ABHI

TRENDS FOR HEALTHTECH - A TEN YEAR PERSPECTIVE

Discussion Paper for
MHRA Board of Directors

February 2021

INTRODUCTION

There are numerous reports available predicting trends for the HealthTech Sector[1] in the years ahead. Many, written from the perspective of analysts and investors, attempt to pick winners and highlight individual technologies or offer examples that purport to indicate the direction of travel of the industry. As a representative body, we have avoided specific illustrations from individual members, and instead speak in more general terms. Whilst our brief is not to enter into any discussion on regulation itself, we have very much kept the relevance of the content for a regulatory audience in the mind. We have added an assessment of where we think regulation will need to evolve in some, specific technology areas as an Annex. This is included to provide a platform for future discussions on the technical elements that will be required, a discussion we hope can be had jointly between regulators and industry.

For the purposes of this paper and to focus the Board's discussion, we have considered three broad trends we see as significant over the next decade.

- Traditional Medical Devices will remain the mainstay of treatment.
- There will be significant advances in innovative surgical interventions.
- There will be significant convergence of traditional device, diagnostic and information technology.

Report authored by
Richard Phillips, Director, Policy & Communication, ABHI

TRADITIONAL MEDICAL DEVICES WILL REMAIN THE MAINSTAY OF TREATMENT

The UK population is predicted to increase in size, from 65.6 million in 2016 to over 74 million by 2039. Without a significant change to existing fertility rates and migration patterns, older people will increasingly outnumber people of working age. Projections by the Office for National Statistics (ONS) estimate that around a quarter of the population will be aged 65 and over in 2046[2]. Whilst life expectancy increases modestly, the proportion of life spent in ill health or disability is projected to increase. A 2017 study into forecasted trends in disability and life expectancy in England and Wales, found that the number of people living with disability will increase by 25% between 2015 and 2025, reaching 2.8 million, reflecting an ageing population[3]. These, well-rehearsed demographic trends continue to drive demand for what might be considered as traditional treatments. Cataract extraction, joint replacements and other planned surgery all help people stay independent and yield important quality of life gains. In the 1990s and 2000s the NHS made large investments to reduce waiting times for planned surgery. Referral to treatment times remain low by historic standards, and GP referrals are flat, but in recent years treatment capacity has not grown fast enough to keep up with patient need, and the number of patients waiting longer than 18 weeks has been steadily increasing[4]. The situation has been dramatically exacerbated by the COVID-19 pandemic. At the start of the pandemic around 1,400 people were waiting more than 52 weeks for treatment, that figure is now in excess of 200,000[5].

The potential for new technology to transform the way many of these patients are treated, whilst clearly significant, has sometimes been overstated. Regenerative medicine, in particular, has been cited for many years as a game changer in numerous diseases. Yet despite the obvious promise, ischemic heart disease is still largely treated with mechanical interventions and bypass surgery. More prosaic challenges exist for joint replacements. Even if regenerative technologies were available and effective tomorrow, there is still a very large, and growing population that needs to be maintained. There are around 160,000 total knee and hip replacements performed each year in the UK, with a similar number being replaced[6]. There are also a some very significant technical challenges to promoting local cartilage regeneration. The sheer forces on joint surfaces make application very difficult and any inconformity under the cartilage hugely limits the life expectancy of compounds. Elsewhere, technologies for other chronic diseases have also been slower to impact routine care than been hoped for. Despite developments in continuous glucose monitoring being used in conjunction with insulin pumps, a fully implantable closed loop system, effectively an artificial pancreas, remains stubbornly "about five years away," as it has for much of the past two decades.

There is also a very large amount of other technology that is essential to the delivery of modern healthcare today, that will remain so in ten years' time. The characteristics of much of the HealthTech sector which differentiate it significantly from biopharmaceuticals, will, then, be recognisable for the foreseeable future. The industry will remain incredibly diverse. There are close to 600,000 medical devices available in the UK today, and 3,500 indigenous companies, the vast majority of them small and medium sized enterprises. The pace of iteration of devices is also extremely rapid, typically occurring in a 12 to 18 month timeframe versus 10 to 12 years for a pharmaceutical product. The challenge of regulating such a rapidly evolving sector will also increase and the use of devices based on AI and deep learning increases. Iteration of these technologies is instantaneous with each new piece of information introduced into an alogorithm.

There are also external factors that will impact the development of traditional devices in the short to medium term. The pace of iteration shows no sign of slowing and will likely increase. The pandemic produced a need, and fostered an appetite for, the rapid development of some technologies, and has created the expectation that solutions can be delivered more quickly than has previously been the case. Set against this is the desire to ensure that technology is as safe as it can be. The Independent Medicines and Medical Devices Safety Review, *First Do No Harm*[7] laid out a series of recommendations, some of which will influence legislation that will be secondary to the forthcoming Medicines and Medical Devices Act. Significant will the development of a medical device information system to produce a *Register* of all available devices, and *Registries* of interventions in specific disease areas, providing detailed real-world evidence on safety and performance. The use of this data is particularly important for medical devices given their rapid iteration, and, whatever else might change, this requirement for increasingly sophisticated post-market information will be a feature of the sector. Data on patient outcomes, collected during real-world use, potentially also has utility outside of the consideration of patient safety. Healthcare systems in the developed world, facing the demographic challenges described above, have been exceptionally focussed on cost containment. The response of some of the HealthTech industry has been to try and focus on long-term value rather than short-term cost. To be successful, this strategy will need robust, transparent and trusted datasets. The data provided by such information systems as it relates to performance, safety and value is, therefore, inextricably linked. The reliable collection and interpretation of this data offers an opportunity for the UK, and its relevant organisations, to emerge as global leader in the rapid and safe development of HealthTech.

Developments in material science and environmental and sustainability considerations will also be significant factors for HealthTech. The desire to eliminate certain materials will be constituent on replacements being suitable for use in human health and coming at a cost that is acceptable to healthcare systems.

THERE WILL BE SIGNIFICANT ADVANCES IN INNOVATIVE SURGICAL INTERVENTIONS

Surgery is a discipline that has and continues to move from "saws and scalpels to robots and lasers."[8] Significant developments over a number of years have occurred in minimally invasive approaches, smaller incisions have reduced procedure times and complications, and increased safety and patient satisfaction. Many surgical disciplines have benefitted, from gall bladder and hernia treatments to endovascular interventions for a range of cardiovascular diseases. Progress is likely to continue and is leading to the development of techniques that reduce the number of incisions needed, such as Laparo-endoscopic single-site surgery (LESS) and Single Incision Laparoscopic Surgery (SILS). Natural orifice transluminal endoscopic surgery (NOTES) goes a step further. Also known as "surgery without scars," NOTES involves a planned incision through the wall of natural orifices to access the peritoneal cavity and perform a surgical procedure avoiding skin incision altogether. To facilitate these further improvements in surgical techniques, new devices will develop to provide access via different approaches, and surgical tools are likely to become smaller, more dexterous and "intelligent."

Perhaps the highest profile element of minimally invasive surgery, is that which is robot assisted. Robot assisted surgery has, so far, been limited in its use and most commonly used in urological, gynaecological and some elements of general surgery. Barriers have been costs, which include the purchase of the robotic system, maintenance and the disposable instruments required for each procedure, training, technical support and additional insurance[9]. The sheer size and difficulty in locating surgical robots has also limited their availability, whilst the learning curve associated with the technology versus conventional surgery is regarded as particularly steep.[10,11] This lack of uptake has resulted in a consequent lack of evidence, exacerbated by the fact that, even by the standards of HealthTech, advances in the design of robots has been rapid.

There is, however, a growing consensus that many of these barriers are being overcome and other specialities such as orthopaedics, colo-rectal and cardiothoracic might expect robot assisted surgery to be used relatively routinely in the near term. Furthermore, new surgical robots will include systems to record the entire procedure, as well as capturing telemetric data from the robotic arm and associated instruments. This could allow better evidence-gathering, audit, the refinement of surgical techniques and, ultimately, improved surgical outcomes.

Whilst the use of autonomous robots is probably much further in the distance, there is already experience going back 20 years of robot assisted surgery happening remotely, [12]something that might reasonably be expected to expand. Similarly, virtual and augmented reality are already established as training and planning tools for surgery and could be adapted further to allow remote specialist support for complex procedures.

This convergence of technology, and the implications for the development of devices and their post market surveillance, will be explored in further detail in the next section of this paper.

One of the fastest growing and most innovative technologies for surgical intervention, and where uptake has been rapid, is in the field of 3D printing. Some analysts are predicting that this will be the fastest growing segment of the HealthTech sector[13].

3D printing software can use patient imaging to print personalised and custom-made guides for surgery and implants replacing resected body parts or anatomical structures affected by congenital diseases. 3D printing technologies have been used to produce facial and cranial implants using a variety of materials for people who have sustained traumatic injuries, or to repair skull or congenital defects. As 3D printing template surgical guides and implants have now become common in many places across the country, the next step will be printing with materials that are better tolerated by the human body, as a precursor to the ability to grow or print tissue. Developments in 3D printing are making surgery safer and more precise and are opening avenues for surgical procedures that are currently too complex or have poor outcomes. Some technological and biological challenges remain, and include improving imaging, the speed of printing, and the compatibility and variety of materials. It is clear, however, that this a technology that is likely to be significant in the production of prosthetics for a number of surgical procedures and possible printed close to the patient. Applications of 3D printing have also been linked to biopharmaceuticals, including stem cell therapy.

These technologies are amongst those that are driving the miniaturisation of medical devices. Smaller devices may be implanted via different approaches. For example, traditional cardiac pacemakers sit in a sub-cutaneous pocket created near the collar bone and therapy delivering leads are attached to the myocardium. The newest models are now able to be implanted directly into the heart via a catheter introduced into the femoral artery and do not require leads at all. Future iterations of other devices will also be transformed by miniaturisation, and materials will need to be suitable to fit and adapt to smaller and smaller spaces.

THERE WILL BE SIGNIFICANT CONVERGENCE OF TRADITIONAL DEVICE, DIAGNOSTIC AND INFORMATION TECHNOLOGY

The most commonly cited driver of change in the HealthTech sector is digitisation. "Digital health" is such an all-encompassing term that ABHI has long abandoned attempting to provide a concise definition. What is clear is that rapid developments in information technology, particularly wireless technology, are driving the convergence of hitherto discrete disciplines.

Perhaps the most obvious example is the explosion in the use of "Smart Devices." The term refers to medical devices that have been become more portable or wearable thanks to advances in miniaturisation and wireless connectivity. These devices can encompass a range of product types, from activity monitors and smartwatches to wearable patches and smart clothing.

Cardiologist Eric Topol[14] identified the starting point for the development of smart medical devices as the introduction of smartphones, specifically the launch of the iPhone in 2007. HealthTech was quick to attract the attention of big tech companies like Google, Amazon and Apple, who have increasingly been making inroads into the digital health market. Such companies have a long-standing culture that emphasises innovation and speed, an approach that is often at odds with the rigorous development process needed in the HealthTech industry. Aside from Apple, the big tech giants have so far found it difficult to translate product ideation into successful medical devices. This has also created something of a grey area between what might be termed "wellness" devices and Apps, and more traditional medical devices and diagnostics. The integration of standard communication tools into medical devices clearly offers significant opportunities in any number of areas, but it also provides significant challenges for companies and regulators alike. We observed earlier that a closed loop, continuous glucose monitor and insulin infusion system, effectively an artificial pancreas, remains stubbornly "about five years away." Actually, such systems do exist, but they exist beyond the oversight of manufacturers and regulators. Tech savvy device wearers, using a free, open source App are doing what companies cannot do[15].

Open source was demonstrated to be of help during the pandemic[16] but we also learnt that it is not always easy for companies from outside the sector to manufacture even basic items to the standards required for medical use[17]. The open source genie is out of the HealthTech bottle and cybersecurity is already attracting the attention of regulators[18], but such considerations are likely to be with the sector on a permanent basis.

Other smart devices will impact clinical management in many other conditions. Hard-to-heal wounds are a common side-effect of diabetes, obesity, pressure ulcers and age-related vascular diseases, and have provoked technological research into improving wound diagnostics and therapeutics via smart dressings. Elements such as microelectronic sensors, microprocessors and wireless communication radios can now be embedded. Significant recent advances include flexible substrates which have replaced rigid circuit boards, sensors that have been printed on commercial wound dressing materials and wireless communication to alert patients and caregivers to changes in tissue viability.

In the management of asthma, smart inhalers, with extra digital features that link to Apps can alert patients when they are in high pollution or high pollen areas, send appropriate reminders, or check inhaler technique. They can also reliably record inhaler use, aiding clinical decision making.

Such is potential impact of advances in information technology on the delivery of patient care, the Secretary of State commissioned Professor Topol to advise on how to best prepare the NHS for a digital future[19].

Topol highlighted three discrete areas that appeared particularly apposite. Genomics has the potential to transform healthcare with more accurate diagnoses of a broader range of diseases with a genetic basis, and to allow patients to know their likelihood of developing one of these diseases. However, he cautioned that there was a need to develop clear frameworks for healthcare staff to use genomic data in a way that safeguards patient confidentiality and inspires the support and confidence of citizens and the wider community.

He pointed out that digital medicine is already changing the way people interact with healthcare. Telemedicine services, often overlooked as digital health, include telephone triage such as 111 and the ability to have video appointments. Remote monitoring is also changing the way care is delivered. Information from any number of devices already described, as well as more traditional implanted technologies such as cardiac pacemakers, can be continuously monitored to inform disease management. Programmable devices will be able to make changes remotely, creating opportunities to alter not only where care can be delivered, but who delivers it.

Topol also called out AI-based technologies, and there can be little doubt that these as well as those based on deep learning will have a far-reaching impact on all elements of healthcare. In diagnostics, automated image interpretation in radiology and pathology will lead to faster diagnosis, whilst the list of conditions that are using algorithms based on AI to enhance diagnosis grows ever longer[20]. It is also hard to imagine any branch of medicine where clinical decision support systems will not be in routine use in the very near future[21].

AI will transform patient-generated data into clinically useful information and empower patients to manage their own health or seek appropriate health support. Patient benefit should be the driving force behind AI and robotics design, with new products co-developed with patients from design to implementation. Technological advances and a greater focus on prevention, health and wellbeing will bring major improvements in patient outcomes and change the nature of how HealthTech is considered and deployed.

The combination of devices and drugs is often referenced as a trend, usually in forward looks at regulation. Such convergence is not new in itself, the delivery of vaccinations is, after all a combination of a medical device and a biological preparation, and many drugs are delivered via devices, either wearable or implanted, or by infusion systems in in-patient and, increasingly, homecare settings. Steroid eluting leads, drug eluting stents and therapeutic coatings on numerous medical devices are also examples of combinations, and examples where the regulatory classification between the two is relatively clear[22]. It would not be unreasonable to conclude, however, that examples of combination therapies will continue to increase and the lines between the elements will blur.

Companion diagnostics[23], medical devices, often an in vitro devices, which provide information that is essential for the safe and effective use of a corresponding drug or biological product, have been used since the late 1990s. It is likely that, with advances in personalised medicine and the ability of companion diagnostics to tailor treatment and reduce costs, their development and use will expand exponentially in the short to medium term.

CONCLUDING REMARKS

HealthTech has become increasingly regarded as having the potential to reduce costs and increase the efficiency of healthcare systems. It is an industry with a long and proud tradition of rapid iterative innovation, usually in response to challenges faced directly by clinicians. Technological advances will drive development in all area of the sector, especially that which depends on the acquisition and transfer of digitalised clinical data. These developments will require a corresponding response in the way of innovative regulations to sustain the breadth of the sector and match the pace of change. It is our belief that this would be best achieved with close and open collaboration with the developers, manufacturers and distributors of HealthTech.

ACKNOWLEDGMENTS

We are indebted to a number of ABHI members and clinicians who have contributed to this paper via informal discussions. We have borrowed heavily from the Royal College of Surgeons of England's Commission on the Future of Surgery[24] which we consider to be the definitive work of its kind, and this paper contains many unattributed extracts. Our thoughts were also stimulated by the KPMG report *Medical Devices 2030*[25] and PwC's *Driving the future of health*[26].

ABOUT ABHI

The Association of British HealthTech Industries (ABHI) is the leading health technology (HealthTech) industry association in the UK. We are a community of over 280 members, from small UK businesses to large multi-national companies. We champion the use of safe and effective medical devices, diagnostics and digital health technologies. The work of our members improves the health of the nation and the efficiency of the NHS.

The HealthTech industry makes a vital contribution to economic growth in our country. The industry employs over 127,400 people across 3,860 companies, mostly small and medium sized enterprises (SMEs). Many companies are working closely with universities and research institutions. The industry is generating a turnover of over £24 billion and has achieved employment growth of greater than 5% in recent years. ABHI's members account for approximately 80% of the value of the sector as measured by sales to the NHS. As the most highly regarded universal healthcare system in the world, the NHS in turn is dependent on technology produced by the industry to enhance the efficiency of services and drive continuous improvement in their delivery. The NHS has grown and developed partly on the basis of the UK's historic 'can do' approach to engineering and problem solving.

HealthTech is accordingly an engineering-based industry, characterised by rapid, often iterative product design and development, and a large number of SMEs. It is one of two distinct subsectors of the broader Life Sciences. Future growth and success will mean the HealthTech sector being recognised in its own right. The sector has evidence, regulatory and adoption needs that differ significantly from those of the other, biopharmaceuticals.

APPENDIX - POTENTIAL REGULATORY CONSIDERATIONS

Surgical interventions	Diagnosis & imaging	Digital Platforms	Remote Healthcare
Robotic surgery	Smart devices	Digitisation	Remote monitoring devices
3D printing / bio-printing	Very early diagnostics	Big Data	Remote diagnosis / self-testing
Miniturisation [MIS]	Companion diagnostics	Digital prophylactic / wellbeing platforms	Telemedicine
AI assisted surgery	Genomics and precision medicine		Smart connected devices
	AI assisted diagnosis		Big Data
	Liquid biopsies		

	Current regulation exists
	Updated regulation required
	New regulation required

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Report authored by
Richard Phillips, Director, Policy & Communication, ABHI

ABHI

Association of British HealthTech Industries
Suite 2, 4th Floor, 1 Duchess St,
London, W1W 6AN

+44 (0)20 7960 4360
enquiries@abhi.org.uk
www.abhi.org.uk
@UK_ABHI