USING TECHNOLOGY TO DELIVER HEALTH SERVICES

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A. INTRODUCTION	1.01	3. Slow procurement	1.49
B. TELEHEALTH AND TELEMEDICINE	1.06	4. Partial interoperability	1.53
1. What are telehealth and telemecine?	1.06	5. Unclear data security standards	1.55
2. The promise of telemecine	1.11	6. Limited change management and digital skills	1.58
3. Challenges to the wider use of telemecine	1.22	E. FUTURE OF HEALTHCARE	1.63
C. MHEALTH	1.24	F. WHAT CAN HEALTHTECH LEARN FROM FINTECH?	1.73
D. CHALLENGES TO THE SCALE-UP OF NEW TECHNOLOGIES IN HEALTHCARE	1.35	1. Big data	1.73
1. Lack of clarity about evidence	1.36	2. Disruption by tech companies	1.77
2. Regulation of digital products	1.46	3. Democratisation of data	1.80
		G. CONCLUSION	1.84

A. INTRODUCTION

The global healthcare market is undergoing fast evolution, with continuous introduction of new technologies. One can already get consultations online, search for a GP on an app and use a smartphone to monitor one's own health. Once a science fiction, having a surgery conducted remotely or by a robot has become a reality. As healthcare systems face significant challenges, such as the ageing global population, increasing levels of obesity and the effects of air pollution, coupled with financial pressures, rapid developments in digital technology present a range of attractive solutions.¹ These include the use of mobile health (mHealth) apps, telehealth and telemedicine. **1.01**

Several factors have conflated to contribute to the advancement of digital technology in healthcare. First, broadband access and smartphone usage are becoming omnipresent, with 90 per cent of the developed world and 41 per **1.02**

¹ Clarkslegal, 'How Tech is Caring for the Healthcare Sector' (6 July 2018).

cent of the developing world on broadband.² Such low barriers to entry are contributing to the continuous rise of mobile healthcare apps, including various wellness wearables. Moreover, the availability of smartphones, projected to reach 40 per cent of the global population by 2021, also enables providers to gather patient details and deliver treatment remotely.³

- 1.03** The information revolution is therefore increasing healthcare practitioners' ability to predict and diagnose diseases earlier and more accurately, select the most effective treatment and influence human behaviour.⁴ This should enable artificial intelligence (AI) to serve as a substitute for scarce clinical skills and knowledge, when appropriate and desirable.⁵ Yet, an increasing expectation of patients to be actively engaged in their own care and an over-reliance on healthcare apps, regardless of patients' desire, may ultimately violate patients' autonomy.⁶ Further, it may also marginalise patients who have no affordable or reliable access to internet or mobile technologies.⁷
- 1.04** Amidst the heightened interest, digital health has also seen an immense diversity of digital tools, with a limited understanding of their impact on health systems and people's wellbeing.⁸ In addition to this lack of uniform evidence standards, there are still a number of barriers that make it hard for new, innovative companies in the healthcare sector to translate their innovations into commercial contracts and scale them across the industry – from slow procurement, onerous data protection and security standards to limited digital skills among healthcare practitioners.
- 1.05** This chapter is structured as follows: Sections B and C describe key characteristics of, and use cases in, telehealth and telemedicine and mHealth, respectively. Section D focuses on the challenges to the scale-up of new technologies in healthcare, while section E zooms in on the UK's policy paper on *The Future of Healthcare*, as an example of a government's initiative to set up policies and enable an environment for the growth of innovation in healthcare.

2 International Telecommunication Union, 'ICT facts and figures 2017', cited in Pratap Khedkar and Dharmendra Sahay, *Trends in Healthcare and Medical Innovation*, World Intellectual Property Organization: Global Innovation Index 2019, at 87.

3 Next Conference, 'How will the End of Smartphones Look Like?' (September 2019), cited in Pratap Khedkar and Dharmendra Sahay, *Trends in Healthcare and Medical Innovation*, World Intellectual Property Organization: Global Innovation Index 2019, at 87.

4 Pratap Khedkar and Dharmendra Sahay, *Trends in Healthcare and Medical Innovation*, World Intellectual Property Organization: Global Innovation Index 2019, at 87.

5 Ibid.

6 Oliver Quick and Anita Ho, 'Smart Technology and Patient Safety – a Double-edged Sword?' University of Bristol Law School Blog (18 June 2018).

7 Ibid.

8 WHO Guideline, *Recommendations on Digital Interventions for Health System Strengthening* (2019).

Section F draws on the experience of FinTech and identifies some lessons learned from the FinTech sector that could be applied to the HealthTech sector. Section G concludes.

B. TELEHEALTH AND TELEMEDICINE

1. What are telehealth and telemedicine?

Telehealth has been defined as the use of electronic information and telecommunications technologies to support and promote long-distance clinical healthcare, patient and professional health-related education, public health and health administration. Technologies include video conferencing, internet, store-and-forward imaging, streaming media, and terrestrial and wireless communication.⁹ **1.06**

Although telehealth and telemedicine are often used interchangeably, telehealth is said to include a broad range of technologies and services aimed at providing patient care and improving the healthcare delivery system as a whole. It refers to a broader scope of remote healthcare services, such as remote non-clinical services, which include provider training, administrative meetings and continuing medical education, in addition to clinical services.¹⁰ **1.07**

Telemedicine, on the other hand, involves the use of electronic communications and software to provide clinical services to patients without an in-person visit.¹¹ Telemedicine technology is frequently used for follow-up visits, management of chronic conditions, medication management, specialist consultations and a range of other clinical services that can be provided remotely via secure video and audio connections.¹² **1.08**

⁹ US Department of Health and Human Services, Health Resources and Services Administration, *Telehealth Programs*.

