The Growing Value of Digital Health in the United Kingdom

Evidence and Impact on Human Health and the Healthcare System
Introduction

The proliferation of Digital Health tools, including mobile health apps and wearable sensors, holds great promise for improving human health. As with other new health technologies, evidence of their effectiveness is a fundamental requirement of the health system and a limiting first step to adoption into clinical practice. Although analyses of the Digital Health landscape published by the IMS Institute for Healthcare Informatics in 2013 and 2015 found evidence still to be scarce and the value of Digital Health difficult to measure, this has now changed and the benefits to patients are becoming clearer. Efforts to incorporate these tools into practice in the United Kingdom are underway.

This report is adapted from the original IQVIA Institute report: *The Growing Value of Digital Health – Evidence and Impact on Human Health and the Healthcare System*, and focuses on the potential value of Digital Health in the United Kingdom. As digital tools focused on the detection, prevention and management of health conditions proliferate, this report explores the growing body of evidence that demonstrates their impact on human health and estimates the potential cost savings to the U.K. healthcare system. Trends in three areas — innovation, evidence and adoption — are examined.

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Executive summary

Over 318,000 health apps and 340 consumer wearable devices are now available worldwide. The value of these Digital Health tools to human health and the healthcare system is still evolving. There has been continued adoption by various stakeholders, exploration of innovative ways to apply these tools to health and growing evidence of their impact on human health outcomes. Since our study in 2015, over 153,000 new Digital Health apps were introduced to the Apple Store and Google Play, nearly doubling the number available, with more than 200 health apps being added each day. General wellness apps still account for the majority of health apps available to consumers, but those focused on health condition management — often associated with patient care — are growing and now account for 40% of all apps.

Although the range of health apps available present an overwhelming amount of options for consumers to choose from without guidance from their healthcare provider, there are now established leaders among apps for consumers to use. Just 41 apps with over ten million downloads each account for nearly half of all app downloads while over 85% of all health apps have fewer than 5,000 installs. There is now also at least one high-quality app for each step through the patient journey. The importance of Digital Health to healthcare is defined by such apps that are the leaders in their respective use category, and the value they deliver, while the plethora of lesser apps have little impact. These leading apps may have high patient ratings, frequent updates, connectivity to sensors, inclusion in healthcare institutions’ app formularies, endorsements and promising clinical evidence.

The overall body of clinical evidence on app efficacy has grown substantially, including randomised controlled trials (RCTs) and meta-analysis studies. Particularly strong evidence now exists for use in diabetes, depression and anxiety, making these categories strong candidates for incorporation into standard of care recommendations by clinical guideline writers. An additional 24 categories have one or more RCTs with positive results making associated apps strong candidates for adoption by healthcare stakeholders (e.g., provider organisations and payers).

The use of Digital Health apps in just five patient populations where they have provided some evidence of reductions in acute care utilisation (diabetes prevention, diabetes, asthma, cardiac rehabilitation and pulmonary rehabilitation) could save the U.K. healthcare system — including the public and private sector payers in England, Wales, Scotland and Northern Ireland — a conservatively estimated £170 million per year. This represents about 1.1% of total costs in these patient populations. If this level of savings could be extrapolated across total national health expenditure (not just these first five disease areas), annual cost savings of £2 billion could be achieved.

While the quality and clinical value of a leading group of Digital Health apps is becoming clear on a global basis, challenges remain in terms of how this value is realised in the United Kingdom. While the NHS Apps Library (Beta) has now listed 42 apps that have successfully navigated the new Digital Assessment Questions (DAQs), thereby endorsing them for use by patients and clinicians, this list only includes 2/26 Top Apps identified in this report (MyCOPD for pulmonary rehabilitation and OWise for breast cancer). While there are many anecdotal reports of pilots of Digital Health apps within the NHS, a minority of worldwide Digital Health efficacy studies have taken place in the United Kingdom. These figures indicate that while the United Kingdom — and specifically the NHS — have growing enthusiasm for Digital Health apps, routes to improve access to high-quality apps and facilitate more local studies of their benefit may be needed.

Despite progress to date, a number of barriers still exist to widespread adoption by patient care institutions, and only a limited level of adoption has yet occurred. Barriers to further use by physicians surround app selection, concerns around privacy and security, malpractice liability, financial incentives and
workflow integration. Few condition management apps – which offer the greatest potential impact on human health care and healthcare costs – have reached the level of workflow integration necessary to gain widespread physician adoption.

Before healthcare can be more fully supported by apps and sensors, a new fit-for-purpose infrastructure must evolve to support their delivery and incorporation into the standard health toolkit, similar to the type of ecosystem that exists to disseminate safe therapeutics. A variety of industry and policy initiatives have now emerged to address these barriers and accelerate the ongoing adoption of Digital Health tools by care facilities. Critically, app curation initiatives are facilitating the creation of formularies of high-quality apps; privacy and security guidelines are being published; patient access is being addressed by programmes such as the NHS England Innovation and Technology Tariff, efforts are underway to align Digital Health programmes with providers’ existing and emerging incentive structure; and interoperability initiatives create the potential for streamlined integration of Digital Health apps into physician workflow.
Proliferation of Digital Health tools

• Over 318,000 health apps and over 340 consumer wearable devices are now available worldwide, with over 200 health apps being added each day.

• General wellness apps still account for the majority of health apps, but the number of apps focused on health condition management — those often associated with patient care — are increasing faster and now account for 40% of all apps.

• Apps that provide disease-specific support and management have grown from 10% to 16% of all apps; the top five therapy areas they focus on are all chronic conditions.

• Very few apps account for the majority of downloads; just 41 apps with over 10 million installs each account for nearly half of all app downloads.

While “Digital Health” is defined in varying ways, the term is used throughout this report as meaning the use of connected mobile devices — including, but not limited to, mobile phones, tablets, consumer wearables, connected biosensors and in-home virtual assistants — to improve health (see Exhibit 1).\(^1\)\(^2\)

The value of these tools typically derives from abilities to communicate information through the internet, web or text messaging, to provide continuous monitoring of human health metrics or display health data more clearly.

MOBILE APPS

While Digital Health tools take on a variety of forms, the downloadable mobile app has taken on a central role, whether it be in aggregating data from wearable and other connected sensors or serving as a video chatting tool for telemedicine visits. This central role of the mobile app is partially explained by the extensive adoption and use of smartphones, with 81% of the U.K. population owning or having access to a smartphone, including 65% of those between the

Exhibit 1: Digital Health Tools

Source: IQVIA Institute, Sep 2017
ages of 65-75. Also, whereas traditional websites are generally a good way for individuals to occasionally obtain health information, mobile apps are well suited as “tools” to be used many times per day, such as to log calories, check blood glucose, or send a message to a health coach. Capitalizing on the opportunity this digital audience presents and the growing consumer interest in wellness, innovators continue to fill the market with mobile health apps.

There are now over 318,000 health apps worldwide – nearly double the number of apps found in our 2015 analysis and nearly five times those available in 2013.

Since our study in 2015, over 153,000 new Digital Health apps were introduced to the Apple Store and Google Play, adding more than 200 new health apps per day on average (see Exhibit 2).

Exhibit 2: Number of Digital Health Apps 2013, 2015 and 2017

In the current study, apps present in the AppScript App Database (representative of the most widely used Digital Health apps by consumers) were analysed by use category to understand the current Digital Health app market landscape. Across the patient journey, Digital Health apps can be divided into two main categories: those focused on “wellness management,” which facilitate tracking and modification of fitness behaviours, lifestyle and stress and diet, and those which specifically focus on “health condition management,” which supply information on diseases and conditions, enable access to care and enable treatment protocols such as medication reminders. Since 2015, consumer Digital Health apps targeting wellness management have dropped as a proportion of total apps from 73% to 60%, with a corresponding 48% increase in the share of apps focused on health condition management (see Exhibit 3). Condition

“The trend line is up and to the right on the percentage of every population who’s starting to track [their health digitally] because it’s becoming easier and easier to do so. You can look at just smartphone adoption in the [U.S.] Medicare crowd…. It’s a common, popular theme to say, ‘Oh this isn’t going to work for the population who’s the most in need of these things’, but it’s just not true. The numbers are still smaller than for 30 year olds who use it but it’s not as small as you might think.”

Christine Lemke, President, Evidation Health
management apps now account for 40% of all Digital Health apps, with notably those focused on specific diseases having grown from 10% to 16% of all apps, and those which provide medication reminders having grown from 7% to 11%.

For apps that provide disease-specific support and management, the top five therapy areas they focus on are all chronic conditions: mental health conditions, diabetes, heart and circulatory conditions, nervous system disorders and musculoskeletal conditions (see Exhibit 4). Mental health remains the largest focus for disease-specific mobile apps, with many apps available for conditions such as autism, depression, anxiety and attention deficit hyperactivity disorder.

