FAST
HEALTHCARE
NETWORKS PLUS

November 2017

Digital Health for Remote Monitoring and Self-Management: A Roadmapping Workshop

1 Introduction

The Digital Health for Remote Monitoring and Self-Management workshop was the second workshop in a series organised by the EPSRC-funded Networks*Plus* on Fast Assessment and Treatment in Healthcare. Held in London at the Farr Institute in London on 5th September, the workshop was jointly organised by Professor Ann Blandford (Computer Science and Institute of Digital Health, UCL) and Professor Andrew Flewitt (Engineering Department, Cambridge University). Its purpose was to provide a forum to develop a Roadmap for engineering and physical science research that would optimise opportunities for using digital health in remote and self-management of disease.

This report, based on the workshop proceedings, aims to provide clarity to researchers about where it would be worthwhile directing research and where there is potential for collaboration.

The report is set out in 4 parts and covers:

- The clinical context
- Technological solutions and their applications
- Challenges and opportunities presented by these technologies
- The Engineering and Physical Sciences Roadmap for Remote Monitoring and Self-Management

2 Method

The Workshop involved participants from academia (including those with an interest in digital medicine in various areas of the health sector, data science and engineering science), health services and the commercial sector. Vital to ensuring that the workshop discussion remained grounded in patient experience, there were also two representatives from patient groups who were able to provide a perspective on what matters to patients in long-term care.

There were three sessions each taking the form of one or more presentations and followed by breakout groups aimed at populating the roadmaps. The sessions covered three main areas:

1. Experiences of developing and deploying digital health management solutions for remote monitoring and self-management
2. Challenges to uptake
3. Future technologies

Information from the individual roadmaps developed by the breakout groups was then collated and synthesised by the workshop organisers.

FAST
HEALTHCARE
NETWORKS PLUS

3 Background

Healthcare delivery is changing rapidly. This is partly in response to the increased age of the population and rises in the number of people with long-term chronic conditions such as diabetes or heart disease and partly also in response to increased demands and recognised benefits for patients in terms of autonomy and their ability to self-manage their care. The monitoring and careful long-term management of chronic diseases is essential for extended life expectancy and quality of life. Age related decline is associated with increased frailty, increased risk of developing chronic illnesses, and increased likelihood of rehabilitation needs following surgery or a stroke. All these factors complicate the way individuals can be treated and monitored.

Current NHS patterns of provision are now thought to be unsustainable and policy makers call for radical transformation. Such transformation is likely to include the use of digital technologies acting as enabling technologies that can lead to changes in care pathways, the transfer of care from hospital settings to the community and even to patients' homes. More care will be provided outside the traditional healthcare settings but these 'digitally enabled' changes in patient pathways will require considerable re-engineering as well as re-training of healthcare staff. It will also increasingly blur the boundaries between wellness, prevention and care management.

4 Clinical Scenario

The clinical scenario explored in this workshop included: the management of chronic disease, with particular examples being taken from diabetes care and care of the elderly, who may have multiple co-morbidities; and the management of acute medicine episodes, with the example given of the diagnosis and management of a sexually transmitted infection, including care for contacts.

4.1 Chronic disease and the ageing population

Diabetes is an NHS priority, with over 4 million people affected in the UK, 90% of them with type 2 diabetes. Individuals are at high risk of complications such as cardiovascular disease (CVD), renal failure and blindness, and many also have comorbidities. The aims of management of diabetes therefore include reducing the impact of the illness on the patient as well as the burden on the healthcare system.

Self-management has been shown to improve outcomes. In diabetes much of this has focused on self-monitoring of blood glucose and since the 1970s individuals have monitored their blood glucose (BG) levels at home with colour changing strips. Similarly, people with hypertension can use home blood pressure monitors and even purchase their own. The employment of digital technology within these self-monitoring systems adds an extra dimension whereby information can be collected and sent directly to healthcare providers via digital means, potentially improving healthcare provision while reducing the need for face to face appointments.

The management of chronic conditions is not solely about dealing with the disease manifestations at a physiological level but also about learning to live with a potentially life shortening illness, addressing the 'totality of the experience of having a long-term condition'. This means coming to terms with strong emotions and learning to continue to live your life in a way that it is enjoyable without detriment to a treatment plan. Currently, the management of chronic disease at a physical level is delivered separately to psychological and emotional management. Providing a combination of the two approaches via digital healthcare may be a way forward.

The workshop heard an example of a digital self-management support programme to help patient self-management of diabetes. This responded to the education need, recognised by the National Institute for Health and Care Excellence (NICE), but not widely taken up in its current face-to-face form. Reasons for poor uptake include the necessity for patients to take time off work, or unsuitability for those from certain population groups (e.g. particular ethnic minorities or people with other disabilities or caring responsibilities.) The researchers used a commercial company to develop HeLP-Diabetes, an interactive web-based education programme, suitable for those with a reading age of 12 years and accredited by QISMET[1]. Development of the tool was extremely participatory to ensure that it fully met users' requirements in both the physical and social contexts. Implementation in existing services was then investigated via a randomised controlled trial (RCT) which compared use of the web-based programme with best current practice. Even though the population recruited was very well controlled at the baseline, to their surprise researchers noted that HeLP-Diabetes did enable patients to improve levels of HbA1C (a measure of how well the blood glucose is controlled). Health economic analysis confirmed that the incremental cost effectiveness ratio (ICER) fell within the boundaries of an intervention that NICE would approve (less than £30K/QALY[2]). It was further shown that the intervention caused an improvement in health outcomes while reducing total costs to the NHS.

Researchers in HeLP-Diabetes were also anxious to understand which populations the web-based education had reached. Within the participating inner London CCGs, there were 1000 users, registering at a rate of around 130 per month and aged between 18 and 92 years. Less than fifty per cent were white British, and more than half (58%) were male, which was claimed as 'astonishing' given that characteristically men are much less interested in self-management. Thirty nine percent had left school at the minimum leaving age and one third had very basic previous computer experience. There was thus no evidence that the 'digital divide' had been a problem in using HeLP-Diabetes to support self-management.

Even though this tool was shown to be cost-effective, there remained a problem of how to roll it out within the NHS. The main barrier was getting GPs and primary care nurses on board, which is something that is hard to achieve given the current pressures within the NHS.

It was also acknowledged that patients should be able to choose between different modes of education; HeLP-diabetes may not suit all and people may also have needs that change throughout the course of their illness.

[1] **QISMET** Quality Institute for Self-Management Education and Training http://www.qismet.org.uk

[2] **QALY** Quality-adjusted life year

Long term management of chronic disease can also be assisted by brief interventions delivered via telehealth – specifically, messaging delivered to people's mobile phones. Important long term conditions studied included high blood pressure, where there is a need for patients to adhere to regular medication regimes. Engaging via telemedicine can improve control of blood pressure and uptake of medicines.

A further example was provided by chronic obstructive pulmonary disease (COPD), a serious long-term respiratory condition that affects about 3 million people in the UK and often involves periods of exacerbation with unplanned and costly hospital admissions and readmissions. It is best managed by a coordinated management package that includes education, support for self-management, behavioural support such as smoking cessation, medication adherence including effective inhaler use and screening for depression and anxiety. A system was devised that supports these various aspects of care through personalised care plans that include monitoring of oxygen saturation measurement. Although there was no evidence that there was an effect on COPD-specific health status in comparison with usual care, there was an overall benefit in generic health status, an improvement in depression score, reduced hospital admission and general practice visits.

Other aspects of disease management where there is a clinical need include monitoring of recovery (or potential deterioration) after medical interventions (e.g. hip replacement) – or monitoring decline in function that might provide early diagnosis of a serious condition such as dementia.

4.2 Acute disease

The diagnosis and management of sexually transmitted infection (STI) provided an example of the use of digital health in a particular area of medicine where the burden of disease is increasing and patients can be hard to reach and manage. There are about half a million people diagnosed with an STI in the UK yet the NHS funding for sexual healthcare has decreased by about 30% in areas of high burden such as London. The particular condition, Chlamydia trachomatis is the most commonly reported bacterial sexually transmitted infection in the UK, with approximately 220,000 cases reported in England each year. It mainly affects people in the 16-24 year age group, a group who are said to 'use digital technology avidly'. Untreated and repeat infections can result in serious and costly problems such as infertility, which have a major impact on the individual and the NHS. The National Chlamydia Screening Programme (NCSP) offers opportunistic screening to young sexually active people and almost half of all patients are treated in genitourinary medicine (GUM) or sexual health services which offer open access specialist care. The first-line treatment recommended is a single dose of oral azithromycin.

Uncomplicated infection was therefore thought to be an appropriate disease and care pathway for an eHealth intervention. This was enabled by a number of factors: access to sexual healthcare services in UK has been partially digitised for a long time; the tests used to diagnose certain STIs such as chlamydia have become less invasive (e.g. urine samples), and so can be carried out at home and with less expertise; patients have been able to order self-testing kits on line (through the NCSP, where it is free for young people up to the age of 25) for some while; the demographic most likely to require STI treatment are those between 18 and 24, and this age group tend to be the most digitally competent. Online services were also driven by commissioners, although there was limited evidence and expert consultation, which had indicated that this would be effective. However, the current system (preceding the eHealth sexual health intervention) still depends on individuals with a positive result visiting a clinic to be given a prescription for antibiotics.

4.3 The clinical roadmap: the need for health systems to develop means of patient education and engagement, remote monitoring and tailoring of care and diagnosis and management of acute episodes of disease

Digital technologies are becoming increasingly valuable for long term and short term healthcare needs. Along with the potential decrease in burden for the NHS there are many positive outcomes for both patients and healthcare practitioners (HCP) by remotely producing and accessing healthcare data. It is hoped that digital technologies may either enhance the systems currently in place for monitoring and delivering healthcare or provide new healthcare pathways that do not yet exist for certain conditions.

The benefits of using remote monitoring via digital technologies are described below.

Benefits to patient:

- **Patient empowerment** – taking control of their own care can lead to better engagement with treatment plans and more awareness of how behavioural changes affect disease manifestations.
- **Convenience** – can fit in easily with everyday life as it can be done anywhere at any time reducing the stress and logistical hassle of visiting the clinic.
- **Reduced anxiety** – the knowledge that a healthcare professional will be receiving results should reduce anxiety about changes observed.
- **Better outcomes and quality of life** – those who self-monitor chronic conditions are more likely to have better health outcomes.
- **Preventive benefits** – early warning signs of disease or complications may lead to earlier treatment which may be less invasive and lead to better health outcomes.

Benefit to healthcare providers:

- **More informed clinical decisions** – the more data available to the HCP the more holistic view of an individual they will have. This includes having more data on disease progression, and more time points, with monitoring at home in real-life rather than just in the clinic.

- **Improved clinical outcomes** – fewer complications
- **Reduction in unnecessary appointments** – reduce the need/frequency of visits to see a HCP and the likelihood of emergency admissions.
- **Greater efficiency** – more patients can be managed without compromising quality of care; by partially or completely negating the need for face to face interaction, digital technology will allow more patients to receive care simultaneously.
- **Preventive benefits** – early detection leading to better outcomes and less costly interventions.

Summary of the clinical roadmap

The clinical developments required:

Technologies that will reduce the cost burden whilst maintaining quality and continuity of care should be highly welcomed. However, it is not as easy to initiate uptake into the NHS as it is to develop a technology that is scientifically sound, efficacious and cost effective. Some of the clinical developments required for successful implementation of remote monitoring platforms include:

Engagement with digital health – Clinical commissioning groups, NHS trusts, GP surgeries and HCPs all need to be on board for these technologies to replace or work in combination with existing healthcare pathways. Patients are more likely to respond well to the prospect of a digital health intervention if those who are prescribing or recommending it are enthusiastic about it.

Education and training – HCPs need to be informed about what digital health is and how it can be used. They also need to be trained in interpreting the data provided by remote monitoring systems so they can make informed clinical decisions.

Collaboration with commercial providers – Working with those who produce digital platforms to enable delivery of digital healthcare.

FAST
HEALTHCARE
NETWORKS PLUS

		Years 0–2	Years 3–5	Years 6–8	Years 8–12	Years 12+
CLINICAL OPPORTUNITIES	General Practitioners	Data capture in clinic/pharmacy -during booking -maximising utility -epidemiology Easy access for patients to recordsand test results and launch through to treatment resources Rapid assessment of clinical need	Improved links between existing automated systems Automated scheduling of appointments to match clinician/patient availability Better use of online data collection -reporting of sexual partners -visibility of data GPs can access data on a wide range of patients	Improves consistency of diagnosis Machine learning/AI taking on some of the role of a GP	Reducing disease burden	
	Specialist Clinicians	Testing when making a booking (e.g. for dementia monitoring)	Data collection following treatment for efficacy assessment Virtual reality consultations	Decision assisted tools based on longitudinal analytics Predictive analytics -better alerts Reducing pressure on consultants by assisted early diagnosis Automation to reduce offline administrative burdem	Testing of arrays of biomarkers at consultation Accelerate new treatment development with more data access	
	Professional Carers	Remote monitoring of frail/elderly without infringing autonomy/provacy	Integrated data for health and social care across users Access to care on demand			
	Lay Carers	Decision support -carers -patients Shortage of carers Access to care on demand	Framework for interaction between stakeholders Reducing the number of duplicate tests Upskilling	Dementia support More access points to treatment than just GP ot A&E	Improve 111 by adding data/patient record access -better risk assessment	
	Patients	Improved access to knowledge and trusted medical resources for patients – 24/7 NHS Mental health -mood tracking -estimation of risk	Better information for patient to accompany access to records Availability of online treatment pathways Personalised prescriptions based on response data	Minimising behaviour change at diagnosis	Improved understanding of patient behaviour and need	
	Lifestyle	Trend analysis -identify needs -focus resource	Personalised wellbeing	Improves equality for patients through continuous monitoring	Use of general population for digital data capture through NHS	Validation of monitoring

5 Technology Background

There are various developments in implementing digital solutions via applications targeting real life problems to produce better results from care pathways. Digital health solutions aim to either modify existing care pathways by the addition of a digital step during care via wearables, video, smartphones, the internet or a combination of devices, or provide an alternative route of care that may not currently exist.

Many of the digital technologies for monitoring and self-management will focus on:

- The development of web-based platforms/tools for education and holistic support for self-management
- The ability for patients to apply diagnostic tests remotely
- The ability for test results to be digitally transmitted to clinicians for decisions and recommendations on management or for self-sampling outcomes to lead to a digitally-enabled care pathway
- The ability to monitor disease remotely based on near patient testing (e.g. blood glucose), the measurement of physiological parameters (e.g. oxygen saturation or blood pressure), etc.
- The ability to monitor activity and behaviours and identify those at risk or diagnose disease early
- The ability for clinicians and those caring for patients to provide advice, support and prescriptions digitally

Some of the technologies and specific applications discussed during the workshop are presented in Table 1.

Table 1 Example technology solutions to remote monitoring.

Type of technology	Monitoring type	Application	What it does	Current progress
Telehealth	Online	HeLP-diabetes for the management of type II diabetes	Online education about living with T2D and personal monitoring of disease management.	In use in 5 inner London CCGs (>1000 users) gaining ~130 patients/ month
		e- Sexual health clinic for STI testing, diagnosis and automated prescriptions.	Deliver online, automated consultations that lead to prescription.	In the process of compiling a proposal for a definitive, cost-effective RCT.
		EDGE for improving quality of life in patients with moderate to very severe COPD.	Internet-linked tablet computer-based intervention	RCT trial results found that generic health status was improved along with a reduction in visits to HCPs.
	Mobile phone with a portable monitoring device	Real-time telemedicine support on glycaemic control for type 1 diabetes	Bluetooth enabled BG monitor that automatically sends results to a mobile phone and then via 3G to a diabetes specialist nurse who can respond with clinical advice and structured counselling.	RCT found that BG dropped below target for those with the intervention
		GDm-health for management of gestational diabetes		Acceptability and user satisfaction trial resulted in half the number of visits to a HCP.
		StAR treatment adherence support programme for people with high BP	Automated mobile-phone text messaging	Trial found that text messages increased prescription pick up and decreased BP after 12 months.
Data fusion of complementary sensors (SPHERE)	Wrist band, environmental sensors and video monitoring	HemiSPHERE for hip and knee operation recovery	Monitoring of behavioural patterns to assess recovery/, predict disease or diagnose disease early	Not yet ready for NHS trials – still in early stages of analysing behaviour manifestations that predict disease.
		CUBOiD for behavioural biomarkers of cognitive impairment		
Telehealth and telecare	Passive infrared sensor monitoring Sensor which detects patient/individual movement	Monitors time spent in bed in patients with respiratory disease to predict deterioration in conditions	Spending less time in bed was correlated with deterioration in condition	Is there a change in behaviour that might prompt a telephone conversation of visit?

The development of these technologies is not straightforward and presenters described some of the considerations during development:

- Whether there was already a commercial solution that could be used or adapted. Implementation may be easiest where there are readily available devices for monitoring and processing.
- The need for extensive involvement of patients and users in developing and fine tuning the application. For example, in the development of the sexual health application there was extensive involvement of young people, patients of both sexes and from different backgrounds. In development of the COPD app there was a need to clarify the questions on symptoms, to change the order of questions about symptoms and to alter the frequency of mood screening.
- It was important that the technology was simple to use and that, where possible, there was personalised feedback.
- The need to involve various groups of health professionals involved in the pathway of care (e.g. clinic nurses)
- Developments must be user centred

- Use of routine data in delivery of interventions needs to be ring-fenced from use for research purposes.
- The need for integrated platforms that include the sensors and the analytics and have functional and protocol interoperability – there needs to be conformity with IEEE standards including ISO/IEEE 11073 for health informatics and medical/health device communication[3]
- Use of data should be maximised for a range of different purposes
- Systems should be designed to solve problems and integrate with clinical pathways
- Involvement of regulators and scrutiny of legal and regulatory (e.g. GMC, MHRA) requirements for online care
- Important to integrate information with the electronic health record for prescribing records at a national level to enhance effectiveness
- Projects need to address a clinical problem and must be based on actual physical and physiological concepts: 'quite a lot of technology simply could not work'

[3] **ISO/IEEE 11073** Health informatics - Medical / health device communication standards enable communication between medical, health care and wellness devices and with external computer systems. They provide automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data. Medical / health device communication standards enable communication between medical, health care and wellness devices and with external computer systems. They provide automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data. See http://www.11073.org/ and the work of Brunel University in this area.

Further information on particular technology developments:

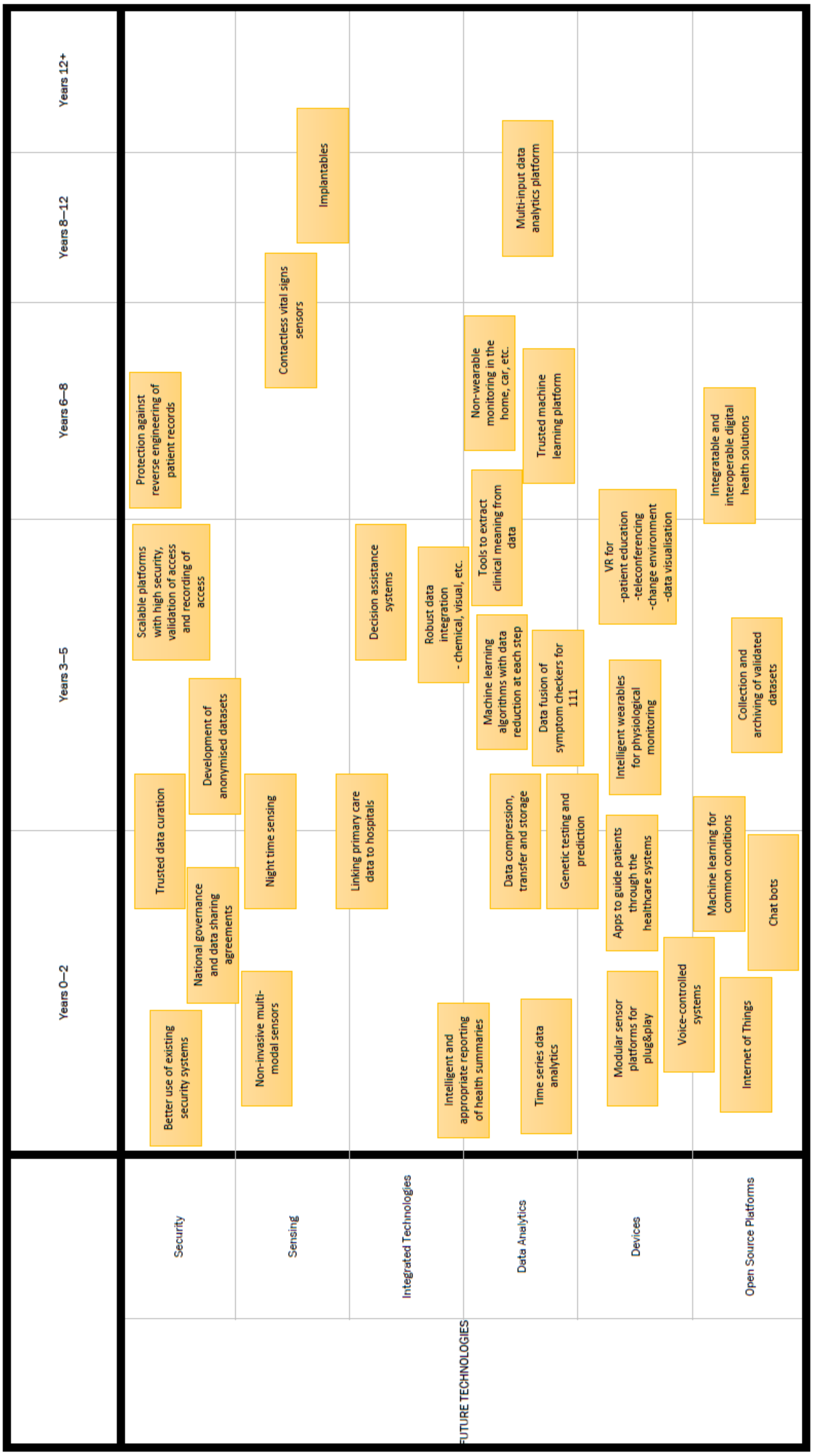
SPHERE[4] (sensor platform for healthcare in a residential environment) is an EPSRC-funded project that is different from telehealth technologies as it is investigating a way to monitor the behavioural characteristics a person is presenting with that may enable the detection and management of various health conditions. We have means to access the genetic, biological and anatomical factors that influence health but we do not have an equivalent for human behaviour. Now in 2017 there are a range of sensors, largely commercially available, that have the potential to deliver valuable insights into behaviour (e.g. fitbits, smartphones, motion sensors). SPHERE aims to harness this information via data fusion and pattern recognition in the home environment. This means that data can be gathered outside the hospital about daily life. The applications for this type of technology are broad but two that are currently being investigated are detailed in table 1.

EDGE for COPD[5] (chronic obstructive pulmonary disease): The mHealth system incorporates support for all aspects of COPD care through personalised treatment plans, supplementing written and verbally presented material with videos and access to medical records, including medication records, to increase the impact of the measures to improve care already in place. In addition, the system includes a monitoring module which incorporates oxygen saturation measurement and a symptom diary with trend analysis to allow both patients and clinicians to identify deterioration

[4] http://www.irc-sphere.ac.uk/

[5] https://www.phc.ox.ac.uk/research/diabetes/studies/edge-copd-study

Summary of the technology roadmap

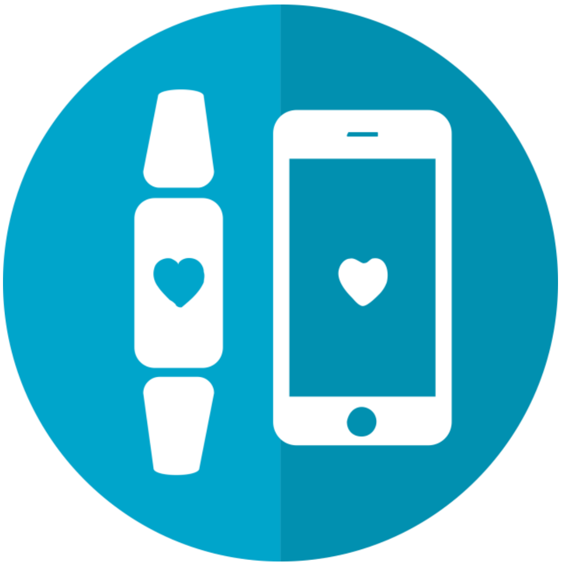


6 Opportunities and Barriers

6.1 Opportunities

6.1.1 Harnessing existing data

Use of medical records can inform research areas to improve management of disease. For example, for diabetes monitoring, Farmer et al. (2016)[6] extracted patient data from 2004-2014 regarding medication adherence and HbA1C levels. For commonly used glucose-lowering therapies they found that reduced medication adherence was associated with smaller HbA1c reductions compared with those taking treatment as recommended. They commented that interventions can be designed with the primary outcome being increased patient compliance.



6.1.2 Greater understanding of real behaviours

Remote patient monitoring enables us to understand real behaviour (particularly surrounding the elderly outside the hospital environment) rather than speculate. For example, the bed occupancy of a patient with chronic obstructive airways disease decreased the more ill they became, a result which seems counter-intuitive.

6.1.3 Automated & artificial intelligence applications

Automated prescriptions – A small piece of funded research was described within the iSense[7] consortium which is looking at automated prescribing and how automated clinical decision algorithms can be used to prescribe for people without face-to face contact, whilst still satisfying medical prescribing guidance. Ultimately, using artificial intelligence (AI) for automated prescribing would save time and money and could be applied to a variety of clinical conditions.

[6] doi: 10.1111/dme.12987

[7] https://www.ucl.ac.uk/infection-sense

6.1.4 Patient group 'champions'

Opportunities for increased patient involvement would ensure that technologies engage with the needs of users. Involving 'patient champions' in the development of a digital health tool is vital both in developing technologies that are effective and in promoting eventual uptake.

6.1.5 Life sciences industrial strategy – digital health implications

The recently published 'Life Sciences Industrial Strategy'[8] provides a number of recommendations pertaining to digital health development, and presents an opportunity to develop the Life Sciences sector in the UK. Among the recommendations put forward in the Strategy are proposals for ePrescription services to be made available across all UK hospitals, the development of several new Digital Innovation Hubs to generate useful datasets that can be accessed by researchers, and the formation of a working group to evaluate the use of digital health care data and health systems.

Amongst the findings of the Strategy is the potential for digitisation and AI to transform pathology and imaging. The report asserts that it should be the ambition of the UK to develop and test integrated AI systems that provide real time data, as 'no other system has the scale to provide such important data that, when captured, could produce a globally dominant commercial offering in this diagnostic space.'

6.1.6 Combination of monitoring technologies will provide more holistic assessments

Collecting and analysing a variety of life-style-related data via digital health devices can help clinicians practice a more holistic assessment of their patient, making it possible to pinpoint the combination of factors that will lead to overall improved health. For example, people with diabetes need not only their medication monitored but also their diet, exercise, nutrition and stress levels in order to understand the full effect of the disease and how best to address its impact on the individual.

6.1.7 Citizen generated data

There is an opportunity to utilise the range of sensors and technologies already available (e.g. in people's homes) to capture data that could be useful in the prevention and treatment of disease. Eventually, it is anticipated that the major players in capturing personal data will be the commercial sector – e.g. Google, Amazon and Samsung. They will collect data from individual citizens' appliances and will have the capacity to undertake the analysis. For example, information from a range of smart technologies that

---

8 https://www.gov.uk/government/publications/life-sciences-industrial-strategy

interact through the Internet of Things could anticipate conditions such as diabetes before they occur, through identifying small behaviour changes such as increased thirst and consumption of processed foods, fatigue and a decrease in physical activity.

6.2 Barriers

6.2.1 Patient acceptance

Digital divide

The elderly are the fastest growing population group and an ageing population inevitably results in increased prevalence of chronic conditions. However, the influx in internet based health interventions and monitoring technologies could result in a huge proportion of the population finding themselves on the wrong side of the 'digital divide', unable to benefit from new health care solutions. Although the digital divide is often associated with the elderly, the problem cuts much more widely across the population, for example including those with poor health literacy regardless of age. Some digital interventions, such as HeLP-diabetes, have been able to overcome this divide to an extent, with users as old as 92 accessing this particular platform. In the majority of cases however, it has been shown that elderly patients do not use internet based or mobile technologies and as a result there is a need to design systems that are tailored to the frail, elderly patient. This problem is complicated by the rise of 'the complex patient'; one who presents with co-morbidities and often both physiological and psychological problems. In these instances, a simplistic system using a single sensor is insufficient. The challenge is how to develop an approach that accounts for those in the population that wish to minimise their active interaction with health technology, whilst still effectively monitoring multiple diseases unobtrusively.

Intrusive nature of monitoring

The intrusive nature of health monitoring often poses another barrier. If designed poorly, wearables can act as a constant reminder to the patient of their condition. Instead wearables or any forms of monitoring should be non-intrusive, patients must be comfortable wearing them. For the most part, they must be 'subtle', although it is acknowledged that there are occasional, relatively rare 'counter examples' where people want to draw attention to their condition.

Facilitating patients' preferences throughout the course of their illness

Not everyone will welcome widespread use of digital health technologies for self-management. Whilst technology presents a fast, convenient form of healthcare, sometimes people prefer face to face contact with a clinician, particularly when anxious about test results and anticipating a diagnosis. In order to overcome this barrier, patients must be able to choose between face to face or online interactions according to their health needs at a particular point in their illness.

Changes in public perception of healthcare

A challenge encountered during the course of the e-sexual health clinical trial was how best to manage patients' changing expectations. People felt that once they had started on the pathway they had a right to their treatment, and this perceived right went over and above any explanation health professionals could give about the medical advisability and safety of providing treatment in this way. The concern is that patients could come to treat healthcare services as they would other commercial transactions.

Potential for overreliance on digital technology

Discussion highlighted concerns regarding the potential that we may become over reliant on digital technologies. How do we balance quality of life with the need to constantly be connected? Should we lose signal or our digital device break, what will the impact of this be when we rely on regular monitoring and our data being automatically transmitted? Will this lead to increased health anxiety and reluctance to travel to places where we may not be able to use/charge our device?

Privacy and monitoring

For sensors and monitors in the home

there were concerns about violation of privacy and problems of anonymity – for example identification of individuals who may not even be the subject of the monitoring (e.g. family members). (It has been found that silhouettes provided an acceptable but still informative solution). Care homes were also very averse to having camera

6.2.2 Data (data sharing and analysis)

Digital health technologies will produce huge amounts of data from a variety of sources that will need to be consolidated, secured and pruned at every level in order to manage them. Merging datasets from medical records and digital health technologies could deliver healthcare benefits; however, there are problems surrounding safeguarding data, and storing it in a manner that is scalable and adaptable. There needs to be a huge amount of capacity for data storage. It will be necessary to create secure portals into common data sources and to ensure that individuals can make informed choices about how their data is used and who has access to it.

Not only do we need to be able to collect and store large datasets, but it will be necessary to analyse them effectively to ensure that data can be turned into actionable information. For example – for sensors monitoring activity in the home, research will be needed to establish when particular behaviour changes are predicting a clinical event for which an intervention would be actionable. It should be noted that it is often not so much the amount of data generated that is the issue in analysis, but the lack of good algorithms. This will require the generation of good corroborating data to allow meaningful clinical conclusions to be drawn.

Beyond research programmes, for routine use, once large numbers of individuals are involved, it will be necessary to automate the analytics in order to keep costs down. However this is much more complex than might initially be thought. For example, automation of diagnosis for a urinary tract infection might not recognise an underlying high blood sugar; where a patient is attending for automated monitoring the system may not recognise underlying home social problems that might affect disease progress or self-management. There will also be a problem if automation (for example of radiology reporting) were to lead to job losses.

6.2.3 Barriers to developing a digital health tool

The following factors were identified as barriers to developing a digital health tool:

- Identifying a genuine innovation that fits with the health and care environment. Ideas must be unique, rather than being investigated by half a dozen others, and ideally should be supported by your Academic Health Science Network (AHSN). These are bodies that connect NHS and academic organisations, local authorities, the third sector and industry, and whose role is to drive the adoption of innovative technologies.
- The need to have an identifiable customer: one with the budget to purchase the device/tool and who is prepared to spend their money on the innovation.
- Raising funds: an increasing number of people are interested in funding digital health start-ups. However, clarity is required about whether the innovation is a medical device. It is also necessary to explain clearly who the customer is and how the patient will benefit, and to include a sensible risk description.
- Complying with all regulation: medical devices must comply with the EU Medical Devices Directive. This Directive has recently been revised through a new EU Medical Devices Regulation which will be directly enforceable on Member States once it becomes operable in 2020. This extends the scope of the definition of medical device under article 2(1), to include devices for the medical purposes of 'prediction' and 'prognosis'. This will regulate digital health technologies that predict conditions such as diabetes or heart failure, where previously these would not have been classed as medical devices. The classification rules have also been modified under the Regulation. An emphasis on risk assessment could see devices up-classed. Higher-class devices are subject to greater scrutiny and stricter requirements as they are associated with a greater degree of danger. Additionally, alongside these considerations is the need to prove that a medical device has been quality manufactured at minimum ISO 13485 & 14971. (Note: Whilst it will become important in the future, it is still unclear how artificial intelligence and machine learning will be regulated, as it changes the way it treats people automatically based on its own learning.)
- The EU General Data Protection Regulation comes into force on 25 May 2018 and will be directly enforceable on Member States. The Regulation establishes data processing principles including the requirement for data minimisation and protection

by design. The legal basis for data processing is explicit consent – this consent must now be “freely given, specific, informed and unambiguous”. The Regulation also requires greater transparency regarding potential uses of data, such as requiring explicit consent if data is to be made available to third parties (although exceptions apply for research). Additionally, it establishes increased fines – up to 4% of annual worldwide turnover for data processing breaches.

- The UK Data Protection Bill (2017) is likely to impact on some aspects of data processing, although its full impact will not be known until it has completed its legislative process.

6.2.4 Barriers to deploying a digital health tool

Selling

Difficulty selling to the NHS was identified by several speakers as a barrier to deploying digital health tools, especially for the first time. Evidence of effectiveness is usually required and tools need to recognise and satisfy both professional users and end users.

Disruptive nature of the innovation

Unlike the introduction of a new medicine, which frequently takes place in a relatively unchanged pathway, digital medicine usually requires a change of pathway. The changes may have impacts on different organisations, in terms of time and budget (for example, introduction may increase costs to the social care budget whilst saving the healthcare budget). There is often a necessity for staff training, and, alongside the pathway changes there may be requirement for recruitment or release of staff. By creating winners and losers all these changes will be problematic to introduce. In addition, as a result of all this complexity, randomised control trials will be very challenging from a practical point of view.

End users

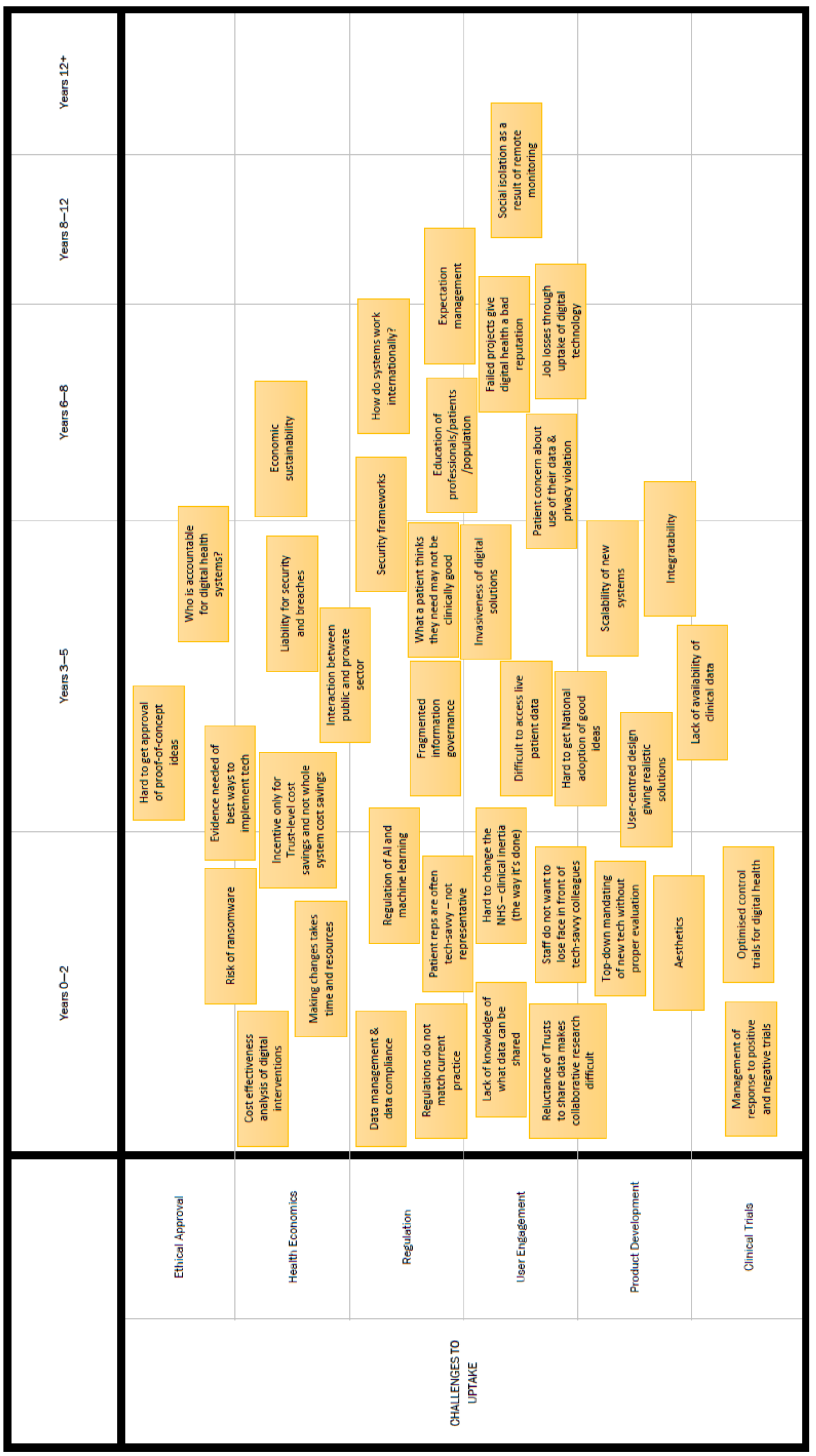
The responses of various end users may also pose barriers for uptake. Examples include differential awareness of benefits of technology, difficulties in patient activation and the effect of the particular relationship with health professionals. Some patients also do not like the idea of monitoring, and find technology difficult; platforms must be simple of given to all.

Awareness of the benefits of technology: A collaboration between the Department of Health and Carers UK attempted to address the question of how to get carers to use more technology. One of the issues was that no one had communicated to them what the benefits of technologies are. In a focus group, 5% said that they currently used technology. But when they saw what the technology would do, that figure went up to 69%.

Challenge of patient activation: Activating patients to pay attention to their health is hugely important, but just assuming that everyone is keen to be healthy is a mistake. An example of this was DALLAS (Delivering Assisted Living Lifestyles at Scale), a programme aimed at introducing telehealth in Liverpool. It was discovered that most people in the poorer part of Liverpool had significant other problems in their lives that meant that they were not able to prioritise health. Where people were unable to afford to eat, or felt insecure in the external environment they could not prioritise 'living well'.

Multi-professional effect: An incidental finding of a telehealth trial (unpublished) showed that consistent involvement with one individual enhanced acceptance of a digital intervention. For example, if one person checked appropriateness of a patient for the telehealth trial, brought the equipment and showed them how to use it, there was almost 100% acceptance. If this was done by three different people then that figure dropped to just over 50%.

Summary of the barriers and opportunities roadmap



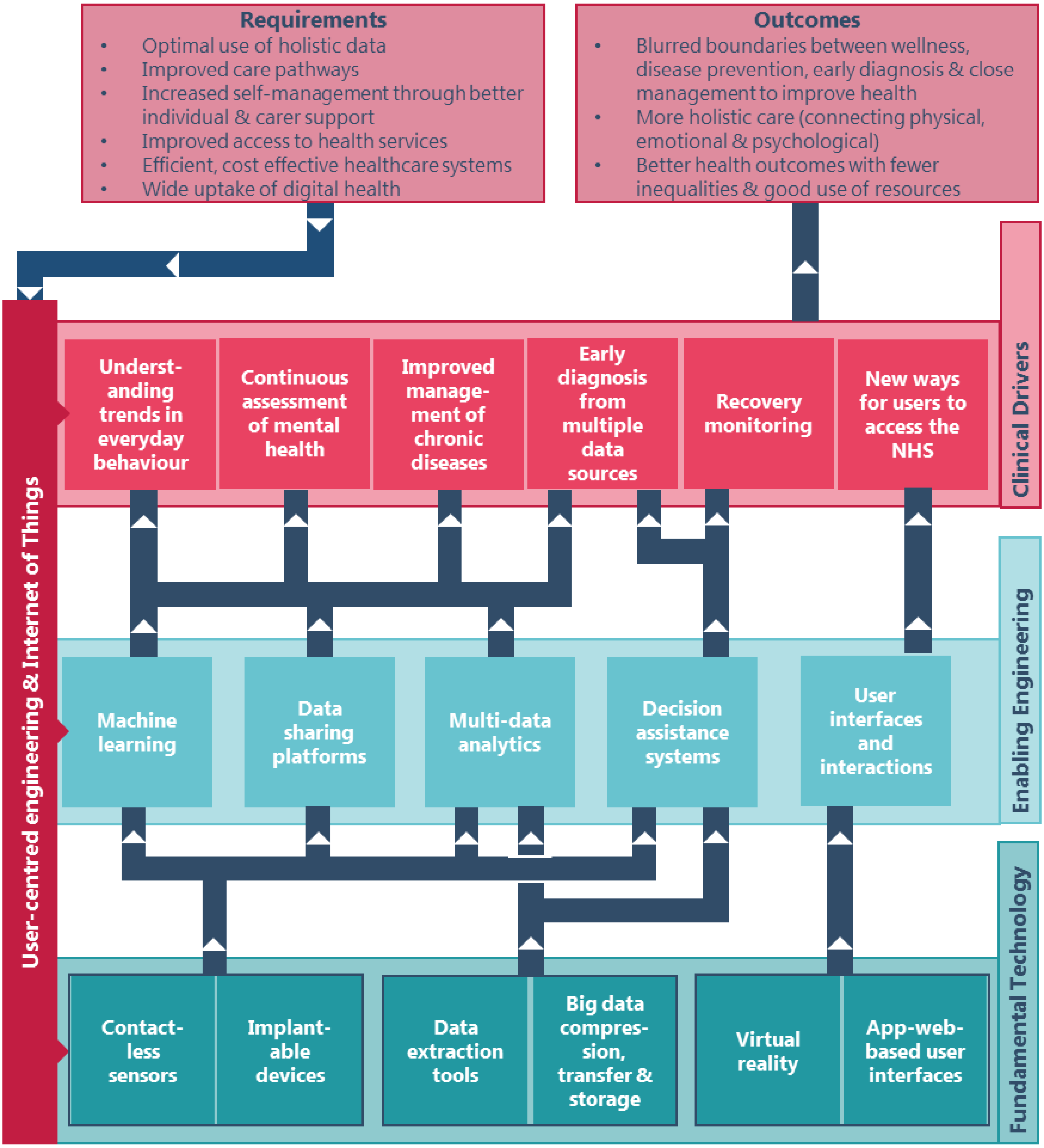
7 Engineering and Physical Sciences Research Roadmap for Digital Medicine, Remote Monitoring and Self-Management

These individual roadmaps lead to an overarching EPS research roadmap which FAST Networks*Plus* is adopting. This roadmap is shown on page 29. Its structure is based upon the 'Three Plane Diagram' developed by the National Science Foundation's Engineering Research Centres[9]. It aims to show how fundamental technology couples directly with enabling engineering to address specific clinical drivers.

The starting point for the Roadmap is a set of Requirements which are distilled from this Report to lead to a set of Outcomes as follows:

Requirements	**Outcomes**
Optimal use of patient generated holistic data Improved care pathways	Blurred boundaries between wellness, disease prevention, early diagnosis, and close management to improve health
Increased self-management through better individual and carer support Empowerment of individuals	More holistic care (connecting physical, psychological and emotional care management)
Improved access to health services, particularly for hard to reach groups	Better health outcomes with less inequalities
Efficient and cost effective healthcare systems	Better use of healthcare resources
Wider uptake of cost effective digital health	
Increasing skills of health professionals	

[9] http://erc-assoc.org/content/three-plane-diagram



Four research fields emerge from the Roadmap which are discussed in turn.

7.1 Generic continuous monitoring from a diversity of information sources

A key theme to emerge from the Roadmap is that we, as individuals, find it hard to pick up on the small changes in our own health and behaviour that might be relevant for future disease. However, long-term monitoring of our behaviour could help to identify these trends and drive care management. There are several specific clinical examples of this which were highlighted in the workshop. One is the management of chronic conditions, such as arthritis, cardiovascular disease, epilepsy or stroke. In these cases, medication could be administered with greater closed-loop control, allowing effects to be measured through long-term trends leading to changes in type of medication and/or dose. Similarly, there could be great benefits to such continuous monitoring to assist in understanding an individual's mental health, for example by potentially allowing early indicators of severe depression to be identified. The third is in the generic understanding of trends in an individual's general health. This could unlock preventative medicine, allowing emerging conditions to be identified at a point when simple changes in lifestyle or other low-level medical interventions could avoid the development of chronic conditions.

The fundamental technology which is needed to address these clinical drivers falls into two broad groups. The first is sensor technologies, and in particular contactless sensors which could be incorporated into clothing, cars or the built environment to monitor movement, cardiovascular performance, respiration, etc., and implantable devices for example to measure changes in key blood markers. The second is around the data itself, including both techniques to handle the large quantities of data that would be generated (compression, transfer and storage) and the basic tools to extract information from data streams.

The potential of these fundamental technologies is then unlocked by three enabling engineering platforms. The first is data-sharing platforms. It is necessary to be able to share data from a number of different platforms in order to build up a picture of changes in behaviour. This requires that data can be shared effectively, whilst maintaining security and privacy for an individual. Analytic tools will be needed that can draw together the multiple data sources as well as machine learning to be able to understand information on an individual in the context of what is known about the population as a whole.

7.2 Recovery monitoring

There are opportunities to improve an individual's recovery from an operation or other form of treatment through continuous monitoring. Unlike the previous example, in this case it is likely to be a small number of specific indicators that need to be measured continuously. Although the fundamental technology around sensors and data remains similar to the generic monitoring, the enabling engineering is different, with a focus on decision assistance systems. These should be able to support a clinician to make active decisions regarding a recovery plan to optimise the patient's recovery process based on real data. As with the generic monitoring, this is giving 'closed-loop control' to the medical intervention.

7.3 Early diagnosis

Sitting between the generic continuous monitoring and the specific recovery monitoring is the opportunity to make an early diagnosis of a condition from

multiple data sources. Examples include provision of monitoring to an individual who is known to be at higher risk of developing a specific condition or where a health professional is concerned about the possibility of early disease. This requires the same fundamental sensor and data technology and requires a combination of all the enabling engineering from the previous two categories namely: machine learning, data sharing and multi-data analytics as well as decision assistance systems. This combination of enabling technologies means that this perhaps represents the greatest data challenge.

7.4 New patient access routes

A distinctively separate theme to emerge from the Roadmap is the need for new ways for users to access the NHS beyond the currently dominant pathways of pharmacies, GP surgeries, '111', urgent care walk-in centres and accident & emergency or 999 services. These currently make little use of the opportunities offered by digital health. New ways of providing contact with the health system can not only make contact faster, more efficient and more effective, but it can also significantly increase accessibility and reduce current inequalities of access. The fundamental technology that underpins this area includes virtual reality systems and new user interfaces based on the web or mobile device apps. Enabling engineering is then required in the development of these user interfaces and interactive systems for users.

7.5 Cross-cutting considerations

Running through all of the roadmap is the need to be user-focused. The needs of the people who will actually use systems that are developed needs to be considered right at the start of the research process. This will almost certainly include the general public and well as representatives of more specific patient groups. It is also important to engage with health professionals who will actually use the system, such as nurses, GP surgery receptionists, pharmacists, hospital porters, GPs, consultants, etc. EPS researchers are strongly encouraged to make engagements at the earliest point practical.

The other common theme is the development of the, 'Internet of Things' (IoT) – the connection of devices over the internet and their ability to communicate with users, applications and each other Many of the technological and engineering research that is highlighted in this roadmap aligns closely with the development of the IoT. It is likely that some piggybacking will be possible as solutions emerge from other IoT areas, for example in sensors and big data. However, it should be remembered that there are very specific additional constraints in the healthcare technology area around system reliability and security.

8 Acknowledgements

Prof Ann Blandford and Prof Andrew Flewitt would like to thank all the participants in the FAST Healthcare Digital Health Workshop which was run on the 5th September 2017. Particular thanks are due to the speakers, from whose talks a significant proportion of this Report is drawn:

- Prof Elizabeth Murray (Professor of e-Health and Primary Care, UCL & GP)
- Prof Andrew Farmer (Professor of General Practice, University of Oxford)
- Prof Claudia Estcourt (Glasgow Caledonian University & Institute for Global Health, UCL)
- Dr Malcolm Clarke (Reader in Telemedicine and eHealth Systems, Brunel University)
- Charles Lowe (Digital Health and Care Alliance)
- Prof Ian Craddock (Professor in Data-driven Health, University of Bristol)

We are also grateful to Dr Hilary Burton and Tanya Brigden of the PHG Foundation, who made detailed notes on the meeting and drafted this Report, assisted by Sarah Cook.

Thanks are also due to Maria Speight for local assistance in Workshop organisation.

Funding for the EPSRC Fast Assessment and Treatment Networks*Plus* by the EPSRC through grant no. EP/N027000/1 is gratefully acknowledged.

Report authors: Dr Hilary Burton (Consultant in Public Health Medicine, PHG Foundation), Tanya Brigden (Policy Analyst (Humanities), PHG Foundation), Professor Andrew Flewitt (Professor of Electronic Engineering and PI of the EPSRC FAST Healthcare Networks*Plus*, Engineering Department, Cambridge University), Professor Ann Blandford (Professor of Human-Computer Interaction, and CI of the EPSRC FAST Healthcare Networks*Plus*, Institute for Digital Health, UCL).