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STUDENTS SHAPING GLOBAL HEALTH POLICY

DIGITAL HEALTH INNOVATIONS IN THE UK

Current analysis and looking forward

PREPARED BY

Chris Gilmartin, Stephanie Bazley, Alicia Szalapak, Sean Day

Commissioned by Imran Mahmud

Introduction

1. Digital Health Innovation in the UK

1.1 Spotlight on startups

The National Health Service (NHS) is one of the largest and best performing healthcare systems in the world. It has provided universal coverage for 70 years, but today it is faced with the challenge of modernising its services to keep up with a rapidly digitising world. Growing financial pressure is also making it increasingly challenging to deliver the high quality care that all patients have come to expect (NHS England, 2017a). There is a growing consensus that change is needed. In its Five Year Forward View, published in 2014, the NHS laid out six complementary approaches for achieving the necessary change including taking advantage of the information revolution and accelerating useful health innovation (NHS, 2014). Digital healthcare technology is going to play an essential role in the ongoing transformation of the UK healthcare system.

So, what can the UK do to promote innovation in digital health? This paper seeks to answer that question by focusing on the startup ecosystem in the UK. Our research, based on interviews with digital health entrepreneurs and a review of available literature, addresses ways in which the policy environment for digital health startups could be better aligned with the NHS's mission of improving the health and wellbeing of patients.

Startup companies are but one source of technology innovation in healthcare. Others include large corporations and the NHS itself. We focus on supporting the startup community because it has increasingly been a potent source of transformative technology in other industries over the past few decades. Moreover as discussed below in Section 2.2, the limited success of large, national healthcare IT projects suggests that perhaps more digitisation of healthcare should be grown from the ground up. The UK has enviable assets for growing a digital health hub, including world-leading academic institutions, technical expertise, available capital, and an advanced healthcare system. This paper makes recommendations for stakeholders, including startups, policymakers and the NHS, for fostering a thriving digital health startup ecosystem in the UK. We hope to lay the groundwork for a national conversation around the nature of industrial strategy for digital health.

1.2 What is digital health?

In order to discuss digital health, we must first define it. For this paper, we consider the term digital health to refer to software-based technology that has a primary purpose of addressing the needs of healthcare systems, patient populations, and/or individual patients. These technologies hold promise to improve the health and wellbeing of patients, enhance the patient experience, reduce inefficiencies in healthcare systems.

We limit the scope of this paper further to focus on digital health products that are used by or interface directly with the NHS. Policy issues that are specific to solely consumer-facing products, such as some personal health and wellness trackers, are not explored.

There are many ways to categorise the range of technologies within digital health. For example, the NHS Stoke-on-Trent Clinical Commissioning Group classifies digital healthcare for clinicians

within their continuing professional development (NHS Stoke-on-Trent Clinical Commissioning Group, 2018). They split digital health technology into four main categories:

- Telecare – assistive technology for those with cognitive, physical or communication difficulties. Can be used to improve functional capabilities.
- Telehealth – healthcare provided remotely, including tracking physiological parameters remotely.
- Mobile Apps and Online Self-Management – digitally-assisted health and wellbeing self-management.
- Telemedicine (Teleconsultation and Telediagnostics) – sensor and electronic communication from client to clinician, or clinician-to-clinician.

Such classifications schemes are valuable in that they facilitate dialogue among different stakeholders in this emerging industry, including healthcare professionals, policymakers and patients. However, in order to encompass the growing number of applications of digital technology in healthcare, a more detailed and robust classification scheme is useful. This year, the WHO published a classification of Digital Health Interventions (DHI), (Figure 1) providing an alternative system that is more wide-reaching, and less prescriptive than the one provided above (Garrett Mehl et al., 2018).

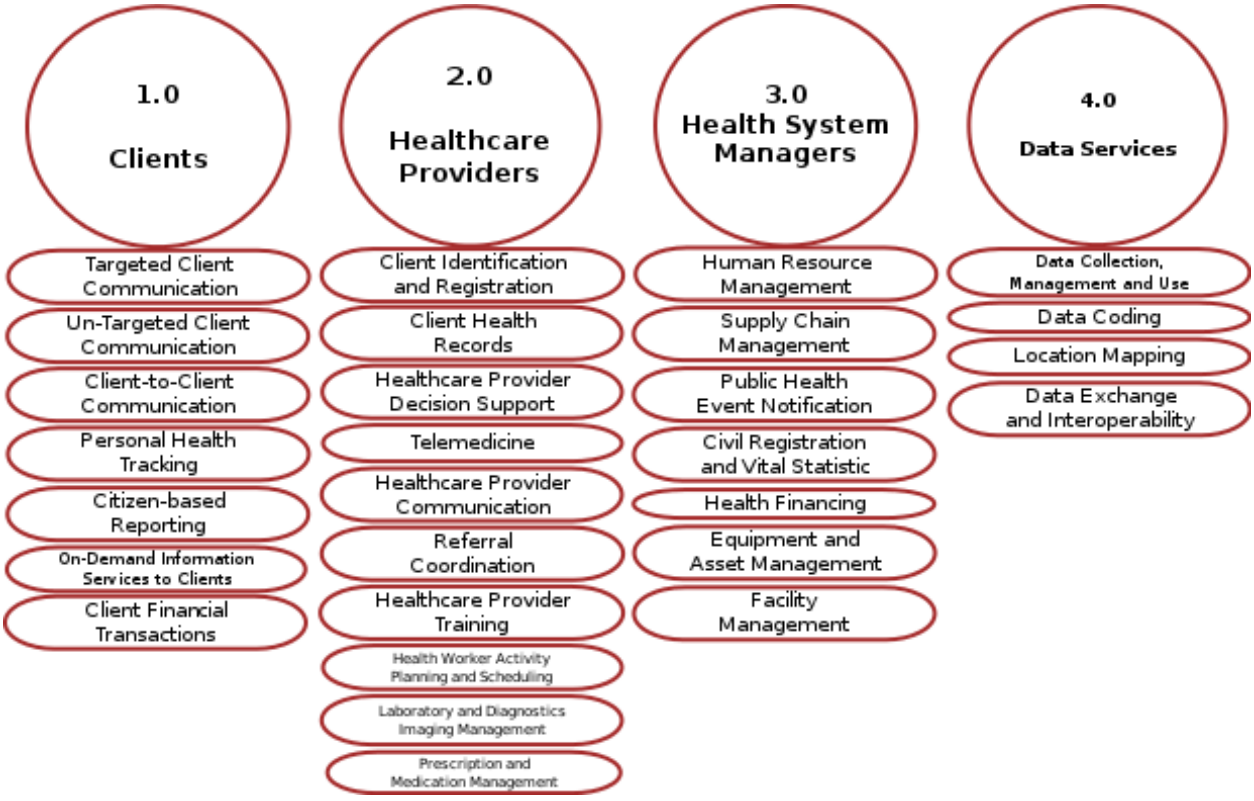

Figure 1: Adaption of the World Health Organisation's Digital Healthcare Intervention classification system (Garrett Mehl et al., 2018)

Initially created because of the confusion currently faced by stakeholders such as governments, policymakers, researchers, and business, this framework is a more comprehensive classification system. By specifying clear purposes and end-users, the framework may serve as a starting point for national conversations about digital health technology policy. There will naturally be different

regulatory considerations around, for example, an AI diagnostic tool for detecting breast cancer than for a weight management smartphone app. The industry as a whole is characterized by similar challenges and opportunities with regards to the UK policy landscape. Our paper focuses on these similarities, discussing policy around the digital health industry as a whole.

