# IMS INSTITUTE FOR HEALTHCARE INFORMATICS

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# Patient Apps for Improved Healthcare

## From Novelty to Mainstream

# Introduction

Apps have become ubiquitous in many aspects of our lives over the past five years, fueled by the widespread availability of tablet computers and smartphones. Tens of thousands of health, wellness, and medical apps are now available for download to Apple or Android devices from online stores. Harnessing the potential power of apps for healthcare has become a focal point of innovation, in particular those apps which can be used by consumers or patients as part of their wellness, prevention or treatment regimens.

While there is a great deal of interest in apps and enthusiasm for their use, they have yet to reach the mainstream of healthcare provision, and indeed in many respects are still viewed as a novelty. In this report, we share the results of a study we have undertaken to look more closely at the consumer healthcare apps that are currently available, including an objective assessment of their type, role, and functionality. We also look at the barriers to apps being more broadly and systematically used by healthcare providers and patients or caregivers, and approaches that are being taken to address these impediments.

The movement toward digital therapeutics is clear. Our intention is that this report provides some objective and balanced perspective on how consumer apps can play a larger and more meaningful role in the prevention and treatment of disease – resulting in improved health measures and outcomes, and a more efficient healthcare system.

The study was undertaken independently by the IMS Institute for Healthcare Informatics as a public service, without industry or government funding. The contribution of Carolyn Gauntlett to this report is gratefully acknowledged.

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# Acknowledgements

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# Executive Summary

Little is currently understood about the diverse array of healthcare apps available to consumers, their role in healthcare, the barriers to increasing their recommendation and support from providers, and the requirements for mobile apps to move into the mainstream of healthcare.

This study includes the analysis of the 40,000+ healthcare apps available for download from the U.S. Apple iTunes app store and an assessment of the potential value they provide throughout a patient's journey.  This clearly demonstrates that to date most efforts in app development have been in the overall wellness category, with diet and exercise apps accounting for the majority available.  Further an assessment of functionality of available apps finds that healthcare apps available today have both limited and simple functionality - the majority do little more than provide information.

There is a significant skew in download volume for healthcare apps, with more than 50% of available apps achieving fewer than 500 downloads.  Conversely, 5 apps account for 15% of all downloads in the healthcare category.  The reason behind the limited downloads, and hurdles to improved uptake, span all stakeholders.  Patients currently face a dizzying array of healthcare apps to choose from, with little guidance on quality or support from their doctors. Some efforts are underway to help provide professional healthcare guidance in both the U.S. and the U.K. but these are limited in scope and impact to date.  Furthermore, apps developed to date do not fit well with the greatest areas of spend in healthcare – those patients facing multiple chronic diseases and typically over the age of 65.  These patients are likely to be among the top healthcare spenders but smartphone penetration is lowest among this group, with only 18% of the U.S. population using them, compared to 55% of those aged 45-54 years.

Physicians can see the potential benefits of mobile healthcare apps but remain wary of formally recommending apps to patients without evidence of their benefit, clear professional guidelines regarding their use in practice, and confidence in the security of personal health information that may be generated or transmitted by the app.  Payers and employer wellness programs also want clear evidence of benefit before considering reimbursement or promoting the use of apps.

Over time, the app maturity model will see apps progress from being recommended on an ad hoc basis by individual physicians, to systematic use in healthcare, and ultimately to an end goal of being a fully integrated component of healthcare management.  There are four key steps to move through on this process: recognition by payers and providers of the role that apps can play in healthcare; security and privacy guidelines and assurances being put in place between providers, patients and app developers; systematic curation and evaluation of apps that can provide both physicians and patients with useful summarized content about apps that can aid decision-making regarding their appropriate use; and integration of apps with other aspects of patient care.  Underpinning all of this will be the generation of credible evidence of value derived from the use of apps that will demonstrate the nature and magnitude of behavioral changes or improved health outcomes.