¹⁰ See Vyopta, 'Is Video Conferencing HIPAA Compliant? An Overview on Telemedicine Software and Video Conferencing' (7 November 2018).

¹¹ According to the WHO, telemedicine is:

the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information, for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities.

WHO, 'Telemedicine: Opportunities and Developments in Member States' (2010), at 9.

¹² Vyopta, *supra* note 10.

- 1.09** Telemedicine can be as simple as a telephone conversation between healthcare personnel or as complex as a real-time interactive video exam of a patient conducted by physicians separated by hundreds of miles.¹³ Patient examinations are conducted using instruments (e.g., stethoscopes, ophthalmoscopes) and examining cameras connected to the telemedicine system, allowing a physician at a remote site real-time access to the patient and real-time interaction with the examining physician, physician assistant or nurse.
- 1.10** A technician or nurse typically operates the instruments with the patient in an examination room. Images and data are then transmitted to the remote physician for viewing and analysis, and further interacting with the patient.¹⁴

2. The promise of telemedicine

- 1.11** The telemedicine market was valued at about USD 21.5 million in 2018, and it is estimated to be valued at about USD 60.5 million by 2024, witnessing a compound annual growth rate of 18.5 per cent.¹⁵ The major factors for the growth of the telemedicine market include the rising healthcare costs, rapid technological innovations, increasing need for remote patient monitoring and growing burden of chronic diseases.¹⁶ Moreover, on the frontlines of the coronavirus pandemic, healthcare providers around the world have been tapping into telemedicine apps to communicate with patients and track the spread of the disease.
- 1.12** Telemedicine patients benefit from no travel expenses or time, less interference with other responsibilities, privacy and no exposure to other potentially contagious patients.¹⁷ Telemedicine providers, on the other hand, benefit from increased revenue, improved office efficiency, better patient follow-up and fewer missed appointments and cancellations.¹⁸
- 1.13** For example, in a pilot study at the Veterans Affairs hospital in the US, patients with inflammatory bowel disease (IBD) were divided into two groups, one received in-person treatment for their IBD condition, while the other received care via secure online video interaction. The study concluded that 'IBD outpatient service may be delivered via a novel telemedicine system. In

¹³ World Health Organization, 'Videoconferencing system, Telemedicine'.

¹⁴ Ibid.

¹⁵ Mordor Intelligence, Telemedicine Market – Growth, Trends, and Forecast (2019–2024).

¹⁶ Ibid.

¹⁷ Vyopta, *supra* note 10.

¹⁸ Ibid., see also Andrea Smith, Why Follow Up Visits via Video Is a Win-Win for Doctors and Patients, *Chiron* (16 November 2015).

this pilot study, we observed a high level of patient satisfaction similar to that achieved with a direct clinical encounter'.¹⁹

Some of the common use cases of telemedicine are described in continuation: **1.14**

(a) *Surgery*

Surgical staff can give patients pre- and post-surgery instructions using telemedicine. With clear instructions delivered prior to surgery, telemedicine reduces patient no shows and saves valuable scheduled operating room time.²⁰ After the surgery, surgical staff can check the patient's bandages visually, confirming adequate wound healing and, through readily accessible remote monitoring and follow-ups, they can deliver guidance to patients and ensure that patients are following their treatment plans.²¹ **1.15**

(b) *Psychiatry and mental health*

Telemedicine can be used to provide a range of psychiatric services including psychiatric evaluations, therapy (individual therapy, group therapy, family therapy, etc.), patient education and medication management. Use of telemedicine in psychiatric treatments has several advantages over traditional psychiatry, including reduced stigma, reduced time off work and better access to mental health specialty care that might not otherwise be available.²² **1.16**

For example, Big White Wall is an app that provides an online community for people who are stressed, anxious or feeling low. The service has an active forum with round-the-clock support from trained professionals. Members can talk anonymously to other members and take part in group or one-to-one therapy with therapists.²³ **1.17**

(c) *Remote experts*

Healthcare providers considered experts in a particular medical specialty are often located in a completely different part of the country or world from the patient seeking treatment. For patients who are unable to travel easily for a quick consultation, a telemedicine solution provides more accessible care.²⁴ **1.18**

19 M Krier et al., 'Potential use of telemedicine to provide outpatient care for inflammatory bowel disease', *American Journal of Gastroenterology* (December 2011).