UK digital health technology policy

2. Overview of UK health services approach to technology

Digitisation promises to empower patients with greater control over their own care. The exact nature of technological change and its impact on the healthcare profession and healthcare organisations themselves is somewhat unknown. In this section, we will describe the current face of the NHS, how digitisation attempts in the past have fared, and what differs with present initiatives.

2.1 The hierarchy of the NHS

The NHS is a grouping of national bodies, regional organisations and local trusts. It would be apt to describe this as complex. The funding for regions of the country is organised into 'footprints' covering given geographical areas. This covers both health and social care and is led by one or more Clinical Commissioning Groups (CCGs). CCGs are mainly composed of general practitioners (GPs) and are responsible for the commissioning of services for their area (or footprint) (NHS Clinical Commissioners, 2018).

Alongside this system, technology-specific bodies have been devised. Academic Health Science Networks (AHSNs) have the role of promoting the development and adoption of innovations into healthcare and can advise developers. Within hospital trusts, Clinical Information Officers (CIOs) support the adoption and improvement of technological services.

This hierarchy of local to national bodies is often confusing for outsiders, yet it may be a necessary evil to enable the delivery of healthcare within the largest employer in Europe (NHS Jobs, 2018).

2.2 Previous approaches to digitisation

The idea of digitising the health sector is not novel. Previous attempts have varied in their degree of success as we will now discuss. The initial moves to digitise healthcare came from GP practices, which are effectively independent contractors organising their business units. Practices adopted measures to boost automation, such as patient registration and repeat prescribing in the 1980-90s (Wachter, 2016). This was boosted by a Micros for GPs programme introduced in 1982, where the government subsidised the costs of systems. The programme structure was altered to direct reimbursement for hardware and software before, in 2004, cutting out the middleman with the Department of Health directly paying suppliers (Wachter, 2016). Today, nearly every GP uses a comprehensive electronic health record (EHR) system (Wachter, 2016).

Similar attempts nationally have not shown the same successes. It is thought this may be due to oversight of a business axiom – know your consumer. The National Programme for Information Technology (NPfIT), launched in 2002, aimed to update the technology of the NHS on a national scale. It failed to engage with clinicians and NHS executives sufficiently, however, so there was insufficient local support to implement nationally purchased systems (Wachter, 2016). In addition to this expensive lesson-learned, there were other more positive achievements in the scheme. The Spine was developed, an IT backbone enabling information sharing between healthcare providers. The NHS number was created – a single national patient identifier. An electronic prescription service (EPS) and national IT network (N3) was also formed, as well as a radiology imaging programme PACS. The foundations were established in the NPfIT programme, yet the ideal of a 'paperless NHS' was a long-way off.

Another endeavour, care.data, attempted to connect healthcare data across the country. This effort collapsed following growing concern from the general population over health data security, with these concerns echoing through medial professional bodies and the media. It failed to adequately persuade the populous of its benefits (Godlee, 2016), leading to its end and the need for a review of data security, consent and opt-outs (National Data Guardian for and Health and Care, 2016).

Case study 1: HITECH, the US approach to digitisation

The US took a different tact to healthcare digitisation, opting to inject vast swathes of money to boost investment following the 2008 economic crash. A new programme was formed, the Health Information Technology for Economic and Clinical Health Act (HITECH) with an allocation of $30 billion and the remit of subsidising the purchase of computer systems (Wachter, 2016). However, to enable fast uptake, there was no insistence on ensuring interoperability between the various healthcare digital systems. This inevitably led to poor interoperability among organisations, exacerbating gaps resulting from HITECH not involving nursing facilities, hospices or nursing homes. A further limiting factor for data exchange in the US is a regulation dating back to the 1990s, preventing the creation of a universal patient identifier. Acting too rashly can lead to long-term inefficiencies. It should also be noted that the HITECH scheme failed to adequately involve users of the systems, making a similar mistake as NPfIT, with poorly designed user interfaces contributing to the demotivation of healthcare professionals (Wachter, 2016).

2.3 Current progress for digitisation

There is often the complaint that NHS IT systems would be more efficient if they were centralized (Tjomsland and Bruland, 2016) (Campbell, 2012). This approach is distasteful following the vast expenses of the NPfIT project, and there is little political will to tap into the public purse for such a project again in the foreseeable future. This history has contributed to the hierarchy found within the NHS, with local bodies such as NHS trusts and CCGs responsible for making technology adoption decisions in an attempt to ensure improvements in healthcare desired at a national level are achieved.

Goals for NHS digitisation were set out under the Five Year Forward View (NHS, 2014), which is better compared to a wishlist than a plan of action. More practical advice was laid out in the

Wachter review (Wachter, 2016) and Accelerated Access Review (Taylor and Bell, 2016).Yet this is a continuous process with lessons being learnt along the way. Currently, there is growing interest around patients having instant access to their EHRs and the remote monitoring of patient health parameters such as blood pressure, temperature and blood glucose.

3. Current UK digital health technology policy landscape

One challenge with regulating digital healthcare technology is the diversity and novelty of products, as discussed in Section 1.1 above. Unlike for products like pharmaceutical or medical devices, digital health products often do not have a clear, well-trodden path through to policy landscape to market. Here we present a brief overview of key regulatory agencies, NHS Digital policies and NHS innovation initiatives relevant to the digital health industry.

Digital healthcare technologies in the UK are also subject to EU legislation. However, given the upcoming exit from the European Union, this section will focus on UK-based bodies, particularly those that relate to the National Health Service.

3.1 Regulatory agencies

The Care Quality Commission (CQC)

The CQC regulates the standard of health, and social care within the NHS and private sector within the UK (Care Quality Commission, 2018). It is a broad regulatory agency, with one of its primary roles being the registration and rating of treatments, procedures, and care. Inspections, and data and information analysis serve to inform the CQC on the safety, efficacy, care, responsiveness and leadership of any regulated party.

Compliance to the standards set by the CQC is policed using the mandatory display of ratings, sanctions on registration, and prosecution. Telemedicine services and homecare devices, as well as treatment and diagnosis tools, extend into their jurisdiction.

Medicines and Healthcare Products Regulatory Agency (MHRA)

The MHRA is responsible for the regulation of medicines and medical devices within the UK. Digital health companies must ascertain whether their product is regarded as a medical device, an area where there is persistent ambiguity, as discussed later (MHRA, 2014). There are various licenses required for marketing certified products within the UK: the parallel import license, the early access to medicines scheme (EAMS), unlicensed medicinal products, and advanced therapy medicinal products. These licenses may or may not be required depending on whether a product is classified as a medicine or healthcare product.

The MHRA also provides regulatory guidelines for the correct labelling of medical devices and advises that generally, if the digital health product falls outside of their jurisdiction, it is to be labelled a mHealth product. The regulatory structure for mHealth products is currently in development by the EU. Specific mHealth UK-standalone regulations do not yet exist, except for the General Product Safety Regulations (MHRA, 2018)

National Institute for Health and Care Excellence (NICE)

NICE develops guidelines for clinical treatment, and also provides technology appraisals for novel products. These appraisals assess the clinical and economic evidence for its entry into the NHS. NICE recommends technology that 'provides similar or greater benefits at a similar or lower overall cost than the comparators' (NICE, 2018a). As a non-departmental public body (NDPB), they are accountable to the Department of Health and Social Care, but independent of government. Independent committees provide guidance and other recommendations.

Due to its recommendation system, NICE has a significant impact on new entry of products to the NHS. In particular, digital healthcare technologies are required to adhere to NICE standards in order to receive a high rating and positive recommendation to the NHS.