Meeting these preconditions will accelerate the movement of apps use from that of a novelty into the mainstream of healthcare – and realizing their full potential in the years ahead.

# Background

Recent years have seen a gradual shift in the relative importance of different healthcare stakeholders - between physician, payer and patient. Although the patient will never have the tools to replace the roles of the physician and the payer, patients are encouraged to take a more active interest in their overall wellbeing and understand the consequences of poor health in later life. By having the patient aligned with the importance of wellness programs and sickness prevention, health systems can hope to realize savings – especially from a lower burden of multiple chronic conditions. As such, there are more frequent examples of healthcare payers and/or governments pushing increasing responsibility for healthcare onto the patient, whether that be by providing incentives to patients to stay healthy (effectively targeting preventive measures) or for adhering to treatment regimes that are prescribed.

**Figure 1: Evolution of Healthcare Stakeholders**



| Previously | Now | Future |
|---|---|---|
| Original Stakeholder: Physician | Key Stakeholder: Payer now as important as Physician | New Stakeholder: Patient more involved in healthcare decision making and choices |
| In the past physicians were key stakeholders acting as gate keepers to healthcare information and treatment options | As the key budget holders, payers have the most influence today over healthcare treatments and patterns and evaluation of outcomes results | With the rise of the internet and all its healthcare information, patients are better informed and enabled to participate in the healthcare decision making process |

In an attempt to rein in health care costs from chronic health conditions associated with unhealthy behaviors, the Patient Protection and Affordable Care Act in the U.S. includes a provision stating that beginning 2014 employers can use up to 30% of the total amount of an employee's health insurance premium to provide outcome based wellness incentives.[1]  Bonuses for health-related behavior in Europe are a key feature of private health insurance systems such as in the U.K.[2]  Recently in Dubai, local government officials announced a 30-day challenge (to coincide with Ramadan) in which it promised to pay participants a gram of gold for every kilogram of weight lost.[3]

This push for the general population to have a higher awareness of - and be more involved in - managing their health is occurring at the same time that technology is enabling the quick and easy access of information. Websites such as WebMD, MDadvice, MedicineNet and NetDoctor all offer patients medical advice and information for managing conditions.  In 2013 the Pew Internet and American Life Project released the latest Health Online survey which found that more than half of all Americans have looked online for health information in the last year, and more than one-third have used the internet to self-diagnose a condition.[4]

The Global Observatory for eHealth (GOe) within the World Health Organization (WHO) defines mobile health or mHealth 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".  mHealth involves the use of voice and short messaging service (SMS) as well as more complex functionalities such as 3G systems, global positioning systems (GPS), and Bluetooth technology.[5]

The advent of smartphones has taken the potential for mHealth to a new level.  The advanced computing capability of smartphones that are typically optimized for internet usage means that individuals can access information and advice from anywhere at any time.  They also provide functionality that is not available via a laptop such as the ability to capture information from sensors on the move and the addition of GPS and camera functions.  There are now estimated to be more than 1 billion smartphones and tablets globally; some sources estimate that this will reach 2 billion by 2014. In 2012 China overtook the U.S. to become the key smartphone market by volume, and other key emerging economies are forecast to see strong growth rates for these devices too.[6]

A mobile application (or mobile app) is a software application designed to run on smartphones, tablet computers and other mobile devices. They are usually available through application distribution platforms, which are typically operated by the owner of the mobile operating system, such as the Apple App Store, Google Play (Android), Windows Phone Store, and BlackBerry App World.[7] Across geographies the majority of smartphone users have more than 20 apps on their device at present; in many cases this is closer to 30 apps.[8] Gaming apps and social media apps such as Facebook remain the categories commanding most of users' time.[9]

Not all apps that have been developed in healthcare are widely available to consumers on their mobile platform stores. Some of the most advanced medical apps are the 100 apps already approved by the FDA and these are not necessarily designed to target general consumers. Some apps have been designed for healthcare practitioners, others are for patients but require a prescription, and others are intended for only a small subset of the population and hence are not added to the general app stores.

