

September 2015

Patient Adoption of mHealth

Use, Evidence and Remaining Barriers
to Mainstream Acceptance



Introduction

The availability of consumer apps continues to grow, particularly in the area of healthcare apps. Commonly referred to as mHealth apps, these apps assist consumers in self-management of overall wellness, disease prevention and disease management. Recognition of the importance of patients taking an active and informed role in their own healthcare has fueled this growth. The proliferation of smart phones and consumer interest in taking a more active role in their health, presents a significant opportunity to leverage mHealth apps in innovative ways. This is especially true as improvements are made in the connectivity aspects of mHealth apps both in how data is compiled and how it is connected back to healthcare providers.

This report provides an update to the analysis of the mHealth app landscape published by the IMS Institute for Healthcare Informatics in 2013. The primary focus of this report is on the consumer or patient use of mHealth apps. The mHealth app availability and usage information is focused on apps available to the general public that support everyday healthcare management in conjunction with their healthcare provider. While the information is agnostic to geographic boundaries, this report is primarily focused on the U.S. healthcare system.

Throughout this report, the term “prescribe” is used in a manner to differentiate between an informal recommendation of mHealth apps by healthcare providers and a “prescriptive” specific recommendation to patients for use of an mHealth app as part of treatment protocols.

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Executive summary

The number of mHealth apps available to consumers now exceeds 165,000 and since 2013 there has been progress in understanding and addressing the barriers to more mainstream adoption of mHealth. In the case of iOS apps, the number available has increased more than 100% over the past two years.

This study of mHealth apps available for download from U.S. Apple iTunes store and Google Play (Android) provides an assessment of the current availability and use of mHealth apps. Similar to the study performed in 2013, the majority of available mHealth apps continue to be concentrated in the areas of wellness, diet and exercise. Nearly a quarter of mHealth apps focus on disease and treatment management reflecting the growing interest in the use of mHealth apps for chronic disease management. When looking at overall functionality and scope of the features, over 50% of mHealth apps continue to have limited functionality, most simply providing information. One in ten mHealth apps have the capability to connect to a device or sensor which greatly improves the accuracy and convenience of data collection for mHealth apps. The ability for mHealth apps to connect to social media has increased by 8%. Of the top mHealth apps, 65% connect to social media underscoring the importance of this feature for consumer engagement. Connectivity and communication of consumer mHealth apps with provider healthcare systems continues to be limited with only 2% having this feature.

The number and variety of mHealth apps available present an overwhelming amount of options for consumers and without guidance from their healthcare provider, patients may either choose the most popular apps or try several apps in an effort to self-determine the best app for their particular situation. This is reflected in available download information which shows that just 36 apps account for nearly half of all downloads, while 40% of apps have fewer than 5,000 downloads.

Healthcare providers show increasing interest, excitement and more than a third of physicians report recommending mHealth apps to patients. The typical 30-day retention rates for mHealth apps prescribed by a provider are 10% higher than average and 30% higher for fitness apps. However, barriers continue to exist, impeding full adoption of mHealth apps in a prescriptive and integrated manner. These barriers include lack of scientific evidence to lack of integration into workflow systems, regulatory and privacy unknowns and lack of provisions for reimbursement. These barriers are further magnified by a complex healthcare system with limited interoperability both within and across healthcare organizations.

The body of evidence that supports the use of mHealth apps to improve health outcomes and help manage costs is expanding. However, there has been limited assessment of the results of this evidence from a quantity, quality, and safety perspective. Based on a directional analysis of 113 quantitative studies, the most notable and positive evidence generated to date is in the areas of Type II diabetes,

cardiovascular health, obesity, multiple sclerosis and mental health. In addition, 300 mHealth clinical trials are underway, of which 53% target the senior population. While evidence is building, additional studies on sub-populations, and for longer time periods, is needed. Rigorous research is also needed around the evidence generated to guide future initiatives and collectively outline the value of mHealth for healthcare improvement. This evidence must also be combined with clarity around how to harness, protect and fully leverage data collected for better outcomes and patient satisfaction.

Further multi-stakeholder effort is required to reach a maturity level where mHealth apps are integrated and systematically prescribed by providers, as opposed to self-determined by consumers or informally recommended by providers. More studies substantiating improved health outcomes and cost-savings through the proliferation of mHealth apps are needed to encourage institutional stakeholders and payers to hasten efforts for reimbursement and full healthcare system enterprise-wide integration, two central barriers to comprehensive mHealth adoption.

Over the past two years, there has been progress across the key components that are necessary for driving greater adoption of mHealth apps by providers. Some healthcare providers have begun to prescribe mHealth apps as a practice. It is anticipated that efforts will continue to accelerate as hospitals meet meaningful use requirements for greater integration and data capture, reimbursement moves towards value-based payment and evidence increases around the added value of mHealth adoption in chronic disease management. For mHealth to fully contribute to improving the value of healthcare delivery and chronic disease management, all stakeholders within the mHealth ecosystem must take a vested interest in addressing the barriers to reaching full adoption. The effort for comprehensive implementation is not small, and the speed of adoption for fully leveraging mHealth will be determined by prioritization of stakeholders in the mHealth ecosystem. Technology solutions and the availability of tools to assist healthcare providers in confidently assessing and navigating the available mHealth apps will be critical to accelerating mainstream adoption.

Availability and profile of consumer mHealth apps

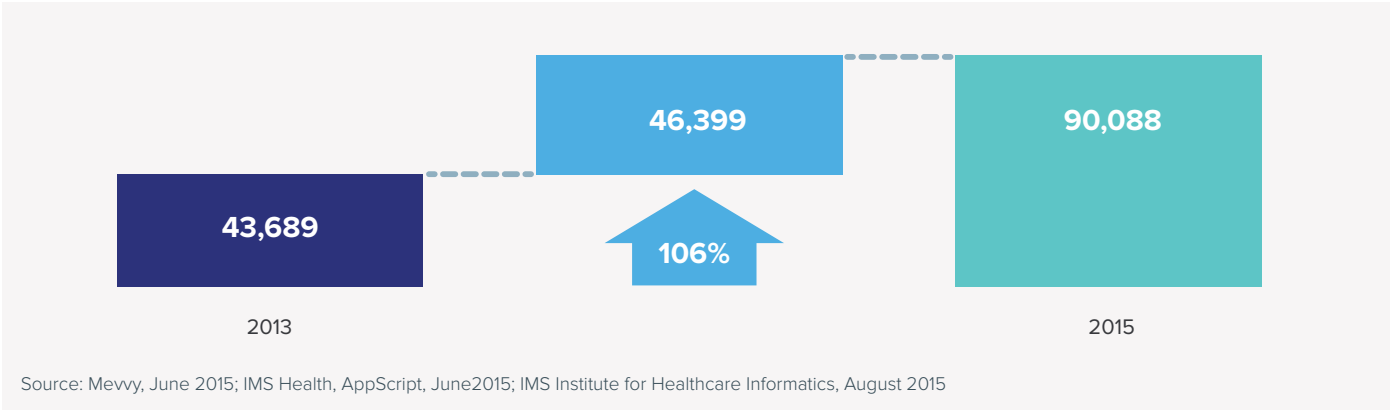
Health and wellness apps available through the iOS platform has more than doubled in the past two years

Today, more than two-thirds of Americans own smartphones and almost 20% depend solely upon their smartphone for internet access.¹ Consequently, the number of mobile apps has increased to meet the demand and opportunity presented by smartphone proliferation of the mobile market. The increase in the number of healthcare apps, otherwise referred to as mHealth apps, available to consumers has grown at an even greater rate given the increased push for patients to become more actively engaged in their own healthcare management.

The term mHealth, used throughout this report, is defined as “medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”² The use of mobile apps in improving healthcare outcomes is of continued interest across industry stakeholders from patients and healthcare providers to healthcare systems and payers.

To better understand the current landscape of use, availability, evidence and barriers to mainstream adoption, a comprehensive follow-up study has been completed to the one performed in 2013 on mHealth apps that are publically available to consumers and categorized as health, fitness or medical. In comparing the number of mHealth apps available on the iOS platform, the number of health and wellness apps increased over 100% from 2013 to 2015 (Exhibit 1).

Exhibit 1: Comparison of iOS mHealth Apps 2013 and 2015

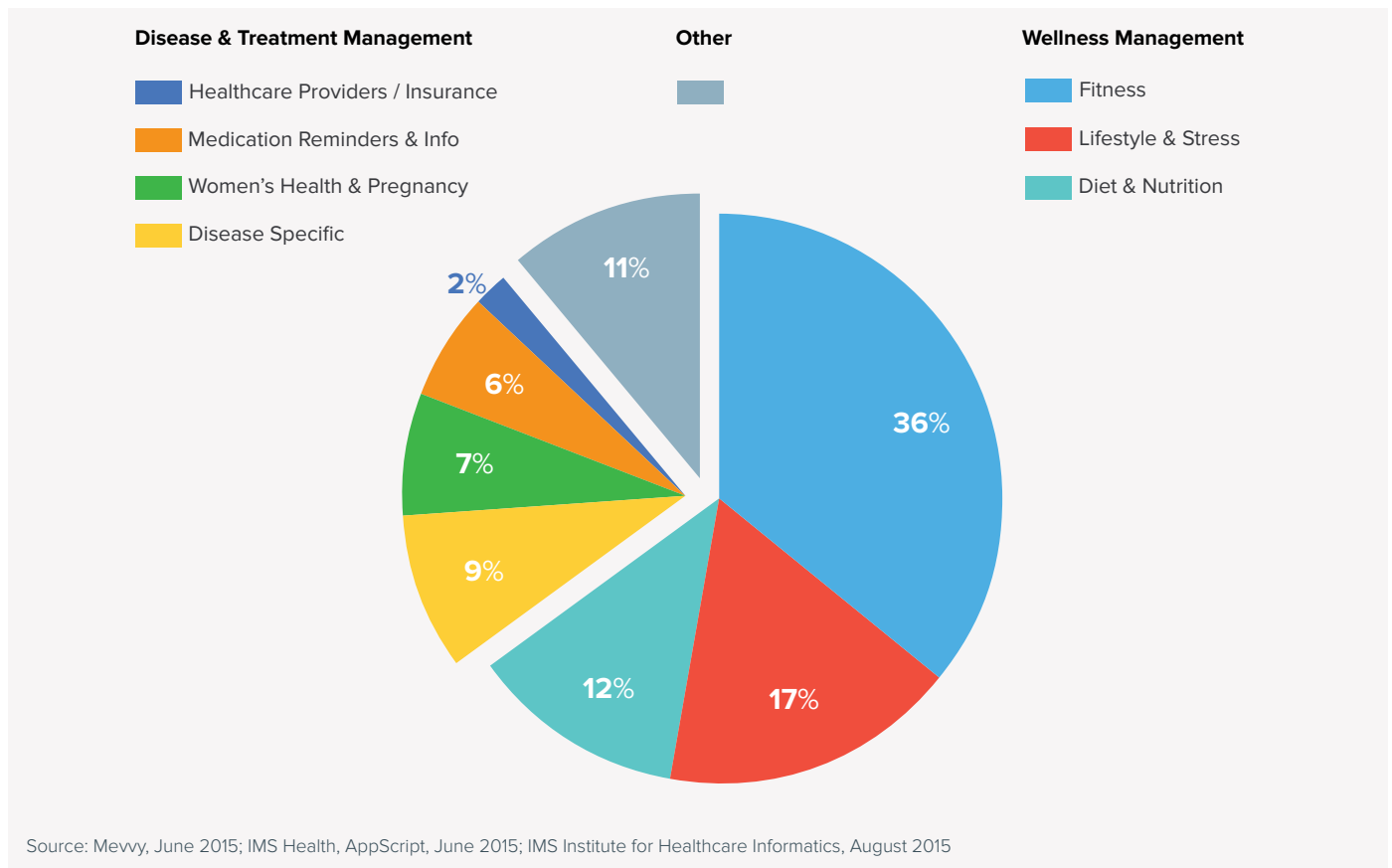


In the 2015 study, over 165,000 healthcare consumer qualified apps were selected for review from both the Apple iOS and Google app platforms. Through review and selection criteria, to include prioritization of the most downloaded apps, 26,864 were selected as representative of the most widely used mHealth apps by consumers.

Across the patient journey, mHealth apps can be divided into two main categories: those which facilitate overall wellness such as exercise and diet, and those which specifically focus on disease management through implementation of treatment protocols such as medication reminders.

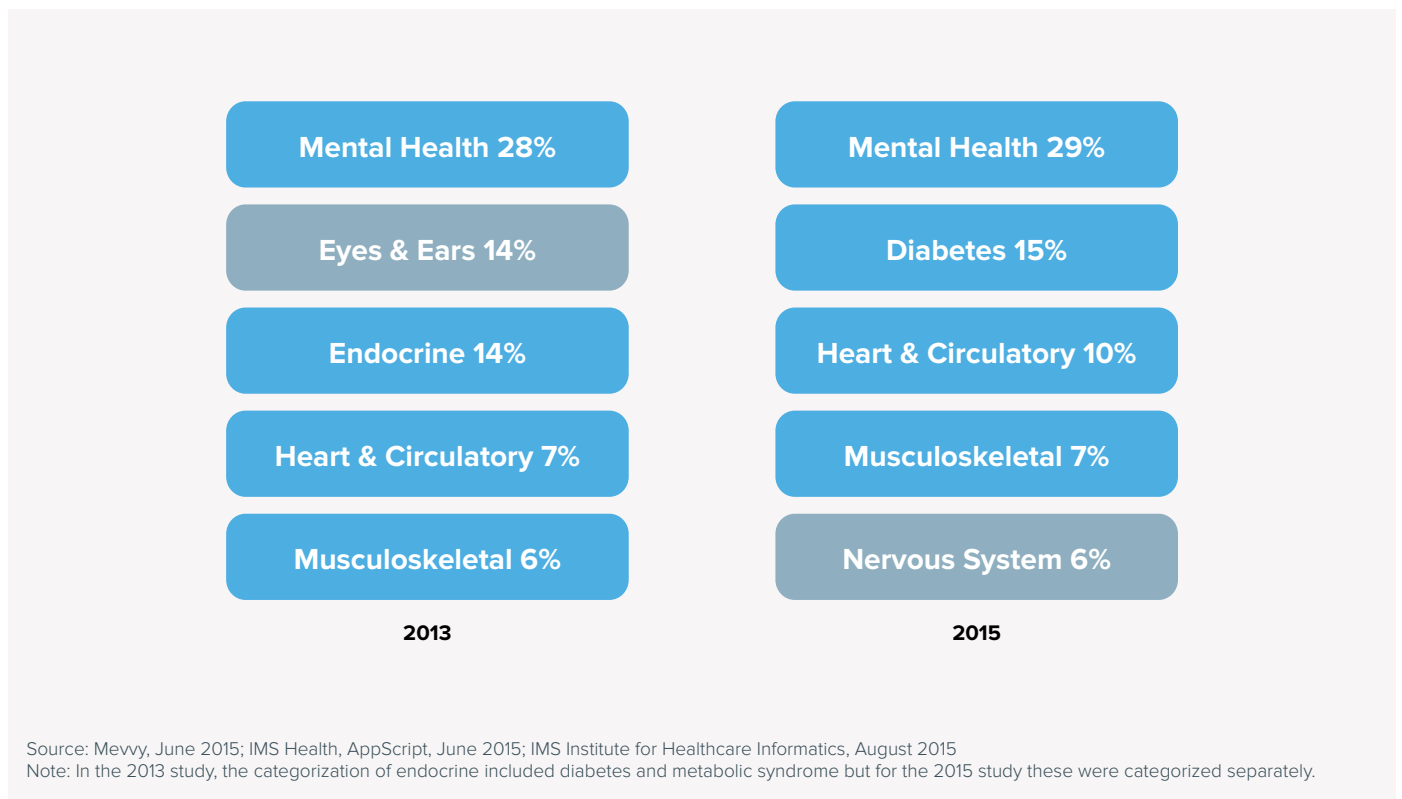
Consumer mHealth apps targeting wellness comprise two-thirds of the mHealth app space. This includes fitness, lifestyle & stress and diet & nutrition. Disease and treatment management comprises approximately a quarter of mHealth apps (Exhibit 2), with only a small share being specific to a particular disease.

Exhibit 2: mHealth Apps by Category 2015



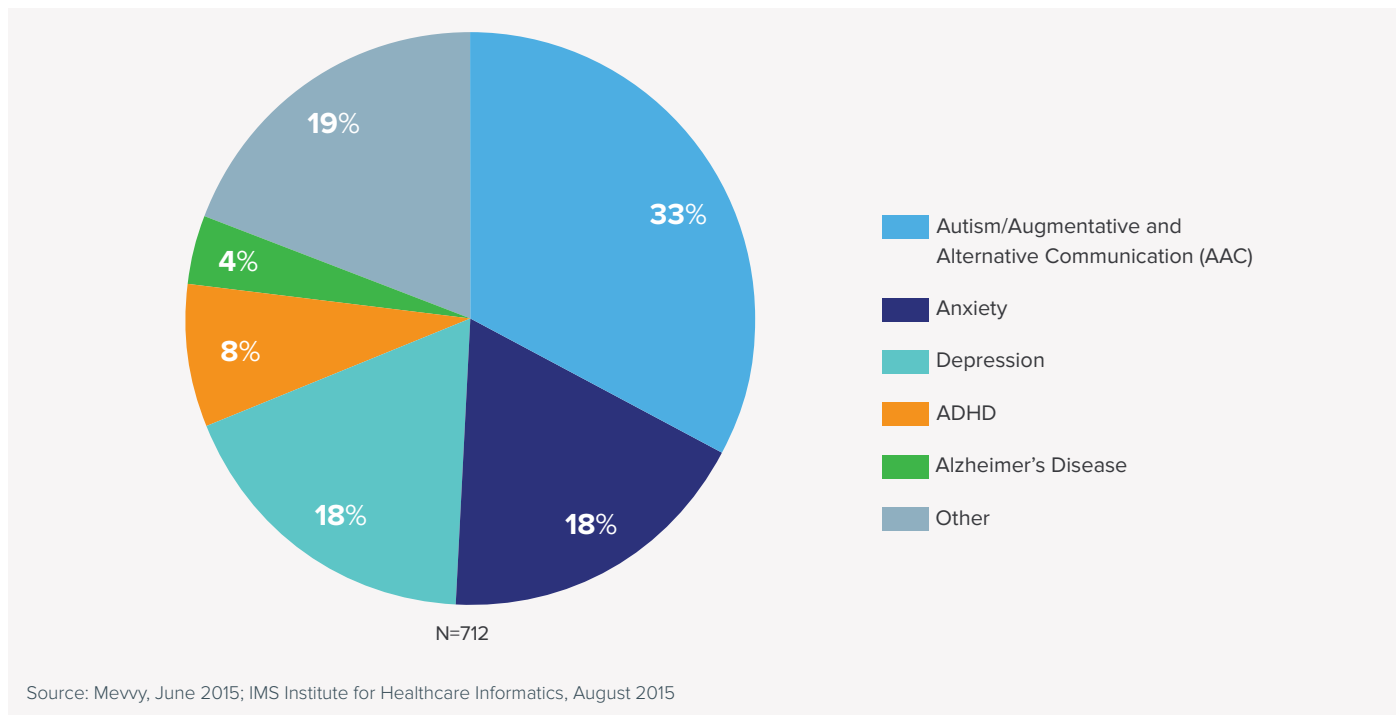
Within the subset of disease specific apps, those geared toward self-management of chronic conditions such as diabetes, blood pressure and mental health conditions are most common. When comparing the 2013 to 2015 studies, mental health, diabetes, heart and circulatory and musculoskeletal have remained in the top five therapy areas. These therapy areas are in line with industry health reform initiatives for the identification, prevention and management of chronic diseases (Exhibit 3).

Exhibit 3: Share of Disease Specific Apps Comparison 2013 to 2015 (Top 5)



Mental health apps comprise almost a third of the disease specific mHealth app space, with the most commonly addressed conditions being autism, anxiety, depression, Attention Deficit Hyperactivity Disorder (ADHD) and Alzheimer’s (Exhibit 4). Autism spectrum disorders (ASD) are expected to continue to rise and estimated to cost the U.S. \$461 billion by 2025, more than stroke, hypertension and diabetes. Autism apps making up the biggest category within mental health reflects a broad set of initiatives around management of autism.³

Exhibit 4: Mental Health Apps by Therapy Area



Over 50% of apps have narrow functionality which limits their role in healthcare

While there is a large number of mHealth apps available to consumers, there is significant variation in their capabilities. Currently, most apps continue to have narrow functionality and are restricted to providing information alone. Although there are multiple dimensions to the term functionality (Exhibit 5), depending on the intent of an app, multi-functionality is not always required to meet the purpose of an app and therefore should not be considered the single factor in assessing or rating mHealth apps.

As more apps are introduced to the marketplace, with the goal of supporting consumers in managing their health, multi-functionality will be required in scenarios such as providing medication reminders or communicating diagnostic test results to healthcare providers for clinical review and action as needed. The capacity to monitor and assist consumers in managing their health is greater in multi-functional mHealth apps than for those which simply seek to inform and educate.

Exhibit 5: Dimensions of App Functionality

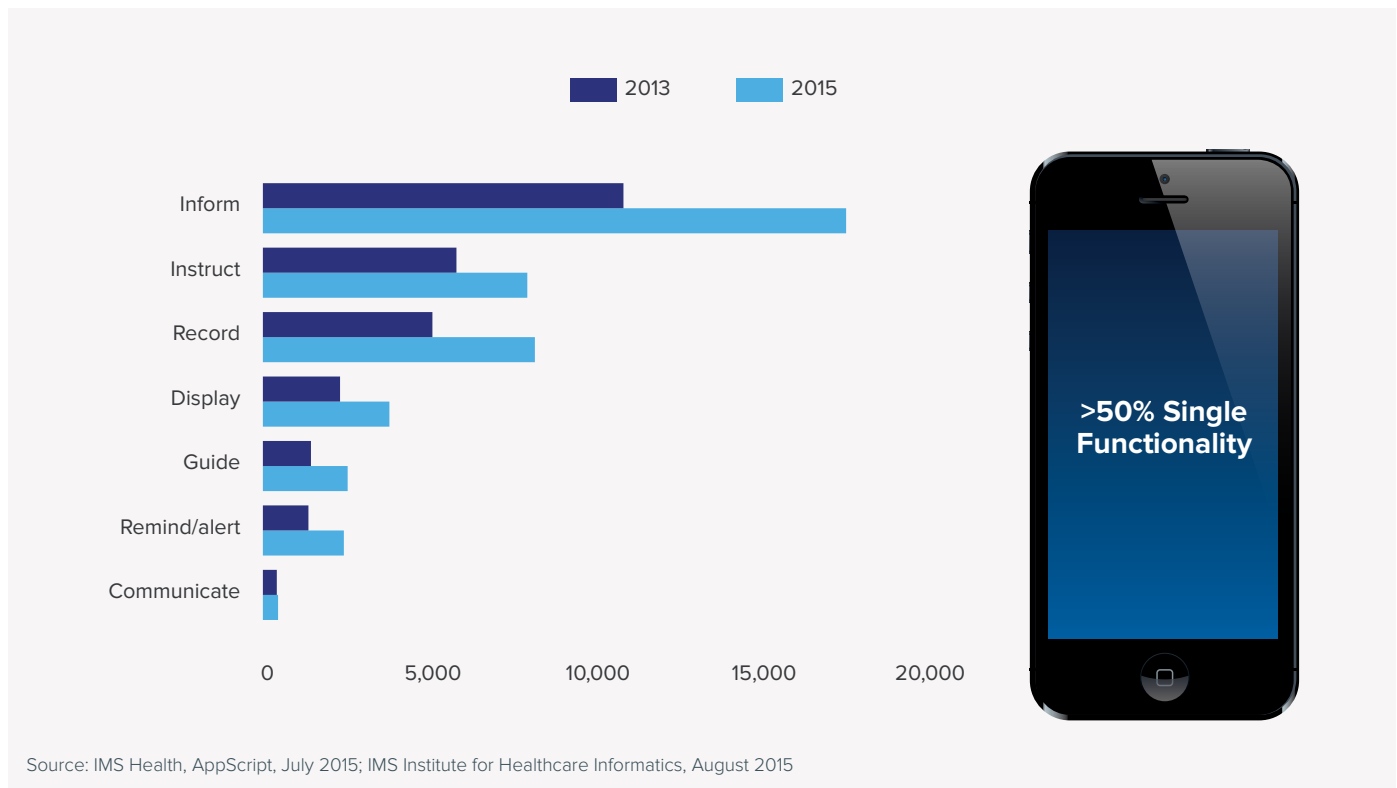
Dimensions of App Functionality

- **Inform:** Provide information in a variety of formats (text, photo, video)
- **Instruct:** Provide instructions to the user
- **Record:** Capture user entered data
- **Display:** Graphically display/output user entered data
- **Guide:** Provide guidance based on user entered information, and may further offer a diagnosis, or recommend a consultation with a physician or a treatment
- **Remind/Alert:** Provide reminders to the user
- **Communicate:** Provide communication between healthcare providers and patients

Over half of mHealth apps studied in 2015 have single functionality, a trend similar to that of the 2013 study. The most common capability is the ability to inform or provide information, representing approximately two-thirds of all consumer mHealth apps (Exhibit 6).

The multi-functionality aspect of mHealth apps is most lacking in the area of communication or connectivity to healthcare provider systems. Healthcare apps with single functionality for the purpose of providing consumers with information or instructing consumers on how to test blood glucose are important; however, the ability to communicate through connectivity and integration into provider healthcare systems establishes the foundation to more fully recognize the value of mHealth apps.

Exhibit 6: Assessment of Consumer mHealth App Functionality



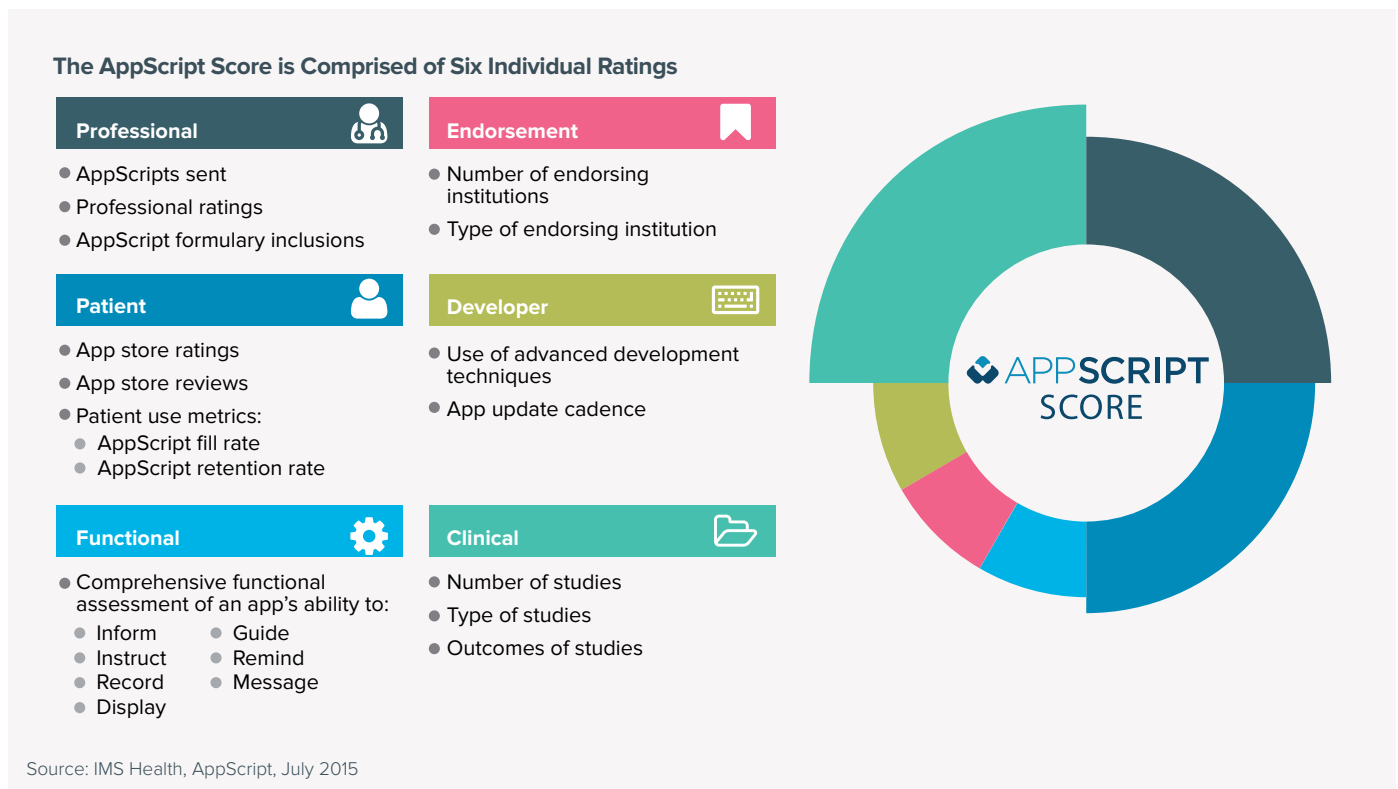
The proliferation of mHealth app options magnifies the need for mechanisms to rate, certify and select apps

The number of mHealth apps available presents an overwhelming amount of options for consumers and without guidance from their healthcare provider, consumers may try several apps in an effort to self-determine the best app for their particular situation. Providers also struggle with the amount of mHealth apps available and the limited mechanisms for assessing accuracy, efficacy and appropriateness of mHealth apps.

Multiple efforts are underway by objective third party organizations, such as Haptique, PatientView, HealthTap, Wellocracy and IMS Health’s AppScript, to provide a mechanism for rating, evaluating, and in some cases certifying, apps.⁴ Most of the rating platforms to date are privately funded but in the U.K. the National Health Service (NHS) recently expanded their publicly funded prescribing platform to include consumer apps which are deemed clinically safe. Each of the rating or certification platforms derive recommendations on available apps by using proprietary inclusion and scoring methods.

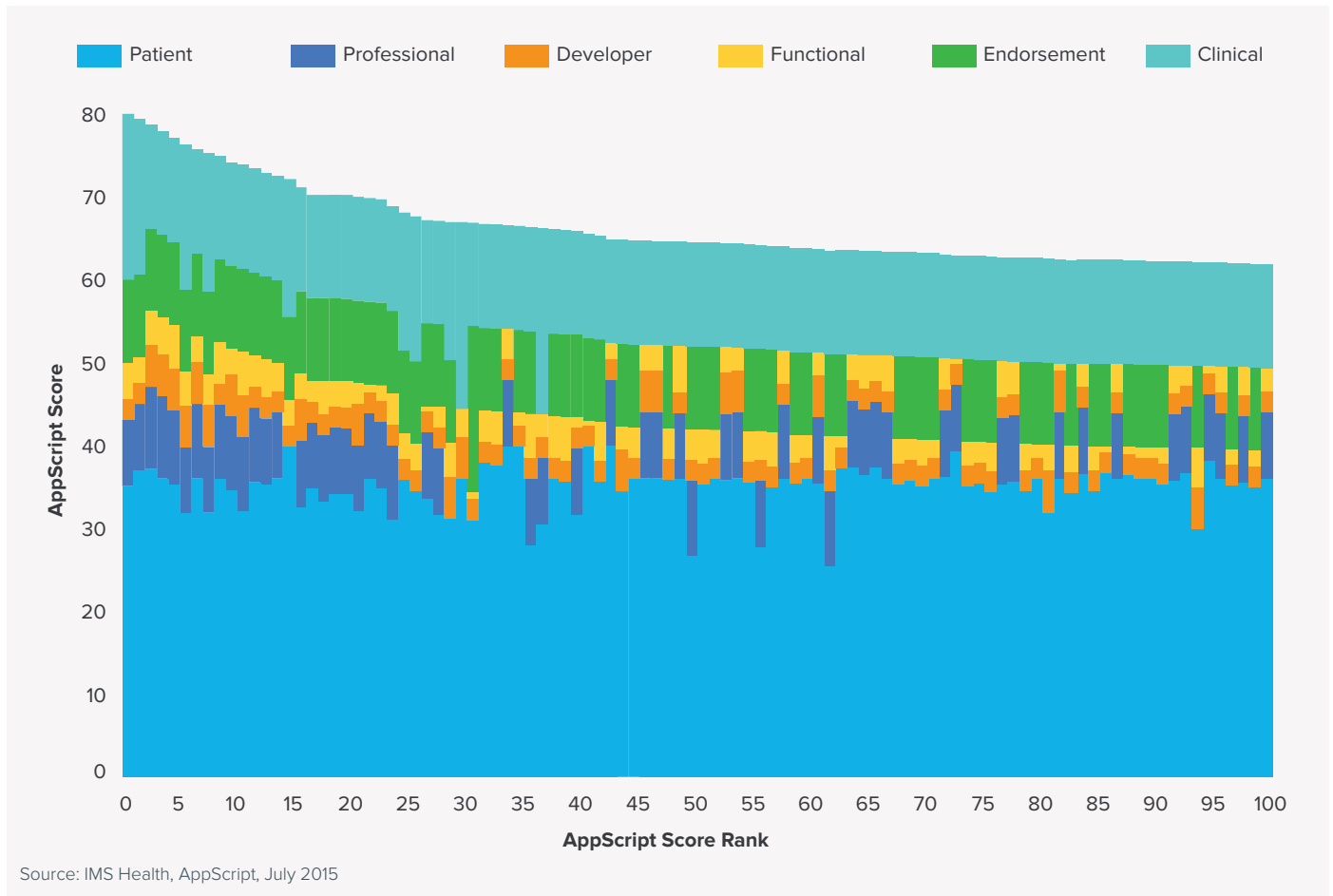
As an example, the IMS Health AppScript solution, a proprietary third-party discovery and distribution tool used by healthcare professionals to “prescribe” apps to patients, derives an AppScript Score leveraging six weighted ratings (Exhibit 7). The AppScript Score provides a comprehensive method for all stakeholders to assess mHealth app appropriateness for provider recommendation and consumer use.

Exhibit 7: IMS Health AppScript Score Overview



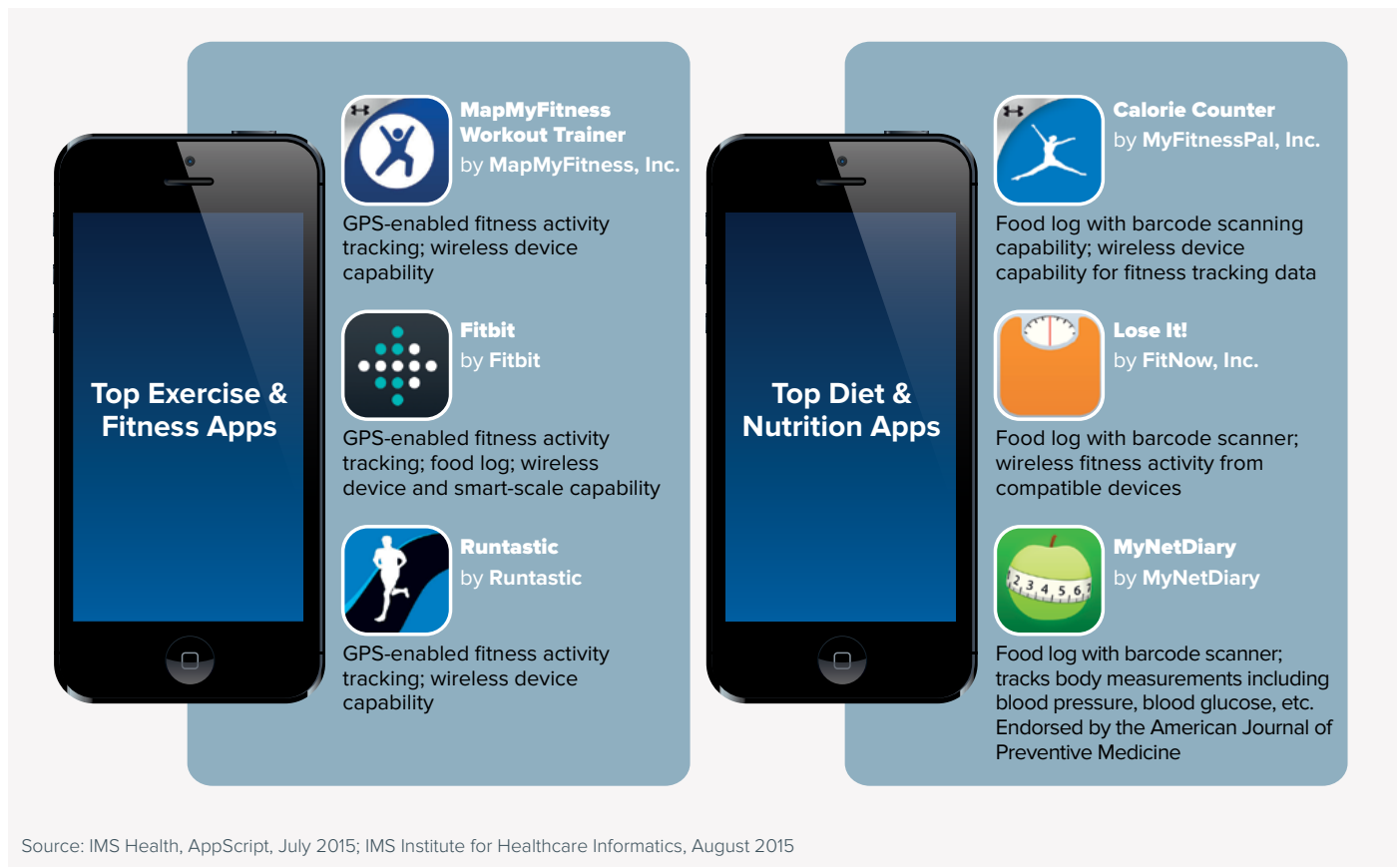
The top 100 mHealth apps, defined by the AppScript Score, typically have a strong foundation based on the individual patient ratings. Some, however, have low functionality scores but are still highly rated due to other factors such as high patient or clinical ratings (Exhibit 8).

Exhibit 8: AppScript Top 100 mHealth Apps Scoring Categorization



The top apps in the area of wellness, as defined by AppScript scoring, are highlighted in Exhibit 9. Of exercise and fitness apps, two out of the top three mHealth apps have a device which collects and records activity automatically, reflecting growing consumer interest in the convenience of devices. The top diet and nutrition apps all provide similar functions focused on counting calories, tracking exercise and entering weight. All of the apps have high consumer ratings and provide a mechanism for social networking, a major component of support especially in weight loss programs.

Exhibit 9: Top Wellness mHealth Apps



The top disease and treatment management mHealth apps, defined by AppScript scoring, are illustrated in Exhibit 10. Adherence to medications is an important factor in following treatment protocols. Managing doctor’s instructions, scheduling tests, ordering prescription refills, comparing drug prices and providing coupons are multifunction activities that are only offered through select mHealth apps.

The top five disease specific mHealth apps illustrate an alignment to key healthcare reform industry initiatives targeting chronic disease such as diabetes, cardiovascular disease and mental health (Exhibit 11). The blood pressure and ECG mHealth apps link to devices automating and improving the accuracy of data collection.

Exhibit 10: Top Disease and Treatment Management mHealth Apps



When assessing the availability of mHealth apps, the regulatory aspects around app development are important factors. The U.S. Food and Drug Administration (FDA) recognizes the opportunity that mHealth apps provide for improving patient care and increasing patient engagement around managing their own health. However, for mHealth apps that present a risk of harm to consumers if they fail to work as intended, FDA clearance is required. Given the amount of mHealth apps available and that the majority pose limited risk of harm to consumers, the FDA has taken a realistic approach to review of mobile medical applications. The criteria for identification of mHealth apps that require FDA clearance includes mHealth apps that are medical devices and present a risk to patients if they do not work properly.⁵ The FDA has also published draft guidelines around the responsible development of devices and their supporting apps highlighting the need for increased accuracy, integration, privacy and standards around the quality of mHealth app development.

The top FDA cleared apps, defined by AppScript Score, align with top disease specific apps and healthcare reform initiatives for improving prevention and management of diabetes, asthma and cardiovascular disease (Exhibit 11).

Exhibit 11: Top FDA Cleared Apps

The graphic features a smartphone on the left with a blue screen displaying the text "FDA Cleared Apps". To the right of the phone is a light blue rounded rectangle containing three app entries. Each entry includes an app icon, the app name, the developer, and a brief description of the app's function.

App Name	Developer	Description
Diabetes Logbook	by mySugr GmbH	Type 1 Diabetes - Manual data entry to "tame the diabetes monster"
AliveECG	by AliveCor	Atrial Fibrillation - Requires an AliveCor ECG to wirelessly record ECG and communicate it to the physician
Propeller Health	by Reciprocal Labs	COPD and Asthma - The Propeller Sensor - Compatible with most inhalers (COPD and Asthma) records time and location each time the inhaler is used and wirelessly sends data to smartphone app

Source: IMS Health, AppScript, July 2015; IMS Institute for Healthcare Informatics, August 2015

One in ten mHealth apps has the capacity to link to a sensor or device

Devices, also referred to as wearables and sensors, are technology that a user interacts with briefly such as a blood pressure monitor or are worn on the body for continuous data collection. Devices collect biofeedback and physiological function data from the user to be uploaded through a physical connection, or more recently, wirelessly to a smartphone or tablet. Recently, connection through devices has increased and greatly improves the accuracy and consistency with which consumers enter health data into apps. While connectivity from devices to the apps themselves has improved, there is still progress needed for consumer app data to be connected and integrated into provider healthcare systems.

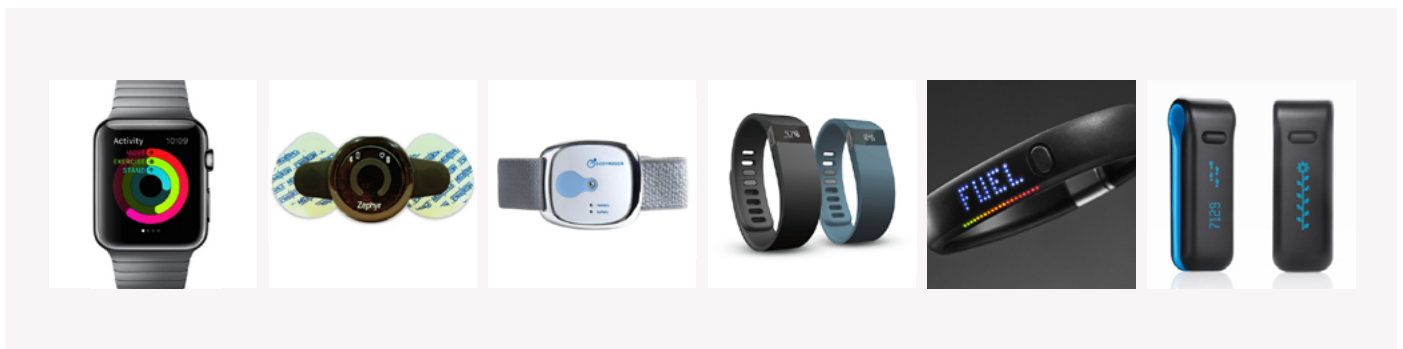
There are two methods by which health data can be recorded: through manual or active user input or through automatic passive upload. For older adults managing chronic conditions, for whom smartphones and apps may remain elusive, automated passive data collection provides a substantial benefit. Scales which automatically record weight and send data wirelessly to an app which records and monitors a patient for sudden weight gain have the potential to decrease acute episodes of congestive heart failure.⁶ High-level functionality and connectivity allows for some biofeedback devices to send data wirelessly to patients' healthcare providers to monitor for critical health incidents.

Currently, 10% of apps have the capability to link to a device. The majority of these are fitness apps but disease management apps such as blood pressure and blood glucose monitors are also demonstrating increased connectivity capabilities that span data collection as well as connectivity into provider systems.

While healthcare providers and organizations have been slower to adopt the use of devices with mHealth app connectivity as part of treatment protocols, consumers have quickly adopted this technology. Consumers interested in diet and fitness are driving the growth in the mHealth app industry due in part to the availability of devices on the market, specifically wearables which integrate seamlessly with smartphone apps (Exhibit 12).

One of the most popular fitness app brands on the market, the MapMyFitness app suite was acquired by Under Armour and boasts integration with over 400 different activity trackers. The platform also connects to MyFitnessPal, a calorie tracker, for an interconnected health and fitness package. Companies such as Withings and Fitbit who offer a broad range of devices provide mechanisms for tracking, syncing and connecting multiple sources of data through smartphone apps to monitor overall health and wellness.

Exhibit 12: Consumer Driven Mainstream Health Wearables



Innovation around the use of devices to support the improvement of health whether it be fitness, stress reduction or monitoring chronic diseases continues to grow (Exhibit 13). Currently, many of these innovative approaches are marketed directly to consumers with an option of provider interaction. Given consumer interest in mHealth, healthcare industry initiatives and marketplace opportunity for mHealth app developers, accelerated growth in available devices and associated apps should be expected.

Exhibit 13: Innovative Health Devices

Sensoria Technology Smart Sock

This device is designed to detect parameters important in helping a person improve running form such as cadence, foot landing, and the type of shoes that a person should wear when running. The Sensoria Technology Fitness App provides real time data, sending information to the companion app. It has the ability to coach the user in improving form and preventing injury from improper foot striking patterns. An anklet can be connected to the sock to track running performance in real time as well.^{7,8}



Propeller Health's Devices for Asthma

The Propeller device attaches to inhalers and syncs with a smart phone to automatically track data. Propeller's platform remotely monitors use of inhaled rescue and controller medications in asthma and COPD, analyzes patient trends, and provides regular feedback. Propeller's platform is FDA cleared to help patients and their physicians better understand and improve asthma and COPD outcomes. Recent FDA clearances expanded to allow promotion of this system in association with specific asthma and COPD medications manufactured by GlaxoSmithKline and Boehringer Ingelheim.⁹



Thync

Thync produces wearable technology focused on changing your mood and falls into the wellness lifestyle and stress category mHealth apps. Low-energy waveforms are delivered through a wearable device to facilitate relaxation, decrease anxiety or increase energy as needed. This type of device is not subject to FDA clearance.¹⁰

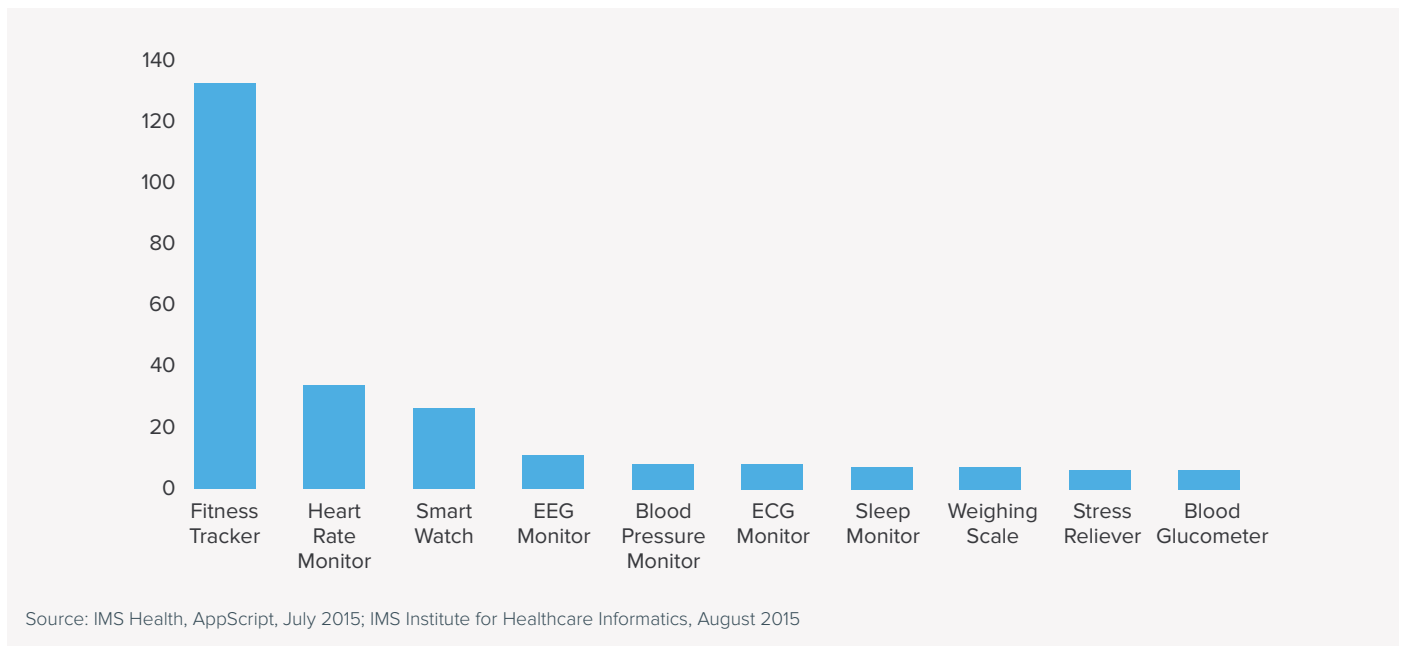


AVAILABILITY AND PROFILE OF CONSUMER HEALTHCARE APPS

The vast majority of devices used in the recording or assessing of health data are fitness trackers, followed by heart rate monitors and smart watches, all used in wellness monitoring (Exhibit 14). The remainder of the top ten device types target chronic conditions such as heart and blood pressure monitoring, as well as diabetes and stress.

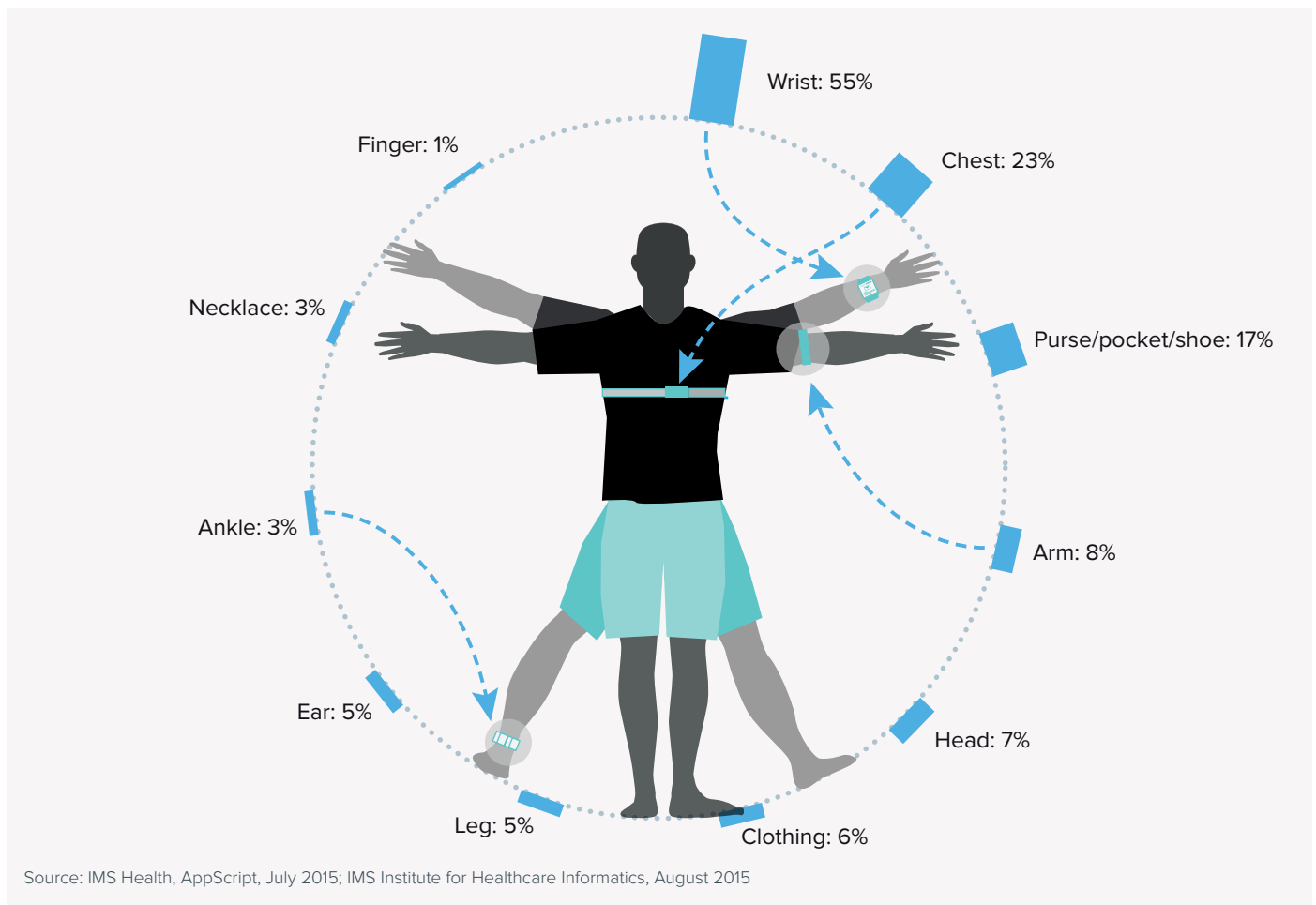
Of the 282 devices assessed, 15% have received FDA clearance. On a percentage basis, only 5% of fitness trackers have FDA clearance, whereas 75% of ECG monitors and 100% of blood glucometers have FDA clearance which is in line with the current criteria for FDA review of mHealth apps. Fitness apps that fail to work properly carry significantly less risk for harm to a consumer than an ECG monitor or blood glucometer.

Exhibit 14: Number of Health and Fitness Devices



Devices and wearables are meant to integrate with daily functions making data collection convenient, automatic and seamless. At this time, over half of wearables are designed for use on the wrist, another 23% designed to be worn around the chest and 17% are designed to be worn either on the purse, pocket or shoe (Exhibit 15). Nearly 90% of devices sync wirelessly with an app to automatically collect and provide access to data for reporting and analysis. There are a growing number of wearables being developed to connect to the ear, a body part which is unobtrusive and can collect sensory information on real-time heart rate, blood pressure, respiration rate, oxygen saturation and steps taken.¹¹

Exhibit 15: Location of Wearable App Use



Connectivity for mHealth apps is increasing but still remains a barrier to full adoption of mHealth

Connectivity plays a role not just in how consumers connect their data from a device into an app but how data collected within an app connects to a healthcare provider, community of like patients and/or social networks which can provide additional support, guidance and references. Connectivity within the app space between consumers, devices and healthcare providers is critical to fully leveraging mHealth apps as a component in maintaining long term, successful disease prevention and management as well as containing overall healthcare costs.

Over the past two years, the percentage of mHealth apps with the capability to connect to social networks increased from 26% to 34% based on the apps studied (Exhibit 16). This increase reflects improved functionality of apps and underscores the importance of including the aspect of social networking in mHealth apps. Social networks provide connections that are motivating and add a different level of engagement around app use whether it be encouragement from a person, as opposed to pre-set encouraging comments from a tool, to sharing real experiences with people in a similar situation. Leveraging these types of connections and interactions is important to the overall consumer experience and success of an mHealth app (Exhibit 17). For the top AppScript apps, 65% have connections to social media.

Exhibit 16: Growth in Capability of Apps to Connect to Social Networks

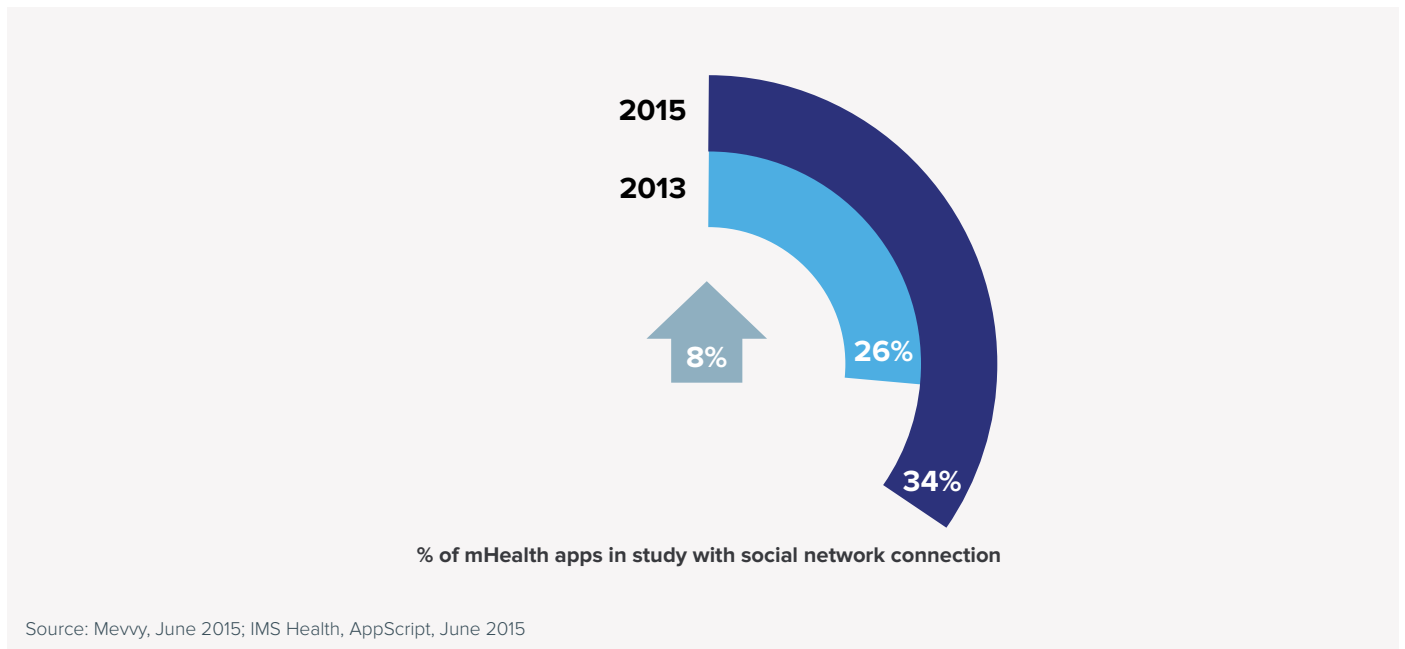


Exhibit 17: Examples of Apps with Capability to Connect to Social Networks



QuitNow!
by Fewlaps S. C.

- Real-time statistics on nicotine consumption
- Online access to others in your situation to keep you from feeling alone
- Share success through Facebook, Twitter and other social media platforms

C25K Couch To 5K
by RunDouble

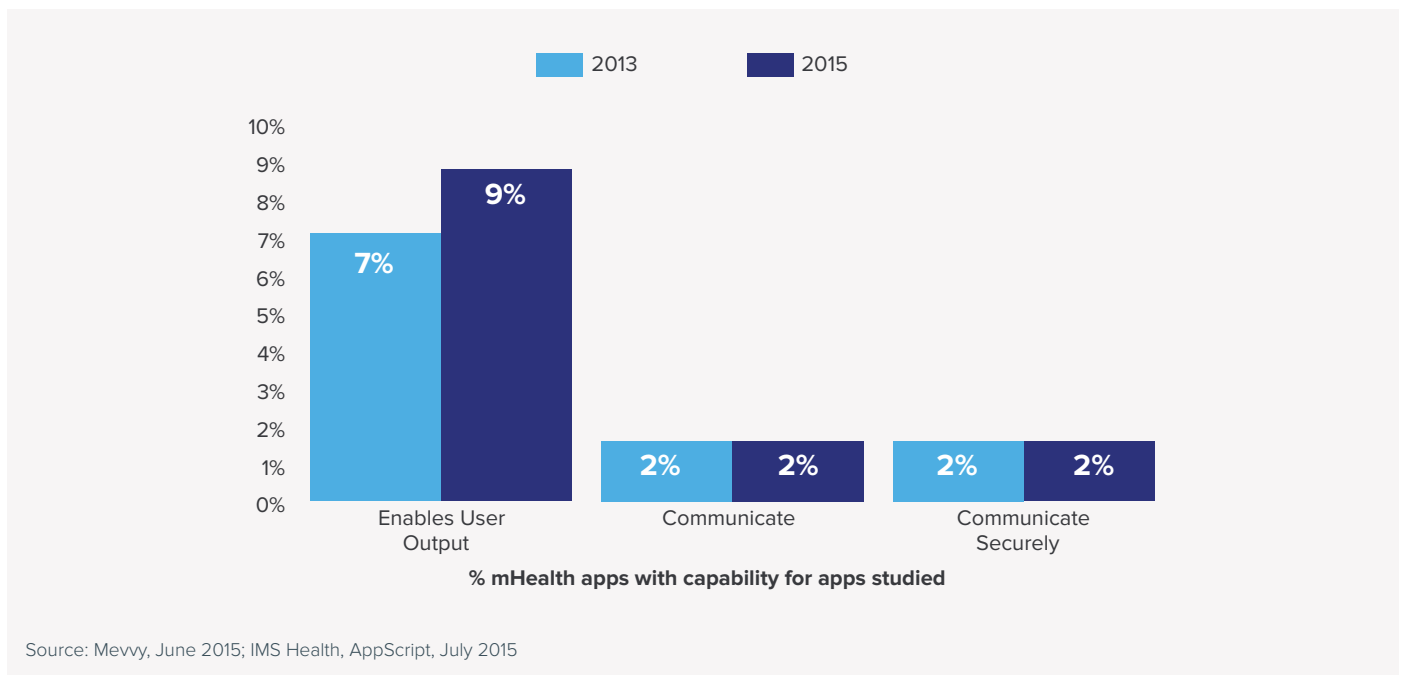
- Training companion, includes programs of varying lengths
- Interactive prompts
- Connects to MyFitnessPal for full fitness integration
- Post workouts and share fitness goals and challenges through Facebook

Source: IMS Health, AppScript, July 2015; IMS Institute for Healthcare Informatics, August 2015

The ability to directly connect with healthcare providers for informing and managing health conditions is also important. However, integrating mHealth with electronic medical records (EMRs) is complex and presents many challenges for full and seamless implementation. EMR companies such as Epic have announced plans for their own app store for apps designed to connect with Epic EMRs throughout health systems in the U.S.¹² Athenahealth and Allscripts, both EMR developers, have built mHealth apps that connect to health IT systems, and integrate with their proprietary EMRs.¹³ EMR companies are also developing standards for app developers to more seamlessly integrate with EMR systems but these efforts are in the early stages.

In the past two years, the share of mHealth apps with the capability to output user data has increased but the ability to communicate externally such as with a provider organization has remained flat (Exhibit 18). While the percent of apps that communicate externally remains low, these apps are able to do so in a secure way. Many apps that are utilized to communicate with healthcare providers and health systems are now required to adhere to Health Insurance Portability and Accountability Act (HIPAA) rules to ensure privacy and security.¹⁴

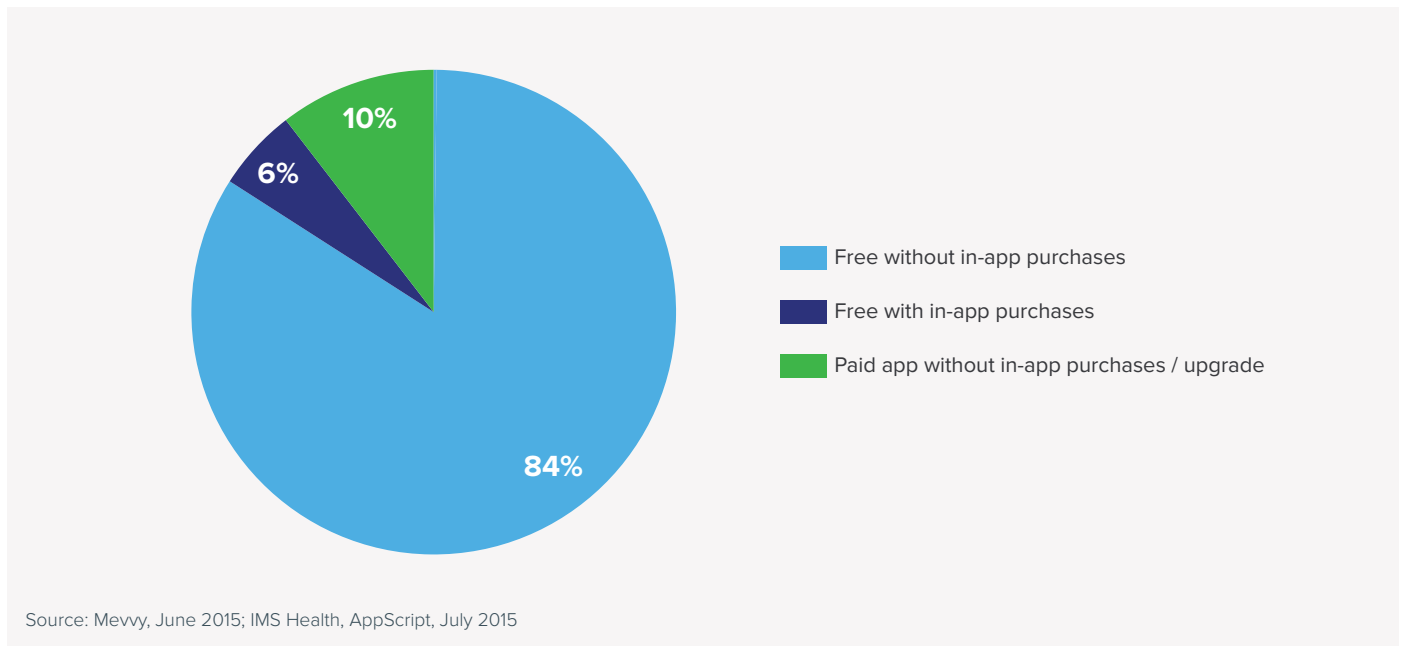
Exhibit 18: Capability of App to Output User Data and Communicate



Over 90% of mHealth apps remain free to consumers

The majority of consumer mHealth apps available through the public domain can be downloaded by consumers at no cost (Exhibit 19). However, this does not include expenses for devices and their connectivity to apps, such as fitness trackers, which must be purchased separately by the consumer for use with the app and may inflate the share of free apps since the cost is incurred outside of the app itself.

Exhibit 19: Consumer Cost for mHealth Apps



When a cost is incurred for an app, the average price of an mHealth app has doubled in two years from \$1 to \$2 per app. A third of apps studied in 2015 required a paid sensor. Overall there has been a 4% decrease in the percent of mHealth apps costing less than \$3 with a subsequent increase in the cost for chargeable apps over ten dollars.

The most expensive apps are those that are disease specific, including apps in the therapeutic areas of autism and augmentative and alternative communication (AAC; Exhibit 20). Of the top 20 most expensive apps, all exceeding \$150, 75% were for Autism and AAC. Although these apps were identified as the most expensive, these apps are beginning to augment and/or replace more costly dedicated devices.¹⁵ These highly customizable AAC devices have very high functionality such as eye scanning, numerous voice selections and increased vocabulary options which are desirable, but very costly to consumers. Reimbursement for AAC devices is often a burdensome process, and insurance companies and Medicare do not currently reimburse for tablets or other non-dedicated speech devices. The AAC mHealth app market is providing additional options, with increasing functionality, at lower cost and with greater accessibility to a growing tablet and smartphone user market.

Exhibit 20: Examples of Paid Disease Specific mHealth Apps



TouchChat
by Fewlaps S. C.

- Augmentative and Alternative Communication (AAC)
- Communication solution for individuals who have difficulty using their natural voice
- Designed for individuals with Autism, Down Syndrome, ALS, apraxia, stroke, or other conditions



Proloquo2Go-Symbol-based AAC
by AssistiveWare

- Augmentative and Alternative Communication (AAC)
- Personalizable and customizable symbol-supported communication app
- Links to social media for supportive and educational community connections

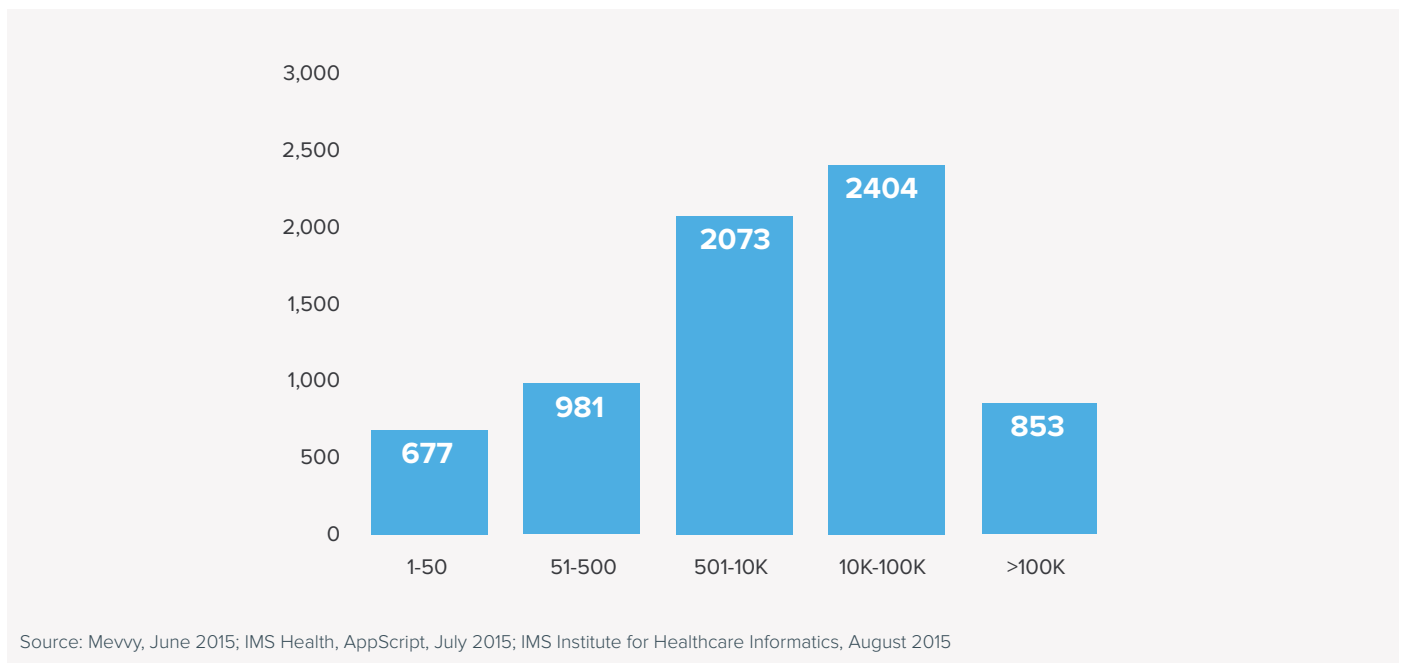
Source: IMS Health, AppScript, July 2015; IMS Institute for Healthcare Informatics, August 2015

Uptake and use of mHealth apps

A small number of mHealth apps are responsible for over 90% of consumer downloads

Given the growth of healthcare apps in the smartphone and tablet market, consumers have the ability to try several apps before staying with one that works for them. The low, or no, cost of apps increases the ability to try apps at no financial risk to consumers. Based on the 6,998 apps for which download information was available, the relatively small subset (12%) of mHealth apps with greater than 100,000 downloads account for more than 90% of downloads overall (Exhibit 21).

Exhibit 21: Android mHealth App Installs



UPTAKE AND USE OF APPS

The most frequently downloaded apps, defined as downloaded by consumers more than 10 million times, are primarily fitness and diet apps (Exhibit 22).

Exhibit 22: Top mHealth Apps with the Highest Number of Downloads (Android only)



Runtastic Running & Fitness by Runtastic
Runkeeper - GPS Track Run Walk by FitnessKeeper, Inc.
Endomondo Running Cycling Walk by Endomondo.com
Nike+ Running by Nike, Inc.
Workout Trainer by Skimble Inc.
My Tracks by Google Inc.
Abs workout by Caynax



Calorie Counter – MyFitnessPal by MyFitnessPal Inc.
Calorie Counter by FatSecret by FatSecret
Cookpad - recipes app by Allthecooks, LLC
Noom Coach: Weight Loss Plan by Noom, Inc



Instant Heart Rate by Azumio Inc.
Cardiograph by MacroPinch



Period Tracker by GP International LLC
Period Calendar / Tracker by ABISHKKING



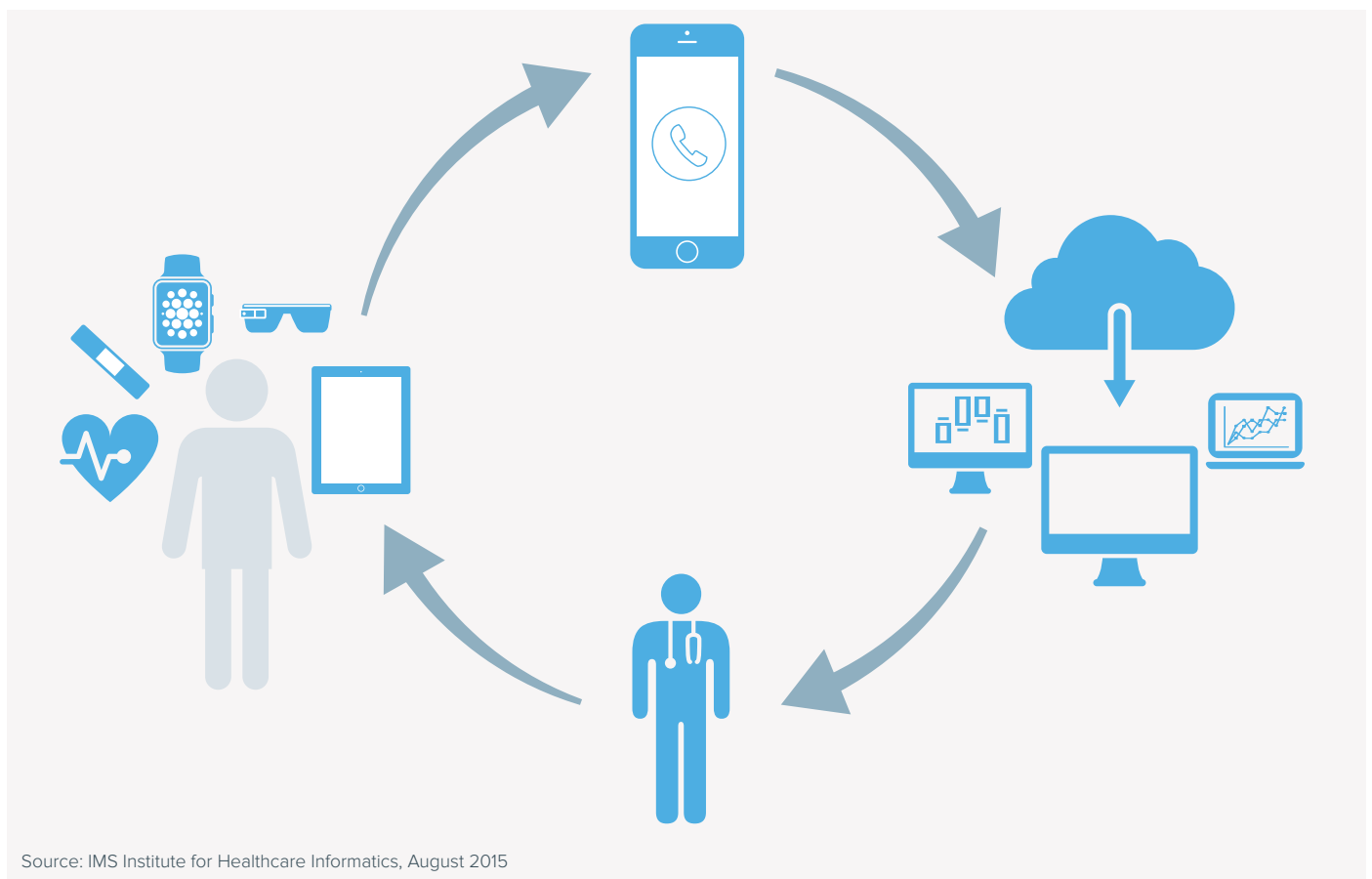
Walgreens by Walgreen Co.

Healthcare provider prescribed mHealth apps illustrate an increase in patient 30-day retention rates

Healthcare payment reforms driving the shift from volume to value based payments facilitate strategic discussions around the value of more fully connected systems, including discussions around leveraging mHealth apps in a prescriptive manner, particularly in the areas of chronic conditions. Therapy areas which require chronic disease management and have high costs to the healthcare system such as congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD) and diabetes are areas for early adoption given the mHealth benefits around patient adherence and the ability to more effectively monitor patient vitals.

There is growing interest in the role of “prescribing” apps to patients as distinct from informally recommending apps. The optimal process flow for prescribing and tracking apps, as illustrated in Exhibit 23, provides a mechanism for continual feedback. The optimal process provides connectivity, communication and reporting of metrics to healthcare providers for monitoring patient adherence and vitals. However, most physician recommendations for the use of apps are not monitored by provider systems nor is the provider time allocated to the review, analysis and follow-up of collated app data. In defense of the current environment, depending on the intent of an app, multi-functionality and optimal connectivity may not be required.

Exhibit 23: Optimal Process Flow for Providers Recommending Apps



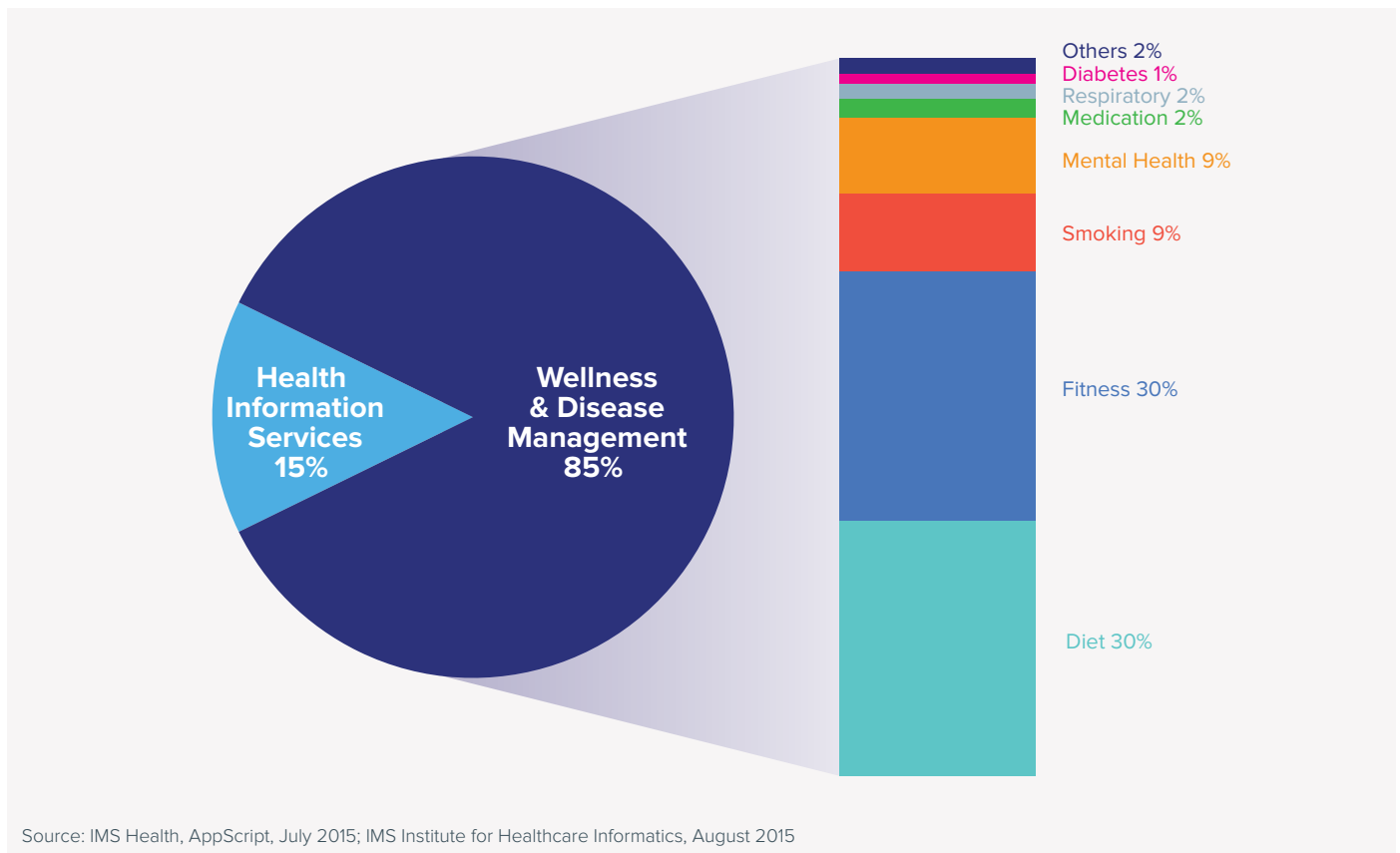
Source: IMS Institute for Healthcare Informatics, August 2015

UPTAKE AND USE OF APPS

Recent industry reported retention rates for mHealth apps is lacking, but for health and fitness apps the 30-day retention rate was last reported as 47% in 2012.¹⁶ The 30-day retention rate for prescribed mHealth apps, as determined by the AppScript provider selection, prescribing and tracking platform, results in 30-day retention rates of 59% across all prescribed mHealth apps and 76% for fitness apps. Conservatively, provider recommendation increases retention rates by over 10% for mHealth apps in general. For health and fitness apps, the improvement in retention rates is over 30%. Additionally, if mHealth app access is streamlined with automatic log-in, upload and connectivity with provider healthcare systems, providers note an even greater potential for improved patient retention rates.¹⁷ Active engagement of providers in prescribing mHealth apps to patients for overall wellness is important and influential. Recognizing the opportunity this provides to the patient, providers and healthcare systems overall, there are a growing numbers of platforms being used by providers to prescribe mHealth apps to their patients, such as Happtique, PatientView, HealthTap, Wellocracy and IMS Health AppScript.

For example, AppScript is a product which enables healthcare professionals, including health coaches, to search, select and “prescribe” the best mHealth applications to patients. Based on a review of this data, healthcare professionals are prescribing 1.74 apps per patient per visit. Most patients are downloading the prescribed mHealth app on the day of their appointment.

Exhibit 24: Apps Prescribed by Providers



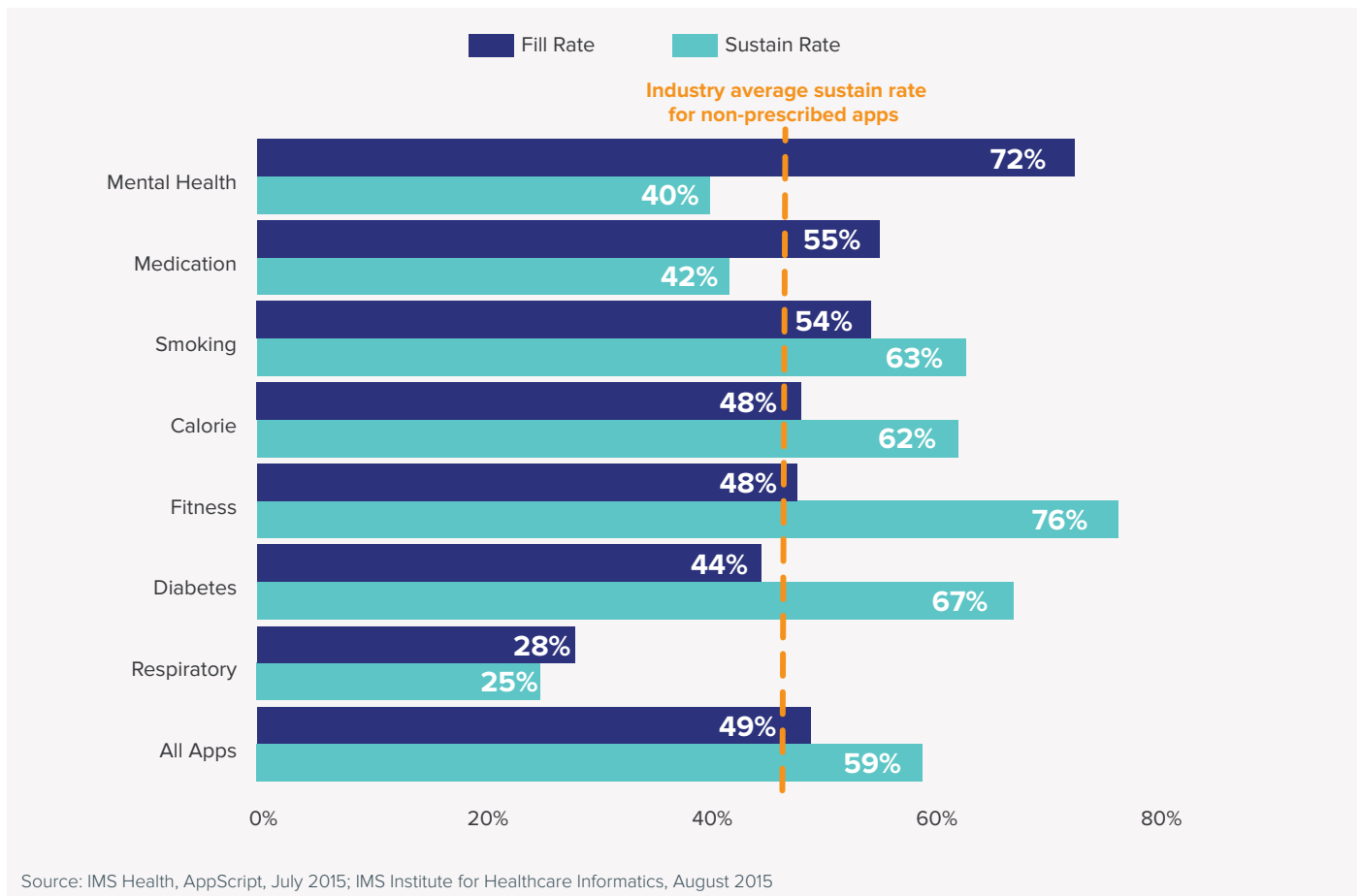
UPTAKE AND USE OF APPS

Of the healthcare providers using AppScript, the apps being prescribed can be segmented into those used to access health information services, such as for scheduling appointments, and apps that are focused on wellness or disease management (Exhibit 24).

Examining the top mHealth apps that are prescribed to patients by healthcare providers, the majority are focused on the wellness and disease management aspect of the patient journey. Within the cohort of wellness and prevention apps, the top prescribed are for diet, fitness, smoking and mental health.

Based on an analysis of the uptake of consumer apps prescribed to patients through the AppScript platform, the rate at which patients are filling apps varies by category, with mental health app prescriptions filled at a higher rate than others (Exhibit 25). However, the 30-day sustain rate of continued use by patients is highest in the fitness apps category. The increasing market share of wearables or fitness trackers may explain the higher app retention by a consumer. Regardless, even in the other categories where devices are not as prevalent, the sustain rate is higher than the industry averages.¹⁸ This supports the case that utilizing a platform in a systematic way within a provider organization yields higher patient retention rates for mHealth apps.

Exhibit 25: Top Apps Average Fill Rate and Average Sustain Rate



Among the most frequently prescribed apps from the AppScript platform, calorie counting and fitness tracker apps lead the group of top apps prescribed to patients; however, an app to aid patients with smoking cessation, QuitSTART, also made the top five (Exhibit 26).

Exhibit 26: Top mHealth Apps Prescribed to Patients

The infographic displays five app cards arranged in a cross pattern. Each card features an app icon, the app name, the developer, and a brief description of the app's functionality.

- Calorie Counter by MyFitnessPal Inc.**
Calorie counting app with a food database of over 5 million foods
- Every Body Walk! by Kaiser Permanente**
Track distance, time and calories burned walking and share via social media
- Map My Fitness – Workout Trainer by MapMyFitness, Inc.**
Log workouts and calories, sync data to other apps for sharing
- Lose It! by FitNow, Inc.**
Customize weight loss with goal setting, calorie and exercise tracking
- QuitSTART by ICF International**
Created by the National Cancer Institute, tracks cravings and moods, monitors goal progress

Source: IMS Health, AppScript, July 2015

Growing body of evidence for mHealth apps

The number of clinical trials utilizing mobile apps has more than doubled in the last two years

While more than a third of U.S. physicians indicate that they have recommended an app to patients, there remains hesitancy to do so in a truly prescriptive manner.¹⁹ The lack of evidence for mHealth apps' effectiveness in improving healthcare outcomes continues to be a key barrier to widespread physician adoption of mHealth apps as part of treatment protocols. The majority of studies published discuss app usage, not app effectiveness in terms of improving health outcomes or lowering healthcare costs. However, momentum is building for providers to prescribe mHealth apps as part of treatment protocols given growing evidence through observational studies and randomized clinical trials (RCTs) to support the value of apps in improving healthcare outcomes.

In addition to the increase in mHealth clinical trials, there has also been an increase in the implementation of clinical programs leveraging mHealth apps, which provides greater real world evidence to support the use of mHealth apps in health management. Historically, mHealth app evidence has been intertwined with telemedicine, SMS-text messaging and mobile app methodologies, but app studies require an evidence base and are beginning to differentiate themselves.²⁰ While certain functions between SMS-text messaging interventions and mHealth app use overlap, such as reminders, information, and instruction, others are specific to the mHealth space and require validation.

Recent mHealth studies have highlighted the positive impact that mHealth app use has on patient compliance, success rates for diet and fitness interventions and the ability to assist in reaching the most needy and hard-to-reach populations (Exhibit 27). Additionally, evidence for the positive impact of mHealth interventions on chronic disease management is beginning to demonstrate results, highlighting opportunities for improved clinical outcomes and cost effectiveness.

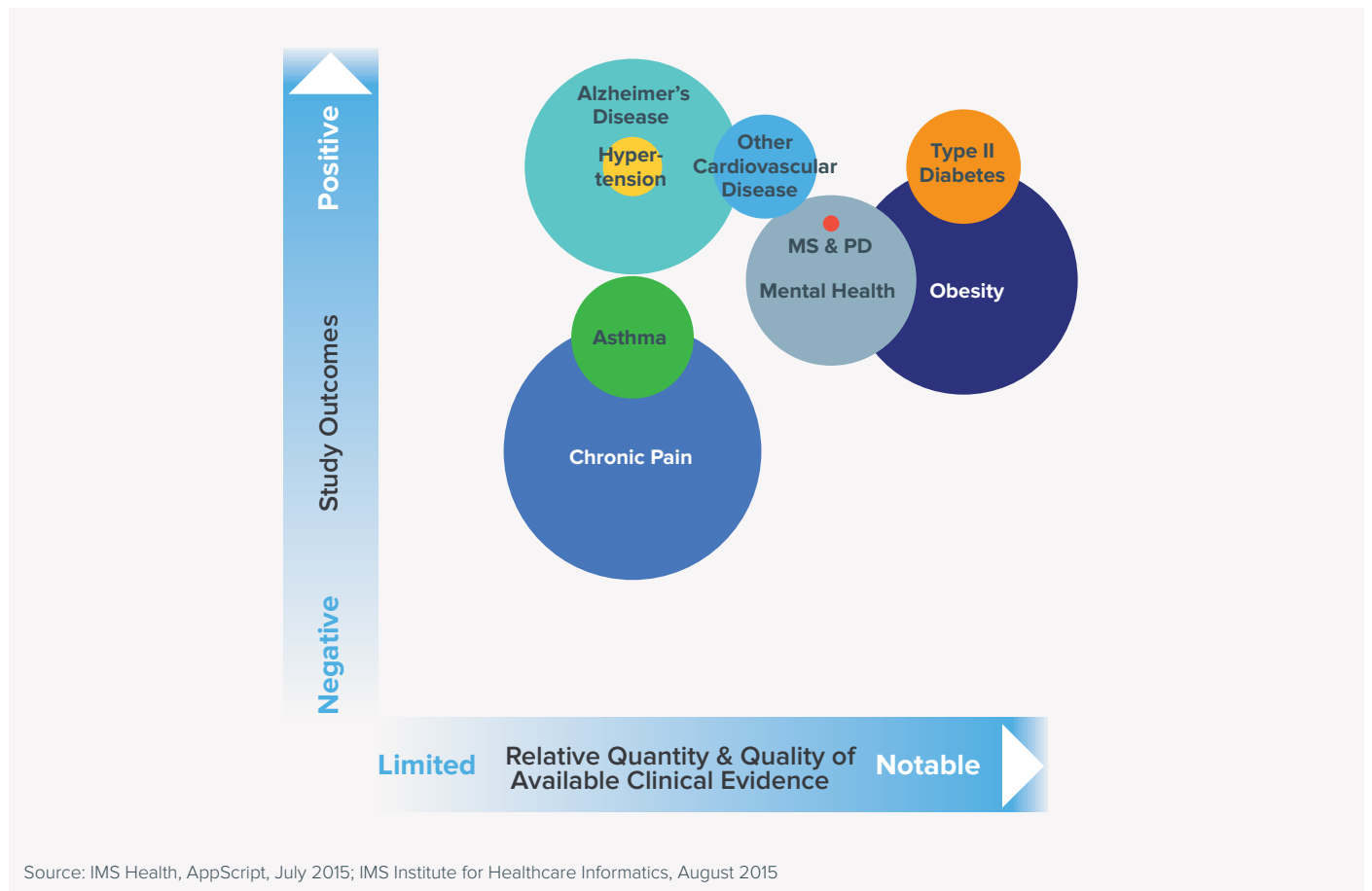
Exhibit 27: Positive Result Examples of mHealth Studies

mHealth Study Results

- Nutrition: Increased adherence to diet monitoring and decreased effort to continue diet without app.²¹
- Wellness: Results of healthy lifestyle indicators demonstrate the positive impact of using web-based app interventions.²²
- Mental Health: Rapid improvements in work and social functioning with participants who had middle to moderate depression, anxiety and/or stress.²³
- Perioperative care: App used effectively in patients undergoing routine cardiac procedures to ensure 100% compliance with instructions along with excellent patient satisfaction scores.²⁴

While the amount of mHealth studies is growing, there has been little scientific assessment of mHealth evidence from a quantity, quality and safety perspective. Rigorous investigation is needed in order to fully understand the scope of available evidence and guide future initiatives. IMS Health reviewed over 580 published studies to provide preliminary insight regarding the current landscape of evidence. After excluding qualitative studies, content reviews and healthcare provider apps, 113 quantitative studies were isolated by therapy area and given scores based on review of the quality of results. Based on this analysis, the most notable and positive evidence generated to date is in the areas of type II diabetes, multiple sclerosis and Parkinson’s disease, cardiovascular disease and obesity. Exhibit 28 provides an illustration of select therapeutic areas, estimated population impacted and scoring for the quantity and quality of studies. General fitness and nutrition apps, applicable to the entire population, are not shown in Exhibit 28, but have neutral to positive results and relatively limited evidence respectively.

Exhibit 28: Directional Review of mHealth Evidence for Select Therapy Areas and Affected Populations*



*Based on U.S. population disease estimates. Note: MS & PD: Multiple Sclerosis and Parkinson’s Disease

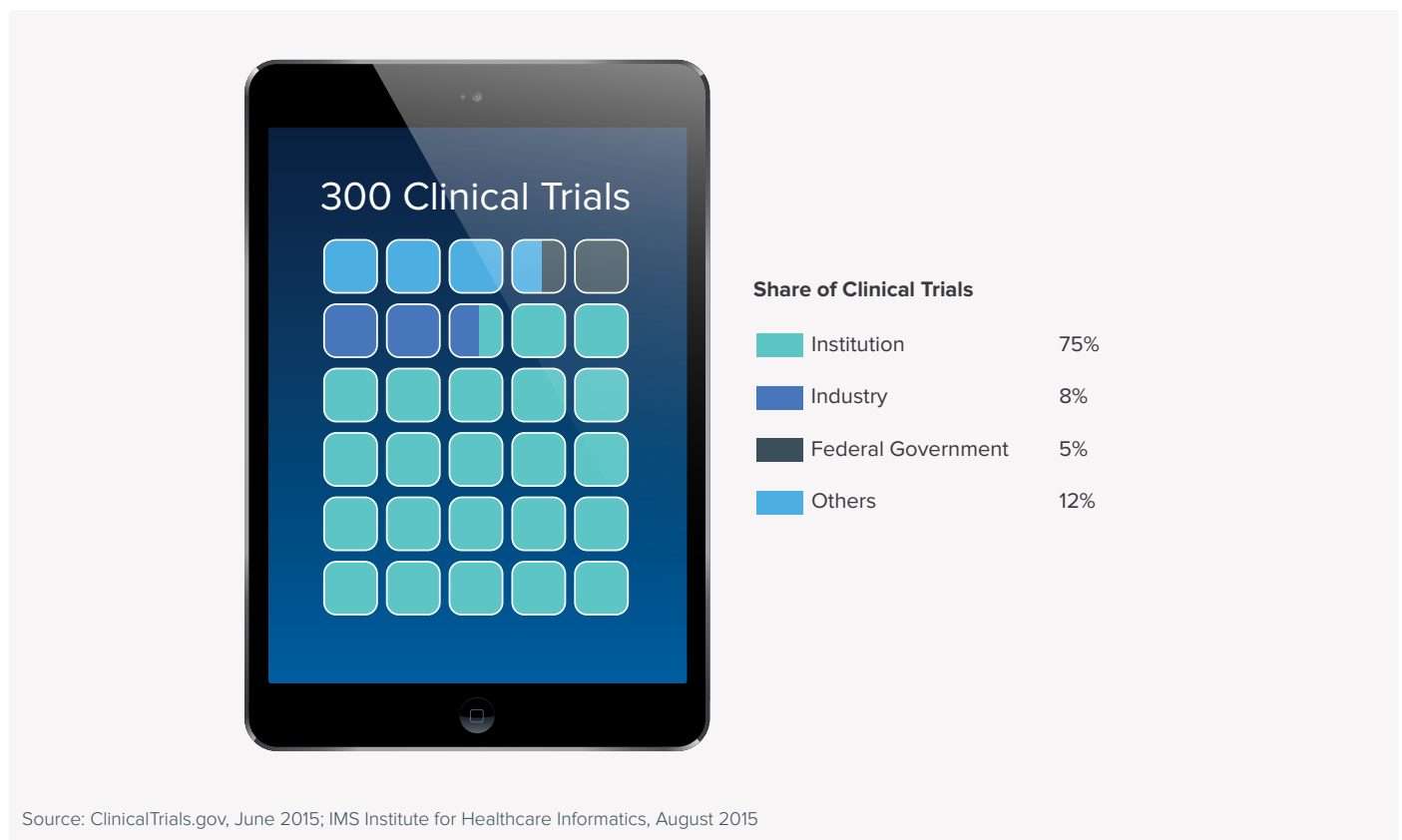
GROWING BODY OF EVIDENCE FOR HEALTHCARE APPS

Based on a review of the clinicaltrials.gov website, the number of clinical trials that utilize mHealth apps has more than doubled in the past two years, increasing from 135 to 300. While observational trials are sufficient for studying outcomes related to supplemental basic mHealth apps, the majority of current mHealth trials are interventional, underscoring the importance of providing rigorous study results to physicians for mHealth app use in patient care management.

Of the 300 clinical trials examined, 75% are sponsored by an institution (universities, colleges, hospitals and clinics), 8% by industry (e.g., pharmaceutical and software companies), 5% by federal government and 12% by others (Exhibit 29). The benefit to the prevalence of institutional support is the scientific rigor and clinical expertise, whereupon physicians may feel greater assurance in prescribing apps to patients. The other category is comprised of disease specific societies and private research institutes and foundations. Industry sponsors are utilizing app clinical trials to improve medication and treatment adherence and disease symptom self-management.

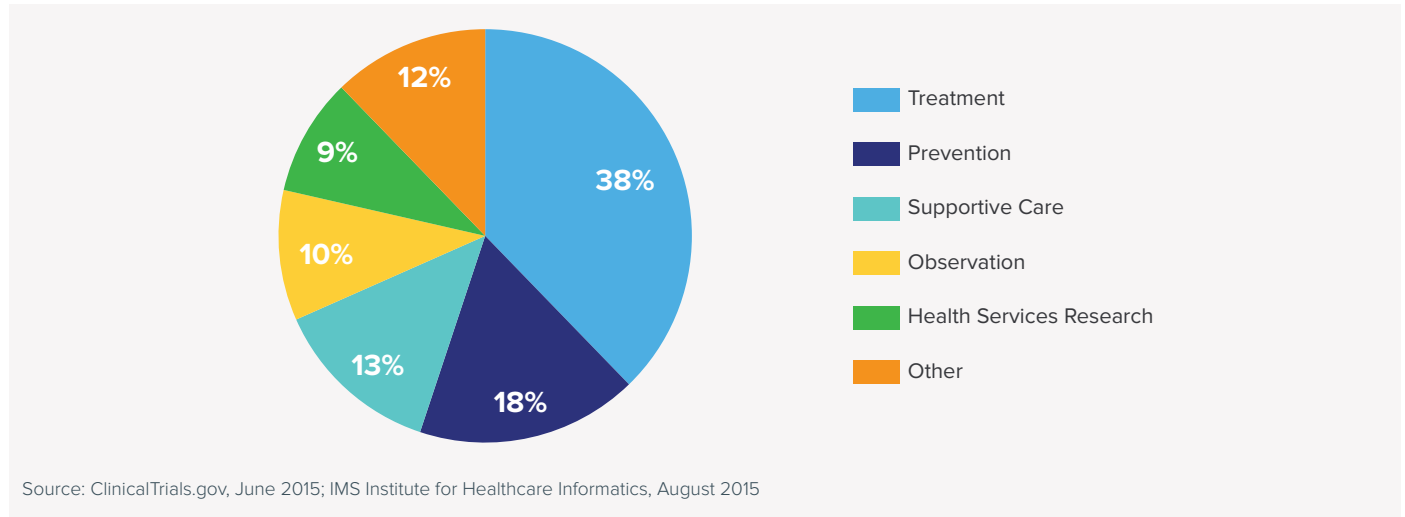
More than 50% of trials are sponsored by more than one organization. The benefit to shared sponsorship and collaboration is the increase in the pool of expertise, consideration of multiple stakeholder perspectives and achievement on wider messaging of study results.

Exhibit 29: Sponsors of mHealth App Clinical Trials



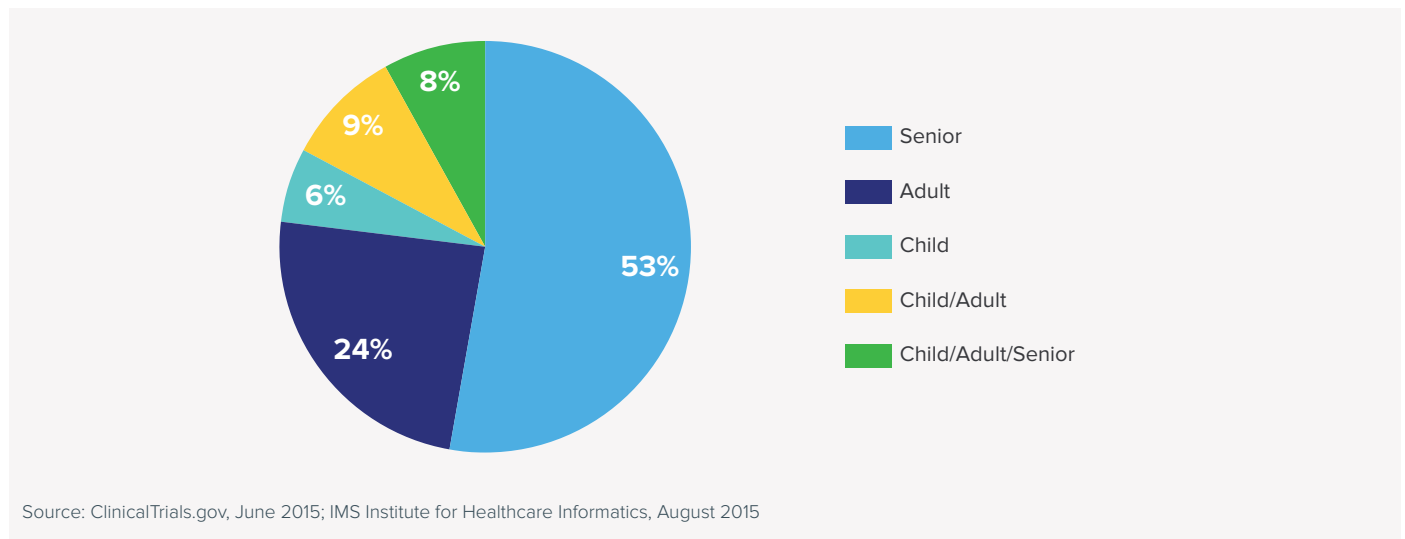
Across all studies, 89% are interventional and the remainder are observational. In terms of the primary purpose for interventional studies, the majority target disease treatment and prevention (Exhibit 30). This coincides with the identified industry need for RCT quality evidence in support of mHealth app use for treating and managing chronic diseases.

Exhibit 30: Type of mHealth App Clinical Trials



Demand has increased for larger clinical trials to better examine sub-populations of app users. The number of enrollees in clinical trials has remained steady, averaging 436 enrollees per trial, almost 60% higher than average medical treatment enrollment.²⁵ Of the mHealth app clinical trials recruiting over 2,000 patients, 53% are directed at the senior population, a key population that requires healthcare management and is targeted for mHealth app utilization growth in the near future. More clinical trials are needed to inform the development of mHealth guidelines and ultimately impact clinical practice behavior change.

Exhibit 31: Makeup of Patients Enrolled in mHealth App Clinical Trials



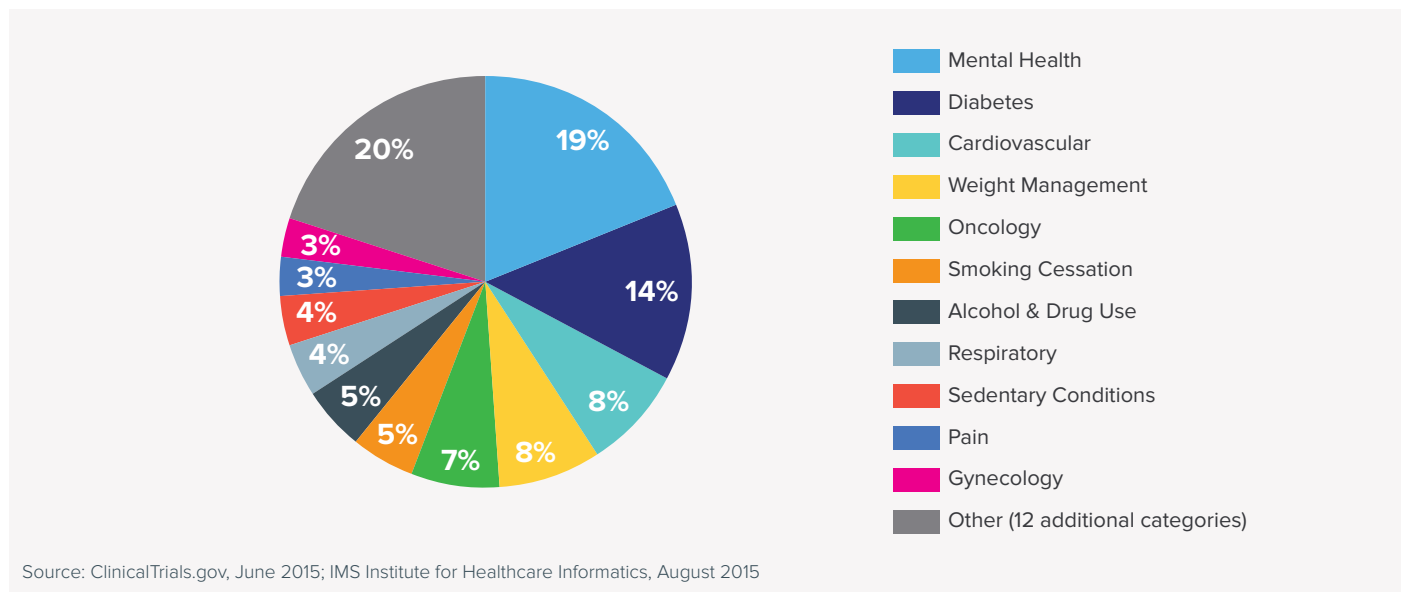
GROWING BODY OF EVIDENCE FOR HEALTHCARE APPS

The ability to reach, manage and engage an ageing population to improve health outcomes is a key component to achieving sustainable healthcare systems that appropriately manage costs, provide access to those most in need and generate positive outcomes. Reflecting the increased interest in this population and recognizing some of the barriers to full adoption within this sub-population, the analysis of clinical trials underway illustrates that more than half of mHealth app clinical trials are targeted towards seniors (Exhibit 31).

With regard to specific conditions targeted by active clinical trials, mental health/behavioral disorders, diabetes, cardiovascular, weight management, oncology and tobacco/smoking cessation comprise the top six areas of focus (Exhibit 32). While not the top areas of focus, there is also support for alcohol/drug dependence, respiratory diseases, pain, gynecology and reproductive health.

The significant increase in clinical trials assessing mHealth app usage and clinical outcomes demonstrates a clear recognition of the need for evidence based mHealth app insights to support greater adoption of mHealth apps for clinical use and integration within treatment protocols. Early proof of concept work in diabetes, cardiovascular disease and weight management demonstrating positive results has led to an increase in the number of studies in those two therapeutic areas. Three-quarters of cardiovascular trials, over 60% of weight management trials and just over half of diabetes trials were submitted within the last two years. Mental health and behavioral disorders also demonstrated an increase in the number of trials submitted in the last two years increasing by 32%.

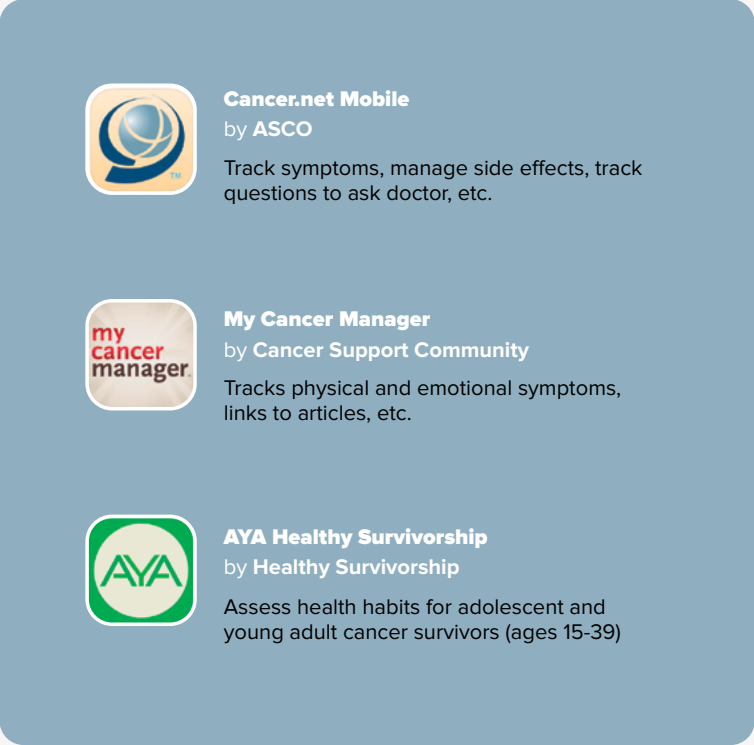
Exhibit 32: Type of Smartphone App Clinical Trials



Implementation of consumer app programs by organizations is increasing

Clinical organizations are taking action to ensure that accurate clinical and public health information is available to support the large population of apps users. The Centers for Disease Control and Prevention has developed a vaccine schedule app, swimming safety app and an app designed to aid international travelers in knowing what is safe to consume. The American Diabetes Association has developed an app to monitor glucose, as well as track food and fitness. The American Society of Clinical Oncology (ASCO) developed a patient-centered app which tracks medications, symptoms and questions patients may have for healthcare providers, in addition to oncologist-approved cancer information (Exhibit 33).

Exhibit 33: Sponsored Oncology mHealth Apps



Cancer.net Mobile
by ASCO
Track symptoms, manage side effects, track questions to ask doctor, etc.

my cancer manager
by Cancer Support Community
Tracks physical and emotional symptoms, links to articles, etc.

AYA Healthy Survivorship
by Healthy Survivorship
Assess health habits for adolescent and young adult cancer survivors (ages 15-39)

Source: IMS Institute for Healthcare Informatics, August 2015

Oncology has historically been at the forefront of healthcare innovation, so it is not surprising that oncology focused organizations are leading the way in terms of mHealth app excellence. One study assessing application of evidence and theory in cancer survivorship apps found that most apps (94%) are evidence-based and grounded in health behavior theory.²⁶ Apps that demonstrated the greatest use of theory based health behavior change technique elements were those sponsored by a health organization (Exhibit 34).

While key clinical organizations are becoming increasingly involved, the U.S. lags behind the proliferation of mHealth interventions when compared with countries in Europe. This is possibly due to the lack of centralized healthcare system in the U.S. making integration difficult. Currently, Denmark is the European Union leader in mHealth utilization, with wearables as a main driver of mHealth adoption. Denmark is best positioned in terms of eHealth adoption, level of digitization, market potential, ease of starting an mHealth business and mHealth regulatory framework.²⁷

In March 2015 the National Health Service (NHS) in England launched a website and accompanying app to help treat depression and anxiety as well as improve access to mental health services (Exhibit 34).²⁸ NHS also publishes a list of NHS-endorsed digital mental health services in order to address barriers such as social stigma and privacy that accompany mental health issues. The NHS implemented this program based off of the growing evidence that online tools are effective in the treatment of mental health conditions.

Exhibit 34: NHS Mental Health Services Website and App



Big White Wall by Big White Wall

- A safe online community of people who are anxious, down or not coping who support and help each other by sharing what's troubling them, guided by trained professionals.
- Available 24/7, Big White Wall is completely anonymous so you can express yourself freely and openly.
- Professionally trained Wall Guides ensure the safety and anonymity of all members.

Source: IMS Institute for Healthcare Informatics, August 2015

Evidence highlights greater need for measuring accuracy, usability and safety of mHealth apps

While recent studies show growing support for mHealth app use in patient engagement and adherence to treatments, studies have also identified concerns around mHealth app content, accuracy and consistency in the standards for app integration with devices and health data reporting tools. Positive results have been demonstrated in some mHealth app studies, but a number of issues have been identified and remain barriers to comprehensive, successful mHealth adoption (Exhibit 35).

Higher level app functions such as calculating insulin dose, diagnosing illness or providing evidence based behavioral interventions have been found to be inaccurate in some instances and potentially harmful to consumers. Most studies conclude that more research is needed in these areas and should be supported by the utilization of health behavior change theories. Greater evidence along with addressing identified concerns will be necessary to support mHealth app prescribing practices, payer reimbursement determinations and employers embracing as part of wellness incentive programs.

The fast-paced growth of the healthcare app market has outpaced the ability to develop oversight and guidance for accuracy of clinical content contained in mHealth apps. The sheer volume of choices in the consumer mHealth apps available in the absence of a mechanism for certifying or ranking apps leaves providers and consumers on their own to navigate app selection. This environment leads to provider reluctance in prescribing mHealth apps given the unknowns about accuracy, efficacy as well as security.

Exhibit 35: Results of mHealth Studies and Concerns Identified

mHealth Evidence-based Concerns

- Diabetes: Inaccurate insulin dose calculation across numerous parameters.²⁹
- Diagnosis: Incorrect diagnosis, but accurate advice on how quickly to see a doctor; more accurate than internet diagnosis and self-triage.³⁰
- Eating Disorder: Eating disorder intervention apps contain minimal evidence-based treatment and principles.³¹

To address the lack of guidance around the accuracy, usability and safety of apps, in July 2015, draft guidelines for the responsible use of wearables, smartwatches and health apps were released by industry and institutional stakeholders for public comment. The guidelines outline standards for the development of technology which concerns data privacy, proper interpretation of data and data accuracy. Recommendations include:

1. Protect the privacy of a user's health data
2. Clearly define who owns a user's health data
3. Make it easy for users to accurately interpret their data
4. Integrate validated scientific evidence into product design
5. Incorporate evidence-based approaches to health behavior improvement
6. Be accessible to marginalized populations

Initiators of the guidelines include Vitality Institute, Microsoft Corporation, the University of California San Diego and others. In the past, innovators that have taken a proactive approach to monitoring quality in their industry have been met with success. However, greater healthcare system stakeholder involvement is required to improve the development of accurate, evidence-based apps.

In addition to data confidentiality, security and privacy concerns that limit more widespread mHealth adoption, self-reported data itself presents concerns. The validity of self-reported patient data, in terms of accuracy and reliability, has the potential for transparency issues when there is non-adherence or sub-optimal results. Self-reporting of health data has the advantages of being real-time, relatively inexpensive and facilitating patient engagement in their health and disease management. However, self-reported data is challenged by recall bias, social desirability for reporting positive outcomes and user inaccuracy in recording of health data.

Certain limitations can be addressed by developers in the design of apps and devices in order to promote greater ease of use for consumers and accuracy of data recorded (e.g., automated rather than manual data entry).

Provider perspectives on mHealth apps and remaining barriers to mainstream adoption

Agreement around the value of mHealth for improving healthcare delivery is high, but barriers to full adoption still exist

Although there has been significant growth in the number of mHealth apps available to consumers over the past two years, comprehensive adoption as a critical component of improving the patient experience and clinical outcomes through healthcare providers prescribing mHealth apps has been limited. When surveyed, most healthcare providers agree that mHealth could improve overall outcomes, decrease the cost of healthcare and facilitate patients taking a much more active role in improving their health. Providers agree that mHealth data integrated with electronic healthcare records (EHR) allows for better communication between patients and providers and provides a platform for proactive identification of personalized patient requirements around prevention, disease management and follow-up services. Providers are especially interested in the potential that mHealth provides in the area of chronic disease management.

Hospitals have begun to include mHealth as a topic in strategic discussions but are cautious due to the rapidly developing industry and platforms. Policies and programs established today may be outdated before full institutional implementation is possible. There is hesitation due to rapid evolution and lack of clarity on what works, but some leading organizations are investing time and resources around mHealth cautiously. Multiple research projects are in progress at university and hospital levels that will further support the best practices and business case for implementing enterprise mHealth solutions.

In order to further explore provider perspectives and progress as it pertains to mHealth, IMS Health interviewed a panel of key influencers from various institutions. The results and perspectives from these interviews are reflected within this chapter.

Interview Methodology

To explore the perspectives of stakeholders across disciplines and expertise, IMS Health conducted interviews with 17 health and technology focused thought leaders and organizational leaders. Interviewees were medical directors, chief information officers, and program directors at world renowned hospitals in the United States. While not a comprehensive analysis of the mHealth climate, interviews provide a perspective on mHealth at these institutions.

Specific topics included potential benefits of mHealth mainstream integration, level of evidence required for integration, institutional barriers, exciting initiatives and metrics to assess progress. Interviews were transcribed and themes were determined through qualitative analysis.

Despite the universal enthusiasm expressed by providers in the survey around mHealth, providers continue to express reluctance in formally prescribing mHealth solutions to patients given current industry limitations and barriers (Exhibit 36). These barriers fall into five main categories:

- Limited connectivity and integration into workflow systems
- Slow paradigm shift in reimbursement processes and delivery of care
- Data confidentiality, privacy, security and regulatory uncertainties
- Lack of scientific evidence to measure the efficacy of apps
- Current ability to reach the most vulnerable cohorts of patients – mainly the elderly or non-English speaking

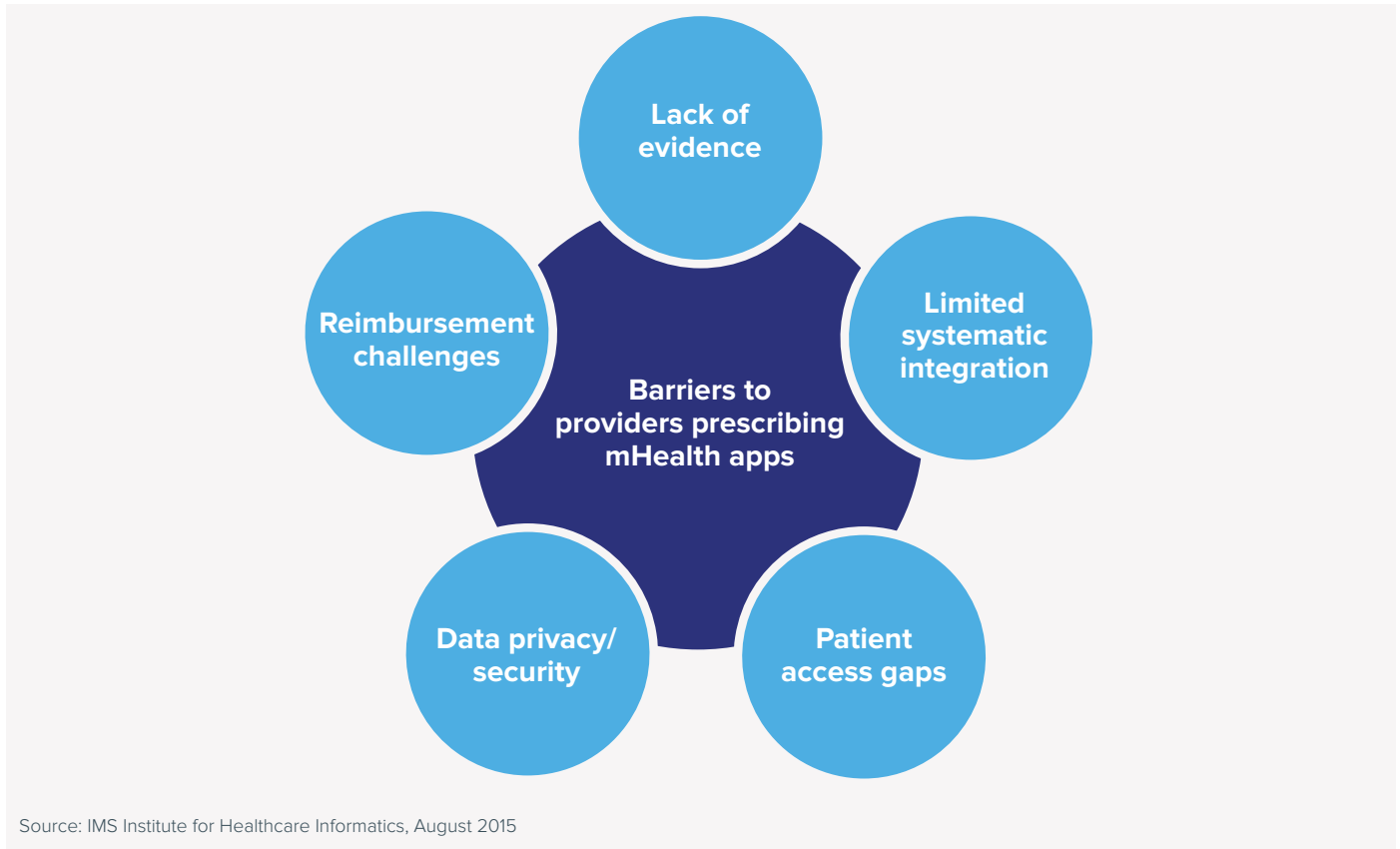
“We’ve completed many proof of concepts and pilots and now we are building out a mobile health framework and infrastructure. It’s part of our new Center for Connected Care. Rather than have all of these one-offs in the organization, we are working to integrate our offerings and leverage the power of a platform.”

Barbara Spurrier, Mayo Clinic

Limited connectivity and integration into workflow systems

Currently, most healthcare apps are being developed outside of health care systems, and therefore, their benefits as part of an overall integrated system are minimal at best. Although some hospitals and universities are working with mHealth app developers to design custom integrated apps, many remain reluctant to invest heavily at this time. Therefore, healthcare providers lack real time information integrated as part of their workflow to aid in clinical decision making. Without mHealth integration into EHRs, development of tools for interpreting health data seamlessly and integration within clinical workflows adoption will be challenging. Some apps require monitoring for an event or a threshold to occur (e.g., weight gain in CHF patients), but without integration of data monitoring into the workflow, recognition of the condition worsening transpires only at scheduled visits or at unplanned visits due to an acute issue. Industry stakeholders are taking note of this key barrier to full adoption, however, due to the complexity of many health delivery systems integrating new technology quickly and changing clinical workflow processes is challenging.

Exhibit 36: Hurdles to Widespread Provider Prescribing of mHealth Apps



The entrance of top technology companies into the healthcare space will help drive greater innovation in the marketplace and accelerate the penetration within hospital and physician office systems.³² For example, Apple’s HealthKit patient digital health platform (PDHP) project is in collaboration with Epic, a leading EMR provider, to leverage new technology and improve patient care. Payers (e.g., Cigna, UnitedHealth and Humana) are partnering with top technology companies (e.g., Samsung, Apple) to leverage new technology to co-develop wellness features and route health data from wearables and devices to PDHPs for physician use in patient care.

“...I don’t think we’re going to do a good systematic job until we can embed it in the EHR. And the only reason I say that is because we haven’t been successful with much of anything else when we weren’t able to embed it in EHR. When we can embed other things in the EHR that way, we’ve been wildly successful.”

Lee Vermeulen, University of Wisconsin

“You could have a great app, but then if it doesn’t connect in with the electronic health record, then you’re missing a lot of crucial data.”

James Hoffman, St. Jude Children’s Research Hospital

Regardless of technology advances and solutions available, if marketplace solutions do not integrate within a healthcare system or provider workflow, the day to day pressures of patient support may compete with broader adoption of mHealth apps implementation. Processes integrated into workflow systems have had rapid acceptance while those developed outside of the workflow have not. Additionally, providers that are part of a broader network may not be comfortable recommending app solutions that are not endorsed or integrated into the healthcare delivery network that supports them.

Providers also emphasize that leadership from clinicians and administrators is necessary to develop buy-in from staff, many of whom have dealt with unsuccessful or cumbersome workflow process improvements in the past. Providers feel that there remains reluctance towards systemic change due to the complicated nature of meeting meaningful use criteria set forth by the Centers for Medicare & Medicaid (CMS). Additionally, meeting meaningful use criteria is a goal to achieve financial incentives, whereas there are no proven incentives to integrate mHealth within workflow although it could be argued that mHealth integration would indirectly provide positive financial outcomes through improved outcomes.

“I think the concept of an app is that it’s simple, it’s fast and it presents data in a format that a clinician is comfortable with and enhances their workflow versus the physician clinician having to adapt their workflow to meet the flow of the app. As a result, I think some things we’ve seen are apps that are designed in conjunction with clinicians that augment and enhance their workflow and are rapidly accepted here.”

Mike Restuccia, University of Pennsylvania Health System

Slow paradigm shift in delivery of care and reimbursement processes in healthcare

While the archetype is changing, the current approach to care remains skewed to a traditional face-to-face patient and provider delivery system. Real-time integrated coordination between physicians, specialists, diagnostic and therapeutic centers, outpatient settings and homecare is fragmented in the current model. The coordination endeavor between healthcare stakeholders requires great effort and the incentives provided for better coordination especially around use of mHealth apps remain low. Increase in value-based contracting and pay for performance programs is improving synchronization, but the progression to true multi-stakeholder integration and specific accommodation of mHealth within reimbursement practices is limited.

“I would say the most significant barrier is that the reimbursement model today still sets us up to be volume based in patient care. With properly aligned incentives and payment models, the case for effective digital health solutions becomes much clearer.”

Greg Weidner, Medical Director, Primary Care Innovation and Proactive Health at Carolinas Health System

Leading organizations are actively working on pilots that address limitations of integration and reimbursement which will be critical for understanding business models that justify return on investment. System implementation and resources for monitoring data analytics require significant investment which must first clearly demonstrate value to key organizational decision makers for broader adoption to be achieved.

At present, medical devices are generally covered by insurance companies, but under the condition of FDA clearance. The FDA has begun to regulate apps, but only those that are companions to medical devices and that meet certain criteria. The decision of mHealth app reimbursement will be influenced by hospital stakeholders, payers, potentially employers and ultimately patients.

Many outstanding questions exist for this new technology regarding reimbursement for mHealth apps and connected devices, such as what third party administrator will facilitate app and device reimbursement as well as which apps will be reimbursed. Employers are moving towards greater management of employee wellness in order to manage risk, but monitoring health data may open employers up to privacy concerns. Currently, prescription benefit managers and health insurance companies are the arbiters of what care is reimbursed for patients, but the space for mHealth apps and connected devices is uncertain.

PROVIDER PERSPECTIVES AND REMAINING BARRIERS

Health insurance companies are well positioned to incentivize – and benefit from – a more focused approach to increasing consumer mHealth app use. Evidence is building to support the use of apps to improve clinical outcomes and lower costs to consumers, payers and the entire health system. The opportunity for consumer mHealth app retention is greater if insurers offer incentives based on use and improved outcomes. Insurers are already connected to provider systems and meet the security and privacy concerns covered by HIPAA.³³

“Our organization is interested in mHealth because we see huge value potential. I will say though that we’re taking a very cautious, cautiously optimistic approach to it because it’s such a rapidly evolving field that we don’t want to lock ourselves into policy positions or programs that might be out of date tomorrow.”

Lee Vermeulen, University of Wisconsin

“It really takes a thought leader, a physician champion to speak to and really push the issue and give healthcare organizations examples of where mHealth works. We need to demonstrate how we can use those tools to help patient care, improve outcomes and actually give patients options for investing in their own health.”

Alisa Niksch, Tufts Medical Center

Data confidentiality, privacy, security and regulatory uncertainties

Providers emphasize that confidence in and measurement of mHealth app success must include the security and privacy aspects of mHealth technologies. Securely connecting patient health data to patient medical records requires HIPAA compliance when collecting, storing or transmitting protected health information (PHI). Most fitness apps which collect calories burned and steps taken do not collect PHI. However, any app that would seek to transmit this data to a HIPAA covered entity would have to be HIPAA compliant. The regulatory space for health apps is expanding, beginning with companion mHealth apps which connect to medical devices.

The distinction for apps which require HIPAA compliance lies in who is using the data. Apps which collect health information for consumer use only do not need to be HIPAA compliant; however, once data is transmitted to a healthcare provider, it becomes PHI and requires coverage. The increased value of communicating larger amounts of patient data comes with a cost to developers of increased requirements to achieve health data security and privacy.

“We are working hard to assure that data are protected and secured for our patients”

Barbara Spurrier, Mayo Clinic

As the regulatory space evolves and works towards ensuring patient privacy, there are implications for patient collected disease management data initially, and subsequently may have implications for patients in clinical trials. Currently, only the FDA regulates mHealth apps and only in cases of use as, or as part of, an approved medical device. Guidelines for personalized health technology released by industry and institutional stakeholders in July 2015 address the issues of data confidentiality and privacy; however, non-biased stakeholder sanction of mHealth apps for prescriber use is considered necessary. Improvements and expansion in PHI security and privacy measures will lead to increased confidence in mHealth across the ecosystem of mHealth stakeholders.

“We’re going through the journey but it’s not as simple as downloading an app onto your iPhone and being able to look at your stocks...which is, I think, the problem is it needs to be secure, it needs to be confidential.”

Mike Restuccia, University of Pennsylvania Health System

Lack of scientific evidence to measure the efficacy of apps

The level of evidence required will differ based on the utility of the mHealth app but evidence is required to increase provider confidence in prescribing mHealth apps. In some cases, observational evidence will be sufficient (e.g., for diet and fitness apps); however, complex apps leveraged in clinical care will require randomized clinical trials. With increasing numbers of mHealth apps in the marketplace, healthcare providers need a mechanism for measuring or rating mHealth apps to recommend to patients.

Across discussions with providers, there is a unified expectation and excitement that mHealth apps will continue moving forward in their importance in the delivery of care and will be more fully leveraged to increase patient engagement and improve clinical outcomes. This growth will be recognized as greater evidence of the efficacy and effectiveness of apps is available, combined with measurement of cost savings by addressing patients in less time and with fewer resources while improving care.

Although the number of mHealth clinical trials has doubled in the last two years, more evidence is needed for prescribers to feel confident in prescribing mHealth apps for patient health and disease management. Perhaps even more importantly, increased evidence is required to facilitate provider organizations and healthcare system investment in integrating mHealth into standards of care and workflow processes for more mainstream adoption.

“I think that experimental studies are important. That is, studies where these technologies are randomly assigned and where outcomes that count to patients and providers are tracked. But I also think that there’s space and an opportunity for observational research as well.”

G. Caleb Alexander, Johns Hopkins Center for Drug Safety and Effectiveness

Ability to reach the most vulnerable cohorts of patients

One clear benefit of mHealth apps is increased communication and instant access to patient information; however, if apps do not reach those patients most in need they will continue to fall short. While progress is being made, elderly patients and those with language barriers are still underserved by the mHealth marketplace. Full implementation will require addressing those patients that are not sophisticated app users to increase skills and comfort levels in using the technology.

With 25% of the adult population diagnosed with two or more chronic conditions, the greatest burden on the healthcare system is chronic disease management.³⁴ Here, high service utilization rates can cost 17 times more per patient than costs for those who are not high users of health services.³⁵ Improving clinical outcomes through comorbid chronic disease management has the potential to contain costs and improve the patient experience in managing their health. However, given that chronic diseases such as diabetes, COPD, and heart disease are diseases of the aged, finding ways to effectively and efficiently manage disease through technological advances that may challenge the skill and comfort levels of aged patients is critical.

“We are trying to integrate mobile health into the lives of people and patients to help empower them in self-management and have the peace of mind to know when to take action.”

Barbara Spurrier, Mayo Clinic

“You really have to simplify digital health solutions, so they make it easier for patients to do the right thing. You have to take into consideration that not everyone is digitally savvy and avoid introducing the additional barrier of understanding complex technology.”

Greg Weidner, Carolinas HealthCare System

Reaching the most vulnerable populations is necessary to achieve the full potential of mHealth in disease management. The use of mHealth apps provides a viable option for patients to stay informed about their conditions, record health data and achieve virtual disease management by healthcare providers. Devices stand out as a key component to monitoring patients especially since they could help overcome some of the barriers for elderly consumers. Wearables and other devices take very little training and do not require manual input from users. The importance of caregivers are also being taken into consideration as part of the equation when developing mechanisms for reaching and managing the health of those most in need but perhaps not as easily reached through typical mHealth solutions.

Call to action

Full maturation of mHealth requires prioritization and effort across all stakeholders in the mHealth eco-system

Efforts are being undertaken by stakeholders across the health system to improve the quality of care, decrease costs and improve patient experience. Providers are no longer seen as the only stakeholder responsible for improving patient care and achieving these goals. Patients who take an active role in improving and monitoring their own healthcare can alleviate some of the burden on the healthcare system. Increasingly, the patient experience is also taken into consideration when measuring successful delivery of care. The importance of integration, along with shared responsibility of payers, healthcare systems and consumers is now understood as critical to improving all aspects of healthcare delivery, associated costs and outcomes. Accurately connecting patients to their providers is a crucial step in healthcare management, especially for the management of chronic conditions and increased patient satisfaction.

“...part of what we want to do is improve the patient experience, which is one component of the Triple Aim. Access to a provider, access to your information, access via mobility, putting the patient first and placing the power into their hands versus traditionally the provider, is really one of the key components of the mHealth drive. In this new world, the patient defines value. Then if you look at the cost side, you have these transactions occur at a much lower cost than what is happening today and placing power into the hands of the patient...”

Craig Richardville, Carolinas HealthCare System

As mHealth apps evolve and reach maturity, there is an increased opportunity for mHealth apps to become a valuable aspect of achieving optimal care by empowering patients and providers with mHealth apps, devices and tools that facilitate efficacy, effectiveness and real time monitoring. Payers, including the Centers for Medicare and Medicaid Services (CMS), have added reimbursement categories for virtual consultations, encouraging healthcare providers to monitor patients' health in a non-traditional way. This transformative type of change in reimbursement policy establishes a framework for providers to reach larger groups of patients more efficiently. Patients are, in turn, empowered to actively participate in their health from preventive care to disease management.

“In the virtual environment, you gain access to the right provider, for the right outcome, the right experience, and at the right cost with easy-to-use tools in the mHealth environment. That hits all three pieces of the Triple Aim.”

Craig Richardville, Carolinas HealthCare System

While progress has been made over the past two years, for mHealth apps to evolve and fully mature as an integrated component of healthcare delivery, key stakeholders within the mHealth ecosystem must work together to address the remaining barriers to mainstream adoption. This means moving progressively through the mHealth app maturity model (Exhibit 37).

“Clearly mobile technology has transformed a lot of industries and it’s in the process of transforming ours. It’s a matter of getting this concept and this technology and end users to find the right tools and to adopt appropriately. It’s an evolution. I think it has great promise and we’re evolving.”

Mike Restuccia, University of Pennsylvania Health System

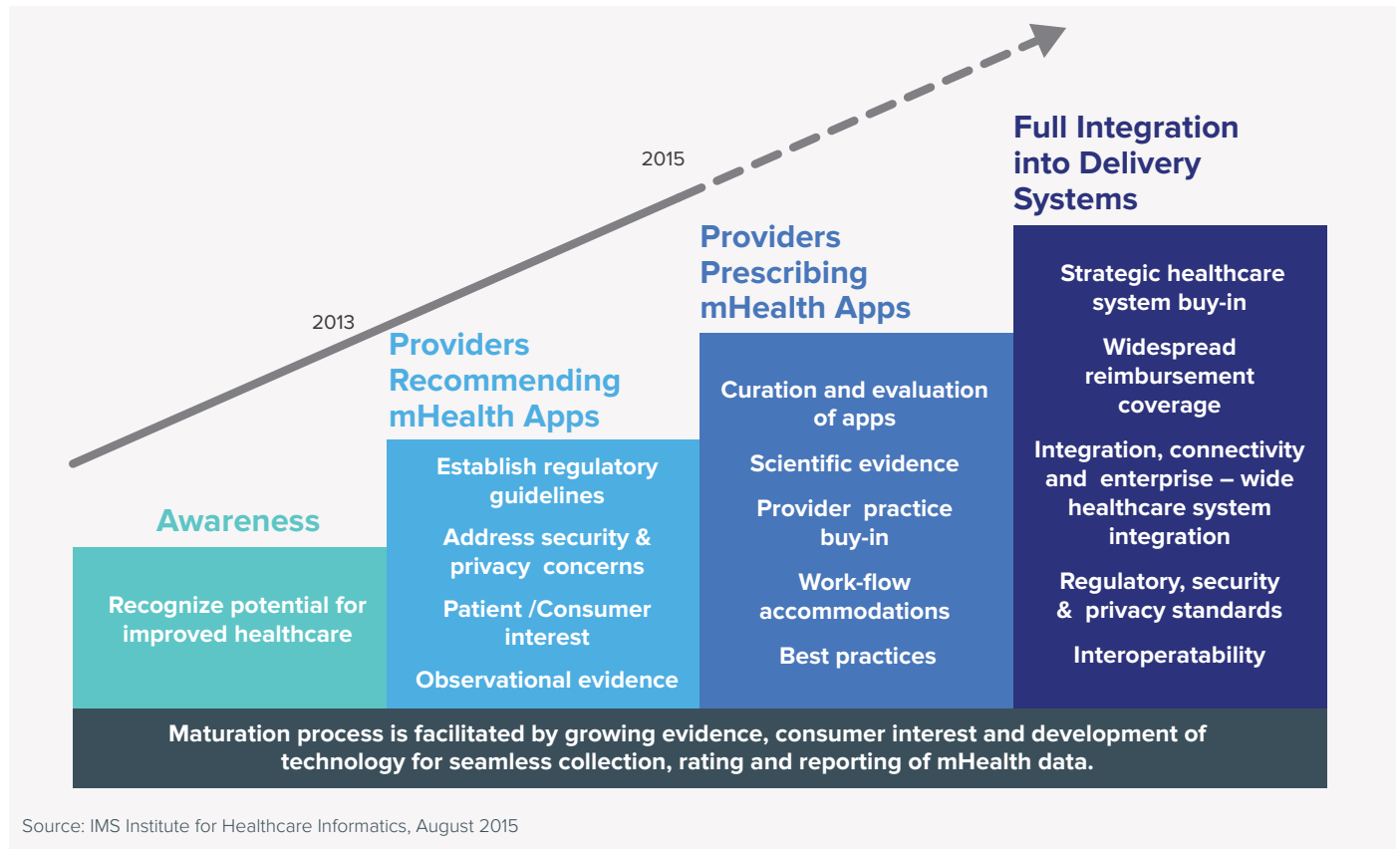
The steps required in support of the mHealth app maturity process key milestones can be categorized as:

- Recognition of mHealth apps and potential for improved healthcare
- Establish regulatory guidelines
- Security/privacy guidelines
- Curation and evaluation of apps
- Inclusive reimbursement models
- Strategic healthcare system buy in
- Integration into workflow systems and optimized connectivity

The stakeholder eco-system is complex and already in the process of change given healthcare reform initiatives, which acts as both a facilitator and barrier to change. Healthcare systems have more EHRs and technology than ever before, but many systems are still in the process of adapting to and managing large scale implementation challenges. Adding mHealth app prescribing platforms and a process for securely obtaining patient-recorded health data into the scope of institutional change generates additional cost, complexity and risk.

Consumer interest creates a marketplace opportunity for mHealth developers and a greater demand for apps which meet the needs of consumers and address the key barriers of privacy, security and integration, driving further maturation. Developers in the mHealth solutions space must focus on innovative ways for reaching novice consumers and more importantly address healthcare system integration needs.

Exhibit 37: Hurdles to Widespread Provider Prescribing of mHealth Apps

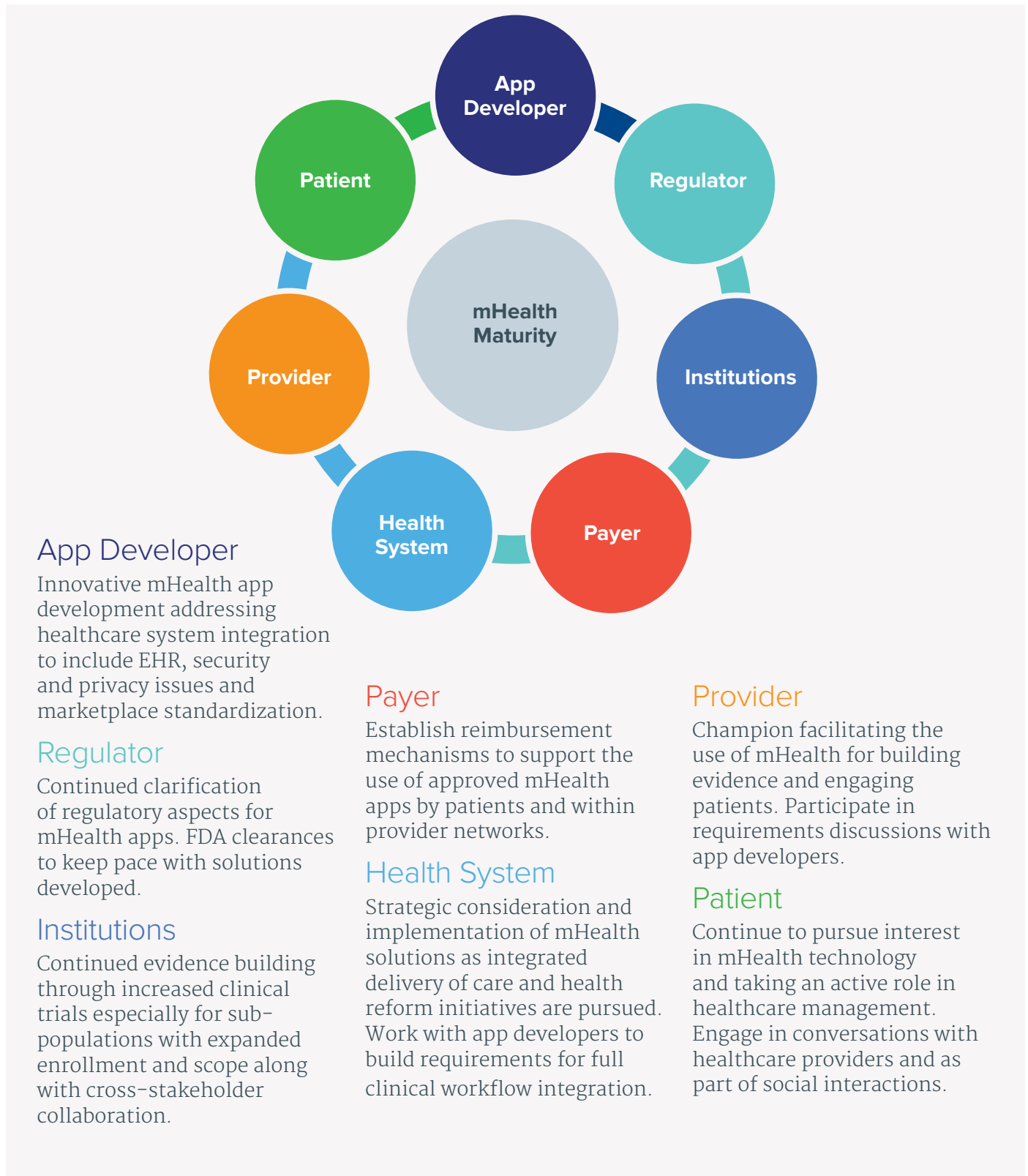


Additional evidence supporting the efficiencies, outcome improvement and patient experience enhancement which can be recognized through mHealth adoption will fuel the maturation process as hospitals, health systems and payers address the paradigm shift taking place from a volume to a value based payment system. Continued development of mHealth solutions outside of healthcare systems does not facilitate fully leveraging mHealth apps.

“...we’re really seeing this phenomenal - continuing to see phenomenal – pressure from the consumer electronics, and telecommunications, and computing, the biggies out there building ever more robust platforms.”
Kevin Patrick, University of California, San Diego

Given growing signs of interest across the eco-system of mHealth stakeholders it is anticipated that within the next five years there will greater movement toward adoption of mHealth against the maturity model. However, the speed of the conversion to greater adoption and integration of mHealth will be largely determined by the collective prioritization of stakeholders in the mHealth ecosystem with shared responsibility for overall success (Exhibit 38).

Exhibit 38: Stakeholder Call to Action Activities



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Methodology

Count of widely available consumer health apps

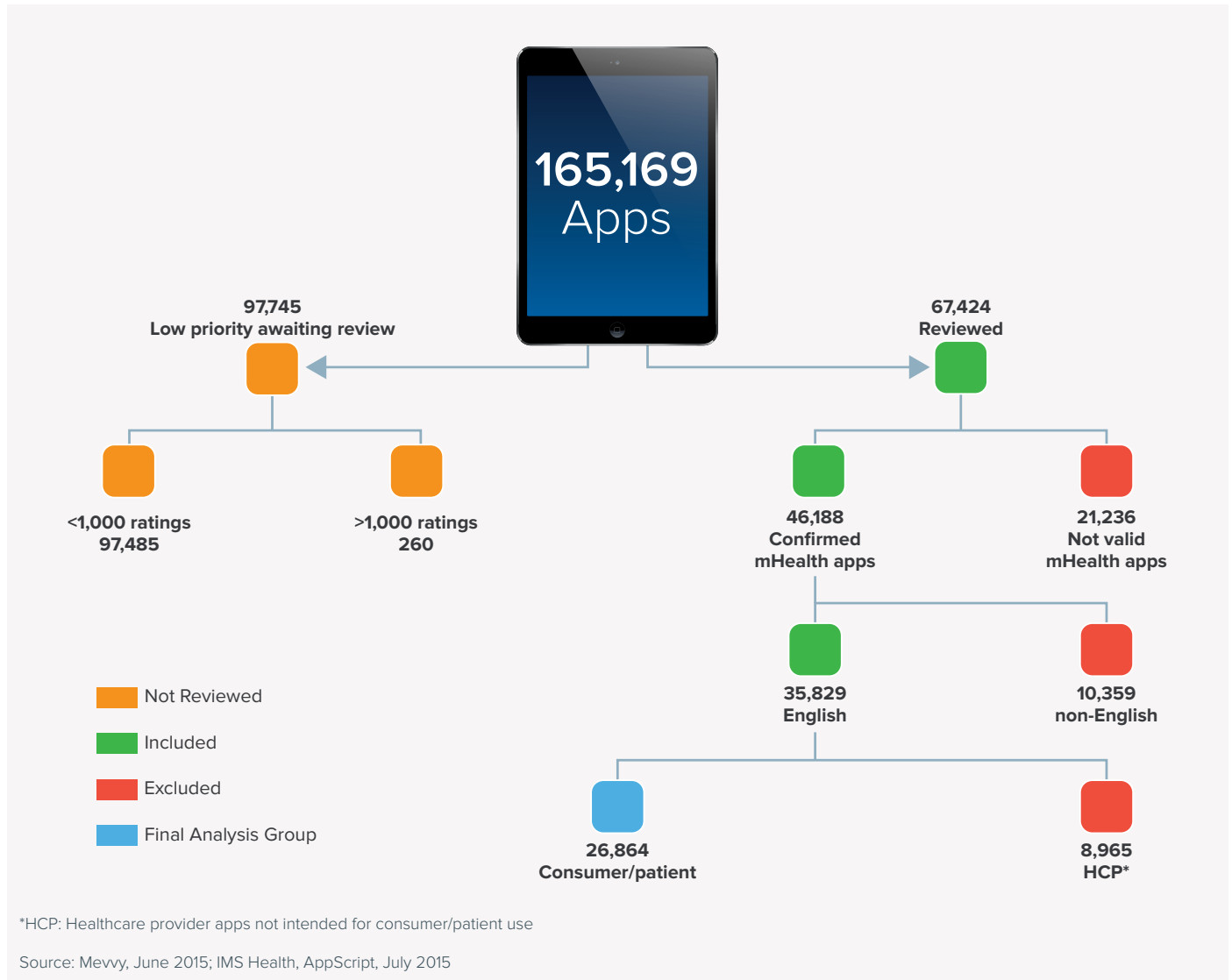
Data for apps was acquired from Mevvy in June 2015. Approximately 41% (67,424) of the 165,169 apps available for download from the Apple iTunes store and the Google Play store as of June 2015 were analyzed. An app may be counted twice if it is available from both the Google Play and Apple App store; however, differences exist between platforms regarding functionality and download volume. Apps with greater than 1,000 user ratings are prioritized 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 the 67,424 apps led to the exclusion of 21,236 apps from further analysis as these were considered not truly related to healthcare (e.g., salons, apps with gimmicks, etc.). Of the remaining 46,188 apps considered genuine mHealth apps, further content analysis excluded 10,359 due to the app language being one other than English. The remaining 35,829 English-language apps were categorized as consumer/patient-oriented (26,864) and healthcare provider-oriented (8,965). The full analysis for this report was conducted on those apps targeting consumers/patients.

It should be noted that there are mHealth apps which are not available directly to the public through the iOS and Google Play app stores, including some of the mobile medical apps that have been approved through the FDA, such as apps which require a prescription or apps which require an access code provided by a healthcare professional such as the BlueStar app from WellDoc. These apps do have significant functionality components, but as they are not available to the general browsing public, they are excluded from the analysis.

Android data download analysis

June 2015 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.



*HCP: Healthcare provider apps not intended for consumer/patient use

Source: Mevvy, June 2015; IMS Health, AppScript, July 2015

IMS Health AppScript Score Analysis

IMS AppScript Score is derived from six sub-scores, or “ratings”, across the following dimensions: Patient, Professional, Functional, Developer, Endorsement, and Clinical ratings (Exhibit 6). 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 condition, but by provider and by patient.

- **Patient Rating** leverages Apple App store and Google Play store average consumer rating and the number of ratings by consumers.
- **Professional Rating** is derived from the number of prescriptions healthcare professionals send to patients using the IMS Health AppScript platform.
- **Functional Rating** measures the feature-set of apps (more detail in Exhibit 4), representing the unique investment by the developer.
- **Developer Rating** determines the professionalism and dedication of a developer based on inclusion of a sensor within the app.
- **Endorsement Rating** is a dichotomous variable based on having a recommendation by one of six reputable healthcare institutions (e.g., U.S. FDA, Joslin Diabetes Center).
- **Clinical Rating** is derived from weighting of study results available based on study rigor (e.g., RCT is weighed more heavily than Observational) through an mHealth literature review.

IMS Health Evidence Analysis

Data for review of mHealth evidence was gathered from a search of Google Scholar and PubMed databases based on relevant keywords across therapeutics areas, study types and technology categories. One-hundred and thirteen studies were included across more than two dozen therapeutic areas. A number of studies were not included because they were qualitative, content review studies or published preliminary results. Studies were categorized by study type (mixed methods, quantitative, RCT, systematic review), outcome (positive, negative, neutral) and primary therapeutic area/medical condition. Positive study outcomes reflect study results demonstrating statistically significant findings of clinical change, whereas negative study outcomes demonstrate no significant clinical findings demonstrated. Values for the x-axis, Relative Quantity and Quality of Available Clinical Evidence, were derived by a weighting of number of studies and quality of studies based on widely-accepted hierarchy of evidence. Values for the y-axis, Study Outcomes, are based on averaged individual study net contribution scores, also used in determining IMS AppScript Clinical Rating. Population estimates were based on published U.S. population disease estimates.

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About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

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 patient care. With access to IMS Health's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS Health information and expertise to support the advancement of evidence-based healthcare around the world.

Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

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