3.2 NHS Digital policies

Safety Standards – Digital healthcare technologies are required to comply with clinical risk management standards to ensure that patients are not harmed with the use of the product (NHS Digital, 2018a). These standards govern the deployment, use and maintenance of health IT systems. Compliance with these standards requires a registered clinician to hold the role of a company's Clinical Safety Officer.

The National Data Guardian - The NHS utilises a vast suite of digital healthcare technologies in its administration and care delivery. As such, they are required to set standards and manage governance for their products. The National Data Guardian, working within, but independently of the Department of Health and Social Care, acts to represent the public's interest in cybersecurity and information governance (Williams, 2016).

3.3 NHS Innovation Initiatives

Accelerated Access Review

From November 2014, the UK government has been actively seeking to promote ongoing innovation within the NHS. The Accelerated Access Review was commissioned to assess how to achieve this goal, with the Accelerated Access Collaborative formed in 2016 as a response.

Accelerated Access Collaborative (AAC)

The AAC was formed to improve the readiness to adopt affordable innovation into the NHS. This collaborative between many healthcare organisations, the health technology industry, and the NHS, will select technologies and facilitate expedited access through the NHS procurement process. This will apply for pharmaceutical, medical devices, diagnostics and digital products. Their first meeting was in January 2018 (NICE, 2018b)

NHS Innovation Accelerator (NIA)

The NIA is designed to expedite the process of entry to the NHS for innovative programs. While this is not designed solely for digital solutions, there are digital healthcare companies that have benefited from this program. This program, however, has a highly competitive entry process. Entry into the program requires not only evidence of both a

significant improvement to care quality, but also significantly lower cost to the NHS than current treatment. Programs must also have reached a point of interaction with users and be ready for dissemination throughout the NHS. It must also have all required regulatory, IP and ethical frameworks in place. NHS England, NHS Digital, AHSNs, NICE and The Health Foundation all play a role in selecting programs to the accelerator, with over 100 assessors involved in the process (NHS Innovation Accelerator, 2017).

Innovation and Technology Tariff (ITT)

The ITT guarantees automatic reimbursement for approved MedTech devices and apps and allows for the NHS to negotiate bulk billing benefits from companies. This relatively new payment system is highly beneficial for startup companies, improving cash flow issues due to long processing times (Fenlon, 2017)

Innovation Technology Payment (ITP)

Innovations that have evidence of clinical effectiveness and are ready for implementation can apply for the Innovation Technology Payment. This program aims to remove financial and procurement barriers to uptake into the NHS. Unlike the NHS Innovation Accelerator, the ITP is purely designed for low cost medical devices, digital platforms and technologies. This program is relatively new, operational from April 2018. As such, only four companies have used the ITP so far. A promising aspect of the ITP is support from the NHS England Innovation and Research Unit (NHS England, 2018a)

Office for Market Access (OMA)

The NICE Office for Market Access (OMA) helps drug, device and diagnostics companies, providing advice to companies that are preparing for the process of adoption within the NHS, which usually occurs following an evaluative programme (NICE, 2018c).

The OMA can be a useful engine for life sciences companies that are wanting to discuss current or future projects, and require assistance navigating the regulatory environment through to product delivery. The OMA offers ‘Engagement Meetings’ which are a confidential service in which companies can discuss their movement through the NHS regulatory structure, through to procurement.

NHS Test Beds Programme

The Test Beds programme allows innovative technologies and practices to be piloted in a real world setting, allowing for collaboration between the NHS, academia, industry and patients. This programme aimed to allow the NHS and external stakeholders to collaborate in transforming current processes and policies, such as information governance policies (NHS England, 2017b)

Wave 1 of this program recently finished, trialling seven new models of care that utilise technology, including 51 digital healthcare products. Five of these models fell under the ‘Health and Care’ banner, with the two other test beds based on care using the ‘Internet of Things’. Wave 1 helped to establish infrastructure and knowledge within the NHS and allowed for collaborative problem solving of the common barriers to increased innovation. Wave 2 began on October 1 2018 and will continue to work towards these goals. This trial will further establish appropriate regulation, and increased uptake, of digital healthcare technologies within the NHS (NHS England, 2018b).

Navigating UK digital health technology policy

4. Overview of digital health interviews

The UK digital health startup scene is active, but there is a sense that a policy environment more conducive to digital innovation would be beneficial for patients and the healthcare system. In this section, we look at startup activity and interaction with the government. Drawing on interviews with active UK digital health startup leaders, we highlight some of the main challenges facing new companies in the current technology policy landscape.

Employees of six digital health startups in the UK, listed in Table 1, were interviewed as a part of our research.

Table 1. Individuals interviewed for this research offered a perspective from six UK-based digital health startup companies.

Company	***Interviewee***	***Product***
DrDoctor	Tom Whicher, Founder	An online and text-based service that allows patients to confirm, cancel, and change bookings digitally
ForwardHealth	Dr Barney Gilbert, Founder and Co-CEO	A secure, GDPR compliant, messaging & workflow app for doctors and nurses which allows for the sensitive transmission of information
Medopad	Alex Gilbert, Partnerships & Talent	A suite of healthcare applications that incorporate remote patient monitoring, mobile technology and advanced data analytics to deliver a personalised care experience.
Myrecovery	Dr Axel Sylvan, Founder	An app for orthopaedic patients that provides them with post-surgery information as well as allows for progress tracking.
OurPath	Mr Mike Gibbs, Co-founder and COO	A digital lifestyle management programme designed to help people, including those with, or at risk of, Type 2 diabetes, manage their lifestyle choices by living more active lives. This is achieved by weight and exercise management, assisted in real time by dieticians and connected scales.
Outcomes Based Healthcare	Dr Nasrin Hafezparast Co-founder and CTO	A population health analytics platform which measures health outcomes in near real time. Works with NHS organisations to help to shift away from fee-for-service towards rewarding for improving patient outcomes.

We also spoke to Dr Malte Gerhold, Executive Director of Strategy and Intelligence at the CQC to better understand their perspective of digital technology and transformation in healthcare.

5. Startup experience with UK digital health technology

Here we present findings from our interviews with startups. The discussion is roughly organised according to startup-government interaction along three phases of product development: development, certification and procurement. Within each of these phases, we extracted critical areas of interest for digital health technology policy stakeholders.

As is the natures of policy, technology and healthcare, it is difficult to draw firm lines without overlaps or exceptions. There are overlaps in the presentation of our findings below, for example, programs like the NHS Innovation Accelerator support startups from development through certification and procurement. Nonetheless, we hope our structuring will provide clarity for this process.

5.1 Development

The idea of innovation has taken hold, and now we need to be brave with it.
Tom Whicher, DrDoctor

5.1.1 Identification of unmet needs

The first step for any startup is the identification of unmet needs. In digital health, these ideas often come from within the system - from doctors or patients who have identified shortcomings present in the NHS.

Both founders of myrecovery.ai, Tom Harte and Axel Sylvan, were trainee surgeons who gained extra insight into the patient's perspective from their own experiences of undergoing surgery. Having seen, first hand, the challenges faced by both patients and clinicians, they set out to improve the experience of surgical care by improving access to information at each key stage.