This report focuses only on the healthcare apps that are widely available to the general public to aid in their everyday healthcare management in conjunction with their physician or other healthcare professional.  While apps are essentially without geographic boundaries, this report is primarily focused on the use of apps in the context of the U.S. healthcare system.  However, the perspectives and considerations for more extensive use of apps are globally relevant.

# Profiling widely available consumer healthcare apps

**Development and use of healthcare related apps is growing rapidly but the current level of functionality is limited and use is mostly for prevention and wellness**

- Despite the large number of healthcare apps developed, the majority have only simple functionality; however mobile apps can be used for remote monitoring providing potential for extra data collection to aid healthcare management

- Almost 50% of healthcare apps available to consumers can be downloaded for free and are produced by a variety of types of developer

- Apps are available across the full spectrum of the patient journey, although healthy living apps dominate the space, whereas self-diagnosis, filling prescriptions and medication compliance have the lowest numbers of apps developed to date

- Some apps cover the full patient journey and are therapy area specific or demographic specific but there are still significant areas of unmet need to be filled

With increasing interest in the use of mobile apps in healthcare, this study sought to undertake the most comprehensive analysis of the 43,689 mobile healthcare apps available to the general consumer through the English language U.S. iTunes store as of June 2013, assessing their functionality, placement on the patient journey map and areas where unmet need still exists.

Every app categorised under "health and fitness" or "medical" was reviewed. In seeking to focus on apps that are purely related to patient health and treatment, examination of the content of these apps led to the exclusion of 20,007 apps from further analysis since these were considered not truly related to healthcare (e.g. salons, apps which use gimmicks with no real health benefits) (see Figure 2). Of the remaining 23,682 apps considered genuine healthcare apps, further content analysis categorized 7,407 apps as healthcare professional (HCP) oriented, and the remaining 16,275 apps as consumer/patient oriented (see Figure 3). A full functionality analysis was conducted on each of the apps targeting consumers/patients.

## Figure 2: App count methodology

**43,689** "Healthcare and Fitness" or "Medical"

**23,682** Apps genuine healthcare related

**20,007** Mis-categorized or only loosely healthcare related on App Store

- Fashion and beauty (e.g. salons)
- Apps intended for members of specific clubs/universities
- Veterinary apps
- Apps which use gimmicks with no real health benefit (eg apps which make the user sound sick, or demonstrate how the user would look if they were obese)
- Apps related to health issues but which do not focus on health (e.g. fertility)
- Product presentation apps for use by sales reps/retailers
- Apps believed to have meaningless claims e.g. "gives you a beautiful way to keep track of your body's biorhythms"

## Figure 3: Distribution of healthcare apps

Apple Store - Number of apps by customer

7407 HCP

16,275 Consumer

- IMS Analysis on all apps present in App Store to June 2013 showed 23,682 apps in the apple store related to healthcare