20 Ali Hyatt, 'Five Medical Use Cases for Telemedicine', *American Well Blog* (13 October 2014).

21 Ibid.

22 Shourjya Sanyal, '5 Surprising Ways In Which Telemedicine Is Revolutionizing Healthcare', *Forbes* (31 October 2018).

23 See Big White Wall website at: www.bigwhitewall.com.

24 Danielle Daoud, '4 Most Common Telehealth Use Cases', *webRTC.ventures* (20 June 2018).

Secure data exchange means that the patient records could be shared with only the remote specialist during the call, ensuring patient privacy.²⁵

(d) *Elderly care*

- 1.19** With telemedicine, geriatric departments can more quickly spot at-risk patients post-discharge and provide interventions to avoid an otherwise unnecessary readmission.²⁶ Similarly, nursing homes can partner with health systems to provide bedside care for their residents at a fraction of the price of an onsite physician.²⁷
- 1.20** For instance, Kraydel is a smart device that sits on top of the TV as a connected device linking clients to their carers, family members and/or friends through their TV screen. In addition to built-in videochat, the service also includes medication, housekeeping and event reminders for the elderly, as well as data-driven automated alerts to caregivers if something seems wrong.²⁸

(e) *In-home care*

- 1.21** For patients who are immobile or for whom travel is difficult, many medical practices include in-home visits by care specialist or nurse. That in-person care provider may want to bring in another physician remotely to talk with the patient over video and help answer any questions the in-home care provider cannot answer.²⁹

3. Challenges to the wider use of telemedicine

- 1.22** At the same time, a possible obstacle to the wider adoption of telemedicine is that it will have to be integrated with the electronic medical records, and the issue of accessibility and broadband infrastructure (particularly in rural areas in developing countries, where basic telephone connection and electricity, let alone broadband coverage, are scarce), as well as system interoperability will have to be resolved.³⁰ Moreover, medical staff will have to be trained to coordinate remote care, and will have to cope with legal liability, accreditation and licencing issues.³¹

²⁵ Ibid.

²⁶ Hyatt, *supra* note 20.

²⁷ Ibid.

²⁸ See Kraydel website at: <https://www.kraydel.com/>.

²⁹ Daoud, *supra* note 24.

³⁰ Vyopta, *supra* note 10.

³¹ Ibid.

Finally, an obvious question for the providers of telemedicine services is whether they are compliant with the applicable health regulation standards. To that end, it is recommended that any provider using a video conferencing solution must have a solution that offers complete encryption of any personal patient data.³² **1.23**

C. MHEALTH

mHealth apps often provide educational and preventative tools aimed at improving overall health – for example, there are hundreds of apps to help individuals sleep better, meditate, eat better, exercise more and improve their cognitive skills.³³ **1.24**

By way of example, based on the same application programming interface (API) as Uber, Esquared allows users to find gym sessions and one-off classes in their area, in real time. It is completely on-demand, which means users only pay for the classes they take and have no contractual obligations to Esquared or the gyms they are visiting.³⁴ Similarly, Rise Today lets users find both classes and other fitness services and sessions in their area quickly and easily.³⁵ **1.25**

MyFitnessPal is a smartphone app and website that tracks diet and exercise to determine optimal caloric intake and nutrients for the users' goals. Users can either scan the barcodes of various food items or manually add them in the database of over five million different foods. The app then works out the calories against users' daily target and tells them how much they have left based on their goals.³⁶ **1.26**

Sleep++ grabs all the vital sleep information while one is asleep. By tracking motion, it is able to work out how restless the user is during sleep and when. Once the user is asleep, the app will instantly analyse the quality of sleep and tell him/her how good or bad it was.³⁷ **1.27**

³² Ibid.

³³ Clarkslegal, *supra* note 1.

³⁴ Jo Davy, 'ESquared App Ushers in New Era of Contractless Fitness', *City Matters* (6 December 2017).

³⁵ Giulia Mele, 'The New Fitness App That Lets You Book Any Class in London', *Healthista* (26 September 2017).

³⁶ See MyFitnessPal website at: <https://www.myfitnesspal.com/>.

³⁷ Christine Kopaczewski, 'How to Track your Sleep with an Apple Watch', *Business Insider* (4 April 2019).

- 1.28** Headspace is an app full of ‘guided meditations’ – audio sessions where one of the company’s co-creators leads listeners through mindfulness-based meditation.³⁸ When starting each instalment, users can select a three-, five-, or ten-minute version and pick between a male or female guide. Each instalment begins with a short lesson about meditation concepts and then transitions into the guided meditation. Available in several languages, the app also offers sleep-themed content.³⁹
- 1.29** In addition, mHealth apps can also be used to help remotely manage chronic conditions such as diabetes and asthma. For instance, MySugr app specialises in care for people with diabetes. It includes diabetes coaching, therapy management, automated data tracking and a connected blood sugar meter with home-delivered unlimited test strips.⁴⁰
- 1.30** AsthmaMD is an app that tracks medications, asthma triggers and patient’s action plan. It charts users’ asthma activity, which can then be shared with the user’s doctor and added to his/her medical records. Users can also opt to anonymously provide your data to asthma researchers who are studying the condition.⁴¹
- 1.31** Further, BrainWaveBank is an app that allows anyone to measure and track their cognitive health at home. Daily brain health is measured using a wireless headset, while playing mobile games for a few minutes a day. The app uses machine learning technology to build a detailed record over time of personal cognitive health, providing insights and advice to the user on how their individual lifestyle factors affect their performance.⁴²
- 1.32** Examples of other mHealth apps also abound: Dubbed ‘carer on demand’, Cera enables people to book online and see a carer within four hours, and then track their care.⁴³ Doctify enables patients to search, compare and book private doctors and health professionals in the UK. It features reviews written by patients and recommendations by other health professionals.⁴⁴ And Flynotes has developed a digital consent app, which aims to address the problem of

38 Ben Gilbert, ‘I Spent 10 Days Using the Popular Mindfulness App Headspace – This is what it’s Like’, *Business Insider* (16 October 2017).

39 Timothy Buck, ‘Headspace: A Guided Meditation Companion’, *TidBITS* (14 October 2019).

40 Roche Media Release, ‘Roche Acquires mySugr to Form a Leading Open Platform for Digital Diabetes Management’ (30 June 2017).

41 Aditi Pa, ‘AsthmaMD Revamps App, Adds Unconnected Peak Flow Meter’, *mobilehealthnews* (8 May 2014).

42 See BrainWaveBank website at: <https://www.brainwavebank.com/>.

43 Laura Stevens, ‘“Carer on demand” service launched’, *Digital Health* (30 November 2016).

44 See Doctify website at: www.doctify.co.uk.

paper consent forms for medical procedures, which often contain errors, making them potentially invalid.⁴⁵

Even the NHS now provides a list of approved mHealth apps.⁴⁶ According to the NHS's website, the NHS assesses the apps based on a range of assessment questions, to make sure that only safe and secure apps and digital tools are published on the NHS Apps Library. The questions in the assessment have been designed by experts from technical and policy backgrounds. They cover national standards, regulations and industry best practice and help the NHS to see how a product performs against important criteria.⁴⁷ Developers must also demonstrate how their product improves health and wellbeing, and prove that they have taken all appropriate actions to keep patients safe using their product.⁴⁸ **1.33**

The NHS also ensures that any personal information collected or shared, by an app or digital tool, is handled in a safe, fair and lawful way.⁴⁹ It also checks that a lay person can understand and use an app or digital tool effectively and that the product is interoperable with other systems. Developers must also demonstrate how patients can report any problems with a product and how the developer will work to correct them.⁵⁰ **1.34**

D. CHALLENGES TO THE SCALE-UP OF NEW TECHNOLOGIES IN HEALTHCARE

A number of factors still impede the mainstreaming of technology changes in healthcare, most notably: (1) lack of clarity about evidence, (2) regulation of digital health products, (3) slow procurement, (4) partial interoperability, (5) unclear data security standards and (6) limited change management and digital skills.⁵¹ Each of these is analysed in continuation. **1.35**

45 GM&C Life Sciences Fund, 'Acea Health announces funding from Catapult Ventures and PUBLIC to launch innovative digital dental and medical consent platform – Flynotes' (24 January 2018).

46 See NHS Apps Library at: <https://www.nhs.uk/apps-library/>.

47 NHS, How We Assess Health Apps and Digital Tools.

48 Ibid.

49 Ibid.

50 Ibid.

51 Nicola Blackwood, 'The Promise of HealthTech', *PUBLIC* (April 2018), at 4–5.

1. Lack of clarity about evidence

- 1.36** Despite general consensus that digital health solutions will be transformative for the health and wellbeing of millions of people, there is considerably less consensus about ‘what good looks like’ with respect to evidence and what data an innovator needs to gather in order to demonstrate that his/her innovation is safe, clinically effective and economically viable.⁵²
- 1.37** In an attempt to address this challenge, the National Institute for Health and Care Excellence recently published ‘Evidence Standards Framework for Digital Health Technologies’. Recognising that evaluating digital health technologies in terms of their potential user and system benefits is challenging, the framework describes the types and levels of evidence needed to show the effectiveness and expected economic impact of digital health technologies in the UK. It also aims to establish consistent criteria against which digital health technologies can be assessed.⁵³
- 1.38** The framework has three components: (i) evidence for effectiveness standards, based on the functional classification of the digital health technology for its intended use(s) (does it work in clinical trials and clinical practice?); (ii) evidence for economic impact standards (does it contribute to more efficient use of resources and offer value for money?); and (iii) supporting resources, including case studies.⁵⁴
- 1.39** Further, the framework calls for economic impact evidence, ranging from a simple budget impact analysis up to cost-consequence and cost-utility analysis. The level of analysis required varies depending on the level of financial commitment needed to deliver the new intervention or service.⁵⁵
- 1.40** In addition, it also outlines the ways developers can gather the effectiveness evidence required – including user testing, data demonstrating improvement in symptoms, and comparative outcomes for patients receiving other or no interventions, for example.⁵⁶

⁵² Ibid., at 20.

⁵³ National Institute for Health and Care Excellence, ‘Evidence Standards Framework for Digital Health Technologies’ (2019).

⁵⁴ Ibid.

⁵⁵ Imperial College Health Partners, ‘Working with the New Evidence Standards Framework for Digital Health Technologies’ (2019).

⁵⁶ Ibid.

Promisingly, the framework has been welcomed by both developers and commissioners as helping them understand what good levels of evidence look like for digital health technologies.⁵⁷ Arguably, with developers following the framework, commissioners will be able to compare the cost and value of differing services or interventions, and make consistent decisions based on quality evidence.⁵⁸ **1.41**

On a more global scale, the WHO has also published the guideline titled ‘Digital Interventions for Health System Strengthening’. The main objective of the guideline is to provide recommendations based on a critical evaluation of the evidence on emerging digital health interventions, based on an assessment of the benefits, harms, acceptability, feasibility, resource use and equity considerations.⁵⁹ **1.42**

By reviewing the evidence of different digital interventions, as well as assessing the risks against comparative options, the guideline aims to equip decision-makers in ministries of health, public health professionals and other stakeholders with implementation related to the following digital health interventions, accessible at a minimum via mobile devices:⁶⁰ **1.43**

- (i) birth notification (digital approaches to support the notification of births, to trigger the subsequent steps of birth registration and certification, and to compile vital statistics);
- (ii) death notification (digital approaches to support the notification of deaths, to trigger the subsequent steps of death registration and certification, and to compile vital statistics, including cause-of-death information);
- (iii) stock notification and commodity management (digital approaches for monitoring and reporting stock levels, and consumption and distribution of medical commodities. This can include the use of communication systems (e.g., SMS) and data dashboards to manage and report on supply levels of medical commodities);
- (iv) client-to-provider telemedicine (provision of health services at a distance; delivery of health services where clients/patients and health workers are separated by distance);
- (v) provider-to-provider telemedicine (provision of health services at a distance; delivery of health services where two or more health workers are separated by distance);

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ WHO, *supra* note 8.

⁶⁰ Ibid.

- (vi) targeted client communication (transmission of customised health information for different audience segments (often based on health status or demographic categories));
- (vii) digital tracking of patients'/clients' health status and services (digitised record used by health workers to capture and store health information on clients/patients in order to follow up on their health status and services received. This may include digital service records, digital forms of paper-based registers for longitudinal health programmes and case management logs within specific target populations, including migrant populations);
- (viii) health worker decision support (digitised job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions); and
- (ix) provision of training and educational content to health workers (the management and provision of education and training content in electronic form for health professionals).

1.44 While the guideline demonstrates that health systems should ensure increased availability and flow of information, the WHO recognises that digital health interventions are not sufficient on their own. Policy-makers and implementers need to constantly review available resources and adapt to new conditions if they want digital tools to provide tangible changes.⁶¹

1.45 Further, the guideline also notes that digital health tools are a valuable complement to, but not a substitute for, face-to-face-interactions. It is also important that consultations are conducted by qualified health workers and that the privacy of individuals' health information be maintained. Finally, the guideline also emphasises the importance of reaching vulnerable populations and ensuring that digital health does not endanger them in any way.

2. Regulation of digital products

1.46 As described in more detail in Chapters 3, 4 and 13, regulation of digital health products is a fast-evolving area, with companies struggling not only to achieve the regulatory standards in the first place, but also to maintain these standards in a constantly changing environment.⁶² In addition, regulatory

⁶¹ Ibid.

⁶² Blackwood, *supra* note 51, at 22.

differences between other countries present a further hurdle to exports for small companies wanting to scale.⁶³

In addition, it has been suggested that the accuracy and validity of various ‘symptom checker’ apps (many of which are developed by entrepreneurs and not necessarily healthcare professionals) is still questionable.⁶⁴ Further, as described in Chapter 2, there are also privacy and data protection considerations. **1.47**

Consequently, regulators should develop clear and ideally standardised guidelines for safety requirements and evaluation of the complexity of a healthcare app and its probability and severity of harm.⁶⁵ To that end, just as FinTech industry has seen an increasing collaboration between regulators, service providers and consumers, healthcare regulators, professional organisations and patient advocacy groups should also partner together to ensure that healthcare providers and patients are educated about the appropriate use and limits of various HealthTech devices.⁶⁶ **1.48**

3. Slow procurement

As described in more detail in Chapter 12, procurement practices have been identified as one of the major barriers to entry for HealthTech companies. For instance, in the UK, the Carter Report on hospital efficiency from 2016 found ‘astonishing variety in the numbers of products and suppliers used across and within trusts’ and ‘a lack of understanding of the hidden costs and inefficiency caused by weak compliance to purchase-to-pay systems, under investment in inventory control and poor engagement with industry on cost containment’. Further: **1.49**

whilst there have been excellent improvements by some trusts, most still don’t know what they buy, how much they buy, and what they pay for goods and services. Very few trusts are able to demonstrate even a basic level of control or visibility over total inventory or purchase order compliance that is common practice in other health systems and industrial sectors such as retail.⁶⁷

⁶³ Ibid.

⁶⁴ See Quick and Ho, *supra* note 6.

⁶⁵ Ibid.

⁶⁶ Ibid.

⁶⁷ An independent report for the Department of Health by Lord Carter of Coles, ‘Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variations’ (February 2016), at 7 and 42.

- 1.50** Unsurprisingly, the report recommends, among other things, that the NHS should ‘incentivise trusts to fully utilise their existing digital systems, and where necessary, enable them to access some of the Spending Review commitment to invest in digital technologies’.⁶⁸
- 1.51** To address the fragmented procurement landscape, the Department of Health and Social Care launched the Procurement Transformation Programme (PTP), aimed at delivering a new NHS Supply Chain, which is a centralised procurement service to the NHS. A step in the right direction, the new NHS Supply Chain is hoped to help the NHS deliver clinically assured, quality products at the best value through a range of specialist buying functions.⁶⁹
- 1.52** Nevertheless, it has been suggested that these reforms create significant legal and governance challenges, given that the new NHS Supply Chain rests on a complex network of contracts that arguably obscure decision-making processes, which raises issues under public procurement and competition laws.⁷⁰

4. Partial interoperability

- 1.53** Arguably, overcoming legacy systems, such as silos in healthcare data and systems, and leading change management for healthcare professionals and other stakeholders will pose significant challenges.⁷¹ In the attempt to address interoperability challenges, the NHS published the Interoperability Toolkit (ITK) – a set of national standards, frameworks and implementation guides to support interoperability within local organisations and across local health communities, which is hoped to bring a level of standardisation to the market.⁷²
- 1.54** Still, more will be required as many NHS organisations are reported to still enter into long-term, wide-ranging contracts with established incumbents who fail to meet these standards, operating out-of-date business models and closed (rather than open source) systems, giving them little impetus to offer a competitive, agile service.⁷³

⁶⁸ Ibid., at 8.

⁶⁹ See NHS Supply Chain website at: <https://www.supplychain.nhs.uk/>.

⁷⁰ For a detailed analysis, see Albert Sanchez-Graells, ‘Centralisation of Procurement and Supply Chain Management in the English NHS: Some Governance and Compliance Challenges’, *Northern Ireland Legal Quarterly* (2019).

⁷¹ Khedkar and Sahay, *supra* note 2 at 91.

⁷² NHS, ‘About the Interoperability Toolkit – ITK’.

⁷³ Blackwood, *supra* note 51, at 33.

5. Unclear data security standards

As described in more detail in Chapter 2, the healthcare industry is subject to heightened data protection obligations because health data is designated as a special category of personal data under the General Data Protection Regulation (GDPR). In addition, with the shift toward digital health including telemedicine and mHealth, companies must be more vigilant than in the past because there are more opportunities for data breaches and other security risks. **1.55**

After a series of headline-grabbing breaches affecting scores of companies and millions of individuals, the last few years have seen fast-moving changes in the regulatory landscape as regulators across the globe are trying to respond to the systemic threats and protect their constituents, while not imposing crippling costs on businesses. **1.56**

Organisations operating in the healthcare space therefore have no choice but to prioritise data protection and ensure that appropriate resources are assigned to the set-up, maintenance, and constant improvement of security and privacy practices. **1.57**

6. Limited change management and digital skills

As described in more detail in Chapter 15, technology is rapidly becoming a key player in care delivery, lifelong learning and education. Yet, unsurprisingly, there are significant variations across the healthcare system in terms of cultural resistance and digital skills to implementing digital transformation, as well as clinical engagement with digital health solutions.⁷⁴ **1.58**

In an attempt to address this gap, in 2017, the NHS launched the Digital Academy, which provides a year-long digital health training course to Chief Clinical Information Officers, Chief Information Officers and aspiring digital leaders from clinical and non-clinical backgrounds.⁷⁵ The Academy was launched in direct response to the independent report on how English healthcare system should best approach the implementation of information technology, which identified ‘a lack of professionals – namely Chief Clinical Information Officers and Chief Information Officers – that can drive forward the transformation agenda enabled by informatics and technology’.⁷⁶ **1.59**

⁷⁴ Ibid., at 37.

⁷⁵ Imperial College London, ‘NHS Digital Academy’.

⁷⁶ Independent Report, ‘Making IT Work: Harnessing the Power of Health Information Technology to improve Care in England’ (2016).

- 1.60** Provided in partnership with Imperial College London, the University of Edinburgh and Harvard Medical School, the Academy encompasses six modules: (i) essentials of health systems; (ii) implementing strategy and transformational change; (iii) health information systems and technologies; (iv) user-centred design and citizen-driven informatics; (v) decision support, knowledge management and actionable data analytics and (vi) leadership and transformational change.⁷⁷ The programme has been recognised as pivotal in bolstering digital leadership in the NHS.⁷⁸
- 1.61** Notably, the implementation of innovation will extend outside a single institution and involve multiple complementary innovation strategies. For example, the incorporation of the polio vaccine into routine medical care required both the manufacturing of large quantities of the vaccine and massive changes in medical education, health policy, public health resources and public awareness.⁷⁹ Similarly, the broad adoption of digital health solutions will require insurance coverage parity with face-to-face care, changes in clinic workflow, and patient and provider education.⁸⁰
- 1.62** Finally, the application of technology should not become an excuse for any dehumanisation of healthcare. The expertise and judgment of healthcare professionals at every level – medical staff, technicians and support staff alike – will remain essential to healthcare even as we enter a new age in which these individuals see their roles evolve as more digital solutions and services develop.⁸¹

E. FUTURE OF HEALTHCARE

- 1.63** Many of the above-described obstacles may be overcome by increasing cost pressures and consumer power, with governments playing an important role in setting up policies and enabling an environment where different stakeholder incentives align to drive the necessary changes.⁸²
- 1.64** In that context, in 2018, the UK Department of Health and Social Care published a policy paper titled, ‘The Future of Healthcare: Our Vision for

⁷⁷ NHS Digital Academy Application Booklet.

⁷⁸ Blackwood, *supra* note 51, at 37.

⁷⁹ John Glaser, ‘How to Ensure Your Health Care Innovation Doesn’t Flop’, *Harvard Business Law Review* (27 December 2019).

⁸⁰ *Ibid.*

⁸¹ Blackwood, *supra* note 51, at 12.

⁸² Khedkar and Sahay, *supra* note 2.