An understanding of both the broader healthcare system and end-users is crucial for successful digital innovation in healthcare. Alex Gilbert of Medopad highlighted the importance of working closely with clinicians to understand their problems and then tailoring solutions to address those concerns (A. Gilbert, 2018). There is a risk that startups may develop products not genuinely addressing the unmet needs of the NHS if healthcare professionals and providers are not more explicit regarding what needs to be improved. Currently, the onus is on the developer, who has a challenging task of balancing competing priorities among stakeholders, for example, cutting costs for CCGs while also reducing NHS staff workload and improving the patient experience. Without an understanding of how each stakeholder operates, for example, what would enhance NHS staff efficiency, the potential for technology developers is more limited.

5.1.2 Funding and support

There are numerous sources of financing available in the UK for digital health startups. Companies may find support from university funding, venture capital, angel investors, or crowdfunding. There are also grants available, such as those listed in Table 2.

Table 2. Select grants available for digital health startup companies in the UK.

Grant	***Description***
SBRI Healthcare	Grants up to £1m for early stage development of products that meet the needs of the NHS (SBRI Healthcare, 2018).
Innovate UK	Support for innovative businesses to accelerate sustainable economic growth (gov.uk, 2018).
The SME Instrument	EU funding and support for breakthrough innovation projects with a market-creating potential [SME Instrument website].
National Institute for Health Research	Largest national clinical research funder in Europe with a budget of over £1 billion (Davies et al., 2016).
Wellcome Trust	A global charitable foundation, whose goal is to improve health for everyone by supporting scientists and researchers (Wellcome, 2018).
Nesta	Supports a small number of exceptional ideas that meet the aims of the charity through grant funding, direct investment or challenge prizes (Nesta, 2018).

A variety of funding options is essential in digital health because timescales tend to be longer in healthcare than in other industries. Traditional technology investors can end up disappointed by the time it takes to see a return on their investment, which can make it more difficult for startups in digital health to compete for venture capital funding. Grants and other sources of funding help make the pipeline of digital health innovation in the UK more stable. Grants from government and nonprofit organisations also reflect the value accounted to patient outcomes and health system sustainability, not just profit, in the digital health ecosystem.

Despite the availability of funding for early-stage projects, our research indicates that significant challenges in scaling companies in digital health exist (A. Gilbert, 2018). Programs such as accelerators and incubators aim to address this through education, mentoring and the building of professional networks for startups. There are several such programs in the UK today, including those in Table 3.

Table 3. Accelerator and incubators for digital health startups in the UK.

Program	***Description***
Digitalhealth.london	A programme aiming to speed up the development and scaling of digital innovations across health and care, and pioneer their adoption by the NHS (Digital Health London, 2018a).
NHS Innovation Accelerator	A national accelerator supporting dedicated individuals to scale their high impact, evidence-based innovations across the NHS and wider healthcare system (NHS Innovation Accelerator, 2017).
GovStart UK, PUBLIC	Brings together experience from the public sector, technology and finance to help startups solve public problems (Loving, 2018).
NHS digital academy	A virtual organisation set up to develop a new generation of excellent digital leaders who can drive the information and technology transformation of the NHS (NHS England, 2018c).
NHS clinical entrepreneur training program	Designed to offer opportunities for junior doctors and other health professionals to develop their entrepreneurial aspirations during their clinical training period (NHS England, 2018d).

These programs provide startups with valuable resources that help with development, scaling-up and NHS procurement. Interviewees highlighted the benefits of building informal professional networks through participation in accelerator programs. These are useful for tapping into the knowledge of experienced health professionals while building and scaling innovations, and finding entry points to the healthcare market. Additionally, participation in some of these prestigious accelerators can be a stamp approval for young companies.

Another option for startups trying to scale their business is to partner directly with larger companies. This was the case with Medopad, which partnered with Apple to develop a tool for remote patient monitoring (A. Gilbert, 2018).

Case report 2: myrecovery

The myrecovery.ai platform enables surgeons and clinical teams to create digital companion apps for their patients that are customised to each procedure. The aim is to enhance the care delivered with a point of reference and a means of tracking progress. The content of the app is curated by each clinical team; who can upload their own information; make their own stage-by-stage explainer videos; choose their own exercise plans and include links to any other websites or videos that they would normally recommend to their patients.

Both Mr Harte and Dr Sylvan were in the first cohort of the NHS Clinical Entrepreneurs, and they are now mentors on the programme. The company has also benefited from the DigitalHealth.London accelerator, yet they have found the NHS procurement process challenging. In order to demonstrate the value of the product, myrecovery has been conducting free pilot trials and research partnerships with different sites across the NHS in the hope that it will facilitate expansion in the future.

5.1.3 Interoperability

Achieving interoperability is a challenge for any digital system. In the NHS, this is especially difficult as different NHS organisations have IT systems which are often unable to exchange patient information with one another (Wachter, 2016),(Hancock, 2018a).

Most of the startups we spoke to require some integration with electronic health record (EHR) systems. Some like Medopad pull data from EHRs into their own products' systems. Others like DrDoctor send data back to the EHR system in addition to pulling EHR data into their own platform. Such examples of data exchange tend to be limited by the existence, comprehensiveness and robustness of application programming interfaces (APIs) and data standards. Secretary of State for Health and Social Care Matt Hancock highlighted tackling the incomplete state of UK digital health interoperability as one of his priorities in a recent speech (Hancock 2018b). Following an overnight observational shift at a hospital on August 2018, he declared that there was "far to go" to improve the interoperability of IT systems. Hancock has previously written that "interoperable data standards over clinical and operational tools and the world class, secure use of data are the basis upon which modern technology and modern research must rest" (Hancock, 2018a).

Some companies such as ForwardHealth work around this problem using something more like a "soft integration" with hospital IT systems. They support the scanning of patient wristbands to populate basic patient data in the ForwardHealth system. They are also betting on increased adoption of the Fast Healthcare Interoperability Resources (FHIR) standard for healthcare data exchange across the NHS, by working on an FHIR proof of concept project (B. Gilbert, 2018).

The lack of true interoperability frustrates innovation in digital health. It presents a significant barrier to scaling a company when new data connections must be developed for every NHS trust. Additionally, the lack of sufficient data exchange standards and APIs means that integration often requires development resources from EHR vendors. This leads to situations like one described by Dr Sylvan. A hospital was keen on integration between their system and myrecovery's product, but the EHR vendor was only able to put the new development at the end of a nine-month product roadmap. Problems with incompatible IT systems are exacerbated by incongruous development timelines between large and small companies, resulting in lost healthcare innovation.

5.2 Certification

5.2.1 Digital medical devices

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for certifying medical devices as safe and effective. These regulatory processes were developed primarily for physical medical devices. In digital health, there remains uncertainty around the distinction between digital products that require MHRA certification as medical devices and those that do not.

By definition, a medical device is any instrument intended to be used specifically for diagnostic and/or therapeutic purposes (European Parliament, 2007). The MHRA has some documentation on this grey area - *Is my product a medical device or not (MHRA, 2018)*, and *Guidance for stand-alone software, including apps* (MHRA, 2014) - but our research suggests that this area needs further clarification.

It appears that uncertainty in this space stems from the unique characteristics of digital products. The software can be frequently updated to fix bugs, improve user experience and expand functionality. For example, the standalone myrecovery app, in its current form, is not a medical device. It sits alongside current practice, enhancing and improving workflows and patient experience. The second phase of the myrecovery platform is to enable insight and access to information for clinicians, and they are working towards certification of the app dashboard as a medical device with the MHRA right now because future versions of the product may require it.

Software components, modules or applications, can also be combined by a single company in different ways to tailor a product to the needs of each organisation or end-user. This is starkly different from physical medical devices and presents a complicated regulatory challenge. The challenge for a technology like this is balancing the need to protect patient safety while also avoiding the burden of re-certifying every new configuration of the platform. One approach available to digital health companies would require MHRA certification for each new combination of features. Medopad solves this by instead certifying their underlying system as a whole.