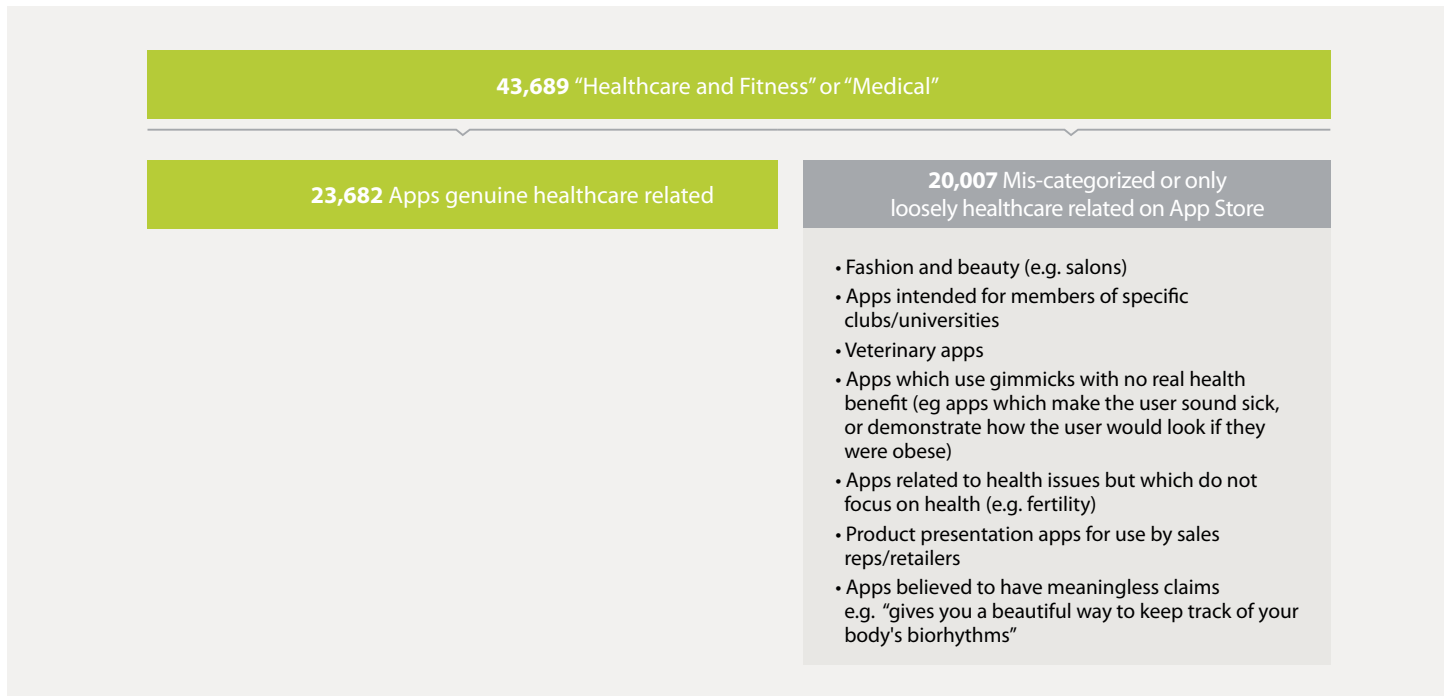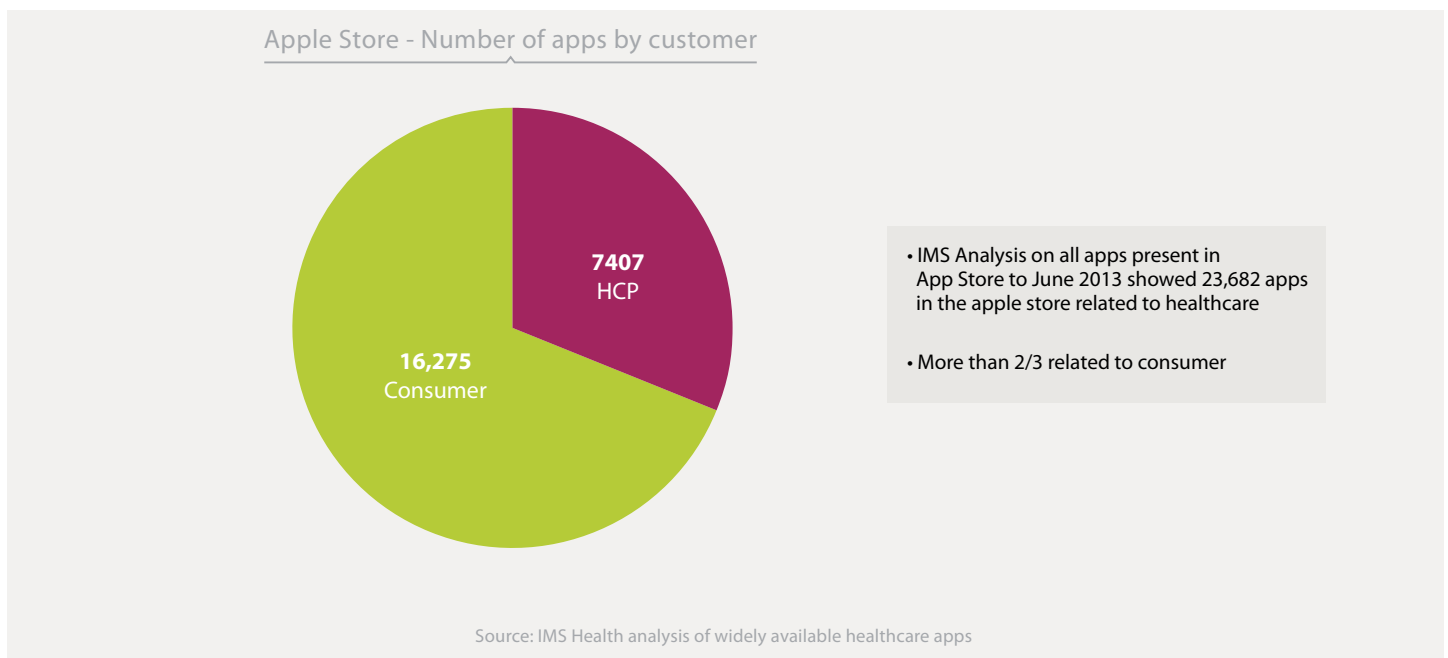- More than 2/3 related to consumer