Digital, Data and Technology in Health and Care', which outlines what is needed to enable the healthcare system to make the best use of technology to support preventative, predictive and personalised care.⁸³ The paper identifies the main challenges to a technology-driven NHS as: (i) legacy technology and commercial arrangements, (ii) complex organisational and delivery structures, (iii) a risk-averse culture, (iv) limited resources to invest and (v) a critical need to build and maintain public trust.⁸⁴

To address these challenges, the paper sets out the following objectives that should guide the NHS's approach to technology: (i) put in place the right infrastructure, (ii) buy the best technology, (iii) ensure that digital services meet people's needs, (iv) enable HealthTech and innovation, (v) develop the right skills and capabilities and (vi) build an open culture.⁸⁵ **1.65**

In order to satisfy objectives (i) and (ii), the Department details some of the steps it is taking to build upon the existing safeguards in legislation and security standards, such as via the Initial Code of Conduct for Data-Driven Health and Care Technology (published in July 2019) and the draft 'NHS digital, data and technology standards framework', published alongside the policy paper. **1.66**

In order to satisfy objective (iii), the paper recognises that there is a 'huge need for the NHS, care providers and commissioners of health and care services to develop solutions and co-create them with industry, recognising the value and expertise that health and social care organisations bring to the table in this co-creation'. **1.67**

In relation to objective (iv), the Department undertakes to 'set national open standards for data, interoperability, privacy and confidentiality, real-time data access, cyber security and access rules' and to even introduce a 'healthtech regulatory sandbox', which will let the Department 'test, iterate and de-risk the most promising innovations – and the relevant regulation – so that when they are ready for uptake across the NHS, clinicians can use them with confidence'. **1.68**

Notably, in January 2015, the NHS launched the Innovation Accelerator, which provides among other things: access to mentorship from a range of **1.69**

⁸³ Department of Health and Social Care, 'The Future of Healthcare: Our Vision for Digital, Data and Technology in Health and Care' (17 October 2018).

⁸⁴ Ibid.

⁸⁵ Ibid.

experts and high-profile mentors, representing a broad skills base and sectors; pairing with and support from Academic Health Science Networks; peer-to-peer learning and support; quarterly learning events, including inspirational speakers and action learning sessions; workshops and webinars on key topics (e.g., business models, business case development, coaching and mentoring, intellectual property, leadership and resilience); specialist briefings as and when required (e.g., NHS procurement, marketing and communications, behavioural economics); speaking opportunities at conferences; and access to bursaries.⁸⁶

1.70 Finally, with respect to goals (v) and (vi), the paper refers to Dr Eric Topol's review titled, 'Preparing the Healthcare Workforce to Deliver the Digital Future', which makes recommendations that will enable the NHS staff to make the most of innovative technologies such as genomics, digital medicine, artificial intelligence and robotics to improve services. The paper also refers to the NHS Digital Academy, which will 'ensure 300 chief information officers and chief clinical information officers are trained by March 2021'.

1.71 Similarly, the Department undertakes to:

empower each board, each procurement team, each chief information officer and each member of staff with a revolutionary idea to take charge of their role in our healthcare ecosystem. We will equip them with clear documentation to minimise the barriers to building a software solution, a supportive and agile culture, and innovation support to help good ideas spread.

1.72 The policy paper has been embraced as a welcome approach by the Department, which sets out a helpful framework for further work in the HealthTech space.⁸⁷

F. WHAT CAN HEALTHTECH LEARN FROM FINTECH?

1. Big data

1.73 The success of technology innovations in the financial sector has seen FinTech become a global boom industry.⁸⁸ Broadly speaking, FinTech denotes the use

⁸⁶ See NHS Innovation Accelerator website at: <https://www.england.nhs.uk/ourwork/innovation/nia/>.

⁸⁷ Bristows LLP, 'A Vision for Health-Tech – New Government Policy Paper sets out Strategy for Digital, Data and Technology use in Health and Care', *Lexology* (26 October 2018).

⁸⁸ Lee Fasciani, 'From Finance to Healthcare: 5 FinTech Trends that will Benefit Digital Health Products', *Healthcare Global* (5 August 2018).

of technology to deliver financial services and products to consumers. Increasingly, FinTech has come to represent technologies that are disrupting traditional financial services, including mobile payments, money transfers, loans, fundraising and asset management.⁸⁹ The key advantages that FinTech brings are the lowering of costs and improvement of services, as well as better, data-driven decision-making.⁹⁰

The parallels with HealthTech are manifold: While finance tracks money, the likes of health apps monitor and record steps and active minutes, heart rate, calories burned and even quality of sleep.⁹¹ The proliferation of health apps empowers and encourages individuals to proactively engage with their wellness, which should also lead to better, data-driven decision-making. Moreover, as individuals become more comfortable with tracking and sharing the details of their lifestyle, big data can be utilised to analyse and predict both short- and long-term impact of lifestyle choices.⁹² **1.74**

For example, Babylon Health and Bupa recently announced the launch of a ‘digital twin’ programme, which will allow Bupa customers to tap parts of their body with their smartphone and get medical assessments.⁹³ This is done by using a large database powered by Babylon’s ‘cutting edge AI technology’ and a deep neural network, presumably through deep learning technology, created from millions of data samples collected and input by their scientists and doctors to provide up to date, accurate information.⁹⁴ **1.75**

Importantly, the ‘digital twin’ only provides health information and not a diagnosis, and all information is based on statistics and risk factors via the information the patient provides in the health questionnaire about past illnesses, current excise rates, etc.⁹⁵ The answers to the questionnaire help create a ‘digital twin’, which is displayed as a transparent human figure, with colourful organ structures, each of which one can click and see the organ health and risk factors for future disease.⁹⁶ **1.76**

89 Jelena Madir, ‘Introduction – What is FinTech?’, in Jelena Madir (ed.) *FinTech: Law and Regulation*, Edward Elgar (2019), at 1.

90 Ibid., at 20.

91 Fasciani, *supra* note 88.

92 Ibid.

93 Hannah Crouch, ‘Babylon Partners up with Bupa for ‘one of a kind’ Health Service, *Digital Health* (18 June 2018).

94 Dan Bland, ‘Digital Twin Tech for Improving Digital Medical Records’, *Challenge Advisory* (September 2018).

95 Ibid.

96 Ibid.

2. Disruption by tech companies

- 1.77** Another emerging trend in both FinTech and HealthTech sectors involves technology (tech) companies entering the financial services and healthcare sectors, respectively. While the financial sector has witnessed the tech company behemoths of Amazon, Apple, Facebook and Google entering and potentially disrupting the financial services sector, the healthcare sector has not remained immune to similar disruptions by tech giants.
- 1.78** For example, scientists from Google and its HealthTech subsidiary Verily have discovered a new way to assess a person's risk of heart disease using machine learning. By analysing scans of the back of a patient's eye, the company's software is able to accurately infer data, including an individual's age, blood pressure and whether or not they smoke. This can then be used to predict their risk of suffering a heart attack with roughly the same accuracy as current leading methods.⁹⁷
- 1.79** In the case of the financial services sector, tech companies operate for the most part in an unregulated environment and are not subject to investor protection rules, which leads to unbalanced and arguably unfair competition.⁹⁸ Similarly, regulators in the healthcare sector will soon have to decide how to regulate tech companies when they offer healthcare services; otherwise, an imbalance of competition will arise if these companies are not regulated, while HealthTech companies face robust regulatory scrutiny.

3. Democratisation of data

- 1.80** The parallels between FinTech and HealthTech can also be drawn in the data sharing supported by the Payment Services Directive 2 and open banking, which encourage the sharing of payment account data by banks and other payment services providers and aim to drive innovation in banking and payment services by making it easier for banks and other payment service providers to securely share data with each other and create a user experience that better suits customer needs.⁹⁹

⁹⁷ Ryan Poplin et al., 'Prediction of Cardiovascular Risk Factors from Retinal Fundus Photographs via Deep Learning', *Nature Biomedical Engineering* (February 2018) and James Vincent, 'Google's New AI Algorithm Predicts Heart Disease by Looking at your Eyes', *The Verge* (February 2018).

⁹⁸ Dirk Zetzsche et al., 'The Rise of TechFins: Regulatory Challenges', in Madir (ed.), *supra* note 89, at 293.

⁹⁹ Ben Regnard-Weinrabe and Jane Finlayson-Brown, 'Adapting to a Changing Payments Landscape', in *ibid.*, at 22.

Increasingly, the healthcare sector is also democratising access to information, which should ultimately lead to greater transparency and flexibility in how services are delivered and supported, and how patients choose and engage with those services.¹⁰⁰ Thus, for example, the NHS is supporting a personal health record app, Evergreen Life, which stores the patient's health information in one place. The app allows people to bring together all their medical and health information in one place and share it with healthcare professionals and carers; they can book their GP appointments, order repeat prescriptions and view test results.¹⁰¹ **1.81**

In the same vein, BioSay app records an individual's pulse and heart rate, and analyses facial expressions using smartphone sensors to measure their physical and emotional state. This data is also combined with environmental factors, which helps identify situations that increase or decrease stress.¹⁰² With this data, the app creates a Bioji, a visual representation that represents emotion with colour and movement. Users can then share their Biojis with others and recommend places that positively or negatively affect their wellbeing in order to help other app users.¹⁰³ **1.82**

As new online and mobile payments technologies and innovative products have already facilitated data sharing and customer experience in the payments industry, the healthcare industry can learn from FinTech about ways to harness data, empower patients and provide meaningful healthcare services for everyone.¹⁰⁴ **1.83**

G. CONCLUSION

The rise of healthcare technology has immense potential to increase patient engagement and ultimately increase life expectancy and quality of life. In addition to offering the opportunity to improve healthcare, it also helps deliver efficiency, improve self-management of chronic conditions and offer personalised treatments.¹⁰⁵ However, although HealthTech has the potential to help address such problems as distance and access, it still shares many of the underlying challenges faced by health system interventions in general, including poor management, insufficient training, infrastructural limitations, and **1.84**

100 Fasciani, *supra* note 88.

101 Shireen Khalil, 'Evergreen Life App Launches Nationwide', *Digital Health* (22 May 2017).

102 Health & Wellness, 'BioSay is a New Way of Tracking our Emotional State'.

103 Ibid.

104 See Fasciani, *supra* note 88.

105 Blackwood, *supra* note 51.

poor access to equipment and supplies.¹⁰⁶ These issues will have to be addressed in addition to the specific implementation and regulatory requirements introduced by HealthTech.¹⁰⁷

- 1.85** And while it seems that HealthTech is poised for an explosive growth, regulators will need to play a key part in ensuring appropriate frameworks that not only enable innovation, but also enforce appropriate standards of care.¹⁰⁸ This includes the development and enforcement of interoperability standards, the reduction of procurement hurdles, the improvement of data security measures and the bolstering of digital skills in healthcare organisations.
- 1.86** Moreover, the reliability of many of HealthTech devices is yet to be proven. The speed of advancements will depend on how the various stakeholders work to find common ground and focus on the right priorities, particularly in relation to common standards for the development and promotion of evidence-based and safe use of HealthTech devices.

106 WHO, *supra* note 8.

107 Ibid.

108 The Office of National Coordinator for Health Information Technology, US Department of Health and Human Services, 'Designing the Consumer-Centered Telehealth and eVisit Experience'.