There was general agreement among several interviewed companies that while MHRA certification can be useful, and often necessary for some products and companies, a lot can be done without it. Impactful digital products can be sold and implemented in the NHS without MHRA certification. For smaller, younger companies the certification process may slow down things too much: “every question mark slows down the rate of change across the board” (Sylvan, September 13). Moreover, as the digital health field is continually evolving, there is much uncertainty around the policies - it is difficult to predict how the certification requirement will change.

5.2.2 Information Governance

Data protection is one of the most critical issues in digital healthcare. Information governance draws together the legal rules on data collection and handling and presents them in a single standard (NHS, 2018). In addition to this, an Information Governance Toolkit (NHS Digital, 2018b) has been developed to allow organisations to assess their own compliance with the IG standards. Commercial third parties are required to submit a self-assessment return annually, where they indicate their compliance level (N/A, 0, 1, 2 or 3) with a list of standards.

Our research surfaced two key challenges for digital health startups with regards to information governance. One is that, in addition to the certification process taking a long time, IG certification has to be done separately for each NHS trust. Some startups rely on help from lawyers and IG specialists, but this is challenging for small or early-stage companies.

Second is the challenge of aggregating of de-identified patient data. Health data for patients exist across a range of NHS organisations including GP practices, hospitals and NHS Digital, and some promising applications of digital technology in healthcare rely on pulling this data together to uncover new insights. Healthcare systems need to take into account whole populations of

patients, and so aggregated patient data is important for so-called 'indirect patient care,' which includes research or reviewing and improving the quality of treatments provided.

Case report 3: Comparing OurPath and Medopad

How is it that the same policy landscape can be burdensome for one company while no problem for another? The simple answer is scale. The lifestyle management application, OurPath, found the regulatory landscape to be demanding and somewhat opaque. The growing startup of around 13 employees hired a consultant to assist in preparing clinical, safety and policy documents, and to develop its information governance policies.

Medopad, a larger company with dozens of employees and diverse revenue streams from non-NHS customers, including population health and pharmaceutical companies, also hires consultants. However, given its resources and experience navigating the policy landscape, Medopad does not find the certification process particularly burdensome.

Such divergent experiences point to a steep hurdle for young digital health companies.

Case report 4: Care Quality Commission

The CQC is the UK's health and care quality regulator, ensuring organisations are improving care for patients. In terms of digital health, the CQC does not directly assess technology in the way that organisations like the MHRA or NICE might. Instead, it examines how patients and medical professionals interact with technology and how it is used safely to improve the quality of care.

Dr Gerhold points out that one of the challenges in digital health is that there is limited literature describing "good" implementation of technology, including staff and patient involvement, as well as what has caused projects to fail. This is an example of where collaboration is required: the CQC currently sits somewhat apart from the rest of the development and marketing process, and yet can play a critical role in determining the value of the final product insofar as it assesses the overall quality of care in organisations. Dr Malte Gerhold argued that the CQC is currently looking to play a more active role in conversations about the risks and benefits of innovation and digital health, stressing that this conversation should not simply be with top tier policymakers yet with all stakeholders, including the public. CQC is also looking at how it can share more concrete examples of successful and unsuccessful attempts at innovation, and how they have improved care quality, so that the industry can learn as a whole.

5.3 Procurement

"I have described my job in selling to the NHS as feeling as if I am pushing several large rocks up a hill, and running between them to make sure that none of them slide gently down behind me."
Katherine Ward (Ward, 2018)

5.3.1 Fragmented CCG procurement policies

It is not easy for startups to sell to the NHS. The first obstacle involves the identification of the buyer, as the NHS is not a single entity but instead consists of c200 CCGs, c350 NHS providers or c8,000 GPs. It is therefore crucial to know and understand the system well before trying to sell. Even within the individual trusts, it is often difficult to identify the person who can decide on the adoption of the innovation. The startups we interviewed discussed several approaches to selling digital health technology to this complicated landscape.

Dr Gilbert stressed the importance of deciding on the scale of the procurement - whether to stay small and have contracts with a few trusts or whether to try to sell nationwide. Otherwise, startups risk getting caught up in the fragmentation across different trusts with different procurement policies, as those are not standardised.

Some interviewees pointed to NHS employee culture as one source of fragmentation. An attitude summarized by Tom Whicher as "if it hasn't been tested here, we don't trust it" means it is important to engage local and regional influencers in the NHS (Whicher, 2018). Forward Health had a similar experience, finding that support from policymakers in Westminster after presenting at 10 Downing Street was not enough to convince clinicians to adopt its product. Dr Gilbert pointed out that clinicians want their own trust or CIO to endorse it; they want a locally mandated solution. There is a culture of needing local approval, so Forward's strategy now is to work with forward-thinking CIOs.

Other interviewees spoke about pursuing a 'land and expand' strategy, which aims to engage individual clinicians in small pilots to build awareness of benefits and then subsequently scaling up. At the same time, while working at the local and regional levels is important, there is value in engaging at the NHS level as well to contribute to broader policy conversations.

5.3.2 Pilots and demonstrating value

An evidence-based product-validation and a compelling return on investment (ROI) case are crucial for selling to the NHS. Many startups we interviewed used pilots as a way to make these demonstrations in a real-world environment. Pilots are beneficial for products at an early stage of development as risk-averse, budget constrained trusts are hesitant to invest in unproven technologies. Some companies have found it difficult to set up pilots with the NHS, which leads them to demonstrate their products abroad. This route was taken by UK startups such as *Feebris* (Saville, 2018), *Episcissors*, *Sleepio*, and *PneuX* (Cox et al., 2018). For other companies like *Medopad*, pilots and other work with the NHS are largely a means for interacting with key opinion leaders and demonstrating value rather than their primary source of revenue.

The programme director for *DigitalHealth.London* identified four challenges affecting the generation of clinical evidence for digital clinical interventions (Digital Health London, 2018b):

1. A lack of clear standards for defining what the bar is
2. Insufficient trial sites
3. Borrowed infrastructure from life sciences trials, and a culture of driving up the cost of clinical studies out of reach for the average digital health innovator
4. Poor visibility of and access to the evidence already out there

Unlike with other medical products like pharmaceuticals, randomised controlled trials (RCTs) are often not a feasible or appropriate way to demonstrate value in digital health. There is some

agreement that clinical trials are unrealistic in this industry because of the rapid, iterative nature of innovation in digital technology. Mr Mike Gibbs, COO and co-founder of *OurPath*, commented that randomised controlled trials (RCTs) are commonly required for clinical evidence but are unrealistic in tech. RCTs take time, but with the rapid pace of the tech field, shorter timelines are needed in order to sustain high innovation within the NHS. He feels that the NHS increasingly recognises this issue, and there is lots of talk about how to fix it. Furthermore, while the data supporting the long-term impact of innovation is important, selling into individual trusts often requires an additional approach: modelling the short-term benefits that fulfill the organisational priorities and those that are of most interest to staff, such as decreased workload.

Case report 5: Forward Health

Today, members of healthcare teams often communicate via Whatsapp®, leaving much to be desired both in terms of data security and efficiency. Forward Health addresses this need with an app for healthcare professionals to communicate confidential patient information with each other over a secure platform.

Dr Gilbert discussed the difficulties that Forward Health has faced when selling to multiple healthcare trusts. Procurement policies are not standardized across different trusts, which means much work is required to apply to each one. Should a company like theirs want to roll out on a national scale, significant resources would need to be mobilized to overcome this.

The path for startups would be easier with some degree of standardisation between trusts. Dr Gilbert suggests one step in the right direction would be standardised return on investment (ROI) documentation. Such a form could allow startups to present their past success with one organisation with regards to ROI to another organisation. This would enable a start-up which has successfully worked with one trust to demonstrate their successes to other trusts reliable manner.

5.3.3 Slow sales cycles

Another challenge for startups is the long sales cycles involved with NHS procurement. It is not uncommon for the NHS to have an 18-month sales cycle. For a small company, this creates real cash flow problems. Some companies like Medopad rely on other types of customers like pharmaceutical and insurance companies for the bulk of their revenue (A. Gilbert, 2018), while others concede that such long sales cycles probably result in greater reliance on venture capital (A. Gilbert, 2018). Alternatively, some companies like HealthUnlocked have opted to sell into another company's existing contract with CCGs, offering a service within services, rather than selling directly to CCGs (Cox et al., 2018).

Case report 6: OurPath

OurPath is an app designed to promote weight loss by changing lifestyle behaviours. The programme includes access to a health coach, meal plans, provision of an activity tracker and a support group, all through the app. The company admitted navigating the NHS through their first tender was a learning experience, despite being accepted into, and completing, the competitive DigitalHealth.London accelerator. The OurPath development team found the complexity and diversity of CCG application forms challenging to deal with, finding sections of the Information Governance Toolkit (previous version of the Data Security and Protection Toolkit) in particular,

to be somewhat burdensome. OurPath suggested that increased assistance and education approximately a year before entering the NHS tendering process would translate into increased accessibility for small startups into the NHS. OurPath has been highly successful in its procurement process and is currently being rolled out to thousands of patients, however, policy to streamline access into multiple CCGs at once would assist their growth within the NHS.

OurPath has also been successful with private consumers, which sustained their business through the long process of NHS entry. This highlights however, the risk that innovative startups may decide against seeking access into public healthcare, instead opting for the less rigorous regulatory structure, and a quicker path to profitability within the private sector.

Digital health abroad

6. International digital health technology policy case studies

In this section, we present three international case studies of public policies that were introduced to support innovation in healthcare. All three are relatively new, so it is not yet known what impact they will have. However, they present innovative approaches and may help to guide solutions to some of the challenges that startups in the UK are facing. These examples provide contrast with UK digital health technology policy, and they suggest potential lessons and ways forward.

6.1 Development: Israeli Technological Incubators Program and the National Digital Health Plan

Israel has been dubbed the startup nation. It has the highest density of startups in the world and is home to nearly 400 as of 2016 healthcare startups (Balicer and Afek, 2017). One of the reasons for the successful development of the Israeli startup scene is the Technological Incubators Program launched in 1990. Its primary aim is to help individuals so that innovative ideas in the initial Research and Development (R&D) stage are transformed into viable startup companies. Between 2008 and 2017, about 600 companies entered various incubators, of which 28% were medical device companies (IATI, 2018). Technology startups can receive a project budget of up to NIS 3.5 million ($1 million) for a period of up to two years. Of this budget, 85% is financed by the government as a grant and is only paid back if the startup reaches the market. Over the years, the government invested over $750 million. During this time, 60% of the incubators successfully raised private investments which have cumulatively surpassed $5 billion (IATI, 2018).

In March 2018, the National Digital Health Program was approved by the Israeli government with a budget of $264 million (Israel Prime Minister's Office, 2018). This will be used for setting up a digital infrastructure for medical research as well as for supporting collaboration between the Israeli healthcare system and local digital health startups. As a part of this program, several projects will be implemented:

- Encouraging pilot trials in the field of digital health, carried out in cooperation with Israeli health organisations.
- Providing startups with access to a newly established database, which will include information provided by patients with conditions that cannot be currently adequately addressed by healthcare. This is possible due to a unique public health system, where all of the personal medical history files are digitally stored since 1990 and managed by four Health Maintenance Organisations. This data will be unified into a single database, in which one's participation is optional.
- Creating Technology Innovation Labs, aimed at promoting innovation as well as strengthening cooperation between multinational corporations and Israeli startups.
- Creating a plan for attracting personnel into the field of data science.
- Launching a National Genomic-Clinical Initiative aimed at sequencing and analyzing the genomes of 100,000 Israeli individual volunteers. This genomic data, together with clinical information, will be available for research (Israel Prime Minister's Office, 2018).

While there are concerns about the privacy risks of opening up large databases with sensitive, medical data for commercial purposes, the availability of such large amounts of comprehensive, good quality data will support advanced research and may set up Israel to become a leader in digital health.

Such a program is possible in Israel due to its advanced digitisation - Israel was an early adopter of digital technologies in healthcare. In the 1990s the medical records of Israeli citizens began to be stored electronically. Similarly, connectivity between the nationwide healthcare providers was introduced (Balicer and Afek, 2017). This illustrates one of the possible benefits of full, interoperable digitisation. Another important feature of this program is the help that the startups will receive in carrying out pilots from the health organisations. As it is crucial to back any healthcare innovation with substantial evidence, testing the products early in the process is likely to help the startups to reach their first client and speed up commercialisation.

6.2 Certification: FDA Precertification Program in the United States

The FDA's pre-certification program is a plan to provide a new regulatory framework that allows for more efficient assessment of the safety and effectiveness of software without inhibiting patient access to the new technologies (FDA, 2018). The regulatory focus will be shifted from the product to the developer so that companies that can demonstrate a culture of "quality and organisational experience" will be able to become pre-certified. Pre-certification should enable companies to certify and improve their digital health products more rapidly. Evaluation of companies will be based on five core criteria: patient safety, high quality products, proactive culture, cybersecurity and clinical responsibility. The pre-certification will allow these companies to submit less, or no, information for regulatory approval before marketing the devices based on the company's experience with delivering devices to market and the risk categorisation of a particular device. In return, the FDA will gain access to real-world data on product performance throughout its' entire lifecycle to ensure continued safety, effectiveness and performance. This will also allow regulatory bodies to respond rapidly to any emerging risks.

This program should allow regulators to work more collaboratively with manufacturers and healthcare organisations. The insight gained by FDA during the pre-certification process, such as the companies' software development strategies, will allow it to adapt regulatory guidelines to suit the market of emerging technologies better.

So far, a pilot program has been conducted since 2017 with nine companies: Apple, Samsung, Verily, Johnson & Johnson, Roche, Fitbit, Pear Therapeutics, Phosphorus and Tidepool. The first version of the program, Pre-Cert 1.0, is expected to have its first few participating companies pre-certified by early 2019 (FDA, 2018).

Concerns have been raised that the pre-certification program will lead to low quality devices being released to the market, putting patient safety at risk. The FDA counters that the process will be based on a 'trust but verify' principle, which means that to retain precertification status, a firm will have to undergo continuous evaluation. This monitoring of companies should also allow for continuous improvement loops.

The new model of designing the regulations around technology signals that traditional process of reviewing medical devices one by one may no longer be suitable because technology progresses at a much faster rate than the corresponding regulations. Until now, strict pre- and post-market regulations meant that it was often impossible to make iterative improvements to software-based medical devices and implement them quickly. This also meant that the devices were not patched regularly enough to defend against cyber-attacks. It should be kept in mind that larger companies may be in a better position to ensure additional measures required for the corporate excellence certification and hence will be more likely to take advantage of the program than the smaller startups.