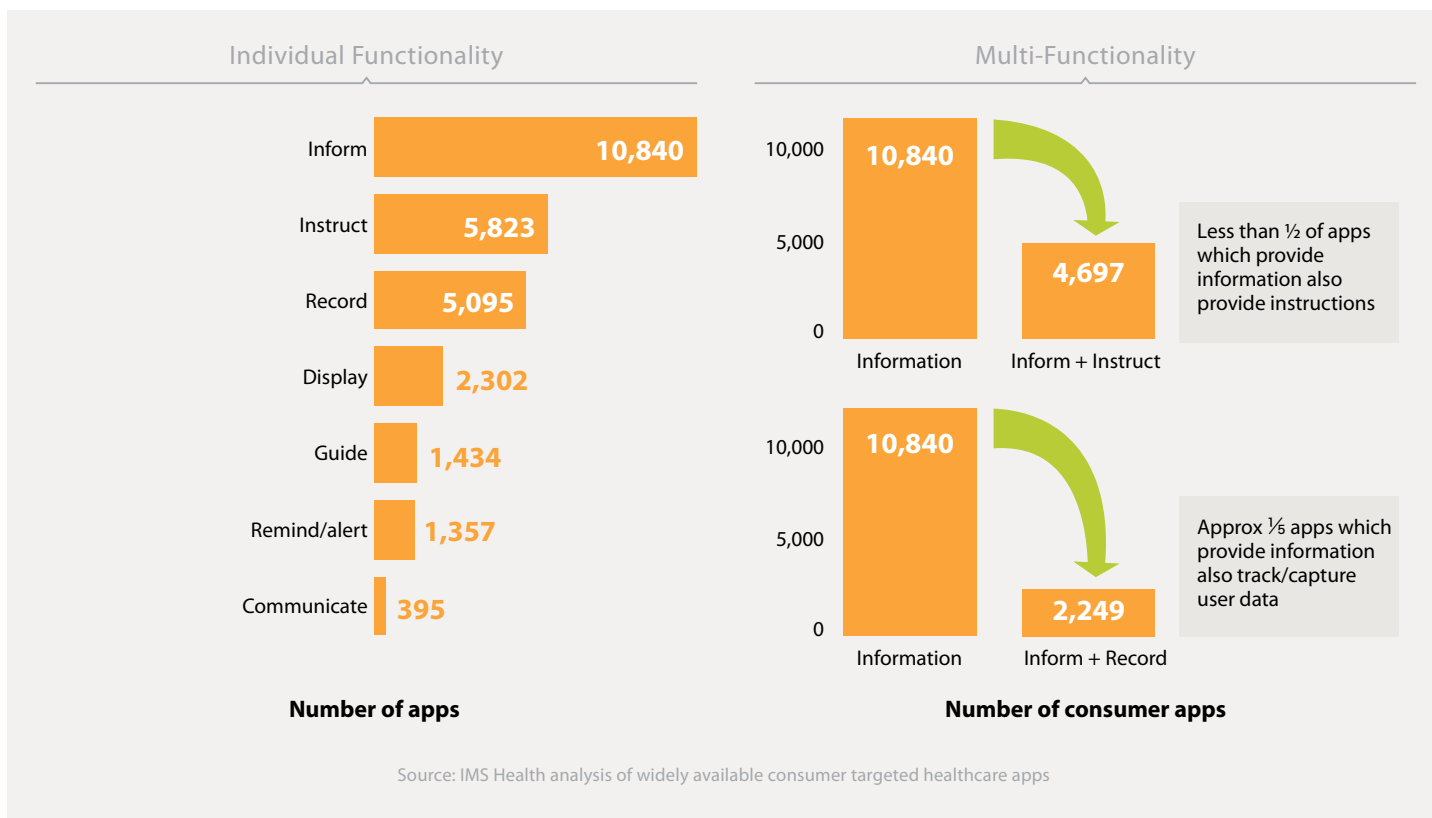Source: IMS Health analysis of widely available healthcare apps

## Assessment of app functionality

Although the number of healthcare apps is large and growing, there is significant variation in capabilities of the current apps, with most having only simple functionalities built into them. An analysis of healthcare apps available to consumers through the iTunes app store resulted in categorization of apps based on whether they could:

- **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 user entered data/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/a course of treatment

- **Remind/Alert**: Provide reminders to the user

- **Communicate:** Provide communication with HCP/patients and/or provide links to social networks

It should be noted that there are mobile medical apps which are not available directly to the public through the iTunes app store, including some of the mobile medical apps that have been approved by the FDA, such as the BlueStar app from WellDoc which requires a prescription. These apps do have significant functionality components but as they are not available to the general browsing public they are excluded from the functionality analysis below.

The most common capability of widely available consumer healthcare apps is the ability to provide information - 10,840 consumer apps have this feature, or approximately 2/3 of all consumer targeted apps. Fewer apps have other functionalities, for example, 5,823 can provide instructions, 5,095 capture data entered by the user and 1,357 apps have a remind/alert function built into them. About 10% of the consumer healthcare apps reviewed, 1,622 apps, have none of these capabilities at all, and include apps such as those to help with relaxation and sleep, and baby monitors. Although there is a subset of apps with impressive functionality (e.g. electrocardiogram (ECG) readers, blood pressure monitors, blood glucose monitors) it is clear that most of the healthcare apps available today are only simple in design and do little more than provide information. This is echoed by an assessment of multi-functionality: although two-thirds of healthcare apps can display information, only half of these can also provide instructions, and only one-fifth could track or capture user entered data (see Figure 4).

## Figure 4: Assessment of consumer healthcare app functionality



Individual Functionality

| | |
|---|---|
| Inform | 10,840 |
| Instruct | 5,823 |
| Record | 5,095 |
| Display | 2,302 |
| Guide | 1,434 |
| Remind/alert | 1,357 |
| Communicate | 395 |

**Number of apps**

Multi-Functionality

Information: 10,840 → Inform + Instruct: 4,697

Less than ½ of apps which provide information also provide instructions

Information: 10,840 → Inform + Record: 2,249

Approx ⅕ apps which provide information also track/capture user data

**Number of consumer apps**

Source: