Cutting through the app:
How can mobile health apps meet their true potential?

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Contents:

Executive Summary

This report examines the evidence for the potential of apps to promote positive health behavioural change in the UK population. After a thorough evidence review of academic and grey literature, the sourcing of case studies and original analysis of the Understanding Society dataset, this report finds:

There are a number of app-based innovations that could benefit individuals – and health systems

- This report identifies several health apps that have been proven to reduce unhealthy behaviours such as excessive alcohol consumption, and increase positive health behaviours such as a healthy diet and physical exercise. If these positive health behaviours are continued across large population groups, this could have a positive impact on non-communicable disease prevalence rates.

- Best practice apps include Gray Matters, that has been shown to improve health behaviours that can reduce the risk of Alzheimer's in older adults, and Step Away, that has been shown to effectively reduce heavy alcohol consumption.

Our analysis suggests the following populations would benefit the most from effective health apps:

- Our original data analysis has identified several population groups in the UK that could benefit from effective health behavioural change apps, such as the ones included as case studies. These include:

  - ► Nearly 1 million 'baby boomer boozers' who are over 60, drink frequently and use a smartphone.

  - ► 760,000 'living fast, dying young' who are under 40 and smoke, drink frequently, have a smartphone and regularly use the internet.

- ► 5.7 million people who 'just need a push' and who eat healthy and don't smoke, but drink moderately and rarely exercise.

- ► 2 million 'connected, healthy and young' who eat well, exercise frequently and regularly use the internet.

- These population groups, if able to easily access clinically effective health apps, could improve their health and provide much needed cost savings for the NHS.

However, there are considerable barriers that are preventing health apps reaching their full potential

- Several studies have shown some health apps to have serious data security flaws.

- The low barriers to market entry and the proliferation of digital technology means that the best-practice, effective health apps are often being drowned out by poor-quality, ineffective apps.

Accreditation is needed to distinguish effective apps from ineffective apps

- Accreditation of health apps need to balance helping consumers identify effective apps, without stifling innovation in this field.

- This report concludes that without an accreditation system that prioritises effectiveness in terms of health outcomes, the potential of apps to positively influence health behaviours will continue to be unmet.

- Several countries and regions, such as the US and EU, have attempted to develop accreditation systems.

- A new accreditation system by NHS England has recently been launched. The accreditation system is more rigorous and demands more evidence of effectiveness than other international or non-NHS accreditation schemes. But importantly it does not stifle innovation in app development; it instead invites interested developers to submit their promising apps to be accredited and receive NHS approval.

- Therefore, the evidence leads to the recommendation that the approach set out by NHS Digital, and the NHS Apps Library is, on balance, the correct approach.

However, the current NHS England App Accreditation system is not perfect

- The system does not fully appreciate how users interact with technology, and too often accreditation is not visible and not integrated with the most popular methods to download health apps (App Store and Google Play).

This paper therefore recommends:

- Appreciating the time-consuming nature of evaluating a health app, NHS England should make available on the App Library information for users on how to make a judgement on whether one health app could be more effective than another.

- Better labelling of an NHS accredited app. At the time of publication, the only fully NHS accredited app did not include accreditation information on its website, and no accreditation mark on the app logo. A clear NHS seal of approval should be given to apps that meet the accreditation process.

Introduction

A personal trainer available to you at any time of the day. A diet planner that tracks what you eat and gives personalised advice on how to lose weight. A coach that can give you encouragement, support and advice on quitting smoking, on call 24 hours a day. Not long ago, these health behavioural aids would be prohibitively expensive for the majority of the population, only available to those who could afford to pay for a personal trainer or a lifestyle coach. The proliferation of smartphone use in the UK, and the availability of apps at minimal or no cost has changed all of this. Now most of the UK population own a smartphone, and have the option to download a multitude of apps that can encourage and maintain healthy behaviours. These apps are becoming increasingly sophisticated, using voice recognition, movement tracking and social networks to increase the options available to users.

But the huge promise these apps have in promoting healthier behaviours across the population is not being met. Whilst there are innovative ideas and services that are reaching the market, for the true potential of health behavioural apps to be reached, challenges around security, evaluation and accreditation need to be discussed. This paper aims to add to this conversation, provoke thought and debate and suggest ways by which the whole system can work more effectively, from developers to researchers to health professionals to government bodies.

This paper will begin with a chapter that introduces the reader to theories of health behavioural change, the current digital health policy landscape in England, and a definition of terms. It will then give an overview of the current health apps landscape, including profiles of current users and market potential. Chapter Three will outline where good innovation is currently happening, before the paper addresses the major barriers to meeting the technology's potential. Finally, the paper will conclude with some ideas for next steps.

Why are we looking at this?

This analysis of the state of play of health behaviour apps is much needed; there is a lack of research on why health apps have, so far, not made a significant impact on the health landscape of the UK despite the rapid technological advances in recent years. There has not yet been a policy-level discussion on the potential of apps in a systematic way. Quite simply, the good innovation that exists is not being used effectively. The challenges need to be addressed now. Technology continues to develop at a fast pace, therefore it is essential that health professionals and health policy makers agree on fundamental issues such as accreditation and evaluation because if costs to market entry continue to decrease, it will become increasingly difficult to understand 'what works' from the multitude of health behavioural change apps that currently exist.

Remit of this report

The remit of this report is a systems-level analysis of the state of play of the health apps market. Analysis is particularly focussed on the barriers faced by health systems in terms of enabling apps to meet their true potential.

This research addresses the barriers faced by consumers, particularly in terms of how consumers identify effective health apps. The report does not, however, address in detail consumer behaviour and preferences. This is due to a limited evidence base. This is addressed in greater detail in Chapter Two.

This report will take a life-course approach and examine the potential health benefits for people of all ages if the transformative potential of apps is realised.

What do we mean by the 'potential' of health apps

Throughout this report, we refer to the 'potential' of health apps, and examine the barriers faced by developers and

HEALTH BEHAVIOURS: "Overt behavioural patterns, actions and habits that relate to health maintenance, to health restoration and to health improvement"[1]. These behaviours can include diet, physical activity, alcohol use, visiting health professionals and adhering to medication.

HEALTH BEHAVIOURAL CHANGE: "An effort to change people's personal habits to prevent disease"[2].

HEALTH APPS: "part of a movement towards mobile health (mHealth) programmes in health care. Some are designed to help consumers make healthier choices in their everyday life by offering advice about fitness or nutrition. Others help doctors and patients communicate from afar[3]. Unlike 'mHealth' solutions, health apps are solely for users, rather than for use by health professionals[4].

health systems that need to be addressed if this potential is to be met. It is therefore important to set out what we mean by this potential.

The potential of health apps is that they could form a substantial part of the answer to one of the biggest challenges faced by the health service, that is improving public health and preventing diseases. Apps have great potential because they offer another modality of public health interventions, and could be cheaper to provide. Such technologies could eventually increase health consumer engagement over a broad span of time, and provide services for a fraction of the cost that human delivered services would incur.

The potential gains could be revolutionary. NHS England's Five Year Forward View stresses the need to incentivise and support healthier behaviour, stating that "the future… sustainability of the NHS, and economic prosperity of Britain all now depend on a radical upgrade in prevention and public health"[5] . Previous analysis from the ILC-UK shows that health spending will increase to an unsustainable proportion of GDP unless productivity gains are made[6]. Discussing digital health more generally, the Nuffield Trust has stated that the "triple aim" of

health, that is, "gains in quality, efficiency and population health" is now in reach if technology is used effectively in healthcare[7]. Many people believe that the most significant gains in healthcare productivity can be made in affecting positive health behavioural change in individuals and across populations, from early in life and before they develop chronic conditions[8]. Health apps are of particular promise due to the democratising effect of the smartphone. With prices decreasing and smartphone use increasing across all ages and socio-economic groups, the transformative potential of app-based health behavioural change can be accessed easily and cheaply by the majority of the population[9].

SHORT INTRODUCTION TO HEALTH BEHAVIOURAL CHANGE

There has been an increased interest from policy makers, including health policy makers, in the area of behavioural change interventions, especially 'nudge theory'. Whilst traditional approaches to health behaviour interventions often restrict choice or prohibit certain behaviours, more subtle behavioural influences that entice people to improve their health have been often shown to be effective[10]. Many apps use this approach, anchoring individuals to goals, and providing these 'nudges'.

There are many competing theories of health behavioural change. These include more standard models such as the Theory of Planned Behaviour, that looks at the "discrepancy between attitude and behaviour"[11], and the Health Belief Model, that focusses on an individual's readiness to act against perceived barriers, perceived benefits and perceived severity[12].

Other theoretical approaches argue that established theories are too linear in terms of how people carry out certain behaviours, and that, especially when technology is involved, there needs to be an appreciation of the variety of forces simultaneously occurring that influence a person's behaviour. 'Staged' theories such as the

Transtheoretical Model of Behaviour Change have tried to encompass these complexities[13].

However, many evidence reviews have found flaws in taking an approach that is too wedded to one theory of change. NICE guidelines explicitly reject an underlying theoretical model of health behavioural change, stating that "the evidence did not support any particular model"[14].

Therefore, NICE suggests that the focus should be less on theories, that are varied and often unproven, and more on actions and behavioural change strategies. This is supported in other academic papers, which support an approach that is "theory agnostic"[15]. What matters, it is argued, are the actions and interventions themselves.

Health behavioural change strategies

In the NICE guidance on health behavioural change, a number of recognised best-practice strategies are listed. These include[16]:

- Outcome expectancies (informing people on health consequences of lifestyle behaviours)

- Positive attitude.

- Self-efficacy (developing self-belief in a person regarding their ability to change).

- Descriptive norms (making people more aware of positive health behaviours in people they compare themselves with).

- Intention formation and concrete plans (aiding people in developing plans and targets for behavioural change).

- Behavioural contracts (helping people to share health plans and targets with others).

- Relapse prevention (developing coping skills to deal with difficult situations).

POLICY CONTEXT

In 2015, Jeremy Hunt stated that his aim was for 25% of smartphone users (which was, in 2015, 15% of NHS patients) to be "routinely accessing NHS advice, services and medical records through apps" by 2017[17]. Whilst recent data is not available, when the Secretary of State made this statement, only 2% of the population "report" digitally enabled transactions with the NHS[18].

To meet this target and other targets of seeing future populations using apps and digital aids to improve health and wellbeing, health policy makers have introduced a number of initiatives. One example is the Innovation and Technology Tariff, which aims to streamline the 'route to market' for innovations such as apps[19]. A new NHS group, the Clinical Digital Council, has been introduced in late 2017 to ensure that NHS England, NICE and Public Health England are keeping up to date with the fast-developing market of digital health[20]. The cross-stakeholder group has published its priorities for 2018, which is to develop digital health standards, create a consensus on what good evidence is in terms of digital health and debate policy and regulation in terms of Artificial Intelligence (AI) and machine learning[21].

NHS Apps Library

The most important initiative, however, is the NHS Apps Library. NHS England, like many health organisations in the UK and other countries, has struggled with issues of accreditation and regulation for health apps, and has a chequered past with commitments not being met and schemes delayed. In March 2013, NHS Choices launched the Health Apps Library, a trial to collate NHS approved apps into one place and make them accessible to the public. It included apps on mental health, weight loss and quitting smoking[22]. These apps were accredited by NHS England and had been badged as trustworthy[23]. However, the website was shut down in October 2015 after a study by Imperial College London highlighted a number of hypothetical security risks[24].

After the closure of the first NHS Health Apps Library, the National Information Board announced that it would use the learnings from the process into developing a new endorsement model that was outlined in their Personalised Health and Care 2020 framework, which at the time was the lead digital health workstream[25].

The planning for a new app platform hosted by NHS England culminated in announcements made in the Next steps on the NHS Five Year Forward View. NHS England set out a number of steps to 'harness technology and innovation'[26]. The use of apps feature prominently in this strategy. It committed to launching a new NHS Digital Apps library, which will have three tiers of apps:

- NHS approved: fully available evidence base, using a NICE assessment.

- NHS connected: these are "tested and approved for connection to NHS systems", with the user able to download information from NHS England into the app.

- Health apps: other health apps that may be useful.

The strategy also states that developers "will have the ability to self-assess against NHS criteria, such as where they store your data and whether they sell or use that data for other purposes"[27].

Finally, in April 2017 and after many delays, NHS England launched a beta version of the new Apps Library.

The difficulties that NHS England, Public Health England and the Department of Health have faced in developing a viable platform and accreditation model for health apps highlights the frustrating nature of health behavioural change apps. Whilst many people can see the potential benefit in terms of health improvements and potential efficiency savings through populations that are healthier for longer, the existing model of app development and promotion means that there are numerous apps

available that are not evidenced and are not stringent enough with data security. Later chapters of this paper address these challenges in greater detail.

Current state of play

This chapter considers the health app market today. Using the most up to date data available, this chapter provides information on smartphone prevalence, the size of the health app market, the population's willingness to use health apps and analysis of what the characteristics are of the people already using health apps. The chapter concludes with original data analysis from Understanding Society, showing the population groups in the UK that could benefit from the effective behavioural change apps that are currently available.
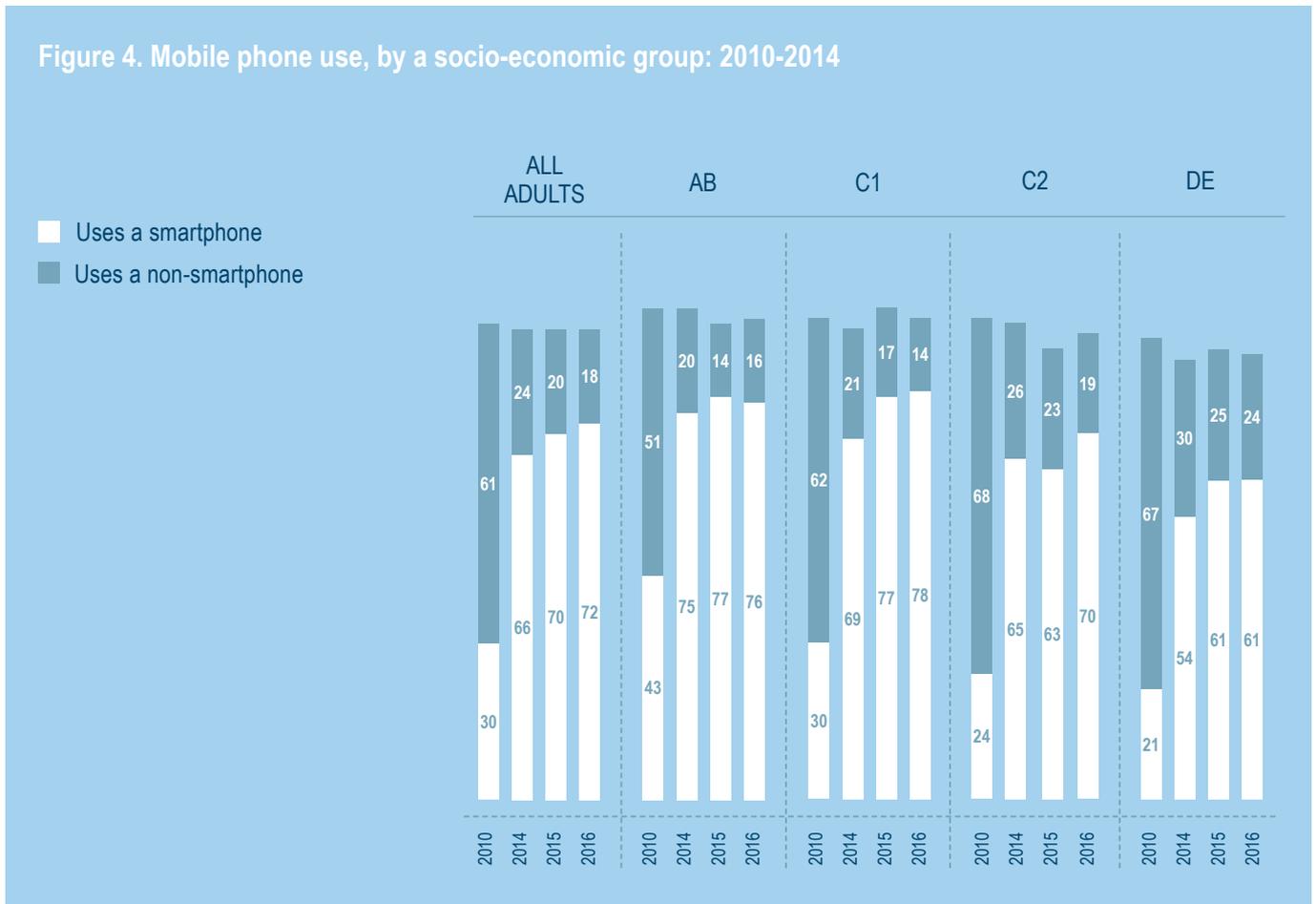
WHO USES SMART PHONES?

Figure 3. Mobile phone use, by age group: 2010-2014

☐ Uses a smartphone
▉ Uses a non-smartphone
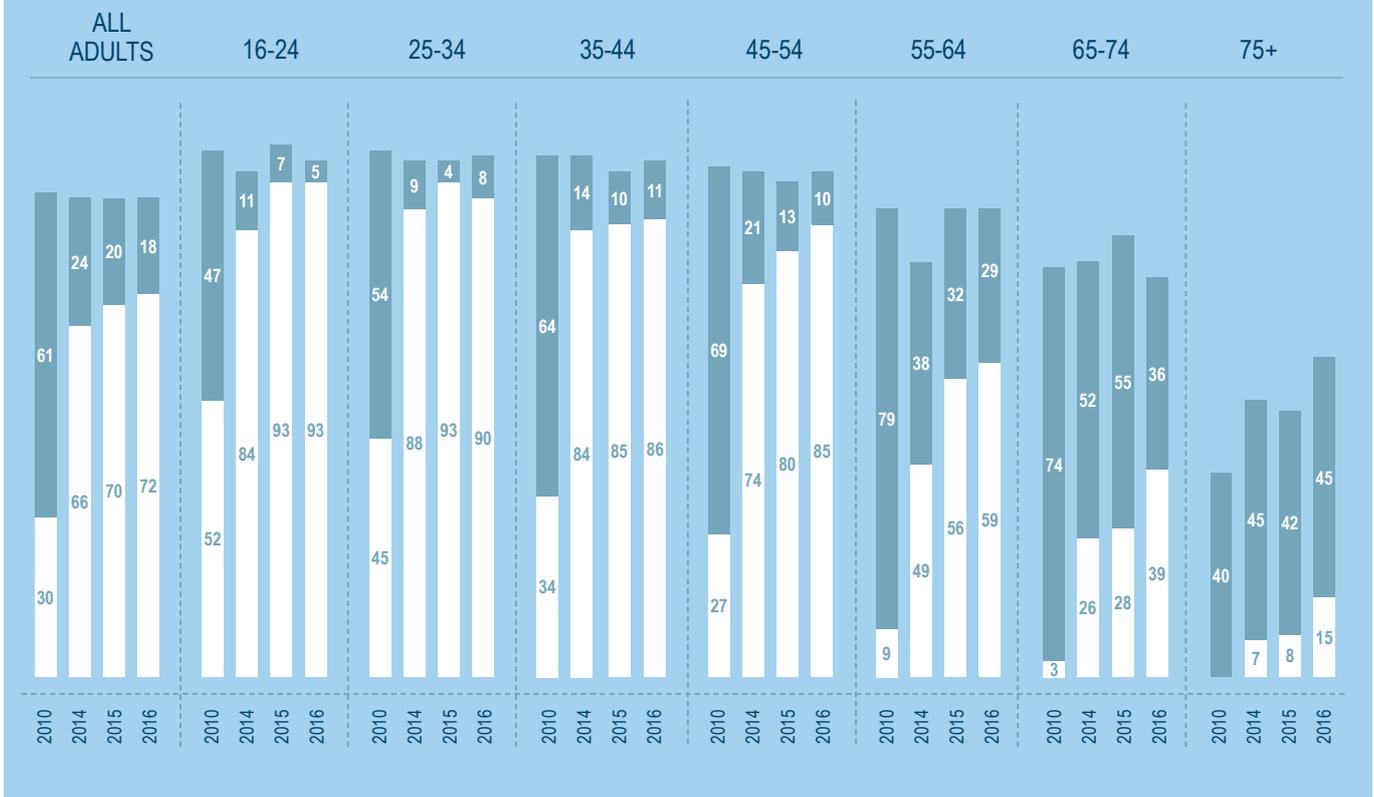
Source: Ofcom 2017

Figure 4. Mobile phone use, by a socio-economic group: 2010-2014

Source: Ofcom 2017

Who uses smart phones?

As the figures above show, smartphone usage has increased dramatically since 2010 across all ages and socio-economic groups, with 72% of the population using a smartphone. Proliferation has increased from 30% in 2010, increasing sharply in 2014, and a slower increase in the years after. High levels of smartphone ownership continue across all age groups except the very oldest. There has been a significant shift in smartphone use in the over 55s, with the 55-64 age group seeing smartphone use increase from 9% to 59% from 2010 to 2016. High levels of ownership also span socio-economic

groups, although ownership levels are slightly less for the DE social group. This could be explained by older, retired people being included in this group.

Who uses tablets?

Of course, not all apps are accessed via a smartphone. Tablets are an increasingly popular mode of accessing the internet. The most recent data from Ofcom suggest that 49% of adults can access the internet with a tablet, including 23% of over 75s[28]. As a way of accessing the internet, tablets are more popular than smartphones in this age group[29].

HOW MANY HEALTH APPS ARE **AVAILABLE?**
325,000
on major app stores[30]

WHO USES HEALTH APPS?

In a recent YouGov Survey, **26%** of Britons have used digital technology to track their health and fitness[31].

75%
OF BRITONS SEEK **HEALTH INFORMATION** ONLINE[32]

WHO COULD USE HEALTH APPS?

90% of Britons
would be open to using their smartphone to interact with a health professional[34].

WHAT TYPES OF **HEALTH APP** DO PEOPLE USE?
Apps by usage of more than once a week[33].

9% use health apps

Zzz **6%** use sleep tracking apps

8% use calorie or diet tracking apps

6% use apps that help them manage their **health and wellness**

7% use brain training apps

7% use **exercise** apps

12% use activity tracking apps

Typical users of health apps

Useful data on what is the 'typical' user of a health behavioural change app in England or the UK is lacking. However, it is important to consider who this typical user may be.

One study from the US used a logistic regression model to assess the characteristics that can predict health app use[35]. People who used health apps were more likely to:

- Have higher levels of education.

- Have higher incomes.

- Report excellent health.

Regarding the association between using health apps and healthy lifestyles, the study found:

- No association between smoking status and app use.

- No association between BMI and app use.

- No association between meeting fruit and vegetable recommendations and app use.

- But app users were significantly more likely to exercise more than 2 hours per week.

In other words, a typical health app user (in the US, but findings can be cautiously applied to the UK) is shown in this study to be younger, more educated and with a higher income. They are more likely to want to lose weight and improve their health. In terms of a healthy lifestyle, there was no association between using a health app and eating the recommended amount of fruit and vegetables, but they are more likely to exercise more than two hours a week.

In terms of making the most of the opportunities provided by health apps, the average user being younger is not necessarily a problem, if these user's health behaviour continues to be positive as they age. As our population ages, it is vital for the sustainability of health systems that more people grow older in better health. Engaging younger adults earlier can contribute to this. More concerning is the data on income. Evidence shows that an unhealthy diet is often associated with a lower socio-economic status[36], whilst lower incomes have been shown to be associated with increased physical inactivity[37]. If the type of health apps that are the focus of this paper, that is, apps that encourage positive health behaviours, are to be truly effective, they need to be accessed by individuals from all socio-economic backgrounds. As long as apps continue to be used by the population cohorts that arguably need it the least, their true potential will not be met. Policies that can help speed adoption in the groups likely to benefit, and therefore reduce costs for the NHS, need to be a priority.

POPULATION GROUPS: WHO IN THE UK COULD BENEFIT FROM EFFECTIVE BEHAVIOURAL CHANGE APPS?

Over 40 million adults in the UK can access health apps through the touch of their fingertips thanks to smartphone ownership. The potential for health apps to influence lives has never been greater. However, it is important to understand which groups might benefit from such apps to influence their health behaviour, so that this new technology can be better targeted and harnessed for health gains in wider society.

What are the consumer perspectives on health apps?

Whilst the focus of this paper is on the state of the health apps market and the respective barriers, it is important to address user and consumer perspectives in terms of what people want from apps, how they interact with health apps, and why they may be incentivised to use them.

There are several limitations in seeking to examine the consumer perspective. Firstly, there is a lack of research on this. What is out there tends to be industry-led surveys, which are of some value but lack depth. Moreover, research in this area quickly becomes out-dated with technological advances, with the market changing rapidly. However, there is some existing research that is of value. We summarise this below.

What people want from health apps

An Australian survey found that for health apps people prioritise[38]:

- Apps that give people control over their condition or keeps them healthy
- Easy to use
- Able to be used regularly
- Allow social networking between other users
- Can be trusted in terms of security and reliability

How interested people are in using digital technology to improve their health or access health information

A survey conducted by EY in Australia found that[39]:

- 70% would be interested in communicating electronically with a doctor or other health professional
- 70% would be interested in ordering prescription drug refills using a mobile app
- 66% would be interested in using a device connected to their smartphone to measure temperature, blood pressure or heart rate, and send the information to their doctor
- 61% would be interested in consulting a doctor by video on their computer

- 60% would be interested in sending a photo of their injury or health problem to their doctor using a mobile phone or computer

Why people may stop using health apps

A US survey examined why consumers download a health app, but then stop using them. The most common reasons were[40]:

- Hidden app fees
- High burden of data entry
- Loss of interest

Health information seeking behaviour by age group

There is a lack of research on people's preference on whether people would prefer to access health information, or receive health interventions, through apps rather than traditional approaches. However, there is some research on health information seeking behaviour that takes into consideration online modes compared to traditional modes.

ILC-UK research found interesting demographic divides on health information seeking behaviour. Whilst 50% of those aged 25-34 in a UK survey preferred to receive health information online, only 15% of those aged 65 and over preferred the internet[41]. The internet remained the favourite source of health information for all age groups younger than 55. Whilst not specifically referring to apps, the fact that many people in this research expressed a preference to seek health information online indicates that there is a strong market for effective health apps.

Population groups using Understanding Society

To compliment this existing research, we conducted original data analysis using the Understanding Society Longitudinal Survey. After assessing the health indicators and behaviours that could be used as variables from the dataset, and prioritising the health behaviours that are addressed in the best-practice apps in this report, we formed these population groups to be used for illustrative purposes to demonstrate how many people could benefit from the type of nudges many health apps aim to provide. These groups, and the key descriptive statistics are documented below:

'SWITCHED ON OLDER PEOPLE':

13 million people
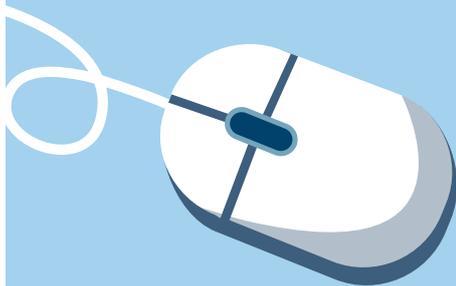
● A group comprising of those over 50, with a smart-phone, who frequently use the internet.

● Those in or making the transition into old age are likely to face numerous health challenges as they grow older. Maintaining healthy behaviour is crucial if individuals want to continue to participate in the labour market or enjoy their retirement in good health.

● 55% of those over 50 use a smartphone. Almost 25% are over 50 and a regular user of the internet. This amounts to over 13 million people.

● his potentially represents a huge market with access to apps, who could benefit from monitoring and improving their health at a crucial phase of their lives.

'HOME BASED EXERCISE':

5.6 million people

● Those over the ages of 50 and 60 who have a tablet or smartphone, but only participate in infrequent physical activity.

● Over 75% of over 50s fail to meet recommended exercise limits of moderate activity lasting 30 minutes or more at least 3 days a week. This is over 10 million people.

● 9.7 million people over 50 have access to apps via smartphone/tablet access who do not exercise frequently.

● Of this, 5.6 million are over 60.

● Apps that help encourage exercise could potentially prove a huge benefit to this group, especially if they are tailored to older people, to help encourage exercises which can be done at home while accounting for the physical challenges older people may be more likely to face.
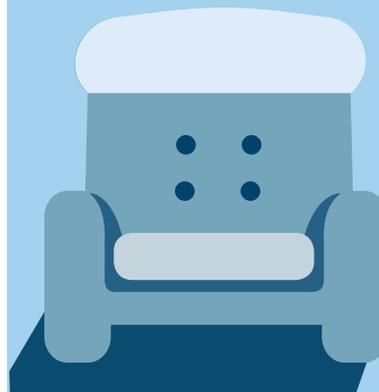
'CONNECTED, HEALTHY AND YOUNG':
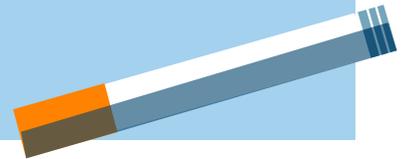
2 million people

- Those under 40 who eat well, exercise frequently and use the internet a lot.

- The largest consumer base for commercial apps remains younger people. Just over 97% of those under the age of 40 have a smartphone.

- Almost 98.5% use the internet every day or several times a week at least.

- There are just over 2 million adults that are under 40, frequent internet users with a smartphone, who eat well and exercise frequently.

- Maintaining good health is just as important for young people. Those who are already displaying positive health behaviours may be more inclined to look for ways to monitor their health and physical activity.

'BABY BOOMER BOOZERS':

960,000 people

- The over 60s who drink frequently and have a smartphone.

- Around 1.7 million people over the age of 60 drink frequently. This is almost 11.5% of the older population.

- Just over 960,000 of this group have smartphones.

- Again, while a relatively small group, apps that help to monitor and encourage control over alcohol consumption could greatly benefit the health of this section of the older community.

760,000 people

'LIVE FAST, DIE YOUNG':

- Conversely, there are those under 40 who smoke, drink frequently and have a smartphone regularly accessing the internet.

- Over 25% of those between 25-29 smoke. In all, there are over 4.2 million smokers under the age of 40 in the UK.

- Just over 2.6 million people under the age of 40, drink frequently, either drinking more than 4 times a week, or more than 6 drinks.

- Only just over 760,000 individuals fall into this category in the UK.

- While a relatively minor group, the benefits for improving health behaviour seem crucial for those who are likely to risk poorer health in later life because of their health behaviours in early adulthood.

'MORTALITY AWARE':

372,000 people

- The over 40s with a smartphone who participate in moderate exercise and use e-cigarettes.

- Over 2.1 million people over 40 use e-cigarettes. This represents over half of the total use of e-cigarettes.

- Over 25 million people over the age of 40 fail to achieve moderate levels of exercise in a week.

- Only just over 372,000 people fall into this category of exercising, e-cigarette using, smartphone owners.

- While niche, this group displays habits that suggest positive health behaviours. Helping this group acknowledge potential ways to improve their health further would likely be in their interest.

'JUST NEED A PUSH':

5.7 million people

● The under 50s who eat healthily and don't smoke, but may drink moderately and rarely exercise.

● Over 60% of those under 50 fails to eat 5 portions of fruit or veg more than 4 times a week. This is over 18 million people.

● Almost 75% of those under 50 fails to exercise even moderately regularly.

● Over 5.7 million people under the age of 50 fall into this category.

● Health apps may help this sizeable group to adapt their health behaviours and make the small adjustments which can help promote better long-term health behaviours that can lead to enhanced wellbeing.

Concluding thoughts.

These groups and statistics provide a snapshot of the markets and consumers who could potentially benefit from health apps, while also having immediate access to them. Through further identification of the health behaviours of different groups, apps will be able to better target the health behaviours that people are likely to benefit from improving, while also generating greater appeal for apps that are more relevant for a larger audience. What is more, as technological trends continue and the proliferation of smartphones, high speed internet and tablets continue across all age groups, the number of people who could benefit from effective health apps will increase.

Where and how is good innovation happening?

This chapter explores where exciting innovation is happening in the field of health apps. It will present a number of best practice case studies that combine innovative approaches with solid evaluation and can demonstrate effectiveness in promoting healthy behaviour. We also identify emerging technologies that have promise. This chapter also goes beyond highlighting good innovation, and asks why these apps successfully prove their effectiveness, with an analysis of the defining characteristics of the best practice case study apps.

Why are these case studies promising?

The case studies below have been selected because their effectiveness has been evaluated to some extent. As shown, these apps show promise and can have a positive effect on health behaviours. It is certainly conceivable that apps like these, if utilised correctly, can have a significant impact on people's health, and the wider population's health. Some of the health behaviours these apps are shown to improve, such as alcohol and diet, are highlighted in NHS England's Five Year Forward View as priority areas if the NHS is to be sustainable. It is important to note that whilst these apps do show promise and have evidence of effectiveness, they are in the minority in the vast world of health apps. Meta-analysis studies of the effectiveness of health apps have shown that while there is evidence that some health apps (such as the case studies above) can change behaviour and affect outcomes, the evidence is often weak, and too many are ineffective[42].

Improving health behaviours can have ramifications for the NHS. Other technological advances, namely in medical devices, increase costs of healthcare by being able to treat more illnesses and more conditions, without decreasing the unit costs of these treatments[43]. In other words, new technology means that more people can be treated more effectively for a whole range of conditions; but the technology does not necessarily make treating these conditions cheaper.

This is undoubtedly a good thing, as more people can live longer and survive diseases and conditions that previously would have killed them. But what this does mean is that there is a renewed importance on saving money through preventing or delaying people developing conditions such as dementia, diabetes and cancer. The case studies below show that if effective apps are promoted, developed and supported, they could contribute towards this, especially because these apps have been shown to have a positive effect on some of the most prominent lifestyle behaviours linked to poor health outcomes such as alcohol consumption, poor diet and smoking.

These apps were sourced from Google searches and searches of academic literature. These apps were selected on the basis of evidence of effectiveness, prioritising peer-reviewed data. Ease of use and overall design of the app was not a factor in selecting these best-practice apps, as the aim of this exercise was to identify apps with a strong peer-reviewed evidence base, before analysing why these apps are able to demonstrate effectiveness whilst so many health apps do not.

myCOPD (UK)

WHAT DOES IT DO?

myCOPD is a tool that can help people with chronic obstructive pulmonary disease (COPD) manage their condition better. COPD is the second most common cause of hospital admissions, and is estimated to cost the NHS £800 million.

HOW DOES IT WORK?

There is no cure for COPD. Therefore, it is important for people with the condition to effectively manage symptoms. The app provides tools such as a self-management plan, tips to stop smoking, provides a pollution forecast and provides instructions on exercises that can prevent adverse symptoms.

Some CCGs offer myCOPD as a free NHS service. If not, a lifetime licence costs £20.

WHO WAS INVOLVED?

The project to develop the app was led by the UK company HealthQuest Solutions. Also involved were University Hospital Southampton Foundation Trust and IT engineers Innovate Design.

The app was assisted by NHS England's Innovation Accelerator programme, who assisted with app diffusion.

WHAT IS THE EVIDENCE?

myCOPD has been shown to correct 98% of inhaler errors without needing a clinical intervention. This improves quality of life for people with the condition.

The app has also been shown to significantly improve COPD symptom scares compared to a control group, with patients also reporting improved health and wellbeing.

Source:
https://apps.beta.nhs.uk/mycopd/
https://www.health.org.uk/programmes/shine-2012/projects/my-copd-solution
https://nhsaccelerator.com/mycopd/

Gray Matters (US)

WHAT DOES IT DO?

This app focussed on adults aged 40-64 years, whose unhealthy behaviour and lifestyle could lead to an increased risk of developing dementia.

The app integrated risk reduction prevention strategies to encourage healthy behaviours, whilst also providing information on the risk factors in developing Alzheimer's disease. These risk factors include stress, lack of physical activity, poor diet and low levels of cognitive stimulation.

HOW DOES IT WORK?

Gray Matters provides app users with a daily 'factoid' based on established health literature on Alzheimer's disease. It then suggests a lifestyle change that can improve the chances of preventing the disease.

App users also answer 12 lifestyle questions over 6 behavioural areas, such as exercise levels and smoking.

Finally, the app features instant performance feedback on their answers to the lifestyle questions. Users get a 'star' rating for each lifestyle behavioural area, with a weekly summary of their progress and changes.

The app is informed by research and established behavioural models, using an 'upward spiral approach' in which users can learn from each relapse.

WHO WAS INVOLVED?

The team was multi-disciplinary, with academic experts in statistics and pervasive computing, alongside software designers, business developers and epidemiologists.

WHAT IS THE EVIDENCE?

The app went through a number of expert evaluations. The app was reviewed by five selected experts, who then completed a survey.

It was then clinically evaluated, trialled for six months on a treatment group and control group.

The evaluation showed that everyone who used the app demonstrated new healthy behaviours compared to the control group. They also reported an increase in socio engagement and intrinsic motivation. The more a person used the app, the greater the changes, and users who used the app everyday showed the biggest improvements.

Source:
http://www.niassembly.gov.uk/globalassets/documents/raise/knowledge_exchange/presentations/series6/nugent080317ppt.pdf

Step Away (US)

WHAT DOES IT DO?

This app is designed for people who want to reduce their alcohol intake.

Some of the most common reasons for not wanting to seek help with problem drinking is that people think they should be strong enough to deal with the problem on their own. Other reasons frequently cited are embarrassment around answering questions and not being able to travel to health centres. These reasons suggested to the developers that an app-based support system may benefit a lot of people.

HOW DOES IT WORK?

There are a number of features built into the app. The user can set an overall objective to reduce alcohol intake, as well as smaller interim goals. The app offers immediate tools such as strategies to deal with bad moods and boredom, and the user can define 'high-risk times' for drinking.

The app monitors progress in the form of weekly reports, can allow users to schedule non-drinking activities into your phone calendar, and can identify 'high risk events' in the upcoming week. The app also allows the user to set up a support team of family, friends or health professionals, and can share progress data with that group.

The app is informed by established research on effective interventions for alcohol reduction.

WHO WAS INVOLVED?

This app was developed in the US. Dr Patrick Dulin, from the University of Alaska, has been the project lead in the development of the app since 2008. The funding for the development and evaluation of the first prototype app, called, LBMI-A, was provided by the National Institute of Alcohol Abuse and Alcoholism.

WHAT IS THE EVIDENCE?

An earlier prototype of this app (LBMI-A) was evaluated, with results published in a peer-reviewed journal. The study found that when the app is used by people who drink heavily, the percentage of days abstinent sharply increases, whilst there are significant decreases in the percentage of heavy drinking days and the number of drinks per week.

Overall alcohol use decreased by over 50%, and heavy drinking days decreased by over 60%.

Source:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4426096/http://stepaway.biz/

My Meal Mate (UK)

WHAT DOES IT DO?

This app is a weight management app that helps the user track their calorie intake and reach a realistic weight loss goal.

HOW DOES IT WORK?

My Meal Mate allows users to self-report weight, diet and physical activity. To make users more engaged, the app gives feedback via notifications, and contains a UK-focussed food database to accurately monitor calorie intake. The user can set goals in weight loss and calorie intake.

WHO WAS INVOLVED?

This app was developed by nutrition scientists at the University of Leeds.

The research was funded by a grant from the Medical Research Council, and the app was developed by a software company, Blueberry Consultants. The team used a company, Weight Loss Resources, for their food and drink database.

WHAT IS THE EVIDENCE?

The team behind My Meal Mate claim that it is the first weight management app available for free that has been informed by scientific evidence and been piloted in a clinical trial. A pilot randomized controlled trial was conducted, and published in the Journal of Medical Internet Research.

128 overweight volunteers were randomly assigned a weightless intervention through either the app, a paper diary or online over six months.

Those who used the apps were more likely to adhere to the weight loss diary than the other two groups (a mean of 92 days for the app, compared to 35 days for the website group and 29 days for the paper-based group).

Weight loss for the app group was also significantly higher than the other groups (4.6 kg in the app group, compared to 2.9kg in the paper-based group and 1.3kg in the website group).

The app users also reduced their BMI and body fat by a greater amount than the other two groups.

Source:
https://www.leeds.ac.uk/news/article/3389/smartphone_way_to_lose_weight
https://www.ncbi.nlm.nih.gov/pubmed/23587561

Activelifestyle (Switzerland)

WHAT DOES IT DO?

This is a tablet-based app, designed for older people. It offers older people a home-based strength and balance training programme, with motivation strategies incorporated into the app. Strength and balance exercises are important to improve fitness and prevent frailty, and can support more older people to remain in their home for longer.

HOW DOES IT WORK?

The app offers a home-based exercise plan to improve strength and balance in older people. Being able to do these exercises at home, independently, can give more people, especially in rural or remote areas, the opportunity to take part in these exercises.

The app monitors and motivates the person doing the exercises at home. The instructions are through videos and written and oral guidance. The app also contains individual motivation strategies, such as setting targets, positive and negative reinforcement and information on the health benefits of these exercises.

WHO WAS INVOLVED?

The app was developed by a Swiss organisation, Spitex Zurich.

WHAT IS THE EVIDENCE?

A peer-reviewed study found that those who used the app intervention had improvements in total walking time and improved their gait and physical performance compared to another group who used a paper-based intervention. Those who used the app improved their walking speed by 10cm per second compared to the paper-based group, and displayed lower variability of gait, which is associated with lower rates of falls.

Source:
https://www.ncbi.nlm.nih.gov/pubmed/24966165

WHAT MAKES FOR A SUCCESSFUL HEALTH APP?

There is a general consensus in the literature on what the ideal features of a health app should be[44][45][46][47]. This is not to say all apps contain all of these features; but the most successful and effective health apps certainly contain many of these:

- User-centric design: An app that is built around the user, with high degrees of accessibility.

- Health professionals involved in the design or development of the app.

- High degrees of interoperability: Data can transfer easily between different devices and broader health systems.

- Informed by best practice: Such as NICE Guidelines.

- High levels of data privacy and security: Visible privacy policies and suitable levels of encryption when sending data.

- Evidenced: Follows health behavioural change theory and has been evaluated.

CHARACTERISTICS OF THE CASE STUDY APPS

There are 325,000 health apps available on major app stores, and many are not evaluated, or have few downloads or not based on credible health behavioural change theories[48]. However, some do. This paper has highlighted some health apps worthy of a closer look. What is of value to health policy makers, health professionals and app developers is to analyse these best-practice apps and consider why some health apps do meet high standards, and others do not. Of course, many apps are developed purely as a business model with limited altruistic purposes. But some health apps do effectively combine business innovation with a product that can demonstrate better health outcomes for people.

From considering some of the best practice health apps in the case studies of this report, it is apparent that successful apps often:

Have a specific focus

There are many ill-defined health apps available that aim to improve general wellbeing, or to improve more than one health behaviour at once. However, the best-practice apps identified through this research indicates that a more successful approach is to focus on one condition or one lifestyle behaviour. Examples of this include myCOPD, which helps users manage the symptoms of chronic obstructive pulmonary disease, and Activelifestyle, which specifically helps older people with restricted mobility exercise. If a health app has a tighter focus, it can be better informed by best practice and theory, rather than trying to adopt a blanket approach to changing multiple health behaviours.

Involve multidisciplinary teams

It is clearly important that the teams who develop these apps come from a varied professional background. The apps in the best-practice case studies all involve combinations of academics, health professionals and app designers. This may appear to be obvious, but research into health apps show that too many are not informed by medical best practice or behavioural change theory. The most important element of the team appears to be involvement of an academic institution. As this paper addresses, one of the main barriers to health apps not meeting their true potential is that too many apps are on the market without a credible evaluation. The potential, in terms of more of the population being able to access effective tools to prevent diseases and improve their health, can only be reached if consumers can easily identify apps that demonstrate improved health outcomes. Academic partners are able to evaluate apps for effectiveness, in a peer-reviewed process. Apps such as Step Away, My Meal Mate and Activelifestyles are all lead by academic teams, who were able to undertake this evaluation.

Are informed by health behavioural change theory

Because these best-practice apps are mostly developed by multidisciplinary teams, this means that they can be informed by relevant health behavioural change theory. My Meal Mate was designed in collaboration with the University of Leeds and an app developer. Whilst many apps are available that claim to improve the user's diet and help them lose weight, this was the first free app of that kind to be informed by scientific evidence, and shown to have clinical effectiveness. The Gray Matters app was underpinned by research into behavioural models, taking an informed approach of learning from each relapse of health behaviour. Clearly, if an app is informed by solid and relevant theory, this improves chances of effectiveness.

Offer instant connectivity

Being able to connect with peers is also a feature of some of these best practice apps. Step Away, designed to reduce alcohol intake, has a feature that allows the user to set up a support network of family and friends, and share progress with these people. For Big White Wall, designed to help people manage their mental health, communicating with peers through the app is the primary function, and can allow people who are stressed and anxious to discuss issues anonymously. The ability to instantly connect with peers is one of the areas that differentiates apps from other health behavioural interventions.

OTHER EXCITING INNOVATIONS

As explained in Chapter Four, there are a number of barriers that prevent an app being evaluated for effectiveness. Primarily, the challenges are the business model of the industry (a low cost of entry resulting in a proliferation of apps, with little commercial incentive to evaluate) and the disparity between the fast development of smartphone technology and the three to five-year period needed to conduct a randomised controlled trial.

However, we should not discount the emerging innovation in health apps that are not yet evaluated. This section examines more recent developments in health apps that should be of interest to health developers. These make use of new technologies, or look to improve outcomes in areas of health that are starting to be recognised more, such as mental health.

New technology

Many of the apps that have been evaluated, and therefore included in the case studies of this paper, rely on the user inputting their data manually. The promising part of the app isn't the data input, which essentially is not that different from writing the data physically, but the usefulness of the app to send reminders and notifications, and to reactively set health behavioural goals.

A next generation of mobile health technology, however, can be even more revolutionary through features such as AI and sensors to passively collect and analyse behavioural data to develop just-in-time interventions based on smart algorithms. Whilst the research and literature is not yet developed enough for this emerging technology to be too much of a focus of this paper, it is valuable to highlight some of the most promising areas of innovation in health apps and mobile health technology:

Sensors: Dexcom are a company that uses a small sensor underneath the skin to continuously monitor blood glucose levels. Diabetes sufferers can then track blood sugar levels on an app, to monitor glucose[49]. Passive sensors that can be used to monitor gait and link changes in walking to health status is promising in the field of care for older people.

Voice interfaces: Amazon's Alexa is being developed to make the voice recognition more useful for health care purposes, such as helping young mothers, diabetes management and age-related care[50].

Scanners: MyFitnessPal can use a mobile phone's camera to scan barcodes of food, before uploading them to an app so a user can track the calories consumed in a day[51].

Smart pills: Proteus is a 'smart pill' that is powered by the body when swallowed. Once inside the body, the sensor can track heart rate, physical activity, sleep patterns and tracks what medication is being used[52]. Abilify MyCite, made by Proteus, has recently been approved by the FDA in the US.

Gamification: A pioneering approach to health behavioural change, the term 'gamification' is used to describe reward-based activities built into apps. For example, mySugr is an Austrian app designed to help people manage their diabetes. It offers rewards points, daily challenges and a goal to beat the 'diabetes monster'[53]. This is designed to increase user engagement and retention.

Social media usage algorithms: Microsoft research developed an algorithm to analyse pregnant women's Twitter feeds. When applied, the researchers were able to predict with 80% accuracy whether a woman would go on to develop postnatal depression[54].

Health hubs: Using the internet of things, there are now products that connect home technology and remote monitoring to provide an integrated 'health hub' in the home, to monitor a person's health and movement and alert health professionals and family members in health emergencies[55].

Mental health

There has been greater public and political awareness of the need to reform mental health services and treatment in the last few years. Recently, the Five Year Forward View for Mental Health has been published, the Government has committed to reform mental health legislation[56]. However, waiting times remain high, with some patients waiting up to more than a year for talking therapies[57]. Delays in treatment not only result in distress to the individual, but people with serious

mental illness "face twice the risk of diabetes and death from heart disease, three times the risk of hypertension and a fourfold increase in all-cause premature mortality when compared with the UK general population"[58]. Therefore, enabling people to better manage their mental health (with appropriate medical support) is vital. Promisingly, research indicates that rather than mode of therapy, it is levels of user engagement that is influential in positive mental health outcomes[59]. On this issue, one opinion piece in the BMJ stated "given that just 50% and 13% of patients currently have a choice of when and where they receive therapy, apps may not only be equally effective as some forms of traditional psychotherapy, but also provide a flexible and pragmatic means of increasing patient access"[60].

Mental health apps, like many emerging health app technologies, must be treated with cautious interest. As discussed in the 'barriers' chapter of this paper, too many apps lack an evaluation. However, the technology evidently has potential, and can provide interesting ways for people with mental health conditions to access support from peers or health professionals, or even receive therapy. Whilst these are by no means at this early stage a replacement for established face to face talking therapies, there is promise.

Wearables and integrated mobile health platforms

It is worth acknowledging some of the most popular pieces of mobile health technology, wearables and integrated mobile health platforms. Wearable devices, such as Fitbit and Apple Watch, are popular with many people, and the manufacturers claim that wearing these devices will motivate users to exercise more[63]. However, the evidence behind wearables is very much still in its infancy, and as the focus of this report is how people can be directed towards 'what works', wearables will not be assessed in this report. In fact, a recent study published in the Journal of the American Medical Association found that people who used wearable fitness trackers lost less weight than a group who self-monitored their diet and exercise[64].

PROMISING MENTAL HEALTH APPS INCLUDE:

BIG WHITE WALL:
An online service to improve mental health and wellbeing. It provides online resources such as self-improvement tools, as well as an online forum that is fully moderated for people to receive peer support[61].

SLEEPIO:
An app that follows a CBT-based course to improve symptoms of insomnia. An evaluation of the app found that it helped 75% of people improve their sleep to healthy levels[62].

Another popular mobile health platform is integrated platforms such as Samsung S Health and Apple Health. Again, these apps have no serious evaluations behind them in terms of positive health outcomes, and therefore not within the scope of this report. However, their potential are worth noting as they could have a useful role in the future, in term of collating different datasets and being an all-in-one platform for different health metrics.

A goal of greater patient engagement

A common thread across these new app developments is that they aim to ensure that people have greater involvement in their own health. This is a positive development. Studies show that if patients record their own data, they are more engaged, which is vital for positive health behavioural change[65]. These technologies all promise to improve this engagement, make people more aware and involved in maintaining or managing their health, and with developments such as predictive analytical systems using home monitoring to accurately identify early interventions, these technologies can benefit both individuals and health systems[66].

What next?

This chapter demonstrates the promise this app technology can hold. Established apps have been shown to be effective in reducing harmful drinking, losing weight and improving cognitive function. There is also evidence

that the market for health apps is open to innovation; new technologies, such as sensors and smart pills, are being developed and connected to apps. These have clear potential to disrupt health behaviours in an influential way. We have also analysed the common features of effective apps, which is helpful for developers and health professionals to considers when attempting to address the barriers that are preventing health behavioural apps reaching their true potential. This next chapter addresses these barriers.

Barriers

This chapter will address the main barriers that developers, policy makers and health professionals face in ensuring that these health behavioural change apps meet their potential. The literature addresses several barriers, the most prominent being evaluation and accreditation and security.

Evaluation, accreditation and regulation

The most fundamental barrier to health behavioural change apps is that whilst there are a number of good apps available in terms of effectiveness and innovation, there are many apps available to the public that are lacking credible evaluations on their effectiveness. This section explores the barriers to effective evaluation, before looking at the barriers faced by setting up effective regulation of these health apps.

Whilst there are a number of health apps that have been shown to have a positive effect on health behavioural change (see Chapter Three), the evidence base for many other health apps is poor[67]. For example, a study on mental health apps found a high volume of apps compared with published evaluations; whilst 1,536 were able to be downloaded, there were only 32 published articles on depression apps[68]. In the old version on the NHS Health Apps Library, only two out of the 14 depression apps applied validated metrics, and only four out of the same 14 accredited apps provided any evidence of patient reported outcomes to provide effectiveness[69]. A study on apps aiming to increase physical activity found varying levels of adherence to established behavioural change theory. From their sample "every app contained at least one BCT [behavioural change theory]. With an average number of 7, and a maximum of 13 BCTs"[70]. The problem of the lack of validation and unevidenced nature of many direct-to-consumer health apps has led to some medical professionals naming them "digital snake oil"[71].

There are two main reasons for this low evidence base; the fast-changing nature of apps make randomised controlled trials often an unsuitable method of evaluating effectiveness, and the low barriers to market entry mean that the sheer volume of apps ensure only a small number are evaluated.

Smartphone technology and the capabilities of apps mean that the gold standard of evaluation, a randomised controlled trial, is often a futile exercise. A sizeable randomised controlled trial can take 3-5 years to complete[72]. This means that "by the time clinical trials are published, there can be substantial differences between the tested version and the current version of the app"[73]. Indeed, the platform on which an app is hosted on may even be obsolete before a randomised controlled trial is complete.

One example is a large scale RCT on the effectiveness of a weight loss programme delivered through a personal digital assistant (PDA) that was published in 2013, long after smartphones had made PDAs obsolete as a technology[74].

Evaluating, regulating and certifying is resource heavy, in a market with low cost barriers to entry. These reasons lead some people to argue that "the number of apps will far outpace any centralised evaluation mechanism"[75]. Whilst poor quality drugs and medical machines rarely reach market, this is not true for health apps, as the market does not currently incentivise evaluation[76].

The challenges leave considerable questions for the NHS. Does it continue to attempt to conduct its own evaluation and accreditation methods, as seen in its relaunch of the NHS Apps Library? Or does the new reality of ever-evolving and proliferating technology mean that a more flexible, responsive evaluation and accreditation framework is necessary? In the next chapter, this paper looks at the characteristics of successful apps, examining why some apps can be evaluated effectively, and explores some possible solutions to some of the biggest barriers that are preventing health behavioural change apps meeting their true potential, including international comparisons of accreditation policies.

Security

At the time of this report being produced, the UK news cycle is dominated by allegations of data mishandling by Facebook, which has provided a catalyst for people to reflect on how much they value their data privacy. Health data privacy is a complex subject, and addresses many concepts and arguments that are beyond the scope of this paper. The increase in importance of data in healthcare has made the balancing act between individual privacy (a person's data is theirs to own and has autonomy in who they share it with) and the collective good (those who use the NHS for free at the point of use should have to allow some of their anonymised data to be used in health care planning and research). These pushes and pulls of data privacy approaches are apparent in legislation, with the Nuffield Trust highlighting the inherent contraction between the Data Protection Act that enshrines personal privacy of patient data and the Health and Social Care Act that encourages data sharing and transparency[77].

However, the data security issues concerning health apps are more fundamental than this. The two main challenges are[78]:

- **Data theft or loss:** This can occur when patient data is stolen by malicious users, through ransomware, especially data stored on the cloud. Alternatively, personal health data could be transferred to another country or area with weaker data jurisdictions. This is of particular concern if data is unencrypted.

- **Unwitting data sharing:** This can occur when app privacy policies are not clear enough, and therefore users do not have enough information to give informed consent. Some apps work on the model of a free tool or service in exchange for personal information, which increases the risk of unwitting data sharing.

A number of studies have demonstrated the privacy concerns of apps in the UK. Out of a sample of 65 randomly selected health apps available in the UK, one study found that 29% did not have a privacy policy, whilst the majority of the apps in the sample shared Personally Identifiable Information with a third party[79].

The most serious concerns were caused by a study in 2015 that had a significant impact on the NHS's approach to using apps[80]. This study assessed all of the apps listed in the original NHS App Library against a number of privacy and security metrics. Concerningly, the study found:

- 66% of apps that sent personally identifiable information online did not use encryption

- 0 apps encrypted locally stored personal information

- 20% of apps did not have a privacy policy

- Four apps sent personally identifiable health information without encryption

The policy ramifications of this were severe. One month after the study was published, NHS England announced the closure of the Apps Library (it was relaunched under a different remit in 2017, see Chapter One).

Will GDPR improve security flaws?

The European General Data Protection Regulation (GDPR) will be enforced by data protection agencies across Europe, including the UK, from 25th May 2018. These changes update the UK's Data Protection Act, and aims to give more rights to individuals around how their data is shared and how individuals can consent to their data being shared. The legislation is complex and wide ranging; however, the most important new concepts of the legislation are that individuals can better access what information companies hold about them, enhanced responsibilities for business to better manage people's data, and stricter fines if these new rules are breached[81]. In the UK, these principles will be enforced by the Information Commissioner's Office (ICO).

At the time of writing this report, the impact of GDPR on health apps is unclear. The initial Directive appears to be robust; as always, it depends on the enforcement. Because every health app collects and stores sensitive data, they will need to comply with GDPR and subject to criminal law responsibility[82]. The threats of brand damage, legal threats and heavy financial penalties arising from GDPR could mean that these security concerns could be solved relatively quickly. However, the impact of the Directive is not yet clear.

These security and privacy flaws in some health apps lead to questions over accreditation. Users cannot be expected to completely understand technology data policies, or research the levels of encryption these apps use to store or transmit data. The system relies on trust. But what needs to be decided on is how users gain this trust. This could be from user ratings, or accreditation from app stores themselves. Or this could be achieved through a formal process of accreditation through the NHS, or a peer review. These issues are explored in the next section on challenges with accreditation.

Meeting the accreditation challenge

As the previous chapter demonstrates, there are a number of significant barriers that are preventing health behavioural change apps from meeting their potential. Promising innovations in health apps does exist, as Chapter Three shows. However, it is clear that without some structures in place to help the public identify effective health apps, their potential as a method for health systems to encourage healthy behaviours and prevent non-communicable diseases will be lost. This chapter therefore looks at the possibilities and challenges of an NHS-endorsed accreditation system.

MEETING THE ACCREDITATION CHALLENGE: WHAT THE NHS NEEDS TO CONSIDER

The evidence compiled in this paper indicates that whilst there are a number of effective apps available that successfully encourage positive health behaviours, the sheer number of apps available mean that it is difficult for users to find health apps that have been shown to be effective in improving health. Therefore, it is clear that accreditation or validation is needed. The NHS has already attempted to design a system of accreditation, that was withdrawn when it was shown to be ineffective (see Chapter One). Recently NHS England has revived these attempts. This section reviews methods of health app accreditation in the UK and internationally, before reviewing the new process from NHS England and analysing whether this approach is correct.

WHAT IS THE MOST APPROPRIATE ACCREDITATION SYSTEM?

There are clearly some arguments against the approach taken by NHS England. The disparity between the time needed for a gold-standard randomised controlled trial and the fast-changing nature of technology is still a challenge. However, the NHS Apps Library is the only system that could be identified in this research that

US APPROACH

In the US, the Agency that regulates medical devices is the US Food and Drug Administration (FDA). The FDA produce guidelines on "Mobile Medical Applications" that set out what they regulate and how they regulate. The FDA will regulate any apps that:

- *"Are intended to be used as an accessory to a regulated medical device"*

- *"Transform a mobile platform into a regulated medical device"*

Examples given include apps that aid in measuring blood pressure or apps that conduct diagnostic assessments using the phone speaker and/or microphone.

The guidelines state that they will use 'enforcement discretion' for other health apps that do not pose a risk to consumers, for example apps that:

- *"help patients self-manage their disease or condition without providing specific treatment suggestions"*

- *"provide patients with simple tools to organise and track their health information"*

This means that for most health behavioural change apps, the FDA does not have any involvement in ensuring quality or effectiveness.

Whilst this can ensure apps are safe, and they will evaluate and regulate apps that have the potential to cause harm, there are no processes to validate the effectiveness of a health app that helps people maintain a healthy lifestyle and manage their disease.

Source: *US Food and Drug Administration: https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm*

placed as its top priority the clinical effectiveness of the app in improving health. Without this priority, pursing a digital health agenda, with all its transformative potential, is pointless.

INDEPENDENT APPROACHES IN THE UK

Outside of the NHS, there are other approaches in the UK to validate health apps. The Organisation for the Review of Care and Health Applications (ORCHA) is an independent organisation that reviews apps. ORCHA actively reviews apps through a process that considers data security, clinical validity and user experience, giving an app a percentage score of each.

The website is user friendly and information is displayed clearly. However, the website does state that "a high-scoring app is not guaranteed to be effective or safe", and clinical effectiveness is only one part of the 'score'.

Source: ORCHA Website: https://www.orcha.co.uk/about/

EU APPROACH

EU-wide regulation of health apps has proved difficult. A working group was established in 2016 to set guidelines; however, no consensus was reached.

Source: European Commission Report of the Working Group on mHealth assessment guidelines: https://ec.europa.eu/digital-single-market/en/news/report-working-group-mhealth-assessment-guidelines

NHS ENGLAND APPROACH

NHS Digital relaunched the NHS Apps Library, with a more rigorous approach to accreditation than the previous version. There is a lot of promise in this approach, with the App Library hosting apps that have "been built on a solid evidence base". The library has a grading system, showing apps that have been fully tested by the NHS and shown to be clinically effective and safe, whilst others indicate that they are currently being tested.

Importantly, the launch of developer.nhs.uk provides guidance and information for developers and organisations who want to develop health apps to be used by the NHS. The plan is for NHS England to advertise what areas of healthcare have been judged to be in need of effective digital interventions. The website shows the 5-step process of assessing apps and gaining NHS accreditation, with information on the evidence needed in terms of safety, privacy and effectiveness required.

Whilst this is still in Beta phase, this is a promising and forward-thinking accreditation programme.

Source: NHS England: https://www.england.nhs.uk/blog/apps-library-is-advance-for-a-digital-nhs/

As we have addressed in previous chapters, a full randomised controlled trial is often unrealistic in terms of app evaluation. The time frame of three to five years to conduct this type of evaluation means that technological development will often outpace evaluation, and health system frameworks will continuously lag. The appropriateness of an RCT for all evaluations of health interventions is also discussed in the literature, with some academics questioning whether it is always the most appropriate evaluation in the complex nature of health interventions with many simultaneous variables[83]. A user-rated system is not effective on its own; it can be helpful in terms of assessing usability of the app, but there is little correlation between a high user rating on an app store and evidence of effectiveness in encouraging positive health behaviour.

NHS England appear to have learned from previous attempts, and the criteria that apps must meet before being invited to start the accreditation process appears to be high enough to filter out obviously ineffective health apps and accelerate the accreditation process, and the emphasis on evidence of effectiveness appears to be at a high enough standard without stifling innovation[84].

However, there are certainly areas that can be improved. NHS England must appreciate human behaviours and how people interact with technology more. For example, there could be more information available on how people can make a judgement on what apps might be more creditable than others. Whilst an NHS accredited app is ideal, the NHS can only evaluate so many apps at once. In the meantime, information on the App Library on what users should look out for (for example is it developed by a university and informed by scientific evidence) would be useful and it is a recommendation of this report that NHS England should develop an easy to read, public-facing guide or checklist so that people can better navigate the world of health apps and can better identify apps that are more likely to be effective.

There are other elements that could be improved. NHS England should work with approved developers to ensure that the NHS 'seal of approval' can be clearly identified by the public. Seeing as a main challenge to health apps making an impact on the population's health is that the sheer number of apps available mean that clinically effective ones are drowned out, these are relatively simple fixes that could increase the visibility of effective apps. These issues should be addressed before more apps are accredited by NHS England.

Conclusion

This research places the development of health behavioural change apps in a policy framework, analysing how health systems and policy makers can make the most of the proliferation of the new technology. This research shows:

Innovations in health apps show great potential

Technology may increase costs in health care; advancements in medical technology increases the number of diseases and conditions that can be treated, without necessarily reducing the unit cost. However, health behavioural change apps have the potential to reduce costs in one the most important areas of healthcare; public health and prevention. This is the area that health systems need to focus on if health spending is to be sustainable in light of population ageing and technological advances.

This report includes case studies of evaluated apps that have demonstrated their effectiveness in areas such as healthy diet, exercise and alcohol reduction. New technology just emerging also shows potential; using smartphone sensors and cameras to more efficiently track diets and measure blood sugar levels. These apps can also have a democratising effect, providing tailored advice and prompts on healthy living that were previously reserved for people who could afford luxuries such as personal trainers and nutritionists.

Our analysis shows large numbers of the UK population could benefit from effective health behavioural change apps

This report includes new analysis of Understanding Society, a large scale representative dataset. Analysing health behaviours that have been shown to be improved by apps highlighted in this report's case studies, we have highlighted groups of the population that could benefit from these apps. These include 760,000 over 60s who drink alcohol frequently and have a smartphone, 5.7 million under 50s who rarely exercise yet otherwise live healthy lives and 'just need a push' to exercise more, and 13 million over 50s who frequently use the internet, use a smartphone and are a population group that, if they reach older age in better health, will save the NHS money.

For maximum effectiveness, multiple actors need to be involved

It is clear from this research that the most successful health apps need to involve a wide variety of actors to produce an effective health behavioural change app. It requires developers to design an app that is user friendly and accessible and health professionals to ensure that app is informed by best practice on 'what works'. Of the apps selected as case studies in this paper, all involved academic institutions. This is vital. Robust evidence of outcomes is the biggest challenge to health apps meeting their potential, and this is often provided by academic partners.

Technology moves fast, and policy needs to respond accordingly

Policy is often too reactive to technological change, and policy makers find themselves playing catch up. This is true not just in health, but in many other policy areas, from transport to security. In terms of health apps, it is clear that different health systems and governments are taking different approaches to health app regulation and accreditation. The NHS and Department of Health have had to already withdraw their first attempts at accreditation in apps. However, there are a lot of positive elements of the new approach from NHS Digital, and it shows that the NHS is determined to be proactive in harnessing the true potential of health apps, whilst not stifling innovation. There will still be barriers that emerge, and there are areas to improve immediately, particularly on visibility of accredited apps. These are reflected in this report's recommendations. However, the building blocks are there of an NHS that is willing to work with developers, start-ups and other organisations to build and promote increasingly effective apps that can improve the health of large section of the population.

This report therefore recommends:

- Appreciating the time-consuming nature of evaluating a health app, NHS England should make available on the App Library information and guidance for users to make a judgement on whether one health app could be more effective than another.

- Better labelling of an NHS accredited app. At the time of publication, the only fully NHS accredited app did not include accreditation information on its website, and no accreditation mark on the app logo. An NHS 'seal of approval' should be easily identifiable on the approved apps logos.

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