The range of health apps available present an overwhelming amount of options for consumers to choose from without guidance from their healthcare provider. In the absence of this guidance, consumers will often select the top app in terms of popularity or downloads (a.k.a. installs), such that very few apps account for the majority of downloads. On the Google Play store, 41 apps with over 10 million downloads each account for nearly half of all downloads (see Exhibit 5). Over 85% of all health apps have fewer than 5,000 downloads.

WEARABLE BIOSENSORS AND OTHER CONNECTED DEVICES
Many apps also connect to sensors. Biosensors, as an overall category of devices, collect information on a variety of health parameters and vital signs by reading or measuring energies from a person – e.g., pressure, temperature, light, etc. – and transmit that data via electric signals to be interpreted. Among these, activity monitors measure consumer motion patterns (e.g., movement, rotation and position) and translate them into measures of routine activity like sleep, steps and exercise, among others. Since the release of Fitbit to the market in 2007, a growing number of individuals have adopted wrist-worn wearables like fitness trackers and smartwatches to help track their
Exhibit 4: Disease-Specific Apps by Therapy Area

Sources: 42 Matters, Jul 2017; IQVIA AppScript Database, Jul 2017; IQVIA Institute, Jul 2017

Note: Includes Android apps only. iOS data not available.

Exhibit 5: Digital Health App Downloads

Sources: 42 Matters, Sep 2017; IQVIA AppScript Database, Sep 2017; IQVIA Institute, Sep 2017

Note: Includes Android apps only. iOS data not available.
activity levels, and provide real-time feedback to aid in motivation. Based on analysis of the AppScript Device database, 344 consumer wearable biosensors are now available worldwide, with fitness trackers and smartwatches accounting for 47% and 13% of these devices, respectively. Although activity monitors have been among the most popular, there are now a vast range of connected biosensors that transmit health information wirelessly to mobile apps (see Exhibit 6). Users can interact with a biosensor briefly, such as a glucometer, or wear them for continuous data collection.

**Exhibit 6: Examples of Connected Biosensors**

<table>
<thead>
<tr>
<th>ACTIVITY MONITORS</th>
<th>PARAMETER-SPECIFIC BIOSENSORS</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Activity Monitor 1" /></td>
<td><img src="image2" alt="Pulse Oximeter" /></td>
</tr>
<tr>
<td><img src="image3" alt="Activity Monitor 2" /></td>
<td><img src="image4" alt="Thermometer" /></td>
</tr>
<tr>
<td><img src="image5" alt="Activity Monitor 3" /></td>
<td><img src="image6" alt="Blood Pressure Monitor" /></td>
</tr>
<tr>
<td><img src="image7" alt="Activity Monitor 4" /></td>
<td><img src="image8" alt="Weight Scale" /></td>
</tr>
<tr>
<td><img src="image9" alt="Activity Monitor 5" /></td>
<td><img src="image10" alt="ECG Monitor" /></td>
</tr>
<tr>
<td><img src="image11" alt="Activity Monitor 6" /></td>
<td><img src="image12" alt="Blood Glucometer" /></td>
</tr>
<tr>
<td><img src="image13" alt="Activity Monitor 7" /></td>
<td><img src="image14" alt="EEG Monitor" /></td>
</tr>
</tbody>
</table>

Sources: IQVIA Institute, Sep 2017

Note: Activity monitors include fitness trackers, smartwatches, sleep trackers and actigraphy devices.
Delivering value to patients and the health system

• High-quality apps – those with characteristics such as high patient ratings, frequent updates, connectivity to sensors, inclusion in Digital Health formularies, endorsements, and promising clinical evidence – now exist for each major type of healthcare use.

• The overall body of clinical evidence on app efficacy has grown substantially and now includes 571 studies, including 234 randomised controlled trials and 20 meta-analysis studies.

• Particularly strong evidence now exists for diabetes, depression and anxiety that may be considered by clinical guideline writers for incorporation into standard of care recommendations.

• The strengthening maturity of clinical evidence in diabetes, cancer, post-traumatic stress disorder (PTSD), arthritis, stroke, genitourinary conditions, pulmonary rehabilitation and dental uses has been significant over the past three years, with new studies showing significant benefits vs. controls; however, exercise, autism and bipolar disorder experienced disappointing study results.

• Of the top 26 apps, 80% have at least one positive observational study demonstrating clinical efficacy, over half connect to an external sensor, one quarter are not publicly available to patients and one-fifth are cleared by the U.S. FDA.

• The use of Digital Health apps in five patient populations where they have proven reductions in acute care utilisation (diabetes prevention, diabetes, asthma, cardiac rehabilitation and pulmonary rehabilitation) would save the NHS £170 million per year and provide tangible health outcomes improvements.

• Extrapolating this level of cost savings – approximately 1.1% – to total U.K. national health expenditures indicates the NHS may experience total cost savings of ~£2 billion per year

VALUE ALONG THE PATIENT JOURNEY
A large supply of apps exists for nearly every use across the patient journey. However, Digital Health apps will ultimately be judged – like any other medical technology – not by their quantity but by their value to human health and the healthcare system. Value in healthcare can be defined as the health outcomes created for patients relative to the cost of generating those health outcomes, as well as the extent to which the “triple aim” of improving the patient experience, improving the health of populations, and reducing the per capita costs of healthcare is delivered.

Digital Health apps have a range of potential mechanisms for delivering value. To patients, Digital Health apps have traditionally been seen as a way to promote their personal wellness goals, however, increasingly, patients are looking to apps to facilitate access to the health system itself with a greater level of convenience. The traditional dynamic is represented by one survey that found 36% of U.K. patients currently use mobile health apps, with exercise and healthy eating apps more popular than clinical records apps (i.e., “patient portals”). More recently, another survey of 100 U.K. adults found that 97% wanted the NHS to provide access to Digital Health technologies including the ability to book mobile app video appointments, and a number of apps have recently been introduced to the U.K. market (e.g. Echo, DIMEC, Healthera) to help patients order repeat prescriptions. These trends seem to indicate that while patients were originally mostly interested in personal wellness apps, they are increasingly seeking apps that provide convenient access to the U.K. health system, whether that be appointments or repeat prescriptions.

Physicians often see the value of Digital Health apps in terms of spurring patient engagement, promoting more efficient provider-patient communication, and creating new modalities for condition diagnosis and monitoring. A poll of 1,300 physicians found that these healthcare professionals are most attracted to Digital Health tools to improve work efficiency, increase patient safety, and improve diagnostic
ability.\textsuperscript{8} Separately, a poll of 595 healthcare executives, clinical leaders, and clinicians found the top benefits of Digital Health tools to be their ability to support patients’ efforts to be healthy (67\% of respondents) and providing input to providers on how patients are doing when not in clinic (60\%) through remote patient monitoring.\textsuperscript{9}

How apps provide value to patients and the health system depends on where the app is used in the patient journey (see Exhibit 7).

**Wellness and Prevention** apps and their connected sensors support patient efforts to set health goals (e.g., losing weight), track daily lifestyle changes (e.g., reducing calories), and monitor their progress achieved (weight loss vs goal). The value of such apps is associated with the mitigation of risk factors, such as obesity or smoking, which impact long-term costs to the health system. Globally, payers with budget responsibility for patients over the longest periods of time, such as the NHS, stand to benefit the most from these apps. This value explains the strong efforts Public Health England and others have been making in encouraging the promotion of high-quality Wellness & Prevention apps in England. Wellness and Prevention apps have also become extremely popular. Under Armour alone – the owner of the popular MyFitnessPal, MapMyFitness, and Endomondo apps – claims more than 200 million registered users with 100 thousand new users signing up each day.\textsuperscript{10} The vast majority of Wellness & Prevention apps are currently downloaded by patients independently of a physician’s guidance, however physicians may begin to take a more active role in recommending such apps. Physicians already have a high level of familiarity with Wellness & Prevention apps, and with a low perceived risk to patient safety many are comfortable recommending them. The expectations for clinicians to take time to review collected data are also modest and there is high availability of good free and publicly available apps. Furthermore, Wellness & Prevention apps – including exercise, healthy eating, smoking cessation and stress management apps – are increasingly being included in the NHS Apps Library. To the extent that the NHS Apps Library creates a real or perceived safe harbour for clinicians to actively prescribe the included apps, clinicians may be more likely to do it.

**Exhibit 7: Digital Health in the Patient Journey**

<table>
<thead>
<tr>
<th>Wellness &amp; Prevention</th>
<th>Symptom Onset and Seeking Care</th>
<th>Diagnosis</th>
<th>Condition Monitoring</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wellness &amp; Prevention</strong></td>
<td>Exercise &amp; Fitness</td>
<td></td>
<td></td>
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<tr>
<td>Diet &amp; Nutrition</td>
<td>Lifestyle &amp; Stress</td>
<td>Stress Management</td>
<td>Sleep/Insomnia</td>
<td>Smoking Cessation</td>
</tr>
<tr>
<td><strong>Wellness &amp; Prevention</strong></td>
<td>Patient Experience</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tools</td>
<td>Information</td>
<td>Checking</td>
<td>Finding a Clinician</td>
<td>Managing Clinical and</td>
</tr>
<tr>
<td><strong>Condition Education &amp; Management</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Self-Monitoring</td>
<td>Remote Patient Monitoring</td>
<td>App-Enabled Rehabilitation Programme</td>
<td></td>
<td></td>
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<tr>
<td><strong>Condition Monitoring</strong></td>
<td></td>
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<tr>
<td><strong>Prescription Filling &amp; Compliance</strong></td>
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<td></td>
</tr>
<tr>
<td>Prescription Discounts</td>
<td>Prescription Filling</td>
<td>Medication Management</td>
<td>&amp; Adherence</td>
<td></td>
</tr>
</tbody>
</table>

Physician may recommend app-supported disease management programmes, connected sensors for remote monitoring, or apps for any use case across the patient journey.

Source: IQVIA AppScript Use Categories. IQVIA Institute, Sep 2017
**Patient Experience Tools** help patients manage their interactions with the healthcare system via new digital channels that offer added convenience. Whether providing access to health records or scheduling appointments (either for physical in-person or virtual telehealth visits), the value of these apps involves their ability to make the experience of healthcare easier and more satisfying for patients while promoting provider efficiency. These tools appear to be a major focus of the NHS moving forward. For example, the U.K.’s Secretary of State for Health, Jeremy Hunt, has discussed the need to have apps that provide seven functionalities by the end of 2018, including the ability to (1) access NHS 111, (2) access health records, (3) book a general practitioner appointment, (4) order repeat prescriptions, (5) set organ donor preferences, (6) express data sharing preferences, and (7) access support for long-term conditions.

**Condition Education and Management** apps provide condition-specific tools, often for daily use by those afflicted with the condition or their family caregivers. Patients with conditions – particularly complex, chronic conditions – often need tools that provide appropriate education on how to perform new tasks (e.g., measuring blood glucose), enable them to store notes (e.g., blood glucose logs), and track progress towards goals (e.g., keeping blood sugar in range). The value of such apps is often measured in terms of traditional health outcome measures, such as improvements in laboratory test results (e.g., HbA1c) or avoidance of condition destabilisation (e.g., hyperglycaemia) leading to acute care utilisation. To date, adoption of Condition Education and Management apps has been predominantly by patients and their caregivers for self-management, however some healthcare providers are beginning to incorporate remote monitoring of patient-generated health data into their workflows. Some examples of condition management tools include:

- **Self-Monitoring Apps** that help patients track their specific condition over time for their own personal use. One example is the Start app by Iodine Labs (acquired by GoodRx), which helps patients monitor the efficacy and side-effects of new antidepressants. Users of the Start app are asked questions from the PHQ-2 and PHQ-9, which are two scales used in depression. Users can see how their results change over time as an objective measure of whether their medication may be working. This information may help patients communicate their symptoms to clinicians at their next office visit, potentially accelerating the process of finding an appropriate antidepressant.

- **Remote Patient Monitoring Apps** that enable clinicians and population health case managers remotely monitor patient data. The value of Digital Health to conduct and optimise remote patient monitoring is significant. By identifying patients with vitals or values out of range, and alerting the care team, Digital Health apps and sensors can narrow the number of patients a nurse or care manager has to call and help prioritise their lists, providing a smarter route to providing continuity of care. By making care managers more efficient they can get relevant patients into the office sooner when there is an issue. Examples of such health interventions, along with physician recommendation of apps, are shown in Exhibit 8.

- **App-Enabled Rehabilitation Programmes**, such as for cardiac and pulmonary rehabilitation patients, that reduce the requirement for patients to visit a physical place multiple times a week. For example, the MyCOPD app provides an app-based alternative to traditional face-to-face pulmonary rehabilitation programmes. A randomised controlled trial (RCT) found the MyCOPD app to be non-inferior to the traditional approach. The app, heralded as way to reduce costs, was nationally commissioned by NHS England to support moderate and severe Chronic Obstructive Pulmonary Disease (COPD) patients up to 20% of each Clinical Commissioning Group’s total COPD patient population.
Clinician sets health goals and targets

Recommends connected sensor or app for condition management (e.g., for hypertension BP monitoring)

Patient or Insurance buys sensor device
Patient measures actively (e.g., glucose, BP) or passively (e.g., actigraph)

Data recorded and analyzed by app

Alerts triggered by app or by EHR when out of range
Health values in concerning range or trend prompts patient or physician

Recommends use of apps and/or sensors

Recommends adherence app related to drug Rx
Ineffective medicine usage can be recorded, offering clinician the ability to instruct patient on proper use or change drug

Recommends app or activity tracker for patient engagement
Patient self-monitoring on interactive wellness apps
Analysis on app of weight loss, activity, meals

Digital tools shipped to patient
Weight scale, activity tracker/pedometer, exercise device, glucometer

Health data collected
Scheduled weigh-ins
Exercise logging from pedometer/glucose monitoring from connected glucometer e.g. Patient reported meal tracking

Data recorded and analyzed by app

App may provide analysis, alerts and guide diet changes (calorie counting)

Health coaching
Either real life or electronic coach for motivational support and guidance; data shared with coach

Participant peer group
Social support helps maintain engagement

Health lessons and daily guided plans

Employers and payers may also pay for disease management and wellness programmes that include incentives

Little physician interaction occurs with data from wellness apps. Data is more often shared with family, or paid health coaches
Wellness data can be shared during telehealth visits via various apps

Sources: IQVIA Institute, Sep 2017; Quan R, Omada Health. Using Data Science to Design Effective Precision Preventative Behavioral Medicine. Slideshare, Nov 2016
Note: Health coaching may come from population health managers, care coordinators, health coaches, case managers and care managers.

Exhibit 8: Use of Apps, Sensors and Digital Health Supported Programmes for Condition Management
“We live in an age of chronic illness. It’s very clear that you can’t just manage chronic illnesses in the four walls of the clinic. You have to be able to reach beyond the clinic, to where the patient lives, where they work, their particular situation in terms of support, from family and others… as well as the social factors that greatly affect how chronic diseases can be managed effectively, and what the outcomes will be. You need these [digital] tools. You need tools that allow you to interact with patients at a distance. You need tools that allow you to monitor certain things at a distance. You just can’t succeed by having the patient come to the clinic every so many months.” 

Dr. Michael Hodgkins, Vice President and Chief Medical Information Officer, American Medical Association

**Prescription Filling and Compliance** apps help patients find the best price for drugs, order repeat prescriptions from general practitioners, refill prescriptions from pharmacies, encourage medication adherence via reminders, ensure polypharmacy is appropriately managed, and provide targeted education on medicines and dosing instructions. They can also help mitigate the challenge that families face to ensure an aging parent is correctly taking their medicines. Digital Health tools in this space that can enhance medication adherence and reduce acute care utilisation offer a route to significantly impact healthcare costs. In that regard there is the potential for broad support from traditional stakeholders. High levels of adherence are associated with lower overall health care costs for a number of chronic diseases including diabetes, hypercholesterolemia, and hypertension where many medications are generic, as well as COPD and severe asthma.

A range of Digital Health tools have emerged to help encourage adherence or even allow caregivers to track and ensure medicines have been taken. Among these are mobile apps, such as AiCure that image and note patients taking their medications; digital “prescription compliance devices” for real time adherence monitoring, such as “smart blisters” (pharmaceutical packages capable of monitoring when a pill is taken out of its packaging) and smart pillboxes (e.g., Wisepill); and ingestible sensors such as Proteus, all of which help control dosage time of day by reminding patients and alerting caregivers to missed doses. Another mobile app, Medisafe, which pushes out medication reminders and alerts, showed it could increase cholesterol medication adherence by as many as three days of therapy per month. Mobile apps in this space have seen tremendous adoption. Google Play states that the Walgreens Android app has 10,000,000–50,000,000 downloads alone. The Medisafe and GoodRx Android apps both have 1,000,000–5,000,000 downloads.

To deliver value for a given use in the patient journey, there must be at least one high-quality app available to support that particular need or use. One approach
that has been developed to measure the quality of apps is the AppScript Score (see Exhibit 9 and Methodology section for quality rating methodology).

While a large number of apps of varying quality are available in each category, most app categories have at least one high-quality app (with an AppScript score of 8 or above).

Exhibit 9: IQVIA AppScript Score Overview – A Way to Measure the Quality of Apps

Rating Averages are Weighted to Create AppScript Scores

- **Professional**
  - AppScripts sent
  - Professional ratings
  - AppScript formulary inclusions

- **Patient**
  - App store ratings
  - App store reviews
  - Patient use metrics:
    - AppScript fill rate
    - AppScript retention rate

- **Functional**
  - Comprehensive functional assessment of an app’s ability to:
    - Inform
    - Guide
    - Instruct
    - Remind
    - Record
    - Message
    - Display

- **Endorsement**
  - Number of endorsing institutions
  - Type of endorsing institution

- **Developer**
  - Use of advanced development techniques
  - App update cadence

- **Clinical**
  - Number of studies
  - Type of studies
  - Outcomes of studies

Sources: IQVIA AppScript, Aug 2017

“For us, we’re not trying to push anyone into a particular channel. What we’re looking for are ways to reduce friction. We have multiple studies which have indicated that the folks who are using our digital channel, [our apps and online experiences], see that it makes things faster, easier and more simple – as you would assume, based on the results of these studies. If you make things easier for people, they are more likely to engage! We end up with adherence lifts and increases across other key performance indicators for people who are using our digital channel.”

Greg Orr, Vice President, Digital Health, Walgreens Boots Alliance
Exhibit 10: Distribution of AppScript Score by Digital Health App Category

Source: IQVIA Appscript App Database; Aug 2017
Score >75) with key quality characteristics such as (1) exceptional patient ratings, (2) connectivity to sensors, (3) rapid update cadence thereby ensuring that apps are reliable and incorporate the latest technologies, and (4) endorsements from at least digital publishers or patient advocacy groups and often from providers or government authorities (e.g., the NHS Apps Library) (see Exhibit 10). While each category generally has at least one high-quality app, average app quality is often low. This implies that while high-quality apps exist, careful app selection is required to ensure quality.

A GROWING BODY OF EVIDENCE
Since 2007, the number of peer-reviewed efficacy studies of Digital Health apps has grown dramatically. Of at least 571 efficacy studies published during this time period, a quarter (n=138) have been published in 2017 year to date (YTD) alone as of August 2017 (see Exhibit 11). Randomised controlled trials (RCTs) and meta-analysis studies, which are favoured by those stakeholders making evidence-based medicine decisions, collectively make up approximately 44% of the studies. Since 2007, 234 RCTs and 20 quantitative meta-analysis studies have been published.

This acceleration in activity is driven by the intersection of a sceptical environment with robust private-sector fundraising, an increasing ability to leverage real world evidence to deliver studies faster and more economically, intense interest from leading academic institutions, and new journals dedicated entirely to the field (e.g., "JMIR mHealth and uHealth").

While the overall volume trend for Digital Health efficacy evidence appears impressive, adoption...
decisions are likely to be made one app use-category at a time. To this end, it is important to understand the maturity of the clinical evidence – including the quantity, quality, and typical results of available evidence – at the category or individual app level.

Taking this approach, a large number of Digital Health app use categories have achieved an impressive level of clinical maturity (see Exhibit 12). Three Digital Health app categories have multiple positive meta-analysis studies, including Diabetes, Depression, and Anxiety. These app categories have been grouped as “Candidates for Inclusion in Clinical Guidelines” in the exhibit as the quality of evidence in these categories has begun to meet or exceed the typical requirements for inclusion in standard of care recommendations. An additional 24 Digital Health app categories have at least one RCT and a high propensity towards positive studies that have met their primary endpoint. These categories have been grouped as “Candidates for Adoption,” as individual commissioners often make adoption decisions based on this level of clinical
evidence. This grouping includes app categories with significant value creation potential including Weight Management, Asthma, COPD, Cardiac Rehabilitation, and Pulmonary Rehabilitation. Categories that have not consistently met their endpoints (e.g., exercise) have been grouped as “Potential Disappointments — More Study Required” as more nuanced approaches to applying or measuring these categories of Digital Health apps may be required to deliver more consistently positive results.

Since 2014, 11 Digital Health apps categories have changed their grouping, eight based on key studies published in 2017 alone (see Exhibit 13). Application of Digital Health apps to stroke, genitourinary conditions (e.g., incontinence), pulmonary rehabilitation, cancer, PTSD, and arthritis were lightly studied in 2014, but now have a clinical case for adoption. Alternatively, bipolar disorder and autism were little studied in 2014, but new studies have failed to create a fresh case for adoption. The story for exercise is even more


Source: IQVIA AppScript Clinical Evidence Database, Aug 2017
Notes: Only includes studies that evaluated the interventional value of a digital health solution (mobile or web app, connected device, or other mobile intervention such as texting) on patient outcomes such as activity levels, lab results, or healthcare resource utilisation. Significant movers defined as switching category. Average of study results for the highest quality evidence available (i.e., meta-analysis > RCT > Observational). Bubble size denotes cumulative number of efficacy studies.
Diabetes Candidates for Adoption

Four additional meta-analysis studies published by Hou et al (2016), Cui et al (2016), Bonoto et al (2017) and Wu et al (2017) show that diabetes apps have consistently delivered statistically and clinically significant HbA1c improvements (0.49%, 0.67%, 0.44%, 0.48%) in Type 2 Diabetics, with greater benefits in T2D than T1D, younger patients rather than older patients, and patients who received healthcare professional feedback via the app vs. those who did not.

Stroke General Lack of Studies

Meta-analysis published by Liu et al (2017) showed that mobile health interventions have generally mitigated key stroke risk factors including glycemic control (HbA1c) and smoking cessation (abstinence).

Arthritis Candidates for Evaluation in an RCT

RCT published by Skrepnik et al (2017) demonstrated that patients with knee osteoarthritis following treatment with hylan G-F 20 that used the "OA GO" app increased their mobility (measured via pedometer) faster than a standard follow-up control group.

Cancer Candidates for Evaluation in an RCT

RCT published by Denis et al (2017) showed that the "MoovCare" web app improved Overall Survival (OS) in lung cancer patients by 7mo (58%) vs. SoC control primarily via earlier and improved initiation of optimal treatment.

Pulmonary Rehabilitation General Lack of Studies

RCT published by Bourne et al (2017) showed that "MyCOPD" app is non-inferior to face-to-face pulmonary rehab.

PTSD Candidates for Evaluation in an RCT

RCT published by Kuhn et al (2017) showed that PTSD patients “PTSD Coach” significantly improved PTSD symptoms relative to a waitlist condition control.

Genitourinary Conditions General Lack of Studies


Dental General Lack of Studies

Observational study published by AlKlayb et al (2017) showed that the iTeethey™ app improved mothers’ knowledge of oral hygiene.

Exercise Candidates for Adoption

Meta-analysis published by Mateo et al (2015) showed that the body of RCTs in which a mobile phone app intervention was used to promote weight-related health measures or physical activity showed weight loss benefits but no physical activity improvements.

Autism General Lack of Studies

RCT published by Whitehouse et al (2017) suggests that the Therapy Outcomes By You (TOBY) app has mixed results in improving Autism Treatment Evaluation Checklist.

Schizophrenia / Bipolar Candidates for Evaluation in an RCT

RCT published by Faurholt-Jepsen et al (2015) showed that an app for self-monitoring and clinical feedback from a physician did not deliver statistically significant benefits on depression or mania (Hamilton Depression Rating Scale and Young Mania Rating Scale, respectively) vs the control group.

Sources: IQVIA AppScript Clinical Evidence Database, Aug 2017
dramatic. While Exercise is one of the most studied categories, recent studies — specifically the first meta-analysis in the category — have called the category into question.

**TOP APPS**

To generate a “Top Apps” list, a top-rated free and publicly available app as well as a top clinical rating app (regardless of business model) was selected across 16 high-priority Digital Health app categories with high app demand and app quality. This yielded 26 Top Apps within top “Free and Publicly Available” apps and top “Clinical Rating” app classifications (see Exhibit 14). This number is less than the 32 that might be expected because certain Digital Health app categories did not have any high-quality free and publicly available apps (e.g., Diabetes Prevention, Atrial Fibrillation Screening, Cardiac Rehabilitation, Pulmonary Rehabilitation) or had a Free and Publicly Available app that also happened to be the top Clinical Rating app (e.g., the Walgreens app in the Prescription Refills category).

Certain characteristics of the Top Apps are descriptive of the current state of the art in Digital Health. The vast majority of Top Apps have at least one positive observational study demonstrating clinical efficacy (21/26; 81%). The majority of Top Apps are iOS apps (17/26; 65%), however most of these apps have Android versions with similar features, endorsements and clinical evidence. More than half (14/26; 54%) connect to an external sensor directly or via a hub such as Apple HealthKit. About one quarter (7/26; 27%) – including about half of the Top Clinical Rating apps – are not publicly available to patients and instead require a payer or provider organisation to contract with the developer. About one-fifth (5/26; 19%) are cleared by the U.S. FDA (MySugr, Kardia by

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**Exhibit 14: Top Rated Apps, 2017**

<table>
<thead>
<tr>
<th>WELLNESS AND PREVENTION</th>
<th>TOP FREE AND PUBLICLY AVAILABLE</th>
<th>TOP CLINICAL RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise</td>
<td>Runkeeper by FitnessKeeper, Inc.</td>
<td>Fitbit by Fitbit</td>
</tr>
<tr>
<td></td>
<td>GPS-enabled fitness activity tracking; HealthKit integrated</td>
<td>GPS-enabled fitness activity tracking; food log, wireless device and smart-scale connectivity</td>
</tr>
<tr>
<td></td>
<td>Food log with barcode scanning capability; HealthKit integrated</td>
<td>Subscription-model health coaching with tracking and relevant content</td>
</tr>
<tr>
<td>Stress Management</td>
<td>Headspace By Headspace meditation limited</td>
<td>Headspace by Headspace meditation limited</td>
</tr>
<tr>
<td></td>
<td>Proprietary guided meditations as well as useful educational background videos</td>
<td>Proprietary guided meditations as well as useful educational background videos</td>
</tr>
<tr>
<td>Smoking Cessation</td>
<td>Kwit by Kwit SAS</td>
<td>Clickotine by Click Therapeutics, Inc.</td>
</tr>
<tr>
<td></td>
<td>Motivates users by tracking the accrued financial and health benefits of not smoking</td>
<td>Subscription programme includes coaching, connection to quit aids, as well as various tracking and educational features</td>
</tr>
<tr>
<td>Alcohol Moderation</td>
<td>AlcoDroid Alcohol Tracker by Myrecek</td>
<td>Drinkaware by The Drinkaware Trust</td>
</tr>
<tr>
<td></td>
<td>Alcohol consumption tracker, drinks diary and blood alcohol content calculator</td>
<td>Lifestyle app that tracks the units and calories in your drinks</td>
</tr>
</tbody>
</table>

Source: IQVIA AppScript Essentials, Aug 2017
<table>
<thead>
<tr>
<th>CONDITION MANAGEMENT</th>
<th>TOP FREE AND PUBLICLY AVAILABLE</th>
<th>TOP CLINICAL RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol &amp; Substance Abuse</td>
<td>My Spiritual Toolkit - AA 12 Steps App Alcoholics by LOOK BEFORE YOU LEAP NET, LLC</td>
<td>Pear reSET by Pear Therapeutics Inc. Contains a series of interactive therapy lessons with information to help support recovery</td>
</tr>
<tr>
<td></td>
<td>Content, personal diary, and calculators for recovering alcoholics</td>
<td></td>
</tr>
<tr>
<td>Diabetes Prevention</td>
<td></td>
<td>Omada by Omada Health, Inc. Intensive behavioral counseling (IBC) app shown to promote weight loss and reduce T2D incidence</td>
</tr>
<tr>
<td>Diabetes</td>
<td>mySugr by mySugr GmbH</td>
<td>BlueStar Diabetes by WellDoc, Inc. FDA-cleared app with 2 RCTs demonstrating efficacy</td>
</tr>
<tr>
<td></td>
<td>Auto-logs data via connected devices for blood glucose and activity tracking. Gamification of blood sugar control</td>
<td></td>
</tr>
<tr>
<td>AF Screening &amp; Dysrhythmias</td>
<td></td>
<td>Kardia by AliveCor, Inc. Works with FDA-cleared Kardia Mobile-a clinically validated mobile EKG solution</td>
</tr>
<tr>
<td>Hypertension</td>
<td>SmartBP by Evolve Medical Systems, LLC</td>
<td>Twine - Collaborative Care by Twine Health, Inc. A collaborative care platform, designed to engage patients in all care team activities</td>
</tr>
<tr>
<td></td>
<td>Manages blood pressure measurements and track progress</td>
<td></td>
</tr>
<tr>
<td>Cardiac Rehab</td>
<td></td>
<td>Healarium (Mayo Clinic Instance) by Apollo Medical Holdings Configurable health management app that can be loaded with content for specific conditions and individual patients</td>
</tr>
<tr>
<td>Pulmonary Rehab</td>
<td></td>
<td>MyCOPD Mobile pulmonary rehab programme shown to be non-inferior to traditional face-to-face pulmonary rehab; NHS Apps Library</td>
</tr>
<tr>
<td>Cancer</td>
<td>OWise Breast Cancer by Px HealthCare B.V.</td>
<td>MoovCare by Sivan Innovation Application that delivers surveys to cancer patients enabling targeted follow up</td>
</tr>
<tr>
<td></td>
<td>Helps individuals regain control during chaotic times of illness and treatment; NHS Apps Library</td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>AsthmaMD by Mobile Breeze</td>
<td>Propeller Health by Reciprocal Labs FDA-cleared, CE marked technology that works with existing asthma and COPD inhalers</td>
</tr>
<tr>
<td></td>
<td>Asthma management application. Asthma diary and visualize asthma activity on a colour graph.</td>
<td></td>
</tr>
</tbody>
</table>

| PRESCRIPTION FILLING AND COMPLIANCE | |
| Medication Refills | Walgreens by Walgreen Co. Online pharmacy serving needs for prescriptions, health & wellness products and health information |
| | Walgreens by Walgreen Co. Online pharmacy serving needs for prescriptions, health & wellness products and health information |
| Medication Management | Medisafe Meds & Pill Reminder by MediSafe Inc. Personalised medication management including reminders, educational content, and biometrics |
| | AiCure by AiCure, LLC Uses patented artificial intelligence (AI) on mobile devices to confirm medication ingestion. It reminds and monitors if you have not taken your medication with interactive visual and audio guidance that automatically adjust to your needs. |

Source: IQVIA AppScript Essentials, Aug 2017
AliveCor, BlueStar Diabetes by WellDoc, Propeller Health and reSET by Pear Therapeutics), but more (e.g., MoovCare by Sivan Innovation) may seek FDA clearance in the near future. A minority (3/26; 12%) have a proprietary device required to use the app (FitBit, Kardia by AliveCor and Propeller Health). No Top Apps were originally developed by pharma. One of the 26 (MySugr) is currently owned by a pharma (Roche), however Propeller Health and BlueStar Diabetes have announced substantive partnerships with specific pharma companies and others including Medisafe have product offerings for pharma partners. Notably, only a small minority of these very high-quality apps (2/26; 8%) have been included in the NHS Apps Library (Beta), namely the OWise breast cancer app and the MyCOPD pulmonary rehabilitation app.

These observations point to an increasingly clinically validated and sophisticated set of apps, but also incredible diversity in terms of business models that is likely to create significant procurement challenges for healthcare providers and payers for the foreseeable future. App accessibility and procurement by U.K. institutions and patients is further complicated by the fact that the majority of these leading apps have initially been built for a global or U.S. audience.

OVERALL VALUE TO THE HEALTHCARE SYSTEM

Guideline writers and individual healthcare institutions typically make adoption decisions category-by-category or app-by-app. However, for key policy setters in healthcare (e.g., Parliament, the Department of Health, NHS England, etc.) an understanding of the total cost savings of Digital Health to the health system may be helpful to guide policy. Given the acceleration in clinical evidence development in recent years, compelling cost savings arguments surrounding Digital Health apps may be within reach.

One very direct approach that can be used to estimate the total potential cost savings of Digital Health apps in the United Kingdom is to take the subset of studies that have measured a quantitative impact on acute care utilisation, including accident & emergency (A&E) visits and emergency hospitalisations, and extrapolate those findings to appropriate national target populations to estimate associated cost savings. The advantage of this “direct acute care savings” approach is that acute care utilisation is linked to cost in a proportionate manner. One only needs: (1) estimates of the number of A&E visits and emergency hospitalisations avoided, and (2) estimates of the typical costs of these acute care events to estimate aggregate cost savings. The disadvantage of this approach is that it fails to capture the vast majority of health outcome benefits reported in the clinical literature that have a more complicated relationship with costs such as weight loss, HbA1c moderation (in diabetics), Asthma Control Test moderation (in asthmatics), various symptom scale improvements in psychological conditions (e.g., depression), and enhanced medication adherence. The approach also fails to capture life extension, which could reasonably follow from many of the health benefits identified. Finally, given that the studies that have found acute care utilisation findings have been small and often observational (as opposed to randomised), results of the direct acute care savings approach will have to be updated regularly as new evidence becomes available. To summarise, the “direct acute care savings” approach is direct, but narrow, meaning that it will likely lead to straightforward, conservative estimates of potential cost savings that will require regular updates as evidence evolves.

The direct acute care savings approach was used to estimate total cost savings. A search for clinical evidence that had an acute care utilisation finding, namely a finding on emergency hospitalisations or A&E visits, was executed. Appropriate studies were found in five high-priority Digital Health app categories including (1) Diabetes Prevention, (2) Diabetes, (3) Asthma, (4) Pulmonary Rehabilitation, (5) Cardiac Rehabilitation (see Exhibit 15 and referenced studies in the Methodology section). For each of these categories, the underlying clinical findings were used to generate a health economic model in which the intervention (and its value) were
applied to an appropriate patient population. For example, since the key Diabetes Prevention study focused on seniors (at least 65 years old), the health economic model only considered benefits in this target population. In each case, estimates were based on a 100% distribution rate to the relevant target population(s), meaning that clinicians or other healthcare institutions must at least recommend the underlying solution to all of their target patients.

While each target patient was assumed to be offered the solution, the health economic model accounted for the fact that not all patients would engage with and benefit from the solution. Changes in hospitalisation and A&E rates were based on findings from underlying app studies. Costs of emergency hospitalisations or A&E visits were defined as costs to the National Health Service (NHS) and were condition-specific if available (i.e., emergency hospitalisation costs specific to a patient whose primary diagnosis is diabetes).

The resulting health economic model suggests that a highly curated set of apps that are consistently distributed to target patients in an initial sample of five target use cases could drive U.K. cost savings of approximately £170 million per year (see Exhibit 16). Most cost savings are driven by reduced emergency hospitalisations and A&E visits, but given that some of the underlying studies also provided cost savings for general practitioner and other ambulatory care visits, prescriptions and other services, these cost savings were also included when available. For example, Diabetes Prevention is somewhat of an exception in that there were significant cost savings derived from reduced general practitioner and other ambulatory care visits as well as prescription costs due to a long-term decrease in diabetes incidence. Pulmonary Rehabilitation (PR) was also an exception in that cost savings were realised primarily due to the lower cost of app-based PR relative to face-to-face PR.
This level of cost-savings may be considered to be significant in light of a number of factors. First, cost savings based on a bottom-up review of individual peer-reviewed publications focused exclusively on acute care utilisation is a very high bar by which to measure value in healthcare. Most new medical innovations deliver higher quality care at greater cost. Digital Health apps have in some cases delivered comparable results to leading drugs (on metrics such as HbA1c), albeit not in head-to-head studies. Relatively few drugs have shown reduced acute care utilisation trends, and Digital Health app have begun to do so. Furthermore, Digital Health apps have traditionally been priced lower than drugs and are often available for free, creating a strong cost-effectiveness argument. Digital Health apps may therefore have a more favourable cost-benefit relationship than other healthcare interventions. Second, the focus of the analysis was on acute care utilisation, so the cost savings potential for ambulatory and prescription drug care was only partially assessed in this initial health economic model. Third, the model assumed no “spillover effects” meaning that no benefits for co-morbid conditions were assessed despite the fact that it would be reasonable to suggest, for example, that diabetics that better manage their blood sugar may have significantly reduced risk of myocardial infarction leading to emergency hospitalisation. Finally, these are only five initial use cases for Digital Health. Given that the apps saved – on average – 1.1% of total costs in their respective conditions of interest and Digital Health apps have shown clinical benefits across a broad array of uses (see Exhibit 12), it is reasonable to expect that similar cost savings will soon become evident across an ever increasing array of uses. If Digital Health apps were able to save the same 1.1% of U.K. national healthcare expenditure, total U.K. cost savings potential would come to approximately £2 billion per year (see exhibit 17). This health economic model suggests the significant cost savings potential of Digital Health with the primary caveat being that the model will have to be regularly updated as the clinical evidence base evolves.

Exhibit 16: Estimated Annual U.K. Cost Savings for Five Initial Uses with Potential to Reduce Acute Care Utilisation, UK£Mn

Key Assumptions
• Use of 5 Curated Apps used in 5 underlying studies suggesting acute care utilisation benefits
• Delivery to each target patient for the given use case (but not necessarily used by patient)
• No “Spill Over” Benefits to other conditions (i.e., no reduced healthcare utilisation for stroke based on improved blood sugar control in diabetics)

Source: IQVIA AppScript Essentials Value Model, Aug 2017
Note: Numbers may not sum due to rounding; A&E (Accident & Emergency), GP (General Practitioner).
Exhibit 17: Total Potential Annual U.K. Cost Savings if Digital Health Apps Reduce Overall Healthcare Costs by Approximately 1.1% as Observed in “First Five” Use Cases, UK£

Source: IQVIA AppScript Essentials Value Model, Aug 2017
Note: Y-axis shows total case-specific health costs (100%) and the percent mitigated by the use of Digital Health.
Adoption of Digital Health

• Adoption of Digital Health by clinicians is increasing but is far from mainstream.

• A variety of industry and policy initiatives have emerged to address barriers to adoption of Digital Health tools.

• App curation initiatives, including the NHS Apps Library (Beta), are facilitating the creation of formularies of high-quality apps that meet quality guidelines.

High-quality Digital Health apps are now available for nearly every conceivable use along the patient journey. The value of many of these apps are now supported by compelling clinical studies that have shown the ability to improve human health and outcomes through the prevention and management of chronic disease. These outcomes benefits potentially create a new and significant opportunity for healthcare systems globally to reduce their costs, including the NHS.

Despite this promise, the adoption of Digital Health apps across the NHS is currently limited. While there are many anecdotal reports of pilot studies of Digital Health apps within the NHS, only a small fraction of published worldwide Digital Health efficacy studies have taken place in the United Kingdom. Separately, clinicians continue to see challenges to leveraging Digital Health apps in their practice. Common concerns include patient privacy and security, concerns around clinical value, concerns around malpractice liability, the lack of financial incentives, and lack of workflow integration. While Top Apps often address the usability and clinical value requirements of healthcare providers, even these do not consistently meet the privacy & security, risk mitigation, financial incentives and workflow requirements of a typical NHS clinician (see Exhibit 18). To fully realise the value of Digital Health to the NHS, these provider requirements will need to be addressed.

Exhibit 18: Fraction of Top Apps that Adequately Address Providers’ Key Requirements and Emerging Accelerators of Adoption

Source: American Medical Association, Digital Health Study, Sep 2016; IQVIA Institute Analysis, Sep 2017
Before healthcare can be more fully supported by apps and sensors, a new fit-for-purpose infrastructure must evolve to support their delivery and incorporation into the standard health toolkit, similar to the type of ecosystem that exists to disseminate safe therapeutics. Emerging accelerators of Digital Health adoption — including app curation platforms, privacy & security guidelines, inclusion in clinical guidelines, merit-based incentives associated with health outcomes improvements, and new interoperability standards — are beginning to create such an ecosystem.

Critically, app curation initiatives are facilitating the creation of formularies of high-quality apps that meet quality guidelines. One such set of guidelines is the Digital Assessment Questions (DAQs) developed by the NHS, which provides guidance on required app parameters like clinical effectiveness, safety, privacy, security, usability, interoperability, technical stability, appropriate regulatory clearance and change management. The NHS Apps Library, a library of apps that have successfully been vetted using the DAQs, helps by endorsing vetted apps for use by patients and clinicians. To the extent that the NHS Apps Library creates confidence in the listed apps, patients’ and clinicians’ apprehensions around app privacy, security and overall usefulness may be addressed. While the NHS Apps Library is new – only 2/26 of the identified Top Apps have been included Library to-date – evaluation and inclusion of such Top Apps is likely to continue, increasing the opportunity for the NHS to realise the value of Digital Health.

Perhaps one of the most vexing challenges to the adoption of Digital Health in the United Kingdom, and elsewhere, will be the careful management of how clinical evidence should be developed and reviewed. Historically, NHS institutions including NICE have shown a strong preference for clinical data derived from studies within the NHS itself. However, in the case of Digital Health, significant clinical evidence has been established outside of the NHS, but little internally. NHS England and NICE have presented a model which addresses this tension in their Improving Access to Psychological Therapies (IPAT) programme. This programme, which will assess 14 digital therapy products by 2020, identifies apps for the treatment of mental health conditions that have at least one positive RCT regardless of the geographic location of the underlying app and its studies. If initial assessments – which are based on the DAQs as well as NICE’s own clinical assessments – are positive, apps are matched with relevant IPAT service providers to test their real world effectiveness in the NHS. To assist with bringing apps into compliance with NHS requirements (e.g., the DAQs), NHS England provides some funding to app developers to support further technology development (e.g., new security features). If successful, this model could serve as a scalable template for how the NHS matches the world’s best apps with its local healthcare system and patient needs.

The NHS – given its long-time horizons in areas like chronic disease prevention – may be uniquely well positioned to realise the significant potential of Digital Health. In the past few years, this potential has moved from intangible claims to tangible benefits that can be calculated based on examples from an ever-expanding base of clinical literature and increasingly real world effectiveness data. To the extent that key policy setters are able to navigate a long list of potential market failures surrounding issues such as physician incentives and workflow integration, the use of Digital Health tools within the NHS is likely to accelerate, creating a bright future for NHS patients.
Appendix

METHODOLOGY

Mobile app data
Global mobile application data was sourced from 42Matters and AppScript in July 2017 and obtained via the AppScript App Database. As of July 11th 2017 when the data was pulled, there were 318,572 health apps available with 166,592 in the Apple Store and 151,980 in the Google Play Store. Although some apps are available on both stores, their unique instances may offer different functionality, and are therefore counted as distinct. Although our 2015 report made use of mobile application data supplied by Mevvy rather than 42Matters, these data sources are believed to be substantially similar, as both suppliers’ source data directly from the relevant app stores. Significant differences are not expected, but minor trend breaks may exist and may have minor impact on longitudinal trends.

The analysis only includes apps available for download on the Apple Store and Google Play Store. Other Digital Health apps, including web apps and closed distribution model apps, are not included in the various analyses of app quantity and category but are included in various clinical evidence assessments.

Mobile patient health app data
Mobile application data sourced from 42Matters was reviewed and supplemented with primary research by IQVIA AppScript to create the curated AppScript App Database of widely available consumer mobile health apps. As of July 11th 2017 when the data was pulled for the 2017 study, a total of 22,357 unique healthcare consumer mobile apps were included in the dataset, including 13,983 iOS apps from the Apple Store and 8,374 Android apps from the Google Play store. This dataset prioritises review of apps in the “Health and Fitness” and “Medical” categories, as well as the most downloaded apps, to define a set of the Digital Health apps most widely used by consumers. Under AppScript curation methods, app store apps with greater than 1,000 user ratings are prioritised for in-depth examination, as well as apps that have already been reviewed and have a version or price update. A thorough examination of the content of apps enables exclusion of apps from further analysis that are considered irrelevant to normal healthcare use (e.g., salons, apps with gimmicks, etc.), unavailable in English language, or for healthcare providers as opposed to patients. The remaining included apps are considered genuine Digital Health apps for patients. For the purpose of counting apps, an app may be counted twice if it is available from both the Google Play Store and the Apple App Store; however, differences exist between platforms regarding functionality and download volume.

Android install data analysis
July 2017 Google Play data contained information on volume of downloads, where downloads were quoted in the following ranges: 10 million to 50 million; 5 million to 10 million; 500,000 to 1 million; 100,000 to 500,000; 50,000 to 100,000; 10,000 to 50,000; 5,000 to 10,000; 1,000 to 5,000; 500 to 1,000; 100 to 500; 10 to 50; 5 to 10; 1 to 5. The median number of downloads was taken for each range, from which a total number of downloads was estimated.

Device Data
Data on available consumer wearable sensors was built using primary research by IQVIA AppScript. As of September 15th 2017 when the data was pulled, a total of 344 unique patient sensors were included in the curated AppScript Device Database.

Clinical trial data
Data was pulled from clinicaltrials.gov on February 24th 2017. Analysis of clinical trials derived from Clinicaltrials.gov were narrowed to studies with the following recruitment statuses: Active, Recruiting, Enrolling by invitation, Not yet recruiting (only those
with a start date before Sept 2017 and completion date beyond Sept 2016 OR a start date in 2016 with null completion date and update in 2016 n=10), and Unknown status (with a completion date in 2017 or beyond). Trial queries included the following search strings: Mobile application or Mobile app; Smartphone; App in Interventions; App in Title; Android App OR Android Application; iOS App OR iOS Application; Wearable AND mobile; Device AND Mobile. Data was cleansed to exclude trials not involving Digital Health – for instance those looking at amyloid precursor protein (APP), etc. Trials incorporating only passive video materials and DVDs were excluded from the analysis. Trials incorporating tablet based questionnaires and virtual office visits were included in the analysis. For analyses of trial sponsorships: Patient Care includes universities, hospitals and clinics; Industry includes pharma, biotech, device and app manufacturers; Foundation includes charities and individuals. The total percent of sponsorships exceed 100% due to multiple sponsors collaborating in a single trial.

**AppScript Score**
The AppScript Score provides a comprehensive method for all stakeholders to assess Digital Health app quality and may be predictive of a given app’s value to the human health and the overall health system. The AppScript Score is derived from six sub-scores, or “ratings”, across the following dimensions: Patient, Professional, Functional, Developer, Endorsement and Clinical ratings (see Exhibit 17).

Across the six rating, more than 70 individual metrics are considered. Some metrics leverage data from the AppScript distribution platform, which enables clinicians to electronically recommend apps, connected devices and digital content to their patients. AppScript Score components are weighted and combined to generate a consolidated score of 1-100. A “good score” is always at the discretion of a healthcare professional and may vary by not only the condition, but by provider and by patient.

Patient Rating leverages commodity Apple Store and Google Play Store ratings and rating counts as well as proprietary AppScript “fill rate” and “retention rate” data pertaining to the number of AppScript app recommendations are downloaded and retained for at least a 30 day period, respectively.

**Professional Rating** is derived from the number of times a given app is recommended to patients by healthcare professionals using the AppScript platform and the number of times a given app has been included in an institution’s Digital Health formulary using the AppScript platform.

**Functional Rating** measures the feature-set of apps (more detail in Exhibit 4), representing the unique investment by the developer and functionality available to users.

**Developer Rating** determines the professionalism and dedication of a developer to deliver high-quality apps that leverage the most recent technologies. Key metrics assessed as part of the Developer Rating include the most recent update date of the app and whether the app interoperates with sensors directly or through a data sharing hub (e.g., HealthKit).

**Endorsement Rating** is based on the number of times a given app has been positively endorsed by credible healthcare organisations such as regulators (e.g., the U.S. FDA through a clearance), healthcare provider institutions (e.g., Joslin Clinic), and health content publishers (e.g., HealthLine).

**Clinical Rating** is an Evidence Based Medicine approach to rating apps focused on the review and scoring of peer reviewed publications. All peer-reviewed publications are scored based on their design qualities and results. Study quality is based on the underlying study design, for example an RCT is scored higher than an observational study. Study result is based on whether the study found that the underlying app provided a statistically significant benefit on a primary endpoint or was otherwise
found favourable by the study’s authors (positive result), showed no statistically significant benefit (neutral result), or was significantly worse than a comparator or was otherwise found unfavourable by the study’s authors (negative result). An app’s Clinical Rating is the average score of all available peer reviewed publications that have assessed its content, usability, accuracy, efficacy, safety, or underlying health economics.

**AppScript Clinical Evidence Database and Clinical Evidence Maturity Assessment**

Peer-reviewed publications are identified and included in the AppScript Digital Health Evidence Database on a rolling basis leveraging database search as well as manual search methodologies. Google Scholar and PubMed databases are searched on relevant keywords across therapeutics areas, study types and technology categories. The AppScript team also monitors relevant trade publications and industry contacts for new studies, which occasionally requires manual entry above and beyond database search methodologies.

The Digital Health App Clinical Maturity Assessment included 571 app efficacy studies included across dozens of app use categories ranging from individual conditions (e.g., diabetes) to prescription management categories (e.g., filling prescriptions). Many types of peer-reviewed publications were not included in the analysis presented as there were no direct and quantitative implications for improved human health, including content review studies, usability studies, technical and clinical accuracy studies, and pure health economic studies (i.e., those based on pre-existing efficacy data). Efficacy studies were categorised by study type (observational, RCT, systematic review or meta-analysis study), outcome (positive, negative, neutral) and primary use category (e.g., therapeutic area/medical condition). Positive study outcomes reflect study results demonstrating statistically significant findings of clinical change.

Studies were summarised via a “Digital Health Clinical Maturity Matrix” (see Exhibit 19). Values for the x-axis, Relative Quantity and Quality of Available Clinical Evidence, were derived via a tiered assessment of the available clinical evidence. The first tier of the assessment was the most heavily weighted and focused on the highest quality study designs currently available for the Digital Health app use category. The study quality point system was scored as follows: No Studies = 0 points, One Observational Study = 1, Multiple Observational Studies = 2, One RCT = 3, Multiple RCTs = 4, One Meta-Analysis Study = 5, and Multiple Meta-Analysis Studies = 6. The second tier of the Quantity and Quality assessment was a minor factor focused on study quantity. Total efficacy studies were counted in each Digital Health app use category, with categories with the most studies receiving close to an additional point and all other studies receiving a fraction of a point based on their relative study counts. Values for the y-axis, Average Study Results, are based on averaged individual study result scores, where each individual study is scored a 1.0 (positive), 0.5 (neutral), or 0.0 (negative). For the Average Study Results assessment, only the highest quality available studies were considered. For example, if a given use case category had many observational studies and two RCTs, only the results of the RCTs were considered.

Apps were divided into five clinical maturity groupings based on typical evidence thresholds across the health system. Digital Health app use categories featuring multiple meta-analysis studies and generally positive results were grouped as “Candidates for Inclusion in Clinical Guidelines” as this level of clinical maturity has likely produced studies that meet the explicitly stated requirements of clinical guideline writers. Categories with at least one RCT and generally positive results were grouped as “Candidates for Adoption” as health plans, healthcare providers and individual clinicians generally regard RCT data as a gold standard evaluation. Categories with only observational studies were grouped as “Candidates for Evaluation in an RCT” as they may be considered sufficiently de-risked to invest in a robust, gold-standard RCT study. Categories without any efficacy studies were grouped as “General Lack of Studies.” Categories with average results of ~0.6
or lower (i.e., at best, closer to neutral than positive) were grouped as “Potential Disappointments – More Study Required” as key health system stakeholders generally expect new healthcare interventions to consistently demonstrate significant clinical value when studied. This being said, given the broad capacity of Digital Health to improve human health outcomes demonstrated in this report, it is likely that many of these “Potentially Disappointing” categories will ultimately find the appropriate functionality, delivery models and patient sub-populations where consistently favourable results are possible.

**AppScript Essentials Value Model**

The AppScript Essentials Value Model is an evolving health economic model that estimates the potential value of available Digital Health apps in terms of clinical outcomes and cost reduction based on a bottom up analysis clinical benefits identified in available peer-reviewed publications and extrapolation of identified clinical benefits to appropriate patient populations.

In the version of the AppScript Essentials Value Model published in this report (v1.0), a search for favourable acute care utilisation findings across priority use cases for Digital Health apps was executed, resulting in the identification of five key studies. First, each study’s patient populations and clinical benefits were considered (see Exhibit 20).

Second, an appropriate model was developed starting with the target patient population defined by underlying epidemiology and considering factors such as smartphone ownership (ability to use) likely engagement rates (likelihood to download and/or benefit) based on available evidence and experience from the AppScript team (see Exhibit 21).
## Exhibit 20: Studies used to develop the AppScript Essentials Value Model

<table>
<thead>
<tr>
<th>USE CASE CATEGORY</th>
<th>APP</th>
<th>STUDY</th>
<th>POPULATION</th>
<th>METHODOLOGY</th>
<th>KEY FINDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Prevention</td>
<td>Omada Health</td>
<td>Chen et al (2016)</td>
<td>&gt;65yo Prediabetics: 1,121 overweight or obese seniors with additional risk factors for diabetes or heart disease</td>
<td>Health Economic Model based on previous experience</td>
<td>Reduction in long-term diabetes incidence and associated healthcare utilisation costs across hospitalisations, ED visits, ambulatory care, and pharmacy net of intervention costs ranging from $1,201–$1,454 per capita per year</td>
</tr>
</tbody>
</table>
| Diabetes | WellDoc | Katz et al (2012) | Diabetics: 32 patients (100% African American; 97% women) enrolled with pre-study mean HgA1c of 8% | Observational Study: Pre-post design | Reduction in ED and hospitalisation rate:  
• 16 (50%) became active users  
• ~58% reduction in ED + Hospital Admissions for Active Group (including 0 hospitalisations)  
• All diabetes care measures improved |
| Asthma | Propeller Health | Merchant et al (2017) | Asthmatics: 330 Propeller Health users with an average of 647 baseline (pre-intervention) and 312 post-intervention days | Observational Study: Pre-post design | Reduction in all cause hospitalisation, ED visits, and physician office utilisation as follows:  
• ~34% lower hospital admission rate  
• ~23% lower ED visit rate  
• ~4% lower physician office visit rate |
| Cardiac Rehab (CR) | Healarium (Mayo Clinic instance) | Widmer et al (2017) | MI: Patients after percutaneous coronary intervention (PCI) for acute coronary syndrome (ACS) | RCT: Digital Health Intervention (DHI) vs. face-to-face CR | Strong trends towards fewer patients visiting ED or being admitted to hospital within 180 days [CV-related rehospitalisations plus ED visits compared to the control group at 180 days (8.1% vs 26.6%; RR 0.30, 95% CI 0.08–1.10, P = .054).] |
| Pulmonary Rehab (PR) | MyCOPD | Bourne et al (2017) | COPD: 90 patients with a diagnosis of chronic obstructive pulmonary disease (COPD), modified Medical Research Council score of 2 or greater referred for pulmonary rehabilitation | RCT: Digital Health Intervention (DHI) vs. face-to-face PR | The study demonstrated that the DHI is non-inferior to face-to-face PR, which has demonstrated value in preventing acute care utilisation |

Sources: AppScript Clinical Evidence Database, Aug 2017; IQVIA AppScript Essentials Value Model, Aug 2017
### Exhibit 21: Methodology for Estimating Cost Reduction in the AppScript Essentials Value Model

<table>
<thead>
<tr>
<th>USE CASE CATEGORY</th>
<th>METHODOLOGY FOR ESTIMATING COST REDUCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diabetes</strong></td>
<td>1. Considered patient population and cost savings included in Chen et al (2016) and concluded that the study only considers benefits across active users as opposed to an entire population of prediabetics  &lt;br&gt; 2. Collected estimates for &gt;65 prediabetic population  &lt;br&gt; 3. Multiplied by estimated &gt;65yo population that own smart phone (rationale: smart phone users are the likely target audience)  &lt;br&gt; 4. Multiplied by estimated % that may “fill” a digital health prescription upon distribution in an outpatient environment  &lt;br&gt; 5. Multiplied by annualised per capita cost benefits (used an average of two models introduced in (Chen et al)  &lt;br&gt; 6. Calculated total cost savings potential</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>1. Considered patient population and acute care utilisation benefits in Katz et al (2012) and concluded that the intervention was applied to a patient population that was sicker than the overall diagnosed diabetic population, but less sick than recently hospitalised diabetics, suggesting that the benefits could likely be estimated by looking at cost savings in (A) the overall diabetic population and (B) recently hospitalised diabetics and averaging  &lt;br&gt; 2. Collected estimates for diagnosed diabetic population and unique hospitalised diabetics  &lt;br&gt; 3. Multiplied by engagement rate from Katz et al study  &lt;br&gt; 4. Applied acute care utilisation benefits from Katz et al study to each of the two populations (note: in calculating status quo ED visit and hospitalisation rates, only diabetes-specific utilisation was considered as opposed to all utilisation with a diabetes diagnosis. This method resulted in a far more conservative estimate)  &lt;br&gt; 5. Multiplied by cost of ED visits, hospital admissions, etc.  &lt;br&gt; 6. Calculated total cost savings potential</td>
</tr>
<tr>
<td><strong>Asthma</strong></td>
<td>1. Considered patient population and acute care utilisation benefits in Merchant et al (2017) and concluded patient population was fairly representative of overall asthma population, however, the benefits were in engaged users (i.e., the study does not consider the fact that not all patients introduced to the intervention would initiate it)  &lt;br&gt; 2. Collected estimates for diagnosed asthma population (all ages)  &lt;br&gt; 3. Multiplied by engagement rate (“fill rate”) from AppScript experience in outpatient digital health prescribing  &lt;br&gt; 4. Applied acute care utilisation benefits from Merchant et al study  &lt;br&gt; 5. Multiplied by cost of ED visits, hospital admissions, etc.  &lt;br&gt; 6. Calculated total cost savings potential</td>
</tr>
<tr>
<td><strong>Cardiac Rehab (CR)</strong></td>
<td>1. Considered patient population and acute care utilisation benefits in Widmer et al (2017) and concluded it may be reasonable to target the intervention (and associated benefits) to the total number of unique patients hospitalised for myocardial infarction (MI) in a given year  &lt;br&gt; 2. Collected estimates for unique patients hospitalised for MI each year  &lt;br&gt; 3. Applied acute care utilisation benefits from Widmer et al study  &lt;br&gt; 4. Multiplied by cost of ED visits, hospital admissions, etc.  &lt;br&gt; 5. Calculated total cost savings potential</td>
</tr>
<tr>
<td><strong>Pulmonary Rehab (PR)</strong></td>
<td>1. Considered patient population in Bourne et al (2017) as well as manufacturers list price for intervention relative to estimates of face-to-face pulmonary rehab costs and concluded that the MyCOPD intervention is being applied to patients currently being referred to pulmonary rehab and cost savings should primarily be a function of the app’s clinical non-inferiority and lower cost  &lt;br&gt; 2. Estimated total pulmonary rehab referrals taking place each year  &lt;br&gt; 3. Multiplied by estimated &gt;65yo population that own smart phone (rationale: smart phone users are the likely target audience)  &lt;br&gt; 4. Multiplied by cost savings associated with app-based PR vs. face-to-face  &lt;br&gt; 5. Calculated total cost savings potential</td>
</tr>
</tbody>
</table>

Sources: IQVIA AppScript Essentials Value Model, Aug 2017
References

1. WHO. mHealth: New horizons for health through mobile technologies. Global Observatory for eHealth Series – Volume 3. 2011


About the authors

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Murray Aitken is Executive Director, IQVIA Institute for Human Data Science, which provides policy setters and decision-makers in the global health sector with objective insights into healthcare dynamics. He led the IMS Institute for Healthcare Informatics, now the IQVIA Institute, since its inception in January 2011. Murray previously was Senior Vice President, Healthcare Insight, leading IMS Health’s thought leadership initiatives worldwide. Before that, he served as Senior Vice President, Corporate Strategy, from 2004 to 2007. Murray joined IMS Health in 2001 with responsibility for developing the company’s consulting and services businesses. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray writes and speaks regularly on the challenges facing the healthcare industry. He is editor of Health IQ, a publication focused on the value of information in advancing evidence-based healthcare, and also serves on the editorial advisory board of Pharmaceutical Executive. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.

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About the IQVIA Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA’s institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including, including government agencies, academic institutions, the life sciences industry and payers.

RESEARCH AGENDA
The research agenda for the Institute centers on five areas considered vital to contributing to the advancement of human health globally.

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

GUIDING PRINCIPLES
The Institute operates from a set of Guiding Principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high-quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.

About the IQVIA Institute