6.3 Market: Procurement by Co-Design in Canada

Procurement of new healthcare technologies is a critical component of any health system's technology policy, yet it is an area that frustrates healthcare technology stakeholders around the world. In Canada, a survey carried out in 2016 across the members of the Council of Academic Hospitals of Ontario (CAHO) indicated 76% of respondents believe that policies, directives and procurement rules constitute a significant challenge to the adoption of innovation within their organisations (Council of Academic Hospitals of Ontario, 2018a), (Dekort, n.d.). Ontario's procurement system made it challenging for companies to sell their innovations. Like with many procurement regimes, hospitals issue a public request describing a solution to an identified need, and companies submitting proposals must meet the specifications. Such systems may limit space for the type of ground-up innovation described in section 5.1.1 above.

To overcome some of these challenges, a panel of experts from CAHO put together a reference guide aimed at informing the companies about the opportunities in procurement in Ontario and dispelling prevalent myths about the process (Council of Academic Hospitals of Ontario, 2018b). CAHO also published a list of critical problems within the hospitals that could be solved with innovative solutions, hence providing innovators with ideas for the development of new devices.

A similar idea, bridging development and procurement lies behind an experimental program at the MaRS innovation hub launched in conjunction with the Ontario Ministry of Government and Consumer Services. In the program, Innovation Partnership: Procurement by Co-Design, healthcare providers are asked to describe a challenge facing their institution, the outcomes it seeks and the criteria that will be used in selecting a vendor (MaRS, 2018). Entrepreneurs can then work collaboratively with the providers on a solution. The co-design approach allows for engagement among key stakeholders during the development process and interaction with end-users to produce solutions that best meet their needs.

Looking forward

Here we present recommendations for tailoring UK digital health technology policy to strengthen the startup ecosystem. First is a set of "low-hanging fruit" actions that should be taken to simplify the route from development to market. On these, stakeholders should act now to ensure safe, and impactful innovations are consistently enabled to reach the health system. Then a set of "strategic planning" actions are discussed. For these, more debate and planning may be required from stakeholders to craft effective policies. We believe the forward-looking recommendations are critical to realising the promises of digital health technology in the UK fully.

7. Low-hanging fruit: simplifying development, certification and procurement for digital health startups

"Regulation just needs to be as clear as possible. That in and of itself will allow a lot of companies to flourish."
Alex Gilbert, Medopad

7.1 Why simplification is required

Imagine driving to a new, distant destination without maps. There is no SAT-NAV assistance, and you are only bearing your way from sporadically placed signs. Developing, certifying and bringing a device to market in the NHS is comparable. There are few comprehensive, centralised resources dedicated to this need, which is an unnecessary brake to innovators, especially given the potential benefits there are to national healthcare and the economy through this inexpensive and straightforward. Beyond that, knowledge silos are also holding back the pace of innovation. With regards to both certification and procurement processes, clarity and transparency are key.

7.2 Where simplification is required

Table 4. Summary of low-hanging fruit recommendations.

Cross-phase initiatives	1) Build a central, online resource to serve as a roadmap to guide developers through government interaction in digital health product development.
Development	2) Promote knowledge diffusion from accelerator programs to the broader innovation ecosystem.
Certification	3) Clarify medical device definitions for software-based devices. 4) Expand information governance support for early-stage startups
Procurement	5) Develop standardised ROI documentation for healthcare technology companies.

7.2.1 Roadmap for developers

There is need for transparency in the entire certification and procurement process for healthcare digital technologies, which could best be resolved by a governmental or NHS body such as NHS Digital designing a section of their website to specifically tackle this issue, or create a new website which is clearly signposted on other NHS and governmental web pages, detailing how each stage transpires, what startups should expect and how they should prepare. There have been some beneficial moves towards making the process more transparent, including publications from the MHRA (MHRA, 2014) and Deloitte (Office for Life Sciences and Accelerated Access Review, 2016), yet what is lacking is a resource linking the entire process together. For a nation attempting to portray itself as a hub for healthcare technology innovation, the UK is grossly lacking a platform demonstrating this.

Recommendation 1: NHS Digital should build and maintain a web page to clearly guide startup companies through business-government interactions across development, certification and procurement phases of digital health product development.

7.2.2 Knowledge diffusion from accelerator programs

From our interviews, we found that companies were highly supportive of accelerator programmes. However, these are competitive, with developers applying and going through selection processes. Start-ups which are not accepted onto these programmes will not have the same access to advice from stakeholders. Although accelerator programmes are highly beneficial in supporting what is thought of as the most promising schemes, innovation would be enhanced by the lessons learned from this process being made publicly available, so more firms can benefit, and the potential rate of innovation entering the health sector may increase.

Recommendation 2: Accelerator programmes should share resources publicly, preferably on a centralised platform such as NHS Digital.

7.2.3 Complexity of information governance is feeding an industry of consultants

Start-ups have a steep learning curve regarding information governance, which they combat through outsourcing to external consultancy firms, with this requirement for outsourcing indicative of a complex system. To reduce the cost and effort required for compliance with information governance, there should be further efforts to develop more explicit national guidance and training, with advice more readily available. Again, it would be helpful for NHS Digital to take the lead in this process.

Recommendation 3: NHS Digital should offer guidance for companies with information governance. NHS Digital should consider establishing a process through which startups and NHS trusts can consult with NHS Digital IG experts on navigating the data privacy and security challenges involved with implementing new technology.

7.2.4 Individual application processes for selling to each NHS hospital trust

The fragmented nature of NHS trusts can be a minefield for startups. Technology firms must decide early in the marketing process how to scale their product, i.e. whether to apply to trusts, AHSNs, or at a national level, as the application process differs for each process. Targeting trusts

or AHSNs may be more realistic for most small firms, yet this process is complicated – each hospital trust has its own individual application process. There is no straightforward way to translate successful implementation at one trust to entry into other trusts where the innovation would have similar benefits. The Accelerated Access Review stresses this difficulty, advising that "national routes to market should be streamlined and clarified" (Taylor and Bell, 2016). The historical failings of a centralised approach to purchasing healthcare technology in the NPfIT programme have led to the current local purchasing policies, yet the Health Department should not use past shortfalls to justify the persistence of inefficient systems. While we support the autonomy of local trusts to decide which digital technologies to procure, there should be mechanisms in place to lower barriers of entry for proven technologies.

Recommendation 4: The NHS should establish a working group of CIOs to develop standard return on investment (ROI) documentation that vendors of digital health technology can use to demonstrate their value. The documentation should allow vendors to communicate past successes with regards to ROI at other NHS organisations to potential buyers at other NHS organisations.

8. Strategic planning: the future of digital health in the NHS

8.1 The future of the NHS

The NHS has three central challenges that require addressing according to the Five Year Forward View (National Information Board, 2014), (NHS, 2014):

1. Health and wellbeing gap
2. Care and quality gap
3. Funding and efficiency gap

These summarise the problems facing many health services today, yet they do highlight what is most important – the health of the population and the quality of care delivered. Any digital healthcare technologies adopted by the NHS must prove their worth in this regard. These challenges need a continuously evolving strategic plan for any improvements to be made.

For a strategic plan to be devised, the end-point must be visualised. We envisage this as a health service serving 'expert patients', who have ready access to their health records, their management plans and professional advice. Telehealth schemes may be introduced in circumstances where they are appropriate, for example, for monitoring investigation results such as for blood glucose for diabetes patients. The NHS will be continuously simplifying pathways to create time efficiencies for patients, its employees and its partners. Hospital services will be built to facilitate easy use by its employees, actively seeking user feedback, with trusts learning from one another in a centrally enforced manner. This should be done to improve staff morale at a time when record numbers of employees are leaving the service (Triggle, 2018). Services will be interconnected, with data integrated between GP practices and hospitals. Furthermore, the NHS will actively participate with all stakeholders, engaging with developers through pilot schemes and test bed programmes, simplifying and streamlining its application processes in response to

developers' feedback. Critically, there will be engagement with patients to ensure they understand and value the worth of digital healthcare technology and that their consent is acquired.

With these end-points in mind, specific advances are required, some of which have been already discussed throughout our report. In this section, we will specifically address novel approaches the UK should consider in this pursuit of continuous development.

8.2 New approaches to address these challenges

8.2.1 A new way to carry out clinical research

Treatment options for patients are continuously being optimised with new discoveries being made. This requires clinical practice to be continuously appraised to ensure the care being delivered is meeting guidelines and that there are no alternative management options or alterations to the patient treatment pathway that would improve outcomes. This process requires analysis of anonymised patient data and is routine within the medical practice: hospital departments and GP practices are obliged to audit their practice to ensure it is meeting standards. However, the statistical power of these research methods is increased when a larger cohort is included in the analysis, enabling more accurate recommendations to be made on how to treat patients. Association studies between risk factors and diseases may also be performed using patient data in this way for public health studies. It is for these reasons that a centralised patient database would be invaluable for clinical research.

The Health and Social Care Information Centre Strategy 2015–2020 (NHS Digital, 2018c) outlined some ways to increase access to anonymised patient data to improve clinical research:

1. Reduce the burden of data collection by introducing data extraction services
2. Make it easier to navigate information currently available and collate it into a shared location
3. Enable data to be provided easily and flexibly with appropriate controls on access and usage

These are broad recommendations, difficult in practice, yet theoretically they could improve the standard of care in the UK. Israel has gone further than this as mentioned in Section 6.1. Since 1990, Israel has stored patient data digitally in four Health Maintenance Organisations, and from the National Digital Health Program approved in March 2018. These will be collated into a single database, according to the individual's optional participation. This strategy has the potential to enhance clinical audits and research vastly.

Recommendation 5: NHS Digital should initiate a project to establish a national database of anonymised patient data, ensuring patient consent, confidentiality and security. The project should coordinate among organisations involved with related efforts in the UK such as Genomics England.

8.2.2 A new approach to digital healthcare technology development

Israel is pioneering a new approach to technology development. The National Digital Health Program will excitingly provide start-ups with access to the newly established central patient

database mentioned in section 6.1 above. This informs developers where the shortfalls in clinical care are and may stimulate them to devise solutions, enabling developers to target their innovation appropriately to the healthcare sector. In Canada, the CAHO's approach to healthcare technology procurement offers a similar lesson: transparency around innovation needs and flexibility to address those needs creatively is a winning recipe. We believe that another way this could be approached would be through collating feedback from patients and healthcare professionals. Direct feedback should help identify gaps in treatments and inefficiencies where the technology may be valuable. A platform such as this could be integrated into EHR platforms which healthcare professionals and patients' access. There are likely many other approaches for elucidating where shortfalls are, such as engaging with the respective professional Royal Societies.

Recommendation 6: The NHS should develop an open database of innovation opportunities based on input from patients and healthcare professionals. Integration with EHRs and patient portals to streamline workflows should be explored.

8.2.3 A new way for certifying digital healthcare technology

The FDA has established a pre-certification programme whereby companies which have proven regulatory adherence will be able to pre-certify products, facilitating faster access to the market. Products entering the market in this way are obliged to have their data monitored by the FDA to ensure continued safety, effectiveness and performance. This system in the US is innovative yet does come with the risk of dangerous products entering the market. As the FDA has a closer working relationship with the developers, it is thought this risk may be mitigated. Nonetheless, this may well place the US ahead of the UK in terms of innovation – if the pathway for established companies to access the market is substantially shortened in the US, there is a significant advantage for firms to base and initially market themselves in the US. If the UK is serious about becoming an international hot-spot for digital health development, the government needs to ensure that slicker regulatory processes across the pond do not outcompete it.

Recommendation 7: The Department of Health and Social Care should establish a review of the possibility of adopting a pre-certification process in the UK, similar to the US.

8.2.4 Interoperability between EHRs

At a national level, there is poor interoperability between trusts. This is frustrating for healthcare professionals working within multiple trusts, as is often the case for consultant doctors, and dangerous for patients that receive care in different places. Interoperability is also critical for digital health innovators who aim to integrate their products with NHS IT systems. The Leeds region is highlighted as a success regarding interoperability (National Data Guardian for and Health and Care, 2016), with a Leeds Care Record that includes live information from GP practices, hospitals and mental health services. Hospital employees have used the GP 'tab' 4,000 times in a month, potentially significant saving the time of both the hospital and GP employees who would otherwise have had to communicate this information over the phone (National Data Guardian for and Health and Care, 2016). However, although interoperability is highly beneficial within a region, in the long-term interoperability across the nation would be better advised. As described in Section 5.1.3, Secretary of State for Health and Social Care, Matt Hancock has called for open data standards for healthcare IT. We support this initiative so long as the appropriate stakeholders are included in the process.

Recommendation 8: The Secretary of State for Health and Social Care should establish a panel responsible for enacting national, interoperable data standards. This working group should include representatives from the NHS including CIOs, physicians and nurses, representatives from industry including EHR vendors, digital health startups and small- and mid-sized enterprises, and patient advocates.

8.2.5 A new way of performing clinical trials

The Wachter review emphasises that the more immediate benefits of digitisation will be improvements in patient care rather than quick economic gains (Wachter, 2016). It is of critical importance that the implementation of new technology is carried out with the direct aim of improving patient care. For this to be affirmed, pilot studies are fundamental for testing the worth of technology to both clinicians and other healthcare professionals

As discussed in Section 5.3.2, the current methodology for validating pharmaceutical products, predominantly through randomised control trials (RCTs), is generally not appropriate for digital health products. A new methodology for validating the clinical value of digital devices and systems is required. The NHS Test Bed scheme, where the devices are developed in regions of the UK alongside patients and healthcare professionals, offers a valuable starting point for addressing this issue.

Recommendation 9: Following the final report of the NHS Test Bed scheme, the NHS and NICE should establish a new way of validating the clinical value of digital devices and systems.

8.2.6 The long path to market

A long drawn out path to market is a disadvantage to small start-ups, which may not have the financial backing to persist and succeed through the process. NHS sales cycles often take longer than a year, and this prolonged period may force startups to turn to venture capital and difficult financial decisions. The problem with this is that it puts pressure on startups to push for quick returns. Earlier receipt of payment from the NHS may lessen this pressure and enable greater focus on patient needs and engagement with providers more interested in long term planning.

The Accelerated Access Pathway (AAP) was devised to shorten the time to market for products identified as of exceptional benefit and need (Taylor and Bell, 2016). Through a horizon scanning process, the Accelerated Access Collaborative designated several innovative products as ‘breakthroughs’ and included them in the AAP. It will be years until we know if the programme succeeds yet measures towards streamlining the certification process may be a lifeline for young digital health companies. We support this initiative and believe there is scope to expand such innovative pathways to allow more digital health products to reach the market more quickly.

Recommendation 10: The Accelerated Access Collaborative should allow more digital health products to reach the market on faster timelines. As an essential first step, NICE should work with industry and clinical partners to develop new ways of appraising digital technologies (see Section 9.23 and Recommendation #10) and identifying breakthrough products through horizon scanning.

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