The Royal Academy of Engineering

Integrating technologies into a clinical environment

The Royal Academy of Engineering brings together the country's most eminent engineers from all disciplines to promote excellence in the science, art and practice of engineering. We work to enhance the UK's engineering capabilities; to celebrate excellence, inspire the next generation and lead debate by guiding and influencing public policy. Working closely with engineering institutions, our aim is to promote and enhance the contribution of engineers at the centre of society, public life, business and the economy.

The UK Focus for Biomedical Engineering, a group hosted by The Royal Academy of Engineering, provides a forum through which the principal organisations concerned with biomedical engineering (also known as medical technology) can communicate, debate and jointly act upon important issues. The group produces policy papers, organises briefing seminars and engages with the policy community.

Introduction

Healthcare has become increasingly dependent on engineering technology. Traditionally in the UK we have the expertise in the research and development of such technology, but historically we have been less adept at exploiting and integrating such development into the clinical environment for the benefit of patients and to the advantage of UK industry; for example the CT scanner was a UK invention, whose implementation into the clinical environment occurred in Japan. In recent years it has become recognised that the benefits of both development and integration need to be realised, and organisations now exist to encourage this. Healthcare technology is complex and expensive and it is important that correct decisions are made regarding its implementation; for example the implementation of IT into the NHS in Wessex in the 1980's turned out to be an expensive waste of money.

New technologies

In the last few decades biomedical technologies have been incorporated into the hospital and clinic environments and have been associated with expensive 'high-tech' medicine. Such technologies have included, but are not limited to the following:

- new techniques for imaging both the structure and function of body organs;
- biomechanical parts requiring prolonged fatigue life for increasingly long lived and active patients;
- sophisticated electrical and hydraulic cardiovascular devices, such as pacemakers and artificial hearts;
- modern respiratory, circulatory and renal support devices for the sickest critical care patients;
- tissue engineering techniques to provide the scaffolding for biological tissues to regenerate;
- information technology designed to handle large quantities of patient data in multiple modalities, safely and efficiently.

In the current era there is now also a pressing need to develop assistive technologies for use in the home to improve the quality of life and independence of an increasingly elderly population, and to keep them out of hospital or other expensive care environments funded by the taxpayer.

Technology adoption in the NHS

However the NHS has a reputation for being inflexible and slow in technology adoption, even though the NHS Technology Adoption Centre (NTAC) has existed since 2007 to help the process. NTAC was founded to ensure that technology implementation will lead to specified improved health outcomes across the NHS, and in particular to help with the detail of the implementation process. In an organisation as large as the NHS, managed as it is in a top down fashion, communication can be inefficient and adversarial, and there are multiple decision makers trying to influence multiple stakeholders. There is evidence that purchasing commissioners are sometimes unaware of the advent of new technologies. Technology adoption carries with it significant financial management challenges, not least the reimbursement to developers and manufacturers in a cash-limited health economy, adjustment of

financial strategies to implement and sustain new technologies, and timely decommissioning of outdated technologies. The National Institute for Clinical Excellence (NICE) exists to act as a gatekeeper for the adoption by the NHS of only the most cost effective and efficacious pharmacological and technological therapies, but has a reputation among clinicians as being a barrier to progressive modernisation and incorporation of new techniques that increasingly patients themselves demand. In his recent review of NICE, Professor Sir Ian Kennedy stressed the need for innovators and NICE to communicate continuously with each other during the developmental phase of techniques and technologies so that these difficulties may be minimised.

Research funding

The Engineering and Physical Sciences Research Council (EPSRC) funds £36M of research related to future healthcare, together with the Medical Research Council, the Department of Health and other providers. The portfolio of medical engineering research includes 231 grants valued at £73M in the fields of biomaterials, biomechanics and rehabilitation, imaging and vision, medical instrumentation, and modeling and simulation. EPSRC also supports research into the strategically important area of health and well-being in the ageing population, in particular ensuring a seamless transition from basic research through proof of concept to initial trials. To get the most out of research ideas and development, EPSRC supports funding partnerships between Universities, business and charities, and encourages integration of knowledge centres for innovative manufacturing research and development. For example Cancer Research-UK and EPSRC have formed a £45M strategic partnership to fund four large cancer imaging centres. The Wellcome Trust and EPSRC have formed a £41M strategic partnership to fund four centres of excellence in medical engineering. The challenge is to ensure that new technologies are used to solve clinical problems to bring maximum benefit for patients.

The Technology Strategy Board

The Technology Strategy Board (TSB) exists to invest in business innovation across a wide range of applications, and it works with businesses, Universities and Government. Medicine is a new application for the TSB, but its chairman's philosophy is that stakeholders must be proactive in encouraging technology adoption, rather than relying on a passive process. It is important that the UK become a global leader in innovation, where technology is rapidly and effectively applied in order to improve quality of life for patients and to create wealth for innovators. There are numerous innovation platforms, such as the areas listed above, and including also the treatment of infectious diseases and other developments for improving the efficacy of pharmacological therapies, whose research and development costs are very high. Within stratified medicine, there is the opportunity to develop technologies to enhance the quality of diagnosis, patient data analysis and treatment. The TSB exists to help stakeholders recognise and develop these opportunities.

The innovator's path: from innovation to integration

Manufacturers recognise the need to develop devices for the modern world, which means devices must be portable, compatible with existing systems, minimally invasive, and must contribute to reducing hospital stay. In fact the field of personalized medicine is evolving to take healthcare out of hospitals and into the home. Most technological devices come out of Universities and SMEs, and an innovator needs a partner with access to the appropriate markets in order to thrive. Innovators are not attuned to business models which can be quite complex, and new devices have to meet regulatory approval, frequently also a complex process. The achievement of CE marking merely puts a device in the field of play. The innovator then has to find a mechanism for reimbursement for his ingenuity and efforts. Clinical evidence of improved outcome is the key for successful reimbursement, and frequently there is up to a two year hiatus in the developmental and implementation process before this is achieved. In the modern healthcare world, a device must either result in better medicine for the same price or the same medicine for a lower price. Frequently the approval process and the reimbursement process are in conflict with each other. The innovator's path is not an easy one, and should be supported.

In UK we have great depth in our ability to innovate, and the organisations discussed in this paper are the keys to technology integration into medical care. The healthcare market is a lucrative one from which the UK economy must benefit, and engineering skills have a major role to play. In order that patients and the wider community all over the world may benefit from better health, it therefore behoves us to support fully, not merely the research and development phases of medical technology, but crucially also the implementation and integration phases.