



PUBLIC

HELPING STARTUPS TRANSFORM
THE PUBLIC SECTOR

THE PROMISE OF HEALHTECH

HOW DIGITAL INNOVATORS ARE
TRANSFORMING THE NHS

Nicola Blackwood

TECHNOLOGY IS CHANGING HEALTHCARE IN WAYS THAT WERE SCARCELY IMAGINABLE ONLY FIVE YEARS AGO. THE CHANGES THAT INNOVATIONS SUCH AS CLOUD COMPUTING, VR, 3D PRINTING, GENOMICS AND ARTIFICIAL INTELLIGENCE ARE BRINGING TO THE NHS CANNOT COME TOO SOON.

PUBLIC

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SUMMARY

Technology is changing healthcare in ways that were scarcely imaginable only five years ago. The changes that innovations such as cloud computing, VR, 3D printing, genomics and artificial intelligence are bringing to the NHS cannot come too soon. They represent one of the few ways that the NHS can sustainably relieve the demographic and financial pressures it faces. Without major reform, the NHS may see a £30 billion funding gap open up over the next three years alone.

Thankfully, the NHS – from top to bottom – realises the power of technology to improve prevention, treatment, care and reduce costs. Much is being done to digitise healthcare. And the supply side – the digital healthtech market – is finally beginning to deliver the breadth and quality of companies required to cater to the NHS. The UK market size was £2 billion in 2014 and is expected to grow to £2.9 billion by 2018, with a compound annual growth rate (CAGR) of 11%¹. And as is evident from our **HealthTech 27** – a list of the most promising, product-led digital health startups – the market is at a very exciting stage.

But the NHS is still very digitally risk-averse. Decision-making processes and procurement systems, as well as attitudes, combine to block innovation and to limit pilots, even if few are consciously opposed or deliberately obstructive. Selling into the NHS is hard. We surveyed hundreds of healthtech startups, the largest-ever such survey, and found the key barriers to selling new technology into the NHS to include:

- **Lack of clarity about evidence:** There is little consensus across the NHS about 'what good looks like' with respect to evidence, and so innovators struggle to scale from one trust to another, as each may impose different standards and every company has to prove their worth from scratch all over again.
- **Regulation of digital health products is fast evolving:** Whether it is data protection legislation moving to the General Data Protection Regulation, or the CQC being given powers to rate non-NHS online GP providers²,



¹ Deloitte Digital Health in the UK: an industry study for the Office of Life Sciences, 2015, p10.

² National Health Executive. CQC given powers to rate non-NHS services including online GPs, 2018.

achieving and keeping up with regulatory standards is very challenging.

- **Slow procurement:** Poor procurement practices remain a major barrier to entry in many parts of the NHS and many trusts still rely on large IT vendors some of whom operate out-of-date business models and closed systems giving innovators little chance to offer a competitive, agile service.
- **Partial interoperability:** Many NHS organisations still enter into long, wide-ranging contracts with established incumbents who fail to meet standards of interoperability, with many systems failing to talk to one another.
- **Unclear data security standards:** Information governance and cybersecurity must be a top priority for digital entrepreneurs, but the lack of clarity from the Information Commissioner's Office and National Data Guardian over their interpretations of GDPR requirements for health companies does not make compliance easy.
- **Limited change management and digital skills:** There remains significant variation across the NHS in terms of cultural resistance and digital skills. Some areas are both supportive and capable of delivering digital transformation, some are almost virgin territory. Most are somewhere in between.

Together, these barriers make the NHS challenging digital terrain. Efforts to overcome them should be redoubled in the coming years.

But startups also need to be savvy about what it takes to sell into the NHS. Regulatory compliance, proof of clinical value, and a cast-iron financial case are fundamental for success. We have drawn up a comprehensive Innovation Checklist which any startups wishing to work with the NHS ought to consult.

In addition, it is worth startups focusing attention on – and building solutions for – the areas where the NHS is likely to be more receptive to innovative technologies.

WE SURVEYED HUNDREDS OF HEALTHTECH STARTUPS, THE LARGEST-EVER SUCH SURVEY, AND FOUND THE KEY BARRIERS TO SELLING NEW TECHNOLOGY INTO THE NHS

We think that in the coming years these areas are likely to be:

1. **PROCUREMENT AND PRODUCTIVITY**
2. **RECRUITMENT AND TRAINING**
3. **PREVENTION**
4. **WINTER PRESSURES AND SUPPORTED SELF-CARE**
5. **AI IN PATHOLOGY AND RADIOLOGY**
6. **PATIENT SAFETY**
7. **MENTAL HEALTH**
8. **SOCIAL CARE**
9. **RESEARCH**

There are, of course, many other areas of the NHS that could use a combination of new technologies and where change will come in the next decade, like Genomics, Immunotherapy and VR. Decisive leadership – in Government, NHS England, CCGs, Trusts and NHS Digital – can and should add these and many other areas to the list. But for now, working in the areas identified above is likely to bear fruit the fastest.

1. INTRODUCTION

Healthcare is facing the kind of transformation not seen since the discovery of antibiotics and anaesthetics. There is scarcely an area of medicine that will not be changed – and improved upon – by new technologies. You can already get consultations online, search for a GP on an app, and use your smartphone to monitor your own health. Chatbots are being deployed by the NHS in London and Liverpool to answer medical questions and triage patients. Scannable wristbands with medication and patient data, digital care records, and electronic observation charts are being trialled at Leeds Teaching Hospitals NHS Trust.

In the future, much more will be digitised. The list of potential changes is long – from the use of VR in medical training to video games to treat ADHD and other neurological conditions including autism, depression, and traumatic brain injuries. Perhaps most important – and with applications across all medical fields – are the advances in artificial intelligence and genomics. These will deliver more accurate diagnoses and design treatments suited to you as an individual. A future awaits where medical information, gathered at the point of care or even at an earlier stage through apps, wearables, digestibles, home-based devices and sensors, is analysed using sophisticated machine algorithms to provide real-time, actionable analytics.

The result of these innovations will be transformative for the health and well-being of millions of people – even if well-rehearsed data security and ethical challenges must also be resolved. Patients will of course still need

specialists with expert knowledge, and the all-important human connection. Research shows that 39% of patients are willing to engage with artificial intelligence/robotics for healthcare. So there is still some way to go before this technology is universally accepted for many kinds of day to day care. But technology will be able to improve nearly all medical interventions.

To many, the list of new technologies will sound like science fiction. When I was Health Minister I was often asked if patients in places like the A&E department in Barrow-in-Furness or Hornsey Cottage Hospital – small rural hospitals far away from a technology-bustling place like Imperial College Hospital in London – would really benefit from digital change. But many tech-driven startups are already beginning to demonstrate how they can offer patients better care, while at the same time delivering a service much more efficiently. And they are not confined to large cities such as London or Manchester.

Examples abound: Echo is helping patients get their prescriptions simply and with no upfront cost while, at the same time, nudging them to keep up with their treatment regime. Doctify has transformed the way that patients can find doctors and book appointments. In turn, Lantum helps hospitals find part-time staff like doctors and nurses, easing the all-important process of compliance checks. Social care-focused Cera uses technology to help both carers and those cared for. And Flynotes is looking to digitise medical consent, such an important step as we move into a new era of well-regulated health data sharing.

These, and many other startups, offer more than just the opportunity to improve healthcare: they help to deliver efficiencies, improve self-management of chronic conditions, offer personalised treatments, and upgrade preventative measures. When properly integrated with effective digital infrastructure and data analytics, personalised care plans and clinical engagement, they are the best hope of meeting the extreme demographic, financial and popular pressures facing the NHS.

The good news is that nearly everyone – from the Health Secretary and the NHS England Chief Executive to surgeons, GPs, and nurses on the frontline – agrees that new technologies are essential for the NHS.

From the Five Year Forward View (2014) and Personalised Health and Care 2020 (2014), to the Wachter Review of (2016), every major policy statement highlights the value of digitisation. In my time in the Department of Health and Social Care, I was struck by how everyone agreed about what the future of healthcare looked like.

Critically, too, the healthtech market is finally beginning to deliver the breadth and quality of companies required. There is a real and growing opportunity for digital health companies to start up and scale in the UK. The UK market size was £2 billion in 2014 and is expected to grow to £2.9 billion by 2018, with a CAGR of 11%, driven predominantly by high growth in markets such as mHealth apps (35% CAGR) and health analytics (24% CAGR).

Interestingly, there is a real similarity of outlook on both the demand and supply side: people are primarily motivated by a vision of delivering better care, more affordably. Everyone wants



to save the NHS. Indeed, many healthtech startups are either founded, backed or supported by medical professionals.

The growth in the market has been driven by a number of factors. First, technological advances: health technology, data analytics and mobile communications have converged to deliver tools for self-care and integrated health and care management. What was talked about five years ago is now available and inexpensive. Second, innovations like whole genome sequencing have allowed treatments to become more personalised. For example, genome sequencing has been used to identify different strains of tuberculosis.

Third, everyone is now connected: UK adult smartphone usage has surpassed 85% and is rising. The number of 55-75 year olds using smartphones is now growing at the fastest rate of any age group. At the same time, there is a greater willingness to see personal data used purposefully: Eurobarometer research found that 74% of those surveyed see having to disclose personal data as an increasing part of modern life.

Finally, many technologies that were previously expensive to build and maintain are now available to the masses. For example, cloud technology has become a commodity, with large suppliers like Microsoft Azure enabling mass transition from on-premise systems and private cloud systems to cost effective cloud solutions.

THAT IS THE GOOD NEWS.

But the bad news is that a number of barriers exist that inhibit the take-up – and especially the scale-up – of new technologies across the NHS. Despite often compelling clinical and financial evidence, few of the startups working in the NHS today have achieved real, systemic uptake. The cost-effectiveness of new technologies has yet to be universally accepted. Past failures provide ample ammunition for sceptics. Officials fear legal challenges from incumbents if they choose new solutions. Everyone wants to play it safe.

THE NHS NEEDS DIGITAL TRANSFORMATION. ITS LEADERSHIP WANTS IT, AS DO ITS PATIENTS. NOW THE MARKET CAN FINALLY PROVIDE IT.

There is no way other way to put this: the NHS is digitally risk-averse. That is not to say that NHS staff are technophobes, and there are some outstanding examples of good practice across the country. But taken as a whole, there is a collective failure of the organisation to provide the requisite opportunities to scale new technologies. This risk aversion is evident in decision-making processes and procurement systems, as well as in attitudes which combine to block innovation and to limit pilots, even if few are consciously opposed or deliberately obstructive.

These barriers persist even though the NHS has done a lot to make life easier for startups.

Many of the initiatives are very new, such as the Global Digital Exemplars and the NHS Innovation Payment, but others like the AHSNs, Test Beds, and NHS Innovation Accelerator are established, and yet still these barriers remain.

I set out to understand these barriers in detail. From my time as Health Minister I had a particular vantage point. But I wanted to understand what the NHS looks and feels like from the innovators' perspective. To this end, we conducted the largest ever survey of British healthtech startups, querying hundreds of digital health companies, as well as interviewing NHS professionals and key decision-makers across the health and care landscape.

From this, we identified the six areas where reforms are most needed: how the NHS requires evidence and evaluates new products; how it then regulates new products; how it procures new solutions; how it enables new purchases to operate across the system; how it ensures the highest standards of data security; and how it recruits and trains a workforce that can understand, adopt and help scale new technologies nationally. Reforms need to start here.

But I also want to help startups to succeed in the NHS. This is not just a report for the Government or the NHS – there are many of those; it is a report to founders, CEOs and innovators. It is meant to help them, to provide a sort of NHS user manual. The important thing to know is that in a system such as the NHS, startups needs to do their utmost to put people – patients, clinicians, and administrators – at ease.

Finally, I have highlighted the areas where the NHS is likely to be most open to change. The list will grow over time, but for now it is where I believe the NHS will be most ready to accept new, transformative digital solutions. And so it is where ambitious startups – such as those we highlight in this report – should focus their attention.

The UK faces an optimal situation. We are approaching a true inflection point. The NHS needs digital transformation. Its leadership wants it, as do its patients. Now the market can finally provide it.

2. THE OPPORTUNITY

There are three well known factors driving the global search for innovations to deliver cost-effective health care:



1.
THE GROWING, AGEING POPULATIONS WHO ARE NET CONSUMERS OF PUBLIC SERVICES – ESPECIALLY HEALTH CARE.

2.
THE RISE IN LONG-TERM, CHRONIC CONDITIONS EVIDENT ACROSS ALL AGE GROUPS.

3.
AND, FINALLY, THE COMPOUNDING EFFECT OF HIGHER DEMAND FOR HEALTH SERVICES AND HIGHER EXPECTATIONS FOR THOSE HEALTH SERVICES AS, IN MANY CASES, MORE EXPENSIVE TREATMENTS BECOME STANDARD.

In total, the NHS is projected to face a £30bn funding gap by 2020-2021 if it cannot deliver on the challenging combination of reforms and savings planned.

IN THE UK, IT COSTS THREE TIMES MORE TO LOOK AFTER A 75 YEAR OLD THAN A 30 YEAR OLD – AND THE NUMBER OF OVER 75S WILL INCREASE BY TWO MILLION BETWEEN 2014-2024.³

³ NHS. Next Steps Forward on the NHS Five Year Forward View, 2017.

THIS IS EXPECTED TO COST £5BN A YEAR BY 2018.⁴

⁴ Deloitte. Connected health: How digital technology is transforming health and social care, 2015.

SO-CALLED ‘HEALTH INFLATION’ IS PROJECTED TO RISE BY 6% IN 2018.⁵

⁵ Health Insurance & Protection Daily. UK medical inflation to hit 6% in 2018, 2017.

DIGITAL DIVIDEND

Digitisation is one of the few ways that these demographic and financial trends can be addressed. The reasons are simple: digital applications replace the high cost of labour with the low cost of silicon. What takes doctors and nurses many humans hours of work – for example, collating information, giving out medication, or telling patients where to park – can be done automatically at a fraction of the cost and much faster. Routine tasks, which previously took man-hours to perform, can now be done in seconds. And people, in turn, can be freed up to undertake other work.

Technology is also increasing the accuracy of interventions. Take breast cancer: screening mammography is still considered the most effective method for diagnosing breast cancer and advancing patients to appropriate treatment as quickly as possible. But mammograms are not always 100% accurate and can produce false-positive or false-negative results.

Software has long been used to help doctors analyse mammogram images themselves, but recent technologies are taking things one step further, by looking at the doctors' reports on these scans, as well as a patient's full medical history, to more accurately determine breast cancer risk. Not only is this 30 times faster, but it operates with a 99% accuracy, reducing the need for unnecessary biopsies.

CASE STUDY

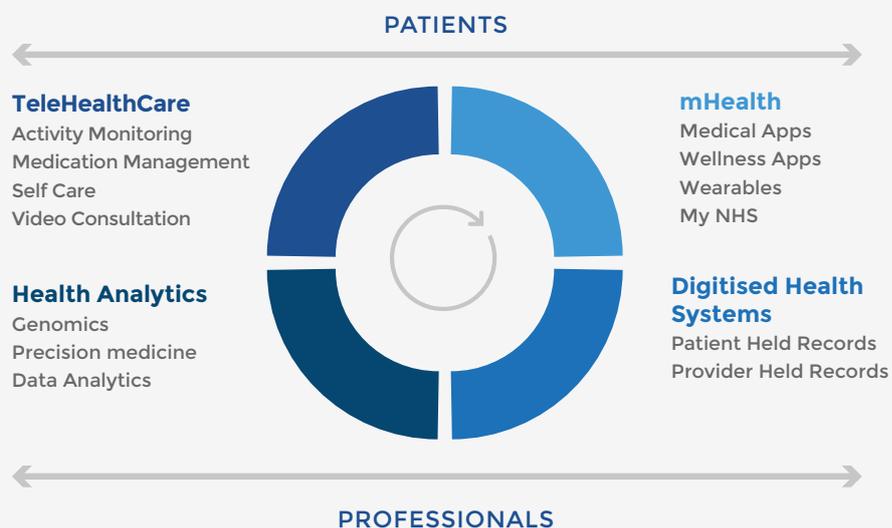


AI IN PATHOLOGY AND RADIOLOGY:

Google DeepMind

Google Deepmind has turned its renowned artificial intelligence expertise to the task of analysing CT and MRI scans from cancer patients in a bid to devise an algorithm that can instantly distinguish cancerous from healthy tissue. An initiative with University College London Hospital NHS Foundation Trust will use DeepMind to study anonymised scans from 700 former cancer patients to see whether it can develop a quick and reliable way to diagnose cancers of the head and neck. If successful, the company could turn its attention to other pathologies, reduce the time in clinic from three hours to 30 minutes. They are currently trialling their platform as a virtual clinic solution with Moorfields Eye Hospital. This tool is not only systems agnostic – so it can integrate with all hospital IT and imaging systems – but is capable of running in multiple languages. Big Picture's future plans involve training the tool for dermatology, orthopaedics and cardiology.

Figure 1: Digital Health Market



Furthermore, if digital solutions can be integrated effectively into existing systems and care pathways, they promise to drive out variation and raise quality, especially in key priorities such as supported self-care. As a result, they will generate long-term savings through early intervention and prevention. For people suffering from chronic diseases such as diabetes, for instance, this can be the difference between engaging with a doctor at an earlier and more easily treatable – less costly – stage, or engaging later with increased health complications and, in turn, higher costs.

There are many other examples. The framework outlined in Figure 1.1, commissioned by the Office for Life Sciences⁶, is a useful way of thinking about the different areas of healthtech, namely: mHealth, health-focused analytics, digitised health systems and telehealth. Each of these technologies are already being deployed in the NHS and internationally, transforming health systems and, crucially, patient outcomes.

Perhaps the most exciting opportunity is to use technology to create integrated, personalised medicine. The vision is for medical care not to be standardised into care pathways, but individualised down to your last genetic mutation and far more effective for it: every patient receiving the best available treatment for them. Secure clouds of genomic, microbiome, blood analysis and lifestyle data following the patient seamlessly from home to primary and secondary care, and all points in between, ensuring earlier diagnosis, more targeted treatment, and even prevention of illness altogether.

By monitoring patients, preventing illness and intervening early and effectively, costs are reduced because fewer patients will get sick and those that do, will get less sick. Furthermore, patients with chronic conditions and complex co-morbidities often find they know more about their care management than their doctors, as they juggle multiple interactions with specialists and carers, each responsible for a discrete aspect of their care. If these patients could be empowered with the tools and support to manage more of their care themselves, evidence shows outcomes would be much better – for both the patient and the health system.

This data-driven vision of the future of healthcare is designed to empower patients and deliver personalised, integrated care – while still

achieving savings. It can only be enabled, however, by increasingly sophisticated digital platforms to manage prescriptions (Echo), appointments (Babylon), staffing (Lantum), procurement (the Edge), social care (Cera) and so on – all services best delivered by startups.

CASE STUDY

Moorfields Eye Hospital 
NHS Foundation Trust

VIRTUAL CLINIC:

Big Picture/Moorfields Eye Hospital

Moorfields were searching for a solution not only to manage high levels of demand at their eye clinics, but also to identify deterioration of eye health earlier and develop a preventative/early intervention model as possible.

Big Picture is a two-year old startup that has built an end-to-end virtual diagnostic tool for eye care. Their tool has the potential to deliver a 40% reduction in the number of patients who need to attend clinics in-person and to reduce the time in clinic from three hours to 30 minutes. They are currently trialling their platform as a virtual clinic solution with Moorfields Eye Hospital. This tool is not only systems agnostic – so it can integrate with all hospital IT and imaging systems – but is capable of running in multiple languages. Big Picture's future plans involve training the tool for dermatology, orthopaedics and cardiology.

⁶Monitor Deloitte, Digital Health in the UK: An industry study for the Office of Life Sciences, 2015.

Humans needed

The application of technology must not, however, become an excuse for any de-humanisation of the NHS. The expertise and judgement of NHS professionals at every level - medical staff, technicians, support staff - will remain essential to healthcare even as we enter a new age in which those staff will see their roles evolve as more digital solutions and services develop so that healthcare jobs become even more of a partnership between man and machine. Already today, it is normal to integrate machines and data into care - the X-ray, MRI, continuous BP, respiratory, and ECG monitoring - are part of day to day patient management across hospitals. New machine learning solutions are taking this a step further, integrating genomic, imaging, and biomarker data into developing diagnostics. These are exciting innovations and hugely helpful for the medical profession as ever greater volumes of patient data are being

CASE STUDY



INTEGRATION:

Social Care Anywhere with Cera

With pressures on UK social care at an all time high, Cera is one of the new class of technology-enabled homecare providers. Cera's priority is not only to increase the capacity and convenience of care, but also to ensure it is delivering best-in-class care at affordable prices. Cera uses digital technology to improve the transparency of its services, allowing clients, families and health professionals to see real-time updates in care delivery.

CASE STUDY



PATIENTS KNOW BEST®
MANAGE YOUR HEALTH

SUPPORTED SELF CARE:

Patients Know Best

The NHS has a patchy record for the coordination of many complex conditions but new digital tools like Patients Know Best allow patients to build their own electronic patient record. Patients Know Best is a SaaS platform that allows patients to hold all their medical information in a single record which they directly control. If a patient chooses, they can invite anyone they wish to their profile, and construct a strong and comprehensive care network which is best suited to them.

gathered. It is clear, however, that this will remain a case of 'Augmented Intelligence' rather than 'Artificial Intelligence.' Not only will we need fully trained medical professionals, who know their patients to remain the final arbiters of diagnostics but also to make the ethical and compassionate judgements so deeply enshrined in the diagnosis, treatment and care of patients. However fast digital healthcare solutions are developing, there is no chance they will be replacing our primary trusted carers - NHS professionals - any time soon.

3. THE MARKET

This year the NHS turns 70 but the digital health market only started a decade ago. Although there were a few progenitors – such as the UK’s mature telecare market which remains globally dominant – it was the sequencing of the genome (2003), cloud computing (2006), and the Apple App Store (2008), that helped fuel the current market for digital health solutions.

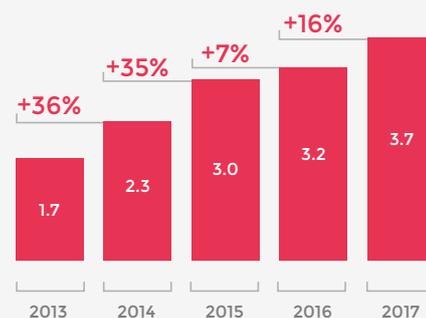
In the traditional healthcare industry, a decade rarely even covers a product development cycle. In digital terms, ten-year old businesses are veteran survivors. These two cultures could not be more different, and yet, as the lightning-fast tech industry and the painstaking healthcare sector co-parent their awkward teenage offspring – digital health – the centre of gravity is shifting inexorably towards the patient.

The UK’s digital health sector is growing fast. Not only did digital health jobs grow at a double-digit rate between 2011 and 2016, the connected health market is also projected to grow by 50% between 2014 and 2018. This is in line with the global market for digital health, which was worth £23bn in 2014 and is expected to almost double to £43bn this year – with most of the growth driven by mHealth.

This year numbers of mHealth apps available globally hit an all time high of 325,000 – 78,000 more than last year (that’s a 50% increase on Android, and 20% on iOS during 2016-17)⁷. Worldwide, this equates to 3.7bn downloads in 2017. This may sound good, up 16% on 2016 (see graph below), but app creations have increased by 45%, outstripping that demand. As a result, the two biggest challenges for the mHealth entrepreneur are developing a revenue model, and generating downloads (and for those in the healthcare services, the third, of course, is regulation).

⁷Research 2 Guidance. mHealth App Economics 2017: Current Status and Future Trends in Mobile Health, 2017, p. 10.

Figure 2: mHealth Download Rates 2013-17



Source: Research 2 Guidance. Current Status and Future Trends, 2017, p. 11.

The statistics tell a clear story of how much easier it is to build than distribute a health app. Most apps only generate a couple of thousand downloads (55% have fewer than 5,000 downloads in 2016). Still, about 3% of apps are reaching high annual download numbers of over one million⁸. Of course, sustainable business depends on retention of customers and low download numbers mean even fewer monthly active users (MAU). 46% of mHealth app developers have fewer than 500 MAUs while only 2% of mHealth apps claim more than 500,000⁹.

⁸Research 2 Guidance. Current Status and Future Trends, 2017, p. 20

⁹Ibid, p. 21.

THE UK IS WELL POSITIONED TO TAKE POLE POSITION IN DIGITAL HEALTH

The growth of the healthtech market is likely to be driven further by a number of factors, including:

- Technological advances.** Health technology, data analytics and mobile communications have converged to deliver tools for self-care and integrated health and care management. These include virtual clinics, over 325,000 mHealth apps, portable diagnostics, digital therapeutics and smart drug delivery. There is increasing confidence from patients and clinicians in using these digital solutions.
- Personalised medicine.** Whole genome sequencing is already being used in hospitals to diagnose and treat patients, at a millionth cost of what it was when the DNA procedure was first discovered. UK tech firm Oxford Nanopore have developed a device that fits in the palm of the hand to sequence the human genome, which has opened up possibilities for using genetics in routine medicine.
- Digital connectivity.** UK adult smartphone usage has surpassed 85% and is rising. The number of 55-75 year olds using smartphones is now growing at the fastest rate of any age group. At the same time, there is a greater willingness to see personal data used purposively: Eurobarometer research found that 74% those surveyed see disclosing personal data as an increasing part of modern life.
- Cost effectiveness.** Many technologies that were previously very expensive to build and maintain are now available cheaply. For example, cloud technology has become a commodity, with large suppliers like Microsoft Azure and AWS enabling mass transition from on-premise systems and private cloud systems to more cost effective public cloud solutions.

The UK is well positioned to take pole position in digital health. The UK market size is £2 billion and with the right support, is expected to grow to £2.9 billion this year with a compound annual growth rate (CAGR) of 11%, driven predominantly by high growth in markets such as mHealth apps (35% CAGR) and health analytics (24% CAGR)¹⁰. The 427 UK digital health companies currently employ an estimated 9,600 people. 109 (26%) of these companies were incorporated in the last five years and 200 (47%) in the last ten years, compared with 700 (14%) and 1,804 (35%) respectively for all life science companies.¹¹

Many of these companies display classic ‘startup’ characteristics: the digital health sector has the largest proportion of companies with fewer than five employees (21% of the total or 255) and the highest number of companies with a turnover of less than £50,000 (129).

Figure 3: Top 5 segments (excluding service and supply companies) in the life science industry in terms of employment, turnover and number of companies¹²

	Employment	Turnover	No of Companies
1	Small Molecules	Small Molecules	Small Molecules
2	Single Use Technology	Single Use Technology	Digital Health
3	Digital Health	Therapeutic Proteins	Assistive Technology
4	Orthopaedic Devices	Vaccines	In vitro diagnostic technology
5	In vitro diagnostic technology	Orthopaedic Devices	Single Use Technology

¹² Office for Life Sciences: ‘Strength and Opportunity 2016: The landscape of the medical technology and biopharmaceutical sectors in the UK’, 2017, p. 12

¹⁰ Deloitte: Digital Health in the UK, 2015, p. 8.

¹¹ Office for Life Sciences: ‘Strength and Opportunity 2016: The landscape of the medical technology and biopharmaceutical sectors in the UK’, 2017, p. 29-30.

Apart from the trend towards increasing personalisation and integration in health care, another key driver pointing towards continued growth in the digital health sector is smartphone penetration and, with it, public acclimatisation to personal control and instant access to information and support in all areas of their lives.

The NHS is the world's largest integrated healthcare system. When combined with our first class science and innovation ecosystem, and a competitive business environment, it should make the UK one of the best places in the world to develop and market digital health solutions. Furthermore, these favourable conditions are on course to get even better over the next decade.

Figure 4: USA, The UK And Germany Are The Most Attractive Countries For Digital Health Solutions – Market Size Is Most Important Factor

Countries currently offering the most favourable environment for digital health solutions; reasons for most favourable environment; population size; GDP and % of health expenditure of GDP¹³

TOP 15 COUNTRIES

1	USA
2	UK
3	Germany
4	Israel
5	Canada
6	The Netherlands
7	Denmark
8	India
9	Sweden
10	China
11	Finland
12	Switzerland
13	Estonia
14	Spain
15	Norway

¹³Research 2 Guidance. Current Status and Future Trends, 2017, p. 14.

In the UK 85% of adults have a smartphone, expected to rise to 88% by mid-2018¹⁴. While adoption is now up to 90% among 18-45 year olds, among 55-75 year olds it has now reached 71% and the compound annual growth in smartphone adoption for this age group since 2012 is 19%, the highest growth in smartphone ownership of any age group¹⁵. Illustrating just how digital a nation the UK has become across all age groups, an Ofcom report showed that 48% of 65-74 year olds have a social media profile.

Another catalysing factor for the growth of the digital health market is the growth of startup companies fed by early-stage investments from accelerators, angels and venture capital firms. Early stage investors have invested approximately \$5.4bn globally into digital health startups in 2016. Deeper investments into the market for digital health – early stage as well as later stage – are fuelling market growth globally.

In the UK, healthcare IT deals (investments and exits) increased by 14.7% during 2016-17, compared to a global increase of 9.8%. It is notable that this is an exponential rise as the CAGR of average transaction values between 2014-17 is 4.8% p.a. In addition, over that period Series A deals are increasing as a proportion of total deal type from 11.8% in 2014 to 17.5% in 2016 and 2017, suggesting more companies are graduating past seed and into bigger rounds, an important trend as companies seek to scale.

However, health inflation is projected to be 6% in 2018 – running about 2% over budget increases. So far the pressure on budgets has driven a search for innovation to improve efficiency in some areas, but in others it has overwhelmed NHS commissioners and clinicians who can feel the value of digital health solutions is outweighed by the challenges of developing the skills and culture change necessary to effectively procure and then implement digital transformation.¹⁶

¹⁴Deloitte. Smartphone adoption: Stable and strengthening, 2017.

¹⁵Deloitte. State of the smart: Consumer and business usage patterns - Global Mobile Consumer Survey 2017: UK Cut, 2017, p. 1.

¹⁶Health Insurance & Protection Daily. UK medical inflation to hit 6% in 2018, 2017.

THE POLICY PICTURE

Our current health policy cycle began with the Five Year Forward View (FYFV, 2014). It is a practical roadmap to delivering its triple aim of better care, better services and sustainable finances. This marked the beginning of a broad consensus about how to 'future proof' the NHS, but also about the risks of what the CQC has called the 'burning platform' on which the NHS stands. The NHS is projected to face a £30bn funding gap by 2020-2021 if it cannot deliver on the challenging combination of reforms and savings set out in the FYFV.

THE CARE AND QUALITY GAP: UNLESS WE RESHAPE CARE DELIVERY, HARNESS TECHNOLOGY, AND DRIVE DOWN VARIATIONS IN QUALITY AND SAFETY OF CARE, THEN PATIENTS' CHANGING NEEDS WILL GO UNMET, PEOPLE WILL BE HARMED WHO SHOULD HAVE BEEN CURED, AND UNACCEPTABLE VARIATIONS IN OUTCOMES WILL PERSIST.

Five Year Forward View¹⁷

¹⁷CQC. The State of Care in Acute Hospitals: 2014 to 2016. Findings from the end of CQCs programme of NHS acute comprehensive inspections, 2017, p. 4

The FYFV set off a series of measures based around 'new models of care' to bring about the 'triple integration' of primary and specialist hospital care, of physical and mental health services, and of health and social care. It also called for significant social care investment, and activism on prevention and public health.¹⁸ It recognized the essential role that technology will play in improving care and driving out variation – as well as delivering efficiencies in the longer term. Notable, and relevant for the digital health space, was the emphasis on designing care around the patient, including much more effective tools and information for supported self care, and the need for

¹⁸NHS. Next Steps Forward on the NHS Five Year Forward View, 2017.

a greater proportion of NHS care to consist of out of hospital services.

In 2016, the Wachter Review published its highly influential findings which noted that secondary care had lagged behind primary care in digitisation and that the NHS would fail to achieve the FYFV goals if this was not addressed.

With a set of ten principles and ten recommendations, Wachter called for a national strategy to digitise secondary care and create a fully digital and – crucially – interoperable health care system in the UK. The Treasury had already allocated £4.2bn for this purpose as part of the National Information Board (NIB) Personalised Health and Care 2020¹⁹ programme

¹⁹ National Information Board. Personalised Health and Care 2020 - Using Data and Technology to Transform Outcomes for Patients and Citizen: A Framework for Action, 2014.

but Wachter emphasized that unlike the failed projects of the past:

- the national strategy would have to be matched with effective local leadership and implementation plans that aligned with local need;
- lessons of every other industry digitization must be learnt. Simply installing the infrastructure was not enough; upskilling the workforce must be an integral part of every single local plan;
- and, finally, pace would be important. While it was right for the Government to be ambitious and set a target for digitisation, trusts would digitise at different rates depending on existing capacity.

Of particular note is the emerging interplay between national health and care bodies and the local NHS as this digital policy has developed.



“PART OF WHY PROGRESS HAS NOT BEEN AS FAST AS IT SHOULD HAVE BEEN [ON DIGITIZATION] IS THAT THE NHS HAS OSCILLATED BETWEEN TWO OPPOSITE APPROACHES TO INFORMATION TECHNOLOGY ADOPTION - NEITHER OF WHICH NOW MAKES SENSE. AT TIMES WE HAVE TRIED HIGHLY CENTRALISED NATIONAL PROCUREMENTS AND IMPLEMENTATIONS. WHEN THEY HAVE FAILED DUE TO LACK OF LOCAL ENGAGEMENT AND LACK OF SENSITIVITY TO LOCAL CIRCUMSTANCES, WE HAVE VEERED TO THE OPPOSITE EXTREME OF ‘LETTING A THOUSAND FLOWERS BLOOM’. THE RESULT HAS BEEN SYSTEMS THAT DON’T TALK TO EACH OTHER, AND A FAILURE TO HARNESS THE SHARED BENEFITS THAT COME FROM INTEROPERABLE SYSTEMS.

“IN FUTURE WE INTEND TO TAKE A DIFFERENT APPROACH. NATIONALLY WE WILL FOCUS ON THE KEY SYSTEMS THAT PROVIDE THE ‘ELECTRONIC GLUE’ WHICH ENABLES DIFFERENT PARTS OF THE HEALTH SERVICE TO WORK TOGETHER. OTHER SYSTEMS WILL BE FOR THE LOCAL NHS TO DECIDE UPON AND PROCURE, PROVIDED THEY MEET NATIONALLY SPECIFIED INTEROPERABILITY AND DATA STANDARD.”

Five Year Forward View²⁰

²⁰NHS. Five Year Forward View, 2014, p. 7.

This conclusion has led to two contemporaneous streams of work. Widespread investment in local digital and data transformation is being driven by the FYFV new models of care, devolution and the new Global Digital Exemplars.

Nationally this is matched by work on interoperability and data standards from NHS Digital and the National Data Guardian, while the National Information Board drives forward the key infrastructure programmes set out in Personalised Health and Care 2020 (November 2014).²¹

Throughout this report we attempt to map these policy initiatives onto the day-to-day experiences of innovators and their meaning for the digital health market in 2018.

²¹National Information Board. Personalised Health and Care 2020

4. BARRIERS TO INNOVATION

Hospitals have been slow to adopt and scale new technologies, especially robotics and artificial intelligence, into patient care, although both have been widely used and tested in other industries. Medicine has traditionally been slow to change, as safety is at its core and the costs of implementation have in the past been prohibitive. But costs are falling due to cloud computing, wifi and the roll-out of open systems. Digital health solutions really are starting to make financial as well as clinical sense.

With public and private sector investment at an all time high, one of the strongest R&D bases in the world and effective industry support now in place, it is not creating the innovation that is the problem in the UK, or even piloting them in one or two locations. The problem for digital health startups comes when they attempt to access the NHS on a commercial basis and then diffuse their product through the rest of the health and care system. Nor is there a dearth of senior-level support for the introduction of new technologies into the NHS.

So why, despite often compelling clinical and financial evidence, have none of the startups working in the NHS achieved genuine systemic uptake? There are number of reasons.

THE APPROACH TO ACCESSING INNOVATION IN THE NHS HAS BECOME INCREASINGLY CHALLENGING; CREATING FRUSTRATION FOR INNOVATORS WHO SEE THE NHS AS AN INTERESTING ENVIRONMENT FOR DEMONSTRATING THE VALUE OF THEIR PRODUCTS, FOR PATIENTS WHO OFTEN HAVE TO WAIT LONG PERIODS OF TIME BEFORE LIFE-SAVING THERAPIES ARE AVAILABLE, AND FOR CLINICIANS WHO ARE FRUSTRATED BY THE MULTIPLE BARRIERS TO BOTH APPROVAL AND ADOPTION.

Accelerated Access Review, 2016

Cost-effectiveness has yet to be universally accepted to be a consequence of digitisation. The legacy of the NHS National Programme for IT (NPfIT), 3 million lives, care.data, and many more abandoned NHS technology programmes provide ample ammunition for the sceptics. At a time of constrained NHS finances and risk aversion, this scepticism is a tough hurdle for innovators to overcome.

Regulatory processes remain slow and complex and often changing; in addition to which almost all NHS commissioning is local and varies from trust to trust creating a frustratingly fragmented picture. While some areas and individuals champion innovation, in many more places the cultural differences between innovative startups and risk-averse commissioners mean that selling new products is very hard indeed.

The diagram below published by NHS England demonstrates just how many stages an innovation must pass through - from idea to purchase and diffusion - if it is to succeed in the NHS. Each of these stages takes time and real expertise to negotiate successfully. By their nature, most digital health companies are smaller and have lower budgets than comparable companies in for example the life sciences sector. As a result they have little capacity to invest in large business development and sales teams to go Trust by Trust or to manoeuvre a multi-stage process.

Then there is a skills gap. While there are examples of good practice, the ability to understand, let alone trial and then scale digital

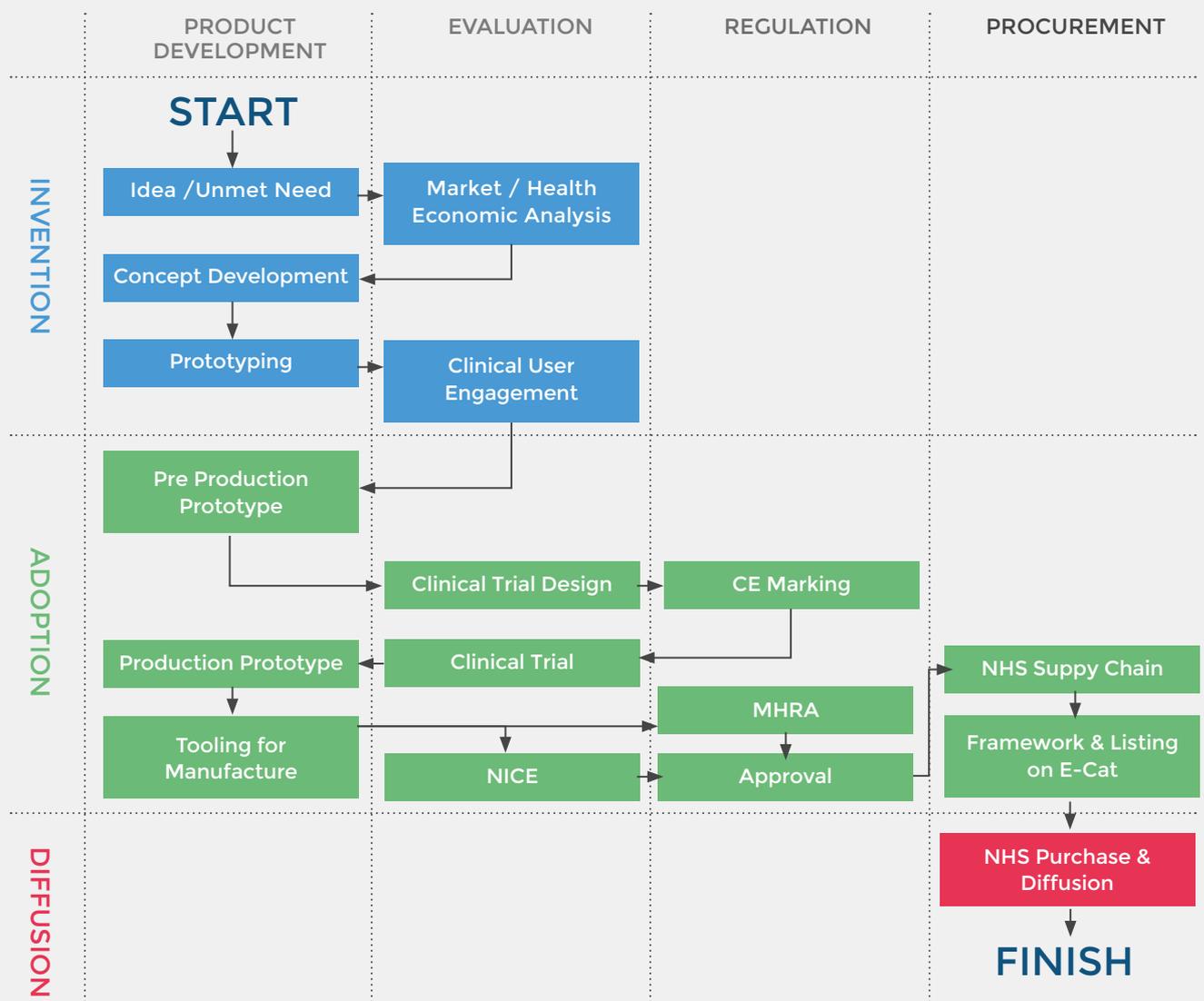
solutions is variable in the NHS. The number of medical professionals who have the digital skills (or at least the tools) to interpret the huge swathes of data being generated, assess their clinical value and effectively incorporate these technologies into care plans, remains small.

We have divided the main barriers into the following categories:

“THE WORD STARTUP SOUNDS HIGH RISK AND PEOPLE DON’T WANT TO BE A GUINEA PIG – ESPECIALLY WHERE IT INVOLVES PATIENT DATA OR PATIENT SAFETY... THERE IS NOT MUCH UPSIDE IN TAKING BIG RISKS IN THE PUBLIC SECTOR AND MASSIVE DOWNSIDES TO FAILURE WHICH COST PEOPLE THEIR JOBS”.

Founder of a healthtech startup

Figure 5 NHS Innovation Path Map²²



²²NHS England. Innovation Road Map to Support Organisations, 2015.

EVIDENCE AND EVALUATION

"IF STARTUPS TAKE TWICE AS LONG AS YOU EXPECT, HEALTHCARE STARTUPS TAKE FIVE TIMES AS LONG. YOU NEED TO BUILD YOUR CREDIBILITY AND ONLY TIME ALLOWS YOU TO DO THAT, SO MAKE SURE YOU ALLOW ENOUGH TIME TO DO SO AND BUILD YOUR CLINICAL EVIDENCE."

PUBLIC SURVEY 2017

Although there is a general consensus that digital health solutions are desirable from a policy perspective, there is considerably less consensus about 'what good looks like' with respect to evidence. The debate is ongoing regarding exactly what data an innovator needs to gather in order to demonstrate that their innovation is safe, clinically (more) effective, and economically viable. Will a paper-based model be sufficient or is a full clinical trial necessary? If so how can such a trial or pilot in an NHS setting be facilitated – short of being selected (through a lengthy process) for a test bed or healthy new town initiative?

If innovators are uncertain about this, so are clinicians and commissioners. Some err on the side of caution and feel they should only prescribe digital solutions that have had the full double-blind, RCT treatment while others feel a proportionate approach based on risk is more appropriate. The Accelerated Access Review (see Appendix I) will make it easier for some innovators to develop evidence and NICE is trialling a more responsive regulatory approach to digital CBT, which has the potential to be rolled out to all digital health solutions in time but in the meantime they are piloting guidance and resources specially aimed at digital health solutions to help both commissioners and innovators develop more effective standards for early evidence gathering

PUBLIC SURVEY 2017

'A CLEARER PATHWAY TO BUILD THE CLINICAL AND HEALTH ECONOMIC EVIDENCE REQUIRED TO BRING NEW INNOVATIONS TO HEALTH THAT IMPACT THE PATIENT'S CLINICAL PATHWAY.'

'EVIDENCE FOR DIGITAL HEALTH SOLUTIONS IS THE KEY, HOWEVER, SMES LIKE US HAVE TO INVEST IMMENSE AMOUNT OF TIME AND EFFORT AT CONSIDERABLE RISK TO BUILD EVIDENCE TO SUIT NHS LEADERSHIP.'

'[ONE OF THE BIGGEST CHALLENGES WE FACED WAS...] GETTING EVIDENCE BASED DATA FROM TRIALS AND OVERCOMING NHS IT HURDLES'

'[ONE OF THE BIGGEST CHALLENGES WE FACED WAS...] PROVING THE HEALTH ECONOMICS BUSINESS CASE.'

CASE STUDY



OUT OF HOSPITAL CARE:

Ask the Midwife

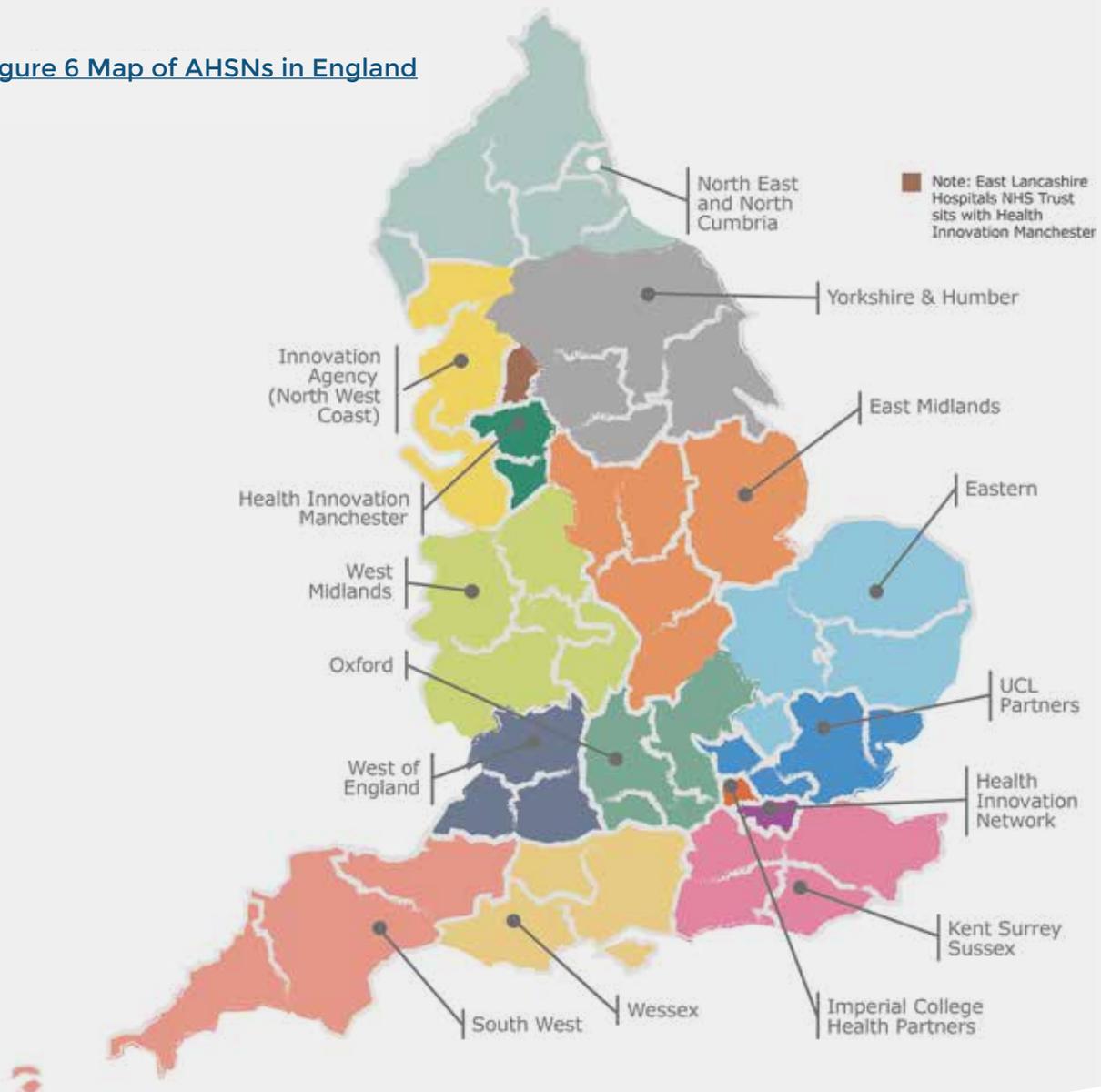
Ask The Midwife is the UK's first online advice platform run by midwives for pregnant women and their families. The service provides fast, accurate advice to reassure women on their journey through motherhood. All the advice provided is given by UK registered midwives. This service also reduces pressure on GP services and unplanned visits to A&E. pathway to build the clinical and health economic evidence required to bring new innovations to health that impact the patient's clinical pathway.'

There is currently no easy answer to this issue as policy and practice have not caught up with the pace of innovation in the digital health sector. Indeed, it is not a problem unique to digital health. There is an inherent contradiction within the heart of medicine: while medics always strive for innovation to improve care, they are also conservative about risk. Of course it is right that patient safety must come first but systems to establish safety and benefit must be proportional and as unbureaucratic as possible. As we saw, for example, with the expediting of the clinical trial for Ebola vaccines during the crisis, when necessary it is perfectly possible to streamline processes without compromising ethics or patient safety. The Life Sciences Strategy and Accelerated Access Review have proposed exactly this and hopefully progress will be seen in the coming months.

In the meantime, the best option is for innovators to work directly with commissioners and clinicians to develop the strongest clinical and economic evidence they can, within a sensible financial envelope.

There are routes to find support. In London various accelerators such as the NHS Innovation Accelerator, DigitalHealth.London, MedCity, and nationally, the Academic Health Sciences Network (see figure 3.2), can assist with advice and support. For research grants and advice there is the £1bn National Institute for Health Research along with a number of other NHS evidence gathering programmes such as the Test Beds and the Healthy New Towns initiative (see Appendix I).

Figure 6 Map of AHSNs in England



INNOVATOR TOP TIP:

CONDUCT QUALITATIVE AS WELL AS QUANTITATIVE EVALUATION TO IMPROVE PRODUCT AND STRENGTHEN FUTURE BIDS

START WITH THE CLINICAL AND ECONOMIC EVIDENCE

REGULATION²³

'THE BIGGEST BARRIER TO SCALING WITHIN THE NHS IS THE SHEER NUMBER OF DIFFERENT PURCHASERS AND REGULATORY ORGANISATIONS.'

PUBLIC SURVEY 2017

For the innovator new to the health sector, regulation and procurement can feel like a minefield. Many investors stay away from health, citing regulatory challenges – but in fact if you know your way round the system these challenges are not insuperable. As discussed above, not only are moves underway to make NICE and the MHRA more responsive and transparent, but accelerators, AHSNs, and others can help with interpretation and implementation where needed.

Realistically, for most startups advice will be needed. Regulation of digital health products is fast-evolving, whether it is data protection legislation moving to the GDPR, or the CQC being given powers to rate non-NHS online GP providers²⁴, or NICE piloting Healthcare Apps Briefings and developing a new assessment programme for digitally assisted therapy²⁵. Many companies have told us that it is not just achieving the regulatory standards in the first place that is the challenge, but maintaining those standards (which is an ongoing process) in a constantly shifting environment that takes up so much time and money. Finally, of course, regulatory differences between other countries present a further hurdle to exports for small companies wanting to expand quickly.

²³Please note this is a summary of some current digital health regulations and should not be taken as legal advice.

²⁴National Health Executive. CQC given powers to rate non-NHS services including online GPs, 2018.

²⁵NICE. New programme will assess how digital therapies can help treat anxiety and depression, 2017.

"REGULATION IS TIGHT AND CONSTANTLY CHANGING"

PUBLIC SURVEY 2017

It is unlikely this will abate in the next few years. The combination of possible Brexit reforms to UK life sciences regulation and the increasing maturity of the digital health market – including the regulatory regime – mean that 2018-2020 is likely to be a period of significant regulatory change. Recognising this, it is essential companies manage and plan for this risk appropriately.

Despite the frustrations, innovators have told us that investing in the relevant quality and data protection standards is likely to make all the difference in the tendering process. Especially at a time when clinician and commissioner confidence in digital health products is still far from universal.

Currently, all medical devices need to be CE marked. Companies either certify themselves or use a notified body. It is a light touch process; most apps are Class 1 at present and these devices are self-certified. The company then needs to register the device with the relevant competent authority. In the UK the relevant authority is the MHRA and registration costs £100. They self declare for each device, apply the CE mark, and details then appear on the publicly available database.

A CE MARK IS A LOGO THAT IS PLACED ON MEDICAL DEVICES TO SHOW THAT THE DEVICE IS FIT FOR ITS INTENDED PURPOSE STATED, MEETS LEGISLATION RELATING TO SAFETY AND CAN BE FREELY MARKETED ANYWHERE IN THE EUROPEAN UNION. THIS IS IMPORTANT AS OFFICIAL ADVICE TO CLINICIANS FROM THE ROYAL COLLEGE OF PHYSICIANS AND OTHERS ON PRESCRIBING DIGITAL HEALTH SOLUTIONS CLEARLY STATES THAT NOT ONLY MUST CLINICIANS ONLY PRESCRIBE DIGITAL SOLUTIONS WITH A CE MARKING BUT THAT THE MARKING MUST BE APPLICABLE TO THE ACTUAL VERSION IN QUESTION AND FINALLY, IF THE APP THEY WISH TO USE DOES NOT HAVE A CE MARKING THE CLINICIAN SHOULD REPORT IT TO THE MHRA.²⁶

²⁶Royal College of Physicians. Using apps in clinical practice guidance, 2015.

The MHRA have developed a useful interactive device determination flow chart with guidance to show which standalone software and apps meet the definition of a medical device and therefore require to be CE marked, and which do not²⁷.

Digital health solutions which are defined as medical devices may of course be subject to further regulation, while those that are not may still fall under other regulations. Online pharmacies for examples must register with the MHRA's list of online retail sellers and participate in the mandatory logo scheme, which includes a set of standards and a maximum penalty of two years in prison for breach.²⁸

The NHS Apps Library is another interim solution that NHS England introduced in recognition of the need to provide practical advice to both patients and clinicians about the safety of mHealth solutions. It has also become a way for digital health innovators to achieve a degree of NHS approval.³²

PROCUREMENT

"PILOTS NEVER TRANSLATE INTO SCALABLE SOLUTIONS BECAUSE OF FRAGMENTED PROCUREMENT"

PUBLIC SURVEY 2017

The 2016 Carter Review team visited 136 acute hospitals (40% of these Lord Carter visited personally), identifying major potential for efficiencies in procurement, pharmacy, data reporting and more. In fact, such was the variation across the country Lord Carter claimed his recommendations could save the NHS £1bn of the overall £9bn spent annually on procurement by the NHS.

"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... FOR EXAMPLE, A SAMPLE OF 22 TRUSTS COVERING APPROXIMATELY 16% OF NHS SPENDING REVEALED THAT IN ONE YEAR THEY USED 30,000 SUPPLIERS, 20,000 DIFFERENT PRODUCT BRANDS, MORE THAN 400,000 MANUFACTURER PRODUCT CODES WITH MORE THAN 7,000 PEOPLE ARE ABLE TO PLACE ORDERS".

Carter Review 2016

³²Department of Health. Operational productivity and performance in English NHS acute hospitals: Unwarranted variations, 2016.

CASE STUDY US REGULATION:

Digital Health Innovation Plan 2017²⁹

In 2016, 36 devices and medical apps received clearance from the US Food and Drug Administration. These include apps to help people with heart conditions, to help diagnose and treat ADHD in children, apps to help patients manage type 2 diabetes, and smartphone-based ultrasound scanners and mobile blood glucose monitors.³⁰

'The healthcare sector is, and has been, subject to intense regulation. Digital as well as non-digital health solutions that could pose a risk to patient safety must be cleared by an approved regulatory body, such as the FDA in the USA. But there are signs of big future changes in regulating digital health. In July 2017, the most prominent regulatory body – the FDA – announced a very new approach to approving digital health solutions (called the Digital Health Innovation Plan). Instead of approving individual digital products, entire companies could be approved, and digital products released by those pre-selected companies would not have to go through a regulatory process for each of their product releases. This development is still very fresh, but the FDA seems to initiate a paradigm change in regulating digital health solutions. This could act as a blueprint for more countries to follow. Regulations differ between countries. For app publishers being subject to regulations, the choice of their target market makes a difference – for instance, in having a competitive advantage or a threshold for market entry³¹.

²⁹Research 2 Guidance. mHealth App Economics 2017, p. 13.

³⁰The Independent The benefits that a digital healthcare system could bring aren't out of reach, 2017.

³¹Research 2 Guidance, p. 13.

²⁷MHRA. Guidance: Medical device stand-alone software including apps (including IVDMDs), 2017.

²⁸COV.UK. New mandatory logo for selling medicines online, 2015.

One of the key recommendations was that hospitals should limit the range of products they buy, including having strict controls around electronic catalogues (achieving over 90% compliance), and full digitisation of their purchase-to-pay (P2P) processes. At the moment, most trusts have some form of electronic catalogue but their use and standard varies widely.

Work has begun to implement these recommendations through NHS Business Services, NHS Improvement and NHS Rightcare, as well as on a local level. Nevertheless, without exception respondents to our survey pointed to procurement practices as a major barrier to entry. All spoke about how slow the process was in comparison with the pace and dynamism within the digital health sector.

CASE STUDY



PROCUREMENT:

the Edge³³

The Edge for Health is a procurement platform designed to perform as a consumer-style, procure-to-pay (P2P) online marketplace. It is GS1/PEPPOL accredited and enables eProcurement, stock & inventory management, product information management (PIM), catalogue management, e-invoicing, track and trace, and analytics.

Many of the trusts in the Shelford Group have already adopted the platform along with several other NHS Trusts. In addition to this, a partnership with NHS Shared Business Services has been agreed to bring The Edge for Health to at least a further 65 NHS Trusts.

³³Virtualstock. What is The Edge for Health?

'THE GAP BETWEEN DESIRING ADOPTION AND ACTUALLY MAKING IT HAPPEN AT FAST PACE WITHIN NHS SECTOR [IS ONE OF THE BIGGEST CHALLENGES INNOVATORS FACE]. THE NHS BUSINESS PROCESS IS 12 TO 18 MONTHS IN MOST CASES, WHILST.. [OUR].. IMPLEMENTATION PATH COULD BE AS SHORT AS 8 WEEKS.'

PUBLIC SURVEY 2017

More than one spoke of how they had been told 'we can't pick winners' as a justification for an unnecessarily legalised procurement process. Some described extensive pre-procurement checks that they had to undertake before even being allowed in the door for preliminary meetings. Other early stage companies spoke of the frustration of having the evidence and the right solution but being unable to provide the required evidence for the tendering process.

'GETTING THROUGH PROCUREMENT HURDLES [IS THE BIGGEST CHALLENGE COMPANIES LIKE OURS FACE]'

PUBLIC SURVEY 2017

For example, despite the well publicised pressures on social care services some local authorities have still not introduced any flexibility into their procurement processes to facilitate digital solutions that will ease the situation.

LOCAL AUTHORITIES USUALLY HAVE TENDER AND CONTRACTS THAT REQUIRE PROVIDERS TO HAVE 2-3 YEARS WORTH OF TRADING. THE LAS TEND TO STICK TO THE STANDARD PROCEDURE FOR TENDERING WHICH MEANS THE BARRIERS TO ENTRY FOR A NEW AND INNOVATIVE [SOCIAL CARE] PROVIDER LIKE...[US].., IS HIGH.

PUBLIC SURVEY 2017

While variation and fragmentation of NHS procurement is at the root of these issues, the skills of commissioners and procurement decision-makers (who are not always the same people) are also a relevant factor – especially when it comes to digital. Some welcome solutions are coming online to improve the quality of these decisions.

CASE STUDY



COMMISSIONING:

Outcome based healthcare³⁴

OBH has developed a population health analytics platform that measures 'true' health outcomes that matter to people and populations, in near real-time. OBH supports commissioners, providers, and health and care systems to organise care around these priorities, measuring the resulting health outcomes. The key focus for OBH is to shift measurement and reimbursement away from solely treating illness, and towards improving people's health. OBH's Outcomes Platform enables commissioners and providers to identify baselines for their selected outcomes, set improvement trajectories and monitor outcomes specific to their local populations on an on-going monthly basis. Outcome sets, designed by OBH, typically measure both the presence of health and the avoidance of illness. By encouraging commissioners to pay providers based on improvements in patient outcomes, health systems are incentivised to combine new and existing care activities to keep patients well.

³⁴<https://outcomesbasedhealthcare.com>

THE GLOBAL
DIGITAL
EXEMPLARS WILL
BE PART OF THE
SOLUTION.

GLOBAL DIGITAL EXEMPLARS

'AN EXTRA POT OF MONEY ASSIGNED SPECIFICALLY TO DIGITAL INNOVATION. THIS WAY CCG'S WOULDN'T BE CHOOSING BETWEEN IMPROVING EFFICIENCY AND PAYING NURSES SALARIES'

PUBLIC SURVEY 2017

The Global Digital Exemplars will be part of the solution. At the NHS Innovation Expo in 2016, Jeremy Hunt personally backed Wachter's analysis (see Chapter 4) and announced the first wave of 12 Acute Trusts that would lead the digitisation of secondary care³⁵ – the Global Digital Exemplars (GDE). Along with funding, he announced a new National Digital Academy that would provide the intensive support to develop the essential digital and leadership skills to deliver digital transformation (including effective procurement of digital solutions) at scale. Further Mental Health Global Digital Exemplars were also announced, as was a further group of 'Fast Follower' Trusts³⁶.

We conducted a close financial analysis of the published +£25,000 invoices of ten of the new Global Digital Exemplars to assess the baseline for progress. These were the ten exemplars chosen based on geographical spread and existing reputation for innovation:

³⁵NHS England. Acute Global Digital Exemplars.

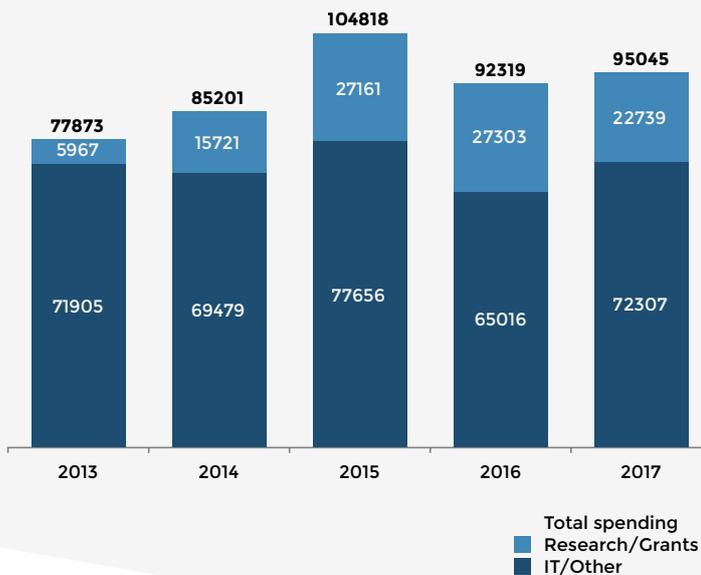
³⁶NHS England. Mental Health Global Digital Exemplars.

Figure 6: 10 Selected GDEs

Region	GDE	GDE II
North	Alder Hey	Salford Royal FT
Midlands	Cambridge FT	University Hospitals Birmingham NHS FT
London	Royal Free	Imperial College Healthcare and Chelsea and Westminster FT (joint Exemplar)
South	Oxford University Hospitals	University Hospitals Southampton FT
Mental Health Trusts	Northumberland Tyne and Wear FT	Oxford Health FT

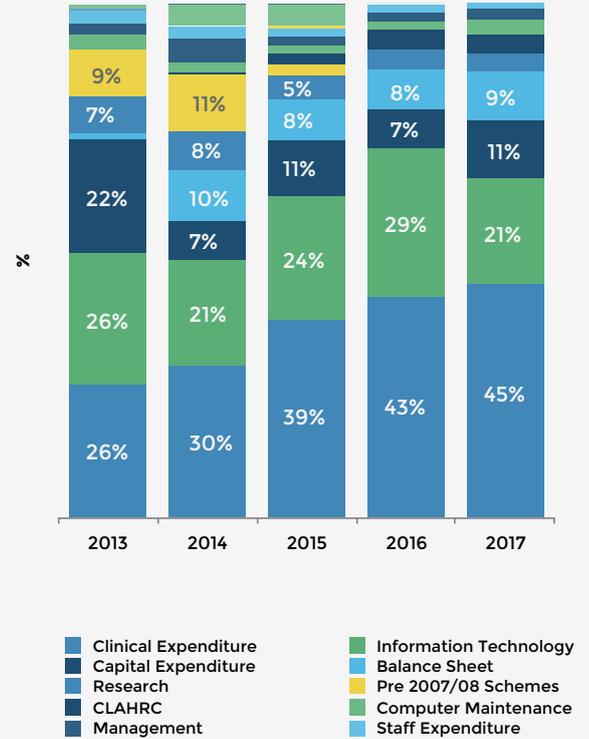
Tech and research spending is increasing for the cohort at c.5.8% p.a. with a particular focus on research spending. Since 2017 spending is year to date we expect further upswing for the full year of spending, which is promising for digital health.

Figure 7: Cohort Tech and Research Expenditure (£k). 2013-2017YTD



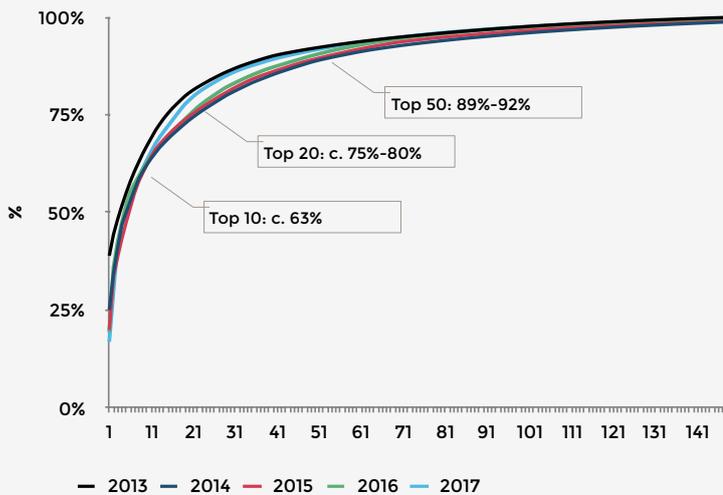
Clinical departments dominate expenditure, suggesting they hold significant sway for suppliers.

Figure 8: Cohort spending by area proportionality (%), 2013-2017YTD



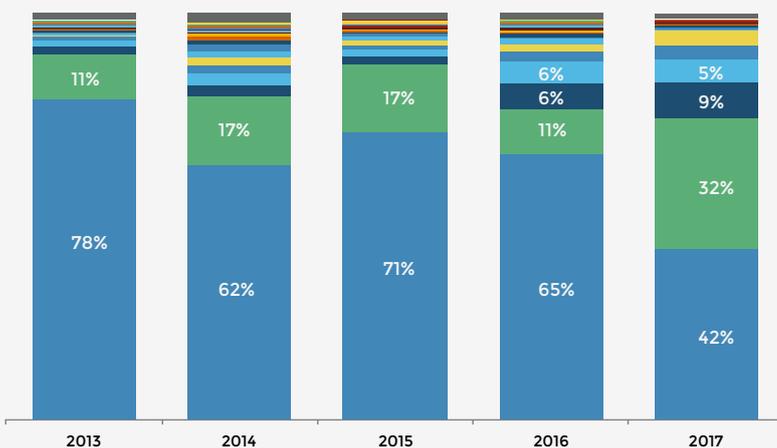
However, when we look at what this means for startups the picture is less rosy. There is considerable supplier consolidation, almost 63% of all spending each year is with the top ten suppliers with all of the Global Digital Exemplars allocating significant portions of their budget to research, as would be expected.

Figure 9: Consolidation of cohort suppliers (%), 2013-2017YTD



At some Trusts this picture was even more starkly painted: at Cambridge University Hospitals, the top 20 suppliers constitute more than 98% of spending 2014-2017, with the top tech supplier shifting from EPIC to Novosco (cloud managed services) which is expected in the current wave of migrations to cloud computing.

Figure 10: Proportion of spend with top 20 suppliers each year (%), 2013-2017



A NUMBER OF INITIATIVES HAVE BEEN SET UP TO TRY TO LEVEL THE PLAYING FIELD FOR STARTUPS

While the purpose of the GDE programme is to drive through full digitisation of secondary care, it is also to promote spending on the innovative new technologies that will improve care and cut costs by ring-fencing funding for that purpose.

While progress towards these goals will be monitored by NHS England and NHS Digital, in the meantime a number of initiatives have been set up to try to level the playing field for startups.

NHS INNOVATION ACCELERATOR³⁷

First launched in January 2015, the NHS Innovation Accelerator (NIA) is an NHS England initiative delivered in partnership with the country's 15 Academic Health Science Networks, and hosted at UCLPartners. The NIA supports exceptional individuals with a passion for learning and a commitment to share their learnings widely, scaling evidence-based innovations for greater patient benefit.

The support includes but is not limited to:

- Access to mentorship from a range of experts and high profile mentors, representing a broad skills base
- Links with Academic Health Science Networks
- Regular meeting and critical challenge from the NIA Core Team
- Peer to peer learning and support
- Quarterly events
- Specialist briefings as and when required, e.g. NHS procurement, marketing and communications, behavioural economics
- Speaking opportunities at conferences
- Access to a bursary of up to £30k



CASE STUDY

Sleepio

NIA:

Sleepio³⁸

Sleepio is a digital sleep improvement programme (available via web and mobile), clinically proven to help overcome even long-term poor sleep. Over a number of weekly sessions, users are taught proven cognitive and behavioural techniques by a virtual sleep expert to help them get their schedule, thoughts and lifestyle on track. Sleepio is now available to patients accessing several IAPT services in the North West of England. Routine data shows that Sleepio is exceeding national targets for recovery – 68% of anxiety and depression patients using Sleepio move to recovery, versus a national average across IAPT interventions of 45%. Multiple global employers are now offering Sleepio as a benefit, and the team has published evidence that it improves both sleep and productivity.

During his time at the NIA, Peter has tested multiple routes to increase access including:

- Direct marketing to the public: Sleepio has featured in multiple media outlets, and is available for purchase via Boots.com
- Sleepio is offered as an alternative to traditional therapies via Improving Access to Psychological Therapies (IAPT)
- Peter has engaged with CCGs and Community Pharmacists about potential opportunities to offer Sleepio as an alternative to sleeping pills
- As part of a new pilot, Sleepio will be offered to NHS employees in 2016/17
- One local authority is exploring the potential to include Sleepio within their population suicide prevention programme³⁹

³⁸<https://www.sleepio.com>

³⁹The AHSN Network. Sleepio digital sleep improvement programme, 2017.

³⁷<https://nhsaccelerator.com>

One of the key lessons to emerge from our survey was that even if a digital health solution is on-target with clinical and economic evidence, regulation and development, when it comes to breaking into the NHS, networking and marketing – getting into the right rooms at the right time – makes all the difference.

That is why initiatives such as MedCity, DigitalHealth.London, OneHealthTech, and, of course, the National Innovation Accelerator, are so essential.

INNOVATOR TOP TIP:

MAKE SURE YOUR MARKETING AND NETWORKING IS A PRIORITY

NATIONAL INNOVATION PAYMENT⁴⁰

The National Innovation Payment, on the other hand, is a direct market intervention. It follows on from NHS England's Innovation and Technology Tariff (ITT) and is designed to support the uptake of technology across the health system.

The ITT has already helped to procure digital innovations such as the myCOPD app across the NHS. Over 30,000 patients are benefitting from being able to self-manage their severe or very severe Chronic Obstructive Pulmonary Disease (COPD) symptoms. To extend the scope of the ITT, NHS England the Innovation and Technology Payment (ITP) will back a wider range of medical devices, digital platforms and technologies, including in primary and community care systems. The ITP is expected to go live in April 2018.⁴¹

⁴⁰NHS England. Innovation and Technology Payment 2018/19.

⁴¹Department of Health, Department of Business, Energy, Industrial Strategy. Making a Reality of the Accelerated Access Review, 2017, p. 10.

CASE STUDY



NATIONAL INNOVATION TARIFF:

MyCOPD⁴²

myCOPD is an integrated online education, self-management, symptom reporting and pulmonary rehabilitation system to help people with COPD manage their condition more effectively. It is available on any device that can connect to the internet and delivers a personalised COPD management system by asking patients a few key questions about their condition. Clinicians are provided with a dashboard, geographical population map view, education, and patient management suite to allow them to monitor and manage their patients remotely. The platform can also be used by local healthcare providers and CCGs to monitor exacerbation burdens in real-time and review potential inequalities in healthcare to plan support services effectively.

⁴²<https://mymhealth.com/mycopd>.

The aim of the Innovation and Technology Payment is to help deliver on the commitment detailed within the Five Year Forward View – creating the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically through the NHS, and to deliver examples into practice for demonstrable patient and population benefit.

The application process is now open. Successful innovation or technology themes will be identified through a competitive process and NHS England will then identify ways of supporting adoption of these across the NHS, for example through introducing a reimbursement for usage or centrally procuring items.

INNOVATION AND TECHNOLOGY PAYMENT

- The Innovation and Technology Payment (ITP) builds on the Innovation and Technology Tariff (ITT) and aims to support the NHS in adopting innovation by removing financial or procurement barriers to uptake of innovative products or technologies.
- It is a competitive process to identify innovations and technologies that will offer the greatest quality and efficiency benefits with wider adoption.
- The ITP is looking to support medical devices, digital platforms and technologies. The programme is not suitable for pharmaceutical products or research projects.
- The aim is to select a range of cost effective innovations that will have a wide-reaching impact on patient care, and maximise learning from the programme while fostering cultural change.
- The ITP is specifically focused on low cost innovations which can deliver significant patient outcomes and savings to the NHS.
- The implementation of any agreed payment mechanism or procurement will be operational from April 2018.
- Day-to-day support and reporting will be via NHS England's Innovation and Research Unit.

CREATIVE BUSINESS MODELS

It is no secret that funding in the NHS is tight and will remain so for the foreseeable future. While national policy makes it clear that technology is part of the solution to reforming NHS services, on the coal face commissioners often struggle to choose investments in risky innovations over tried and tested suppliers. As this report has already outlined, this is understandable when commissioning bodies – trusts, GP federations, CCGs – are both at financial capacity and often lack the digital and change management skills to implement those innovations seamlessly at a time when services are already running 'red hot'. This risk-reward analysis does not often come out in favour of choosing innovation, even where the evidence is clear that it will be cost-saving.

To breakthrough then, innovators not only need to lower those risks but also rise above their competition. This is no small challenge and only the very best, most needed innovations will make the grade. At the moment, however, many genuinely good innovations are failing unnecessarily. We have already discussed many initiatives the NHS and Government are putting in place to try and put this right. And there are many more incubators where investors hold the hands of innovators through this process - some of which are very good.

Respondents to our survey warned that achieving success in the NHS takes time and resilience. There is no lack of elegant looking software. So in addition to the innovation tips throughout this report, innovators can maximise their chances of success by thinking creatively about their corporate structure and business model early on – in particular by considering collaborative go-to-market strategies and forming strategic partnerships in order to shortcut access into the market. Other advice included:

- Establishing early credibility by building the strongest possible leadership team
- Building strategic partnerships to maximise your market reach
- Offering a creative business model in which the NHS is a partner in distribution and success rather than just a client

INNOVATORS CAN
MAXIMISE THEIR CHANCES
OF SUCCESS BY THINKING
CREATIVELY ABOUT THEIR
CORPORATE STRUCTURE
AND BUSINESS MODEL
EARLY ON

CASE STUDY



DOCTIFY:

Transforming perceptions of the NHS

Doctify is an example of an innovative startup that first built credibility - and a successful business model - in the private healthcare market. The company is now bringing that experience to bear in changing the public's perception of the NHS and improving the quality of care through patient feedback.

Utilising patient-satisfaction data is an effective way to improve both patient-centered care and the overall quality of care in a delivery system. Doctify has built an intuitive review app that can be accessed via a tablet to gather patient reviews on their experiences at GP clinics, hospitals and other medical centres.

Doctify reviews are securely gathered through an intuitive interface, aggregated on a custom dashboard and perhaps most importantly, exposed online to patients searching for information (either on Google or other search engines). Doctify is looking to transform the reputation of the NHS by displaying the Friends & Family Test (FFT) results in the form of star ratings. These stars and positive comments will appear high up on Google search (as opposed to FFT results at the moment).

[As a result, medical centres can more easily point to satisfied patients, transparency and pride in the system can be restored, and patients and commissioners alike can more easily compare performance and make more informed decisions.

PUBLIC SURVEY 2017

"[THERE IS A..] LACK OF CORE SPENDING ON NEW TECHNOLOGIES THAT'S COMMITTED FOR MULTIPLE YEARS - CURRENTLY ONLY OPTION IS SHORT TERM IN-YEAR BUDGETS. DUE TO THIS, WE SELL TO 3RD PARTIES TO AVOID THE BUDGET SCALING ISSUE"

"START AS SMALL AS POSSIBLE, BUILD EVIDENCE BASE AND PLAN FOR IT TO TAKE 10X AS LONG AS A NORMAL SAAS BUSINESS"

"SUCCESS IN THE NHS IS GOING TO TAKE 4 TIMES LONGER AND BE 10 TIMES MORE PAINFUL THAN YOU THINK"

"PARTNERSHIPS ARE KEY, WORKING WITH EXISTING SUPPLIERS TO FORM CONSORTIUMS OR STRATEGIC PARTNERSHIPS SAVES A LOT OF TIME, BUILDS CREDIBILITY AND ENABLES STARTUPS AND SMES TO GAIN ACCESS TO EXISTING NETWORKS OF CLIENTS"

However, before any of that innovators told us there are certain technical steps that can help lower the risks (discussed in greater detail in the next chapter):

- Co-production - bringing the NHS into the design process early so the product is ideally suited to their needs
- Ensuring smooth interoperability
- Discussing a realistic go-live plan with the client and building in tolerance, training and support

Some of these incur extra startup costs so need to be taken into account early in development.



INNOVATOR TOP TIP:

DEVELOP COLLABORATIVE DISTRIBUTION AND REVENUE MODELS

ESTABLISH CREDIBILITY WITH A STRONG LEADERSHIP TEAM AND STRATEGIC PARTNERSHIPS

CLEARLY DEFINE THE MARKET YOU OWN

“BE AWARE OF ALL THE HIDDEN COSTS AND MAKE SURE THERE IS A WATERTIGHT BUSINESS PLAN”

PUBLIC SURVEY 2017

In addition to the largely systemic challenges outlined above, there are a number of technical hurdles specific to the NHS which digital health companies must navigate if they are to succeed. The most significant of these are interoperability, data security and implementation.

“PART OF WHY PROGRESS HAS NOT BEEN AS FAST AS IT SHOULD HAVE BEEN [ON DIGITIZATION] IS THAT THE NHS HAS OSCILLATED BETWEEN TWO OPPOSITE APPROACHES TO INFORMATION TECHNOLOGY ADOPTION - NEITHER OF WHICH NOW MAKES SENSE. AT TIMES WE HAVE TRIED HIGHLY CENTRALISED NATIONAL PROCUREMENTS AND IMPLEMENTATIONS. WHEN THEY HAVE FAILED DUE TO LACK OF LOCAL ENGAGEMENT AND LACK OF SENSITIVITY TO LOCAL CIRCUMSTANCES, WE HAVE VEERED TO THE OPPOSITE EXTREME OF ‘LETTING A THOUSAND FLOWERS BLOOM’. THE RESULT HAS BEEN SYSTEMS THAT DON’T TALK TO EACH OTHER, AND A FAILURE TO HARNESS THE SHARED BENEFITS THAT COME FROM INTEROPERABLE SYSTEMS.

“IN FUTURE WE INTEND TO TAKE A DIFFERENT APPROACH. NATIONALLY WE WILL FOCUS ON THE KEY SYSTEMS THAT PROVIDE THE ‘ELECTRONIC GLUE’ WHICH ENABLES DIFFERENT PARTS OF THE HEALTH SERVICE TO WORK TOGETHER. OTHER SYSTEMS WILL BE FOR THE LOCAL NHS TO DECIDE UPON AND PROCURE, PROVIDED THEY MEET NATIONALLY SPECIFIED INTEROPERABILITY AND DATA STANDARD.”

Five Year Forward View

Despite this official policy position adopted by the Department of Health and NHS in 2014, too often it can be unclear to innovators what the NHS wants to build itself as opposed to contract third party providers to build. And sometimes the choice the NHS makes is clearly not right: when there are companies like Echo built by former Apple executives providing an NHS prescription delivery platform, why is the NHS trying to compete to build its own, especially when it is already a crowded market with strong, well established incumbents? Recent history provides plenty of other cautionary tales in this area so that it is now received wisdom that the NHS will have the greatest digital success by focussing on developing and improving its core technology and architecture so it can then turn to innovative startups for feature rich services. As a result greater clarity in this area would help stimulate solutions for NHS providers and patients, by (i) making it clear what data is available for startups to build on top; (ii) ensuring that the progress startups could then make would not be undercut by large incumbents sitting on datasets; and (iii) would create a level playing field where the relative merits of third party offerings could be easily evaluated.

Interoperability

The NHS has been attempting to address interoperability – the ability of different systems to integrate and work together – and has encouraged the introduction of open systems for many years. There is now a good level of similarity in business process, data requirements, and technical alignment in some areas but others maintain competing, even incompatible, solutions. Addressing this has been a key plank of all NHS digital policy from the FYFV to Personalised Health and Care 2020 to Wachter and beyond.

There are two national initiatives to deliver this – the infrastructure programme currently being delivered by the NIB and set out in Personalised Health and Care 2020, and the published interoperability and data standards. Key amongst these is the Interoperability Toolkit (ITK) which attempts to solve current problems by providing a number of specifications and technologies that are consistent and applicable across a wide range of domains and localities.⁴³

The ITK uses open international standards and is aligned with HL7 and ‘Integrating the Healthcare Enterprise’ (IHE). An ‘ITK conformance’ means a system supplier has proven that a product has been developed to and tested against ITK specifications.

Nevertheless, many NHS organisations still enter into long, wide ranging contracts with established incumbents who fail to meet these standards, operating out of date business models and closed systems giving them little incentive to offer a competitive, agile service.

“THERE ARE LARGE INCUMBENTS WHO HAVE CORNERED THE MARKET AND CREATED BARRIERS TO ENTRY WHO ARE VERY EMBEDDED AND REFUSE TO INTEGRATE WITH OTHER TECHNOLOGIES”

PUBLIC SURVEY 2017

It is encouraging however that new contracts will be tendered on the basis of open systems while some areas, like Plymouth, are going further than this already:

IT CAN BE
UNCLEAR TO
INNOVATORS
WHAT THE
NHS WANTS TO
BUILD ITSELF
AS OPPOSED
TO CONTRACT
THIRD PARTY
PROVIDERS TO
BUILD.

⁴³NHS Digital. The Interoperability Toolkit, 2018.

CASE STUDY



OPEN PLATFORMS:

OPeNeP Plymouth's Open E-Prescribing Platform⁴⁴

Plymouth Hospitals is the first NHS Trust in England to implement the paperless prescribing and medications administration (ePMA) system OPeNeP. An open source ePMA solution, it is built on an open standards, vendor-neutral health data repository, Think!EHR PlatformTM, and is a "first of type" implementation for the NHS which has been supported by Code4Health and NHS Digital.

OPeNeP will replace time-consuming manual prescription and medication administration processes, which can often lead to duplication and waste. The system uses open, sharable standards and supports Personalised Health and Care 2020's and Wachter's principles of interoperability.

Plymouth Hospitals NHS Trust will implement OPeNeP in partnership with Marand, the Apperta Foundation and CGI.

⁴⁴Apperta Foundation. NHS Trust To Launch Ground-Breaking ePMA, 2017.

INNOVATOR TOP TIPS:

OPERATE ON OPEN AND INTEROPERABLE SYSTEMS

For innovators this is challenging. While it is tempting to develop your system for ideal compatibility with your largest group of customers (e.g. Cerner for Acute Trusts or Systems One for primary care), one should be prepared for unexpected changes in regulation or national contracts which may alter those standards. The clear (if slow) direction of travel across the NHS is towards open, interoperable systems – even if some parts of the NHS are moving faster than others.

Data Security: Caldecott and the GDPR

No digital transformation of the NHS will be possible without improving cybersecurity across the NHS system, improving the digital skills of all parts of the NHS workforce and establishing a clear set of standards and principles for health data sharing. None of us need to think very hard to recall a health data breach, and no digital health will succeed without watertight security and adherence to NHS specific standards on data ethics and management. This is not an afterthought or more tedious bureaucracy; it is the only way patients will trust the NHS enough to allow them to share their data – and sharing health data is the only way we will see significant improvements in direct care, research and commissioning.

For this reason health entrepreneurs need to know the principles of NHS data ethics backwards. In particular, Caldecott established Ten Data Security Standards for those handling NHS health data. Following the 'Wannacry' attack, these principles could not be more relevant. These are obviously designed for NHS settings but for digital innovators who want to sell into the NHS market, understanding these are a must:

LEADERSHIP OBLIGATION 1⁴⁵

People: Ensure staff are equipped to handle information respectfully and safely, according to the Caldicott Principles.

Data Security Standard 1: All staff ensure that personal confidential data is handled, stored and transmitted securely, whether in electronic or paper form. Personal confidential data is shared for only lawful and appropriate purposes.

Data Security Standard 2: All staff understand their responsibilities under the National Data Guardian's data security standards, including their obligation to handle information responsibly and their personal accountability for deliberate or avoidable breaches.

Data Security Standard 3: All staff complete appropriate annual data security training and pass a mandatory test, provided through the redesigned Information Governance Toolkit.

LEADERSHIP OBLIGATION 2

Process: Ensure the organisation proactively prevents data security breaches and responds appropriately to incidents or near misses.

Data Security Standard 4: Personal confidential data is only accessible to staff who need it for their current role and access is removed as soon as it is no longer required. All instances of access to personal confidential data on IT systems can be attributed to individuals.

Data Security Standard 5: Processes are reviewed at least annually to identify and improve any which have caused breaches or near misses, or which force staff to use workarounds which compromise data security.

Data Security Standard 6: Cyber-attacks against services are identified and resisted and CareCERT security advice is responded to. Action is taken as soon as possible following a data breach or near miss, with a report made to senior management within 12 hours of detection. Significant cyber-attacks are to be reported to CareCERT immediately following detection.

Data Security Standard 7: A continuity plan is in place to respond to threats to data security, including significant data breaches or near misses, and it is tested once a year as a minimum, with a report to senior management.

LEADERSHIP OBLIGATION 3

Technology: Ensure technology is secure and up-to-date.

Data Security Standard 8: No unsupported operating systems, software or internet

browsers are used within the IT estate.

Data Security Standard 9: A strategy is in place for protecting IT systems from cyber threats, based on a proven cyber security framework such as Cyber Essentials. This is reviewed at least annually.

Data Security Standard 10: IT suppliers are held accountable via contracts for protecting the personal confidential data they process and for meeting the National Data Guardian's data security standards.

⁴⁵Department of Health. Your Data: Better Security, Better Choice, Better Care, 2017, p. 53.

CASE STUDY



PATIENT CONSENT:

Flynotes

Flynotes is a digital consent platform for dental and medical procedures. It provides an easy-to-use and robust consenting process, which addresses the rising litigation and poor user experience that clinicians and patients face. Flynotes intends to be the most comprehensive way to achieve informed and valid consent.

In the future, of course, the GDPR will place additional requirements on handlers of personal data. It represents a major change in the way data must be collected, processed, securely stored, and shared, and requires controllers of processors of data to be able to securely wipe personal data. Despite Brexit, Ministers have been clear they will incorporate the principles of the GDPR into UK law with the upcoming Data Protection Bill. Details of this Bill are yet to fully emerge but assuming they adhere to the GDPR principles, new measures will include:

- Non-adherence could result in revenue-based fines of up to 4% of annual worldwide turnover (Article 83 (5))
- Any person who has received material or non-material damage due to a GDPR breach will be able to claim compensation from the data controller (Article 82(1))
- Data subjects enjoy the right to an effective legal remedy against a supervisor or controller or processor (Articles 78 & 79)

Innovators who can seamlessly strengthen cybersecurity and digital identity for digital health solutions will obviously be in high demand as the full effects of the GDPR begin to be felt across the sector. Startups like Eyn are well-positioned to step-up exactly when they will be needed most:

CASE STUDY

EYN

SECURE DIGITAL IDENTITY:

Eyn

Eyn transforms smartphones into real-time biometric verification devices. By combining advanced facial anti-spoofing techniques and public key cryptography, Eyn provides anyone with a unique private biometric identifier that can be used anywhere in the digital world to securely prove someone's identity.

Frustratingly, even at this late date there remains a lack of clarity for digital health companies from the ICO and NDG over their interpretations of GDPR requirements for health companies. One company told us that on approaching the ICO to ask for advice on how to become GDPR-ready and ensure they were compliant in the eyes of the ICO, the ICO responded they had "no specific advice for health companies". With the GDPR coming into force imminently, this is clearly worrying for data-driven health companies and needs to be addressed as a matter of urgency.

INNOVATOR TOP TIPS:

**KNOW YOUR DATA PROTECTION
AND CYBERSECURITY
PROTOCOLS INSIDE OUT**

Change Management and digital skills

“THERE IS A CULTURE CHANGE THAT CLINICIANS NEED TO GO THROUGH. WE HAVE TO STOP UNNECESSARY VISITS TO PATIENTS AND ALLOW [OUR TECHNOLOGY] TO SUPPORT PATIENTS ON THEIR BEHALF”⁴⁶

It is clear from all the evidence that we have received that there remains significant variation across the NHS in terms of cultural resistance and digital skills to implementing digital transformation, and similarly with clinical engagement with digital health solutions. Some areas are both hugely supportive and capable of delivering digital transformation, some are almost virgin territory. Most are somewhere in between.

This is why the Digital Academy will be so pivotal in the success or failure of the Global Digital Exemplar programme. Without bolstering digital leadership in the NHS – as Wachter and Carter both identified – digital transformation and the systemic uptake of game changing digital health solutions simply will not happen.

The Digital Academy Commissioned by NHS England, the Academy is delivered by a partnership of Imperial College London, the University of Edinburgh and Harvard Medical School. The NHS Digital Academy is a virtual organisation set up to provide a year long world class digital health training course to Chief Clinical Information Officers, Chief Information Officers and aspiring digital leaders from clinical and non-clinical backgrounds.⁴⁷

At the same time this responsibility does not lie wholly with the NHS. Successful companies not only agree with their NHS partner to build in contingencies around the ‘go-live’ period but also offer the necessary training and ongoing support needed to help their NHS buyer make the transition to their service.



MANY OBSERVERS AND STAKEHOLDERS MISTAKENLY BELIEVED THAT IMPLEMENTING HEALTH IT WOULD BE A SIMPLE MATTER OF TECHNICAL CHANGE – A STRAIGHTFORWARD PROCESS OF FOLLOWING A RECIPE OR A CHECKLIST. IN FACT, IMPLEMENTING HEALTH IT IS ONE OF THE MOST COMPLEX ADAPTIVE CHANGES IN THE HISTORY OF HEALTHCARE, AND PERHAPS OF ANY INDUSTRY. ADAPTIVE CHANGE INVOLVES SUBSTANTIAL AND LONG-LASTING ENGAGEMENT BETWEEN THE LEADERS IMPLEMENTING THE CHANGES AND THE INDIVIDUALS ON THE FRONT LINES WHO ARE TASKED WITH MAKING THEM WORK. SUCCESSFUL IMPLEMENTATION OF HEALTH IT ACROSS THE NHS WILL REQUIRE THE SUSTAINED ENGAGEMENT OF FRONT-LINE USERS OF THE TECHNOLOGY.

Wachter⁴⁸

⁴⁶NHS Providers. New Care Models: Harnessing Technology, 2017, p. 13.

⁴⁷<http://www.imperial.ac.uk/study/pg/medicine/digital-health-leadership>.

⁴⁸Wachter. Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England: Report of the National Advisory Group on Health Information Technology in England, 2016.

INNOVATOR TOP TIP:

*BETA TEST AND BUILD IN
GO-LIVE TOLERANCE*

*ALWAYS OFFER TRAINING DURING
INSTALLATION AND ONGOING SUPPORT*

*WORK WITH STAFF AND PATIENTS TO
DEVELOP USER-CENTRIC DESIGN*

“YOU’LL LEARN FAR MORE IN TWO WEEKS OF BEING “LIVE” THAN IN TWO MONTHS OF PLANNING AND STRATEGISING”

PUBLIC SURVEY 2017

Indeed, this process starts far earlier than the go-live stage. Many respondents told us how collaborative development of user-centric design made all the difference in smoothing uptake challenges. This has been more broadly recognised in the approaches taken by the National Innovation Accelerator and the AHSNs. A recent report into success of new care models had this advice: “think through how the solutions will support existing systems, processes and ways of working. Central to this is engaging staff in the development process, understanding how they work and want to work in future, and providing ongoing support and training.”⁴⁹

“I wish I’d known more about how to find the incredible, existing NHS innovators and opinion leaders. They are the people that can enable and accelerate the change.”



⁴⁹NHS Providers. New Care Models: Harnessing Technology, p. 13.

5. LOW HANGING FRUIT



“FOCUS ON SOLVING A PROBLEM THAT A DEFINED PERSON HAS AN URGENT NEED TO RESOLVE, AND WHO ALREADY HAS A SUFFICIENTLY LARGE BUDGET SIGNED OFF TO DO SO”

With the barriers to innovation in the NHS, it is important to know the healthcare landscape and ensure all the required standards are met. But innovators should also consider focusing on areas that both the NHS nationally and locally see as a top priority if they are to overcome these budgetary and bureaucratic hurdles.

We have identified the key commissioning trends of the next two to three years – the low hanging fruit that is ready to be picked. We have then mapped out our HealthTech 27: the most promising companies we have identified against these trends. And we have drawn out some conclusions about the key characteristics of a successful venture in today's healthtech climate.

KEY TRENDS INCLUDE:

1. PROCUREMENT AND PRODUCTIVITY

The Carter Review identified up to £5bn of productivity savings through Acute Trusts reforming their procurement, prescriptions, data reporting and more if these were above 7% of their income in 2015/6. There is a drive to follow through on these recommendations through programmes run by individual Trusts, NHS Business Services, NHS Improvement, and NHS Rightcare. Examples of work underway have been given above, but there is still a long way to go and budgets to be made available to make it happen.

2. RECRUITMENT & TRAINING

The health and social care workforce make up 13% of all jobs. In 2018 a National Workforce Strategy will be published (it is being consulted on now), including everything from recruitment and retention to training.⁵⁰ In the meantime, every Government Review, from Personalised Health and Care 2020 (2014) to Wachter (2017) to the Life Sciences Sector Deal, recognized the need for greater, easier to deliver training for the NHS workforce in digital skills, change management, leadership and much more. The new Digital Academy is leading on this through the Global Digital Exemplar programme but it seems a no brainer that diffusing and maintaining this training throughout the workforce will require a digital solution.

3. PREVENTION

The rise in chronic conditions and co-morbidities is expected to cost the NHS £5bn a year in 2018 – the Five Year Forward View was clear that without a ‘radical upgrade in prevention and public health ... we would be faced with a sharply rising burden of avoidable disease.’⁵¹ This is proving to be the case. Diabetes affects 4.5 million people and its complications cost the NHS a tenth of its budget,⁵² Cardiovascular disease is the second leading cause of death affecting 7 million and costing the NHS £9bn,⁵³ while there are 850,000 people living with Dementia today, this will increase to 2 million by 2050. Numerous pilots and technologies (with budgets) are coming on line to try and gather evidence on what will work from the Healthy New Towns programme, to the Test Beds, and New Models of Care. The National Diabetes Prevention Programme is one of the key constituents of this movement and it includes a significant digital component.⁵⁴ The need for digital solutions for wellness, supported self-care for patients with chronic conditions, AI driven behaviour change models and personalized patient education solutions is only going to increase.

4. WINTER PRESSURES & SUPPORTED SELF CARE

Winter pushes many services to the limit. Solutions which relieve pressure on A&E, prevent unplanned visits to hospital and boost out of hospital care capacity, target support to highest risk patients (elderly and patients with respiratory conditions), and smooth Delayed Transfers of Care are all top priority for almost every Trust, GP and CCG. A number of pilots and programmes are already underway in this area.

5. AI IN PATHOLOGY & RADIOLOGY

The Life Sciences Sector Deal backed the implementation of AI and technology driven health solutions and singled out pathology and radiology as ripe for innovation, announcing a high profile collaboration to get the reform underway. It is clear why: not only is pathology one of the key areas of unwarranted variation in need of improved efficiency identified by the Carter Review, but radiology is under huge pressure.⁵⁵ Nearly one-in-ten UK radiologist posts (8.5%) are vacant while the number of CT and MRI scans rose by more than

⁵¹NHS. Five Year Forward View, p. 3.

⁵²Diabetes UK. Facts and Stats, 2016.

⁵³British Heart Foundation. CVD Statistics – BHF UK Factsheets, 2017.

⁵⁴NHS England. NHS Diabetes Prevention Programme.

⁵⁵Department of Health. Operational productivity and performance in English NHS acute hospitals, p. 70.

*SOCIAL CARE IS A
£15BN MARKET. 55%
OF LOCAL AUTHORITY
BUDGETS ARE SPENT
ON SOCIAL CARE*

⁵⁰Health Education England. Facing the Facts, Shaping the Future. A health and care workforce strategy for England to 2027, 2017.

30% in England 2013-16 – three times the rate of workforce growth. This meant that last year, only 3% of NHS imaging departments were able to report all their patient scans within normal working hours, and the NHS spent nearly £88 million in 2016 paying for backlogs of radiology examinations to be reported – the same amount could have paid for at least 1,028 full-time consultants.⁵⁶ A note of caution: East West Radiology Consortium who are collaborating with GE Healthcare to deliver a cloud based radiology solution have experienced serious problems since signing the ten year contract in 2015 with 68 cases of patient harm reported.⁵⁷⁵⁸ This is an area where patient safety is paramount.

6. PATIENT SAFETY

The Health Secretary, Jeremy Hunt, who has championed patient safety since his appointment, has ordered an inquiry into so-called ‘never events’ amid concern that the number of serious mistakes are not reducing. Solutions which improve patient consent, record keeping, develop effective safety checklists, and improve communication between patients – especially vulnerable patients – and their clinical teams are all going to be on the minds of commissioners.

7 MENTAL HEALTH

In her first NHS speech, the Prime Minister made driving up the quality and availability of mental healthcare her personal priority. In that same speech she announced £67m to expand digital mental health solutions, including digitally assisted therapy (or IAPT). Mental ill health will affect one in four of us, and costs the economy £100bn. It also places huge pressure on mental health services, which have faced decades of underinvestment. FOI reports suggest up to a third of trusts are failing to meet the 18 week waiting time standard.⁵⁹ It is clear that easy to access, affordable, preventative mental health support is urgently needed. Clinical evidence shows that digital CBT is as effective as face-to-face, and often more appropriate for patients who may avoid face-to-face treatment for fear of stigma or missing work. Other mental health solutions tackle insomnia, prevent anxiety and panic attacks, assist with stress management, and much more.

⁵⁶Royal College of Radiologists. Latest workforce report underlines “no end in sight” for UK’s radiologist staffing crisis, 2017.

⁵⁷<http://emrad.org>.

⁵⁸digitalhealth. East Midlands radiology consortium experiences major IT issues, 2017.

⁵⁹BBC News. Two-year wait for mental health help in areas of England, 2017.



8 SOCIAL CARE

Social care is a £15bn market. 55% of local authority budgets are spent on social care with an additional £2bn being added from the NHS via the Better Care Fund.⁶⁰ It costs three times more to look after a 75 year old and five times more to look after an 80 year old than a 30 year old. Yet today, there are half a million more people aged over 75 than there were in 2010. And there will be two million more in ten years’ time.⁶¹ 2016 saw 150,000 days of delayed discharge from hospital, mostly due to a lack of social care. Health and care systems up and down the country are looking for innovative solutions to deliver out of hospital care, integrate primary, secondary and social care, and solve their care recruitment and retention problems.

9 RESEARCH

The Life Sciences Sector Deal proposed not only a new £210m Health Advanced Research Programme ‘to enhance the power of health data and technology to diagnose life-changing diseases at the earliest possible stage’ but also proposed a radical streamlining of clinical trials processes while maintaining ethical standards. With early adopters like uMotif and Antidote already making waves in this space, it is an area ripe for digital innovation.

⁶⁰BBC News. 10 charts that show what’s gone wrong with social care, 2017.

⁶¹NHS. Next Steps Forward on the NHS Five Year Forward View, p. 9.

HEALTHTECH 27

Top three companies in each category plus honourable mentions

1. PROCUREMENT AND PRODUCTIVITY	2. RECRUITMENT & TRAINING	3. PREVENTION
<p>Echo</p> <p>is a free service that delivers medicines to the door and reminds patients when and how to take them and when a repeat prescription is needed. Echo links in with patients existing NHS GP practices and only works with fully accredited, UK-based NHS pharmacy partners. Echo reduces last minute GP/A&E appointments related to prescription administration, reduces prescription fraud, and enables better communication – for instance, by tracking and managing prescription errors and handling drug recalls seamlessly.</p>	<p>The Touch Surgery platform</p> <p>is an interactive surgical simulator for healthcare professionals; providing a realistic and detailed guide to every step of a procedure. Users can quickly learn surgery, instantly test their knowledge, and rehearse for surgery. Touch Surgery is being used all over the world and is also helping to deliver tailored training for residency programmes (hospital surgical training programmes), and medical device representatives.</p>	<p>OurPath</p> <p>is a three month digital behavioural change programme that helps people to sustainably improve their health and wellbeing, and helps reduce people’s risk of chronic diseases such as type 2 diabetes. It includes structured educational content via web and mobile, wireless scales and activity tracker delivered to the door, and a health coach and support group to keep people on track. The average activity increase over the programme is 22%, the average amount of weight lost over six weeks and sustained over six months is 5.3kg with a 50% reduction of avoidable disease.</p>
<p>Flynotes</p> <p>is a digital consent platform for dental and medical procedures. Flynotes provides an easy-to-use and robust consenting process, which addresses the rising litigation and poor user-experience that clinicians and patients face. Flynotes intends to be the most comprehensive way to achieve informed and valid consent.</p>	<p>Lantum</p> <p>is a cloud-based tool built to help NHS Providers fill empty shifts in their clinical rotas. Designed by doctors and rota managers over the past five years, this tool has been specifically developed for staffing managers working in the NHS. So far the service has been adopted by 35 GP federations resulting in over £3m savings for the NHS and 30% – 50% more shifts being filled by providers’ own clinical staff banks, reducing use of agency staff and improving continuity of care.</p>	<p>Livesmart</p> <p>is a platform that offers connected, personalised solutions for those who want to lose weight, become more active, or reduce stress or the risk of developing a chronic disease in the future. What sets Livesmart apart is its at home fingerprick blood testing to integrate biomarker analytics into full medical and lifestyle profiles which are then supplemented with longitudinal analytics of wearables data. GPs and registered dietitians write the medical reports and health coaches manage the programmes. A recent study of their data with Imperial College London found participants had a 50% increase in moderate-intensity exercise, quadrupled their amount of vigorous-intensity exercise quadrupled and seen a 50% reduction in red/processed meat eaten each week.</p>

1. PROCUREMENT AND PRODUCTIVITY	2. RECRUITMENT & TRAINING	3. PREVENTION
<p>DrDoctor</p> <p>is an online and text-based service that allows patients to confirm, cancel, and change bookings digitally. For hospitals, this means they can maximise and manage patient volume to best fit their capacity. The technology can target long waiting lists and automatically book patients into empty slots in clinics. In addition, it provides digital assessments before and after appointments, saving time for both patients and caregivers. It has reduced time to first contact by eight days and reduced DNAs by 40% cutting waiting lists by 10-15% and producing an average saving for each acute trust of £1.5 million.</p>	<p>3D Life Prints</p> <p>offer patient specific 3D printed anatomical models based medical image data are used by surgeons for a variety of purposes such as pre and intra (after sterilisation) surgical assessment and planning in preparation for complex surgeries, and for education. Surgeons have reported a decrease of planning required while in theatre, and a reduction in the time the patient is under anesthetic and overall operational expenses (c. £1200 – £2000 per hour). 3DLP has contracts with 20 NHS and private medical institutions and ten+ universities, including an embedded facility at the University of Oxford.</p>	<p>Sleepio</p> <p>is a digital sleep improvement programme (available via web and mobile), clinically proven to help overcome even long-term poor sleep. Over a number of weekly sessions, users are taught proven cognitive and behavioural techniques by a virtual sleep expert to help them get their schedule, thoughts and lifestyle on track. Sleepio is now available to patients accessing several IAPT services in the North West of England. Routine data shows that Sleepio is exceeding national targets for recovery – 68% of anxiety and depression patients using Sleepio move to recovery, versus a national average across IAPT interventions of 45%.</p>
<p>MedShr,</p> <p>developed by doctors, is a messaging platform for medical professionals to discover, discuss and share clinical cases and medical images. It now has a over 300,000 members worldwide. All members are verified doctors, healthcare professionals and medical students sharing knowledge and learning from each other in a private, professional network.</p>	<p>Meducation</p> <p>is a personalised education platform for professionals and students with over 160,000 members and 25,000 resources. Meducation goes beyond the textbooks with thousands of videos, podcasts, slideshows, mindmaps and mnemonics while the network share knowledge, discover and discuss educational content.</p>	<p>Digital Therapeutics</p> <p>have created the first digital quit smoking app: QuitGenius. The team of medical grads are developing digital behavioural change programmes, which can be as, if not more effective, at preventing and treating chronic disease than their pharmaceutical counterparts. Not simply data visualisation, it is about structured behaviour change utilising big data, evidence-based therapies and user-centred design. Quit Genius utilises evidence-based principles from gamification combined with cognitive behavioural therapy (CBT) to tackle the developed world's greatest public health challenge: smoking cessation.</p>
<p>Outcomes Based Healthcare</p> <p>has developed a population health analytics platform that measures 'true' health outcomes that matter to people and populations, in near real time. OBH supports commissioners, providers, and health and care systems to organise care around these priorities, measuring the resulting health outcomes.</p>	<p>Open Simulation</p> <p>is creating a suite of low cost simulation tools for surgeons to learn and practice surgical skills in complete safety. 'LapKit' is a low cost laparoscopic simulator that runs on a mobile.</p>	<p>Physitrak</p> <p>is a digital physiotherapy platform providing remote patient engagement with clinical exercises, outcomes analysis and Telehealth. Physitrak has over 3500+ HD videos, tracks outcomes in real-time and has secure video calls for patient support when needed.</p>

4. WINTER PRESSURES & SUPPORTED SELF CARE	5. AI IN PATHOLOGY & RADIOLOGY	6. PATIENT SAFETY
<p>myCOPD</p> <p>is an integrated online education, self-management, symptom reporting and pulmonary rehabilitation system to help people with COPD manage their condition more effectively. It is available on any device that can connect to the internet and delivers a personalised COPD management system by asking patients a few key questions about their condition. Clinicians are provided with a dashboard, geographical population map view, education and patient management suite to allow them to monitor and manage their patients remotely. The platform can also be used by local health care providers and CCGs to monitor exacerbation burdens in real-time and review potential inequalities in healthcare to plan support services effectively. Three CCGs have now implemented myCOPD covering a population of 32,000. It has demonstrated a reduction in acute admissions for severe patients saving the average CCG £370,000 per year.</p>	<p>Kheiron Medical</p> <p>is a medical imaging company that has developed a computer-aided radiology diagnostics tool powered by machine learning. This will allow radiology departments, imaging centres and hospitals to improve the efficiency, consistency and accuracy of radiology reporting and tracking. Not only will this save time and cognitive workload for doctors, it will also save costs for hospitals, and improve patient outcomes through faster response times and higher accuracy rates. Their software is currently being validated in a series of clinical trials, before full implementation in late 2018.</p>	<p>MyRecovery</p> <p>is an app specially designed for orthopaedic patients. It contains information created or approved by surgeons to optimise treatment and recovery. It acts as a guide, giving patients the right information at the right time, while tracking and monitoring progress. MyRecovery allows patients to track and monitor progress, to help them stay focused on their goals. MyRecovery is integrated with electronic health systems, registry programmes and digital wearables, and has demonstrated a 63% reduction in post-op phone calls from patients as communication through the app improves patient communication and understanding of their care pathway.</p>
<p>Pushdoctor</p> <p>is a platform to allow patients to book online GP appointments on laptop, tablet or mobile, receive medical advice, receive same-day prescriptions, referrals and fit notes. Sharing NHS medical records with the doctor is optional. GPs are available seven days a week between 0600-2300. Pushdoctor is regulated by the CQC and following a suboptimal inspection is addressing concerns.</p>	<p>Ultromics</p> <p>is a cardiovascular diagnostics company that has combined machine learning and one of the world's largest cardiac imaging datasets to automatically diagnose heart disease from echocardiograms with a 90% accuracy rate. Echocardiograms contain vast amounts of data, most of which is not currently analysed by cardiographers when making diagnoses. The technology developed by Ultromics analyses over 80,000 data points for every echocardiogram scan to provide the world's most accurate diagnostics system. Their first stand-alone echocardiography product will be available for cardiologists in 2019.</p>	<p>OWise</p> <p>is the first personalised care app for patients with breast cancer. It allows people to record in real time side effects and overall quality of life, and collates fully anonymised patient-reported data with a view to improving clinical outcomes for cancer. It is being used by over 400 patients.</p>

4. WINTER PRESSURES & SUPPORTED SELF CARE	5. AI IN PATHOLOGY & RADIOLOGY	6. PATIENT SAFETY
<p>ArtemusICS</p> <p>is a data-driven population health intelligence platform, which supports community teams to identify and keep patients out of hospital and A&E through earlier detection and intervention. It also enables commissioners to assess the needs of their local populations better. So far it has reduced hospital admissions by up to 75%, 999 calls by 65-70% and GP and nurse visits by 40-50%.</p>	<p>xRapid-Medical</p> <p>uses deep learning Artificial Intelligence, to diagnose malaria from thick or thin blood slides simply by attaching a smartphone camera to a microscope providing an accessible diagnosis of one of the world's biggest killers for health workers in the lab and in the field in less than 100 seconds.</p>	<p>Coordinate my Care (CMC)</p> <p>is a web-based IT platform enabling digital, multidisciplinary urgent care planning for end of life care. Frequently, a lack of continuity and coordination can lead to fragmented delivery of urgent care. Patients using CMC have seen 78% compliance with their stated preferred place of death, equating to 17% dying in hospitals compared to 47% nationally. CMC is on average saving the NHS £2,100 per patient equating to an annual saving throughout England of over £556m.</p>
<p>WaitLess</p> <p>is an app that reduces pressure on A&E by providing patients with real time information on local services and waiting times. 125,000 uses to date, 11% reduction in minor injuries activity in A&E, specifically during the busiest times of day, 5% reduction across the board.</p>	<p>Cirdan</p> <p>delivers turn-key solutions that allow rapid implementation of a robust and scalable digital pathology workflow into laboratories and mobile care situations. Evolve is the Mobile-Enabled Healthcare platform offered by Cirdan. Evolve solves a range of healthcare delivery challenges including an iPad-based Electronic Patient Record designed for paramedic use and a fully integrated care platform. It allows healthcare solutions to be quickly developed and deployed using sophisticated tools to integrate custom forms with workflows to meet clinician's needs.</p>	<p>ERAS+</p> <p>Each year, more than 200,000 major elective surgical procedures are performed in England and Wales, which carry a post-op pulmonary complication (PPC) risk of up to 30%. This can lead to increased length of stay and reduced life expectancy. ERAS+ works to reduce the PPC risk by better equipping patients and families in their preparation for and recovery from major surgery. It provides advice and structure for training on exercise, nutrition, lifestyle and oral healthcare information to help patients play a more active role in preventing PPC, with a focus on the six weeks prior to and the six weeks after surgery. ERAS+ successfully reduced PPC by over 50% for more than 700 patients. It has reduced post-operative hospital length of stay by three days already delivering £200,000 in annual savings.</p>
<p>Healthy.io</p> <p>is the first company to turn the smartphone into a regulatory-approved clinical device. Its first product, Dip.io, uses computer vision and user centric design to turn the smartphone into a urinalysis device. Built around existing semi-quantitative urinalysis dipsticks, Dip.io complements established clinical efforts by empowering patients to test themselves at home with no quality compromise, and securely share results with a clinician.</p>	<p>Big Picture</p> <p>is a two-year old startup that has built an end-to-end virtual diagnostic tool for eye care. Their tool has the potential to deliver a 40% reduction in the number of patients who need to attend clinics in-person and to reduce the time in clinic from three hours to 30 minutes.</p>	<p>Patients Know Best</p> <p>allows patients to hold all their medical information in a single record which they directly control. If a patient chooses, they can invite anyone they wish to their profile, construct a strong and comprehensive care network best suited to them. Patients have created over 217,000 records on PKB. There has been a 58% growth in the number of sites using the platform and PKB has created 52 new services.</p>

7 MENTAL HEALTH	8 SOCIAL CARE	9 RESEARCH
<p>leso</p> <p>is a platform connecting patients to therapists who can deliver cognitive behavioural therapy (CBT) to patients in real-time through written conversation online, using a secure virtual therapy room. Therapy is confidential and discreet, accessible from their computer, tablet or smartphone. This allows flexibility, with appointments able to be scheduled for any time of the day, including evenings and weekends. As the therapy is online and in written format, patients can review their appointment content and transcripts at any time during and after treatment. Ieso has demonstrated clinical effectiveness in 20,000+ patients treated to date. They have a proven track record of delivering better than average recovery rates with fewer missed appointments.</p>	<p>Cera</p> <p>is a technology-enabled homecare provider, delivering door-to-door healthcare services. This allows a patient to order not only the treatment and prescriptions they need, but a whole host of auxiliary services - such as food or taxi services - providing patients with 24/7 access to care while alleviating pressure on front-line nurses and care workers. This is supported by a live dashboard, allowing clients, families and health professionals to see real-time updates in care delivery. The platform also includes a functionality which assists caretakers with elderly patients by giving them advice based on past interactions.</p>	<p>uMotif</p> <p>is a fast, scalable & engaging patient-centred data capture platform for modern research which includes Symptom, medication and wearable device data capture from patients & participants, secure research team dashboard & data downloads and clinically valid eCOA / ePRO questionnaires and ethics / IRB approved e-consent. In a recent trial with 200 Parkinson's patients their symptom tracker service showed a 10% improvement in adherence and better quality clinical follow-up. If rolled out to neurology departments across the UK, the uMotif platform could save the NHS over £20m in Parkinson's costs each year. The platform is also used in 15 other clinical conditions, which could save the NHS over £1bn each year if the uMotif platform were made available to the 15 million patients with other Long Term Conditions.</p>
<p>BrainWaveBank</p> <p>allows anyone to measure and track their cognitive health at home, taking just a few minutes everyday. Daily brain health is measured using a wireless headset, while playing mobile games for a few minutes a day. They use machine learning and brain-reading technologies 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. The platform can securely gather, store and analyse data from users, building cognitive profiles of individuals and populations / demographic groups, and this data can support clinical trials and the development of new therapies and diagnostics.</p>	<p>Kraydel</p> <p>has developed TV-enabled video software that allows family members and professional care workers to provide remote care for the elderly in their own homes. In addition to built-in videochat, their service also includes medication, housekeeping and event reminders for the elderly, as well as data-driven automated alerts to caregivers if something seems wrong. This is accompanied by a user-friendly dashboard service, which allows caregivers to quickly and easily view data about those in their care at daily, weekly and monthly intervals. In 2018, they will launch an integrated intelligent wristband, which can detect falls and seizures, and monitor heart-rate and skin temperature.</p>	<p>Dementia Citizens Beta</p> <p>is a platform that connects people affected by dementia with researchers. People with dementia and their carers can go to the Dementia Citizens website and sign-up to take part. Once they've signed up they can download a Dementia Citizens app. Each app is a research study that tests a different hypothesis about dementia care. For example, the study app Playlist for Life tests the hypothesis that playing personally meaningful music improves wellbeing and quality of life for people with dementia and their carers. In this way, each study app lets people with dementia and their carers try out an activity and track its impact on their lives. With this approach Dementia Citizens aims to enable people living with dementia to take part in their own homes, in their own time; give academic researchers access to a large pool of real-world data; open up communication between people with dementia, carers and academic researchers, and generate findings about new ways of improving dementia care.</p>

7 MENTAL HEALTH**Psious**

has developed a mental health VR therapy solution, called PsiousToolsuite. The online platform enables therapists to apply hyper-virtual reality therapy to patients through a smartphone, low-cost VR goggles and a biofeedback sensor. Currently, their product provides treatment for range of mental health pathologies, including anxiety disorders, depression and extreme phobias, as well offering mindfulness and meditation exercises. The software also includes a live control function, which allows therapists to get a real-time look at what their patients are seeing, and adjust the features of a treatment to ensure maximum efficacy.

Big White Wall

is a digital mental health service supporting people with anxiety, depression, and other conditions to improve their emotional wellbeing. At the heart of Big White Wall is its community of members, who support, help each other, and share what's troubling them in a safe and anonymous environment. The project has also developed focused online courses on losing weight, stopping smoking, and cutting down alcohol, specifically for people with mental health problems. 67% report improved wellbeing from using BWW. For 48% members, Big White Wall was their first step in accessing mental health support, outside of professional intervention. One in two members share an issue for the first time on BWW.

8 SOCIAL CARE**Rally Round**

is a free and secure online tool that family and friends can use to provide joint care for their loved ones. The platform includes the ability to create private social networks for caregivers, as well as a series of online collaboration and information sharing tools, such as to-do lists and group noticeboards. This enables everyone in a network to share and distribute caregiving tasks in real-time, and volunteer to help out with care support. The platform also includes automated text and email notifications to keep everyone in the loop, and remind users within a network about upcoming or outstanding tasks.

RemindMeCare (ReMe)

is a platform to improve care of elderly and dementia patients. Patients build profiles which are then automatically mated to sourced internet content. Built with remote family participation, ReMe's digital My Story is at the heart of ReMe and learns and grows through activities undertaken with the individual. Person centred care, community engagement, care circle interaction, all improve when the profile of the individual is better defined. ReMe puts the person at the centre of the care process. As a result, it's applicable to many care sectors and therefore becomes ideal for people with multiple conditions.

9 RESEARCH**Antidote**

is accelerating the breakthroughs of new treatments by bridging the gap between medical research and the people who need them. Antidote Match \square is a clinical trial search platform that helps patients easily find studies right for them. Connect Network \square is a network of health communities who've embedded the Match search engine on their websites, accessible to millions of patients. Antidote Bridge allows researchers to add simple, but critical, details about their studies for patients who are searching for trials. Antidote Base \square introduces research sites to patients who are actively looking for clinical trials in their area. Antidote Match \square API creates a decision tree for every clinical trial search and dynamically screens patients for all, or some, studies. It can be applied to programme-level recruitment, EMR traversal, and more.

Congenica's Sapienta

is an analytics platform that enables healthcare professionals to inspect the human genome for mutations. Their cutting-edge technology is able to identify, annotate and interpret whole genome DNA sequence data and pinpoint single gene mutations that are responsible for a patient's disease, based on vast historical datasets of clinically significant variants. On average, it currently takes over five years for patients to receive a genome diagnosis; Sapienta has completely revolutionised this process, and provides the rapid identification and interpretation of diseases with much higher levels of accuracy. It is now in use in half of all Genomic Medicine Centres as part of the UK 100,000 Genome Project.

7 MENTAL HEALTH**PsyOmics**

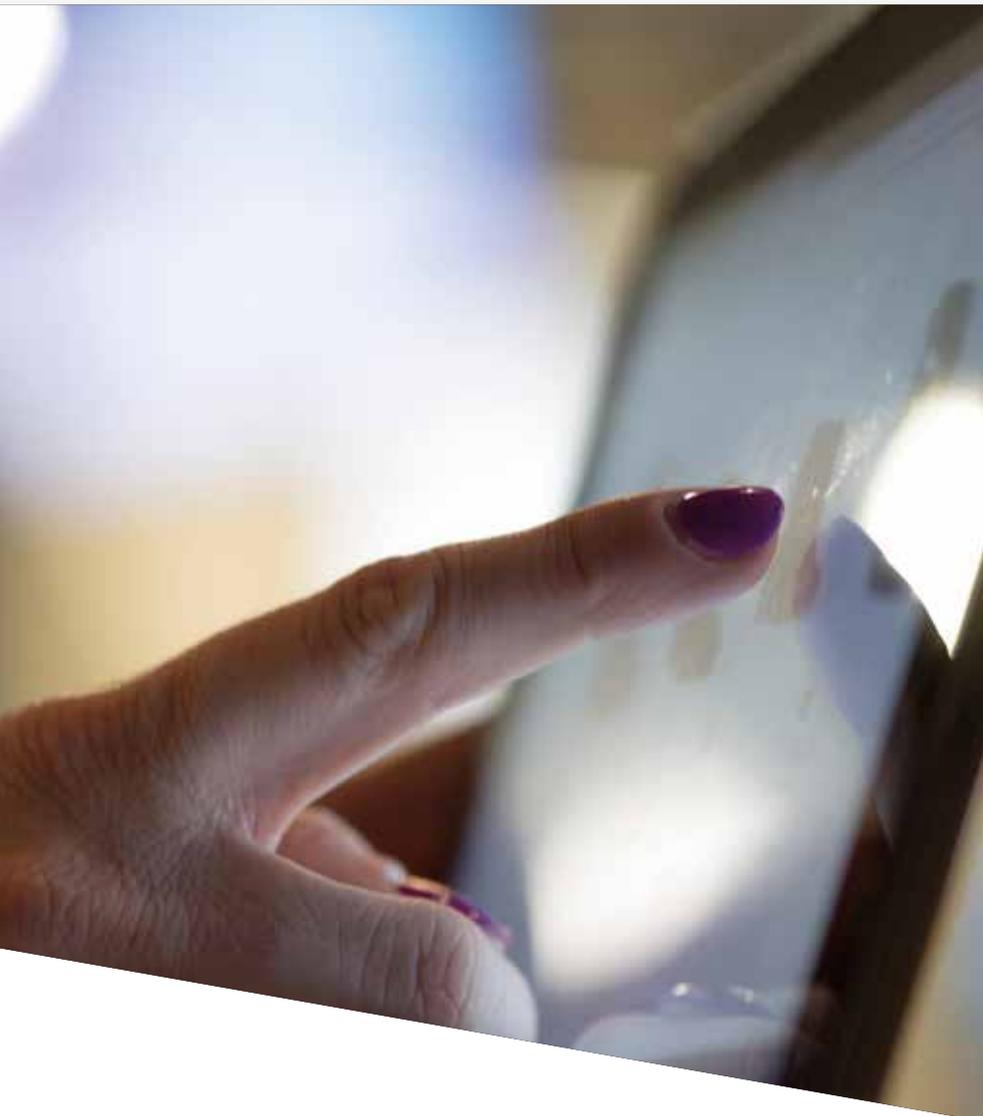
is a University of Cambridge spin-out working to improve the prevention, diagnosis and treatment of neuropsychiatric disorders. Tresilio is a digital solution that integrates data from wearables, personalised questioning, and biomarkers to enable users to monitor and improve their psychological resilience. Their underlying algorithms use this data to deliver personalised recommendations and solutions. Through an intelligent understanding of the individual's circumstances and psychology the aim is to provide the right sign-posts towards improved resilience.

8 SOCIAL CARE**everyLIFE Technologies**

created an intelligent care management platform, the PASSsystem, the only digital care management system that is NICE compliant, referenced in CQC and Care Inspectorate reports, and recommended by NHS England. Launched in 2015, it provides real-time delivery and analysis of digital care notes, drives up quality of care, and helps deliver efficiencies and service compliance. Real time provision of care record data is helping care providers meet NICE guidance, CQC, CSSIW and Care Inspectorate standards.

9 RESEARCH**Eagle Genomics**

have built a smart data platform to help life sciences professionals efficiently analyse and manage the exponentially growing volume of data generated by genomics research. The Eagle Genomics' software platform provides an easy to use intuitive approach to curating, integrating, sharing, analysing and valuing scientific data for your clinical and molecular studies, as well as in other industries where similar challenges have been addressed.



6. CONCLUSION

Digital health is as an essential tool for the NHS to deliver efficiencies, improve self-management of chronic conditions and, crucially, to enable more effective integration. But new technologies promise to do so much more – whether it is the Da Vinci Robot, which is helping surgeons to make increasingly accurate incisions when removing tumours, thereby cutting down on scar tissue; or the way in which companies like Babylon Health are offering a fully online GP-like service.

It is no coincidence that the big tech players like Microsoft, Google, Apple, IBMs and Facebook have all expanded into healthcare. They see a real opportunity. But the HealthTech 27 list shows just how impressive the UK's own healthtech ecosystem is; and as we laid out, it is projected to grow further still, on the back of a number of trends. The UK market size is £2 billion and with the right support is expected to grow to £2.9 billion by 2018.

Yet despite both sides of the market – i.e. the demand for new technologies and the supply of the right kinds products – being theoretically aligned, there is a problem. Barriers, as outlined in this report, make it hard for new, innovative companies to trial their digital products, expand these into commercial contracts and scale them across the NHS. Large incumbent IT vendors are well-positioned to block innovation, and the NHS itself often tries to compete with private companies, for example, in competing to build the best app. Digital skills vary dramatically. The difference in the appetite for change between hospitals and between GP surgeries is wide.

Rather than fighting one fight, startups risk having to fight 209 fights – one for each CCG in the country. Because of this, the NHS is not able to offer the kind of healthcare that we know is possible. The pay-out of the digital dividend is, so to speak, being postponed. Addressing the barriers to change, should be a top Department of Health and Social Care and NHS England priority.

THE NHS IS A MUCH-LOVED INSTITUTION ACROSS THE UK, BUT IT IS UNDER INTENSE AND INCREASING PRESSURE. NEW TECHNOLOGIES, OFTEN BEST PROVIDED BY INNOVATIVE STARTUPS, CAN HELP.

But startups also need to do their bit. They need to understand the NHS system and to show compliance with the requisite standards. Furthermore, startups would do well to focus, in the short-term at least, on the areas where the NHS is most open to change and new digital solutions. We have outlined the areas we believe are the best to target. We hope the list will grow, but for now we believe it represents the best estimate of where startups should focus their attention.

The NHS is a much-loved institution across the UK, but it is under intense and increasing pressure. New technologies, often best provided by innovative startups, can help. Giving them a chance to do so will be critical to the future of the NHS and the health of the nation.

APPENDIX 1

POLICY INITIATIVES

LOCAL DIGITAL AND DATA TRANSFORMATION

Global Digital Exemplars

At the NHS Innovation Expo in 2016, Jeremy Hunt personally backed Wachter's analysis and announced the first wave of 12 Acute Trusts that would lead digitisation of secondary care⁶² – the Global Digital Exemplars (GDE). Along with funding, he announced a new National Digital Academy that would provide the intensive support to develop the essential digital and leadership skills to deliver digital transformation at scale. Further Mental Health Global Digital Exemplars were also announced, as was a further group of 'Fast Follower' Trusts.⁶³

The GDEs, however, were building on work which had been going on across the country to assess and improve the digital maturity of the health and care sector.

Local Digital Roadmaps

In 2015, local commissioners, providers, and social care partners organised themselves into Local Digital Roadmap Footprints (there were originally 73 but these have subsequently been reduced to 65 to align more closely with STP areas). NHS providers within the Footprints completed Digital Maturity self-assessments. Local Digital Roadmaps were then developed and published by local areas in January 2017.⁶⁴ These strategies form the digital backbone of the 44 Sustainability and Transformation Plans which are still in development and are intended to integrate and transform health and care services in local areas so they can be sustainable and responsive to local needs.⁶⁵

The STP recognises that simply expanding the current model of delivery is not going to meet the challenges faced by the health and care system ... the innovative use of technology and a focus on being 'paperless at the point of care' is essential to underpin and realise this transformation.

THE STP RECOGNISES THAT SIMPLY EXPANDING THE CURRENT MODEL OF DELIVERY IS NOT GOING TO MEET THE CHALLENGES FACED BY THE HEALTH AND CARE SYSTEM ... THE INNOVATIVE USE OF TECHNOLOGY AND A FOCUS ON BEING 'PAPERLESS AT THE POINT OF CARE' IS ESSENTIAL TO UNDERPIN AND REALISE THIS TRANSFORMATION.

NHS South West London, Local Digital Roadmap⁶⁶

Vanguards

At the same time, 50 local health and social care systems, or 'vanguards', were selected to take the lead on the development of the new care models set out in the FYFV. There are five models of vanguard:

- **integrated primary and acute care systems:** joining up GP, hospital, community, and mental health services
- **multispecialty community providers:** moving specialist care out of hospitals and into the community
- **enhanced health in care homes:** offering older people better, joined up health, care, and rehabilitation services
- **urgent and emergency care:** new approaches to improve the coordination of services and reduce pressure on A&E departments
- **acute care collaborations:** linking local hospitals together to improve their clinical and financial viability, reducing variation in care and efficiency.

A number of these vanguards have put digital solutions at the heart of their models.

⁶²NHS England. Acute Global Digital Exemplars.

⁶³NHS England. Mental Health Global Digital Exemplars.

⁶⁴ NHS England. Local Digital Roadmaps.

⁶⁵The King's Fund. Sustainability and transformation plans (STPs) explained, 2017.

⁶⁶NHS South West London. Local Digital Roadmap, 2016, p. 4

CASE STUDY



NEW CARE MODEL:

Salford Together, An Integrated Primary and Acute Care System

Salford Together is a partnership between Salford City Council, NHS Salford Clinical Commissioning Group, Salford Royal NHS Foundation Trust, Salford Primary Care Together and Greater Manchester Mental Health NHS Foundation Trust.

Salford Together vanguard aims 'to help those who are well and healthy to stay active and busy, so they stay healthier for longer, and support those who have care needs to improve their quality of life and independence.'⁶⁷ The programme is also anticipated to deliver around £27m of recurrent savings by 2021 through reducing hospital admissions and aligning care across the health and social care system into an Integrated Care Organisation (ICO).

Crucial to this vision is an interoperable IT system so Salford Royal have selected Allscripts CareInMotion population health management platform and their Sunrise Clinical Manager, an electronic health record solution, in order to deliver Salford Together's new model of integrated care.⁶⁸

⁶⁷NHS England. Salford Together.

⁶⁸NHS Providers. New Care Models: Harnessing Technology, p. 20.

Devo-max

The final new model of care is Devo-max as it has been called. Complete devolution of health and social care – including public health – under the provisions of the Cities and Local Government Devolution Act 2016 to large local authority areas.⁶⁹

The Greater Manchester Devolution Agreement 2015, also known as 'Devo Manc', is the most far reaching. This pioneering model will see responsibility for services such as planning, housing, transport and policing handed over to a directly elected mayor by 2017. Responsibility for the £6 billion combined budget for health and social care in Greater Manchester was devolved at the start of April 2016.⁷⁰

London has signed a similar Devolution Deal to Manchester, although due to the complexity of the health landscape, change will be more gradual in the capital and will begin with pilots. Cornwall and Liverpool have also signed Devolution Deals focused on reducing pressure on A&E and prevention respectively.⁷¹

NATIONAL DIGITAL AND DATA TRANSFORMATION

At the NHS Innovation Expo 2016, Health Secretary Jeremy Hunt set some interim Personalised Health and Care targets for the NHS England, NHS Digital and the NIB to deliver by 2019:

- The expansion of the existing NHS 111 non-emergency phone line service to include a new online 'triage' service for less serious health problems
- NHS England will launch a library of NHS assessed apps
- A relaunch of the NHS Choices website to improve the range of services (including registering with a GP, seeing and booking appointments, and ordering and tracking prescriptions)
- Instant access to personal health records online
- The MyNHS website will give better data on how NHS services are performing across dementia, diabetes, learning disability, maternity, cancer, and mental health services⁷²

⁶⁹legislation.gov.uk. Cities and Local Government Devolution Act 2016.

⁷⁰GMCA. Taking Charge of Our Health and Social Care in Greater Manchester, 2015.

⁷¹BMA. Devolution and Health, 2017.

⁷²GOV.UK. New plans to expand the use of digital technology across the NHS, 2017.

APPENDIX 1

POLICY INITIATIVES

Healthy New Towns

NHS England are also working directly with ten housing developments across England to shape the health of communities, and to rethink how health and care services can be delivered. The aim of this programme is 'to develop best practice, case studies and guidance to help ensure all new housing developments embed certain principles, promoting health and wellbeing, and securing high quality health and care services.'⁷³

⁷³NHS England. Healthy New Towns.

CASE STUDY



HEALTHY NEW TOWN:

Bicester

The Healthy New Town Programme at Bicester is a place-based population-wide prevention programme, using the opportunities presented by population growth to test innovations in the built environment, new models of care, and community activation to identify the impacts they have on public health and to replicate the learning elsewhere in the county and country.

Digital Innovation is a key enabler and is led by Oxford Academic Health Science Network. This includes new digital technologies and health related applications to promote self-diagnosis, self-monitoring and self-care. This includes the joint development of A2Dominion's Shimmy tablet, a new diabetes pathway, a mental health website to support teens and offer advice to their parents.

Test Beds

Meanwhile, seven NHS and industry partnerships are piloting complex innovations in real-world settings, under the Test Beds Programme. Health and care workers, innovators, and patients are currently testing and evaluating combinations of digital health solutions and care management with the core aim of keeping patients well and independent longer. Successful test beds will then be available for national roll out.⁷⁴ The Department of Health are currently in the early stages of developing plans for a second wave of test beds. While the test bed process has been criticised as being slow and unwieldy, it remains an excellent opportunity for innovators to establish an unquestionable evidence-base and foothold into the NHS.

Life Sciences Sector Deal

The Lifescience Sector Deal was announced in December 2017. It is part of the UK Industrial Strategy and represents the Government and the life sciences industry partnership agreement to keep the UK at the forefront of medical innovation. At least 25 global organisations have pledged over £1bn 'significant investment' in the UK which the government hopes will ensure the next wave of technological advancements in medicine will happen in Britain. The main digital health announcements included:

- Accepting the recommendations of the Accelerated Access Review (see below)
- Developing a number of regional, interoperable Digital Innovation Hubs
- Set out clear and consistent national standards and approaches for data and interoperability
- Streamline legal and ethical approvals for data access for researchers via NHS Digital
- Create a sandbox for remote access to data access for anonymised data in a safe environment

The Deal also made recommendations about greater use of Artificial Intelligence (AI) and technology solutions in healthcare, stating 'relationships between healthcare

⁷⁴NHS England. Test Beds.

organisations and people will never go away. But AI will play a primary role in making those relationships stronger through new AI-driven services that help curate, advise and orchestrate lifestyle and care for people.⁷⁵

MAJOR COMPANIES INCLUDING PHILIPS, ROCHE DIAGNOSTICS AND LEICA ARE IN DISCUSSION WITH THE GOVERNMENT AND THE NHS TO DEVELOP A TRAIL-BLAZING DIGITAL PATHOLOGY PROGRAMME USING ARTIFICIAL INTELLIGENCE. A SIMILAR PROGRAMME IS BEING EXPLORED WITH THE SECTOR IN RADIOLOGY WHERE WE HAVE HAD INTEREST FROM PHILIPS, SIEMENS, GE HEALTHCARE AND TOSHIBA MEDICAL SYSTEMS

Life Sciences Sector Deal, 2017

The Accelerated Access Review

In March 2015, the Government commissioned the Accelerated Access Review (AAR) to make independent recommendations on how to improve NHS patients' access to innovative medicines and medical technologies. The AAR Final Report was published in October 2016 and NHS England was quick to commit to supporting implementation to improve alignment between the various stages: regulatory approvals, NICE HTA assessment, NHS England commissioning/reimbursement, and local innovation diffusion processes.⁷⁶

The government responded in November, accepting these recommendations and has announced new funding of up to £86 million for UK firms to develop and test new technologies in the NHS.⁷⁷ This could include innovations such as digital technologies to help patients manage their conditions from home instead of a hospital, or to develop new medicines.

The funding is split into four packages. These include:

- £39 million of funding to the Academic Health Science Networks (ASHNs),
- £35 million Digital Health Technology Catalyst for innovators – this will match-fund the development of digital technologies for use by patients and the NHS
- up to £6 million over the next 3 years to help SMEs with innovative medicines and devices get the evidence they need by testing in the real world
- £6 million Pathway Transformation Fund, which will help NHS organisations integrate new technologies into everyday practices

⁷⁶Accelerated Access. Review of innovative medicines and medical technologies, 2016.

⁷⁷Department of Health, Department of Business, Energy, Industrial Strategy: Making a Reality of the Accelerated Access Review.

⁷⁵Accenture Consulting. Digital Health Technology Vision 2017: Technology For People, 2017.

APPENDIX 2

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APPENDIX 3

METHODOLOGY

The proprietary data for the 'HealthTech 27' was constructed using an aggregation of UK procurement contracts, DueDil, inbound introductions from the London venture capital and angel community, Crunchbase, and the national AHSN and NIA network.

We controlled for the key elements of the 'Innovators Checklist' when constructing the company checklist including, leadership, clinical and economic evidence, collaborative business plan, go-live strategies, data security, etc. We also considered company size and structure.

Leadership is the least quantifiable category but can be extrapolated from the founding team's track record, the company culture, the calibre of people throughout the organisation and recruitment and retention rates.

Structure is simple. Only companies with corporate status qualified – joint ventures or subsidiaries were excluded.

Company size was also important given this report intended to interrogate access to the NHS market for innovative digital health startups. For the purposes of this report, therefore, we use the same definition as the PUBLIC Local Government Report. That is the European Definition of SME (i.e. less than 250 employees, annual turnover not exceeding €50 million, annual balance sheet not exceeding €43 million).

All the companies have either sold into the NHS or care sector or are in advanced conversations to do so.

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