engineering Applications, *Tissue Eng Part A*, 17(1–2):231–242

Wilshaw, S.P., Rooney, P., Berry, H., Kearney, J.N., Homer-Vanniasinkam, S., Fisher, J. and Ingham, E. (2012). Development and Characterization of Acellular Allogeneic Arterial Matrices, *Tissue Eng Part A*, 18(5-6):471–483

The King's Fund, Medical Advances. www.kingsfund.org.uk/time-to-think-differently/trends/medical-advances

Acknowledgements

The Royal Academy of Engineering would like to thank the following speakers for their contribution to Innovation in medical technologies:

Chair

Sir John Parker GBE FREng
President
Royal Academy of Engineering

Speakers

Dr Alison Cook
Associate Director
NIHR Horizon Scanning Centre

Dr Andrew Elder FRCS
Lead Healthcare Partner
Albion Ventures LLP

Dr Chris Elliott MBE FREng
Director
Leman Micro Devices SA

Professor John Fisher CBE FREng FMedSci
Director, Institute of Medical and Biomedical Engineering
University of Leeds

Dr Chris Gibson
Scientific Director of NHS South of England (Central)

Professor Guang-Zhong Yang FREng
Director and Co-Founder, Hamlyn Centre for Robotic Surgery
Imperial College London

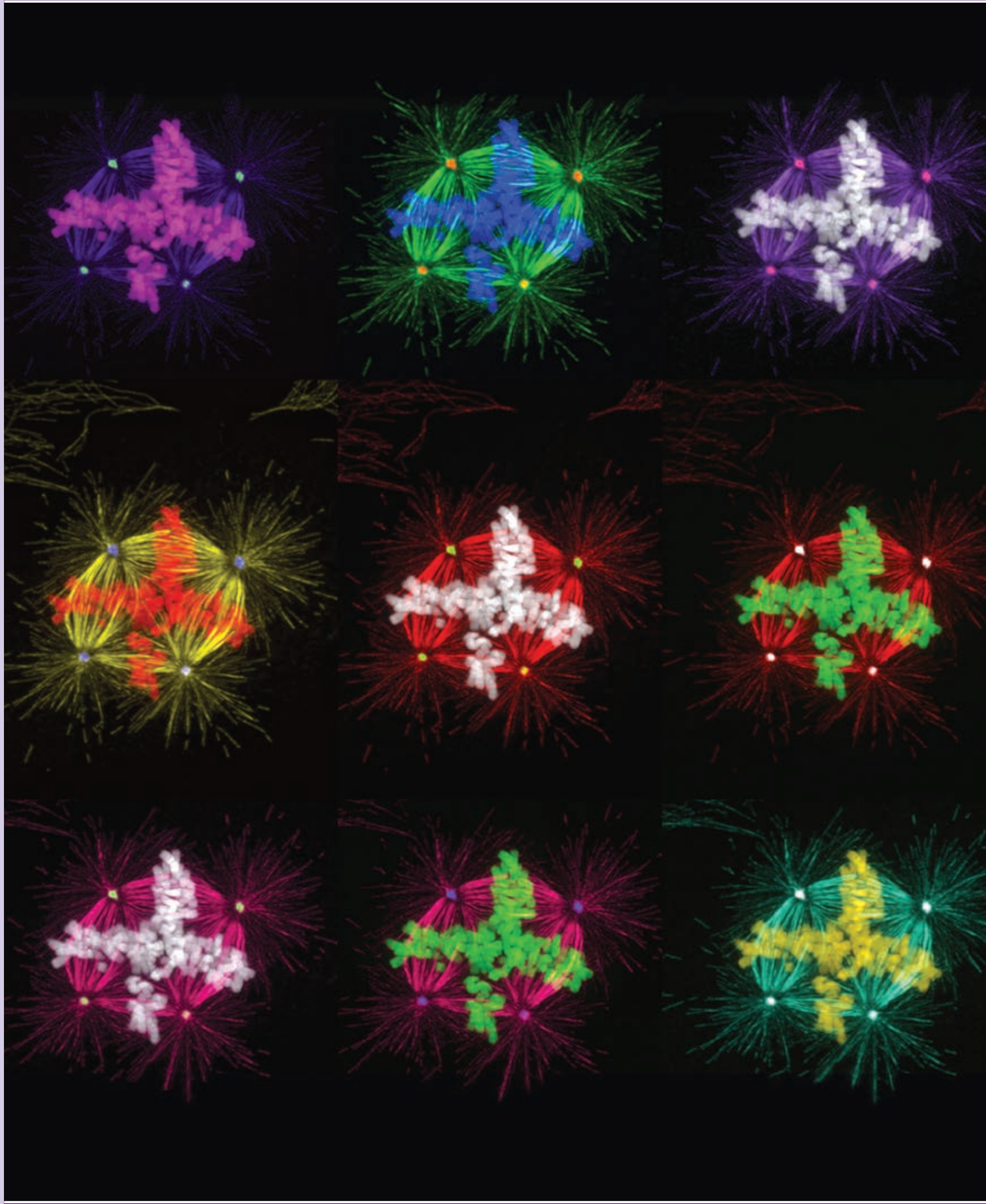
Professor Shervanthi Homer-Vanniasinkam FRCS
Consultant Vascular Surgeon
The General Infirmary at Leeds

Professor Robyn Norton
Principal Director
The George Institute for Global Health

Professor Lionel Tarassenko CBE FREng FMedSci
Professor of Electrical Engineering, Institute of Biomedical Engineering
University of Oxford

Jeremy Taylor
Chief Executive
National Voices

Professor Saeed Zahedi OBE FREng
Technical Director
Chas A Blatchford and Sons Ltd



ROYAL ACADEMY OF ENGINEERING

As the UK's national academy for engineering, we bring together the most successful and talented engineers from across the engineering sectors for a shared purpose: to advance and promote excellence in engineering. We provide analysis and policy support to promote the UK's role as a great place from which to do business. We take a lead on engineering education and we invest in the UK's world class research base to underpin innovation. We work to improve public awareness and understanding of engineering. We are a national academy with a global outlook and use our international partnerships to ensure that the UK benefits from international networks, expertise and investment.

The Academy's work programmes are driven by four strategic challenges, each of which provides a key contribution to a strong and vibrant engineering sector and to the health and wealth of society:

Drive faster and more balanced economic growth

Foster better education and skills

Lead the profession

Promote engineering at the heart of society

Royal Academy of Engineering
Prince Philip House
3 Carlton House Terrace
London SW1Y 5DG

Tel: +44 (0)20 7766 0600
www.raeng.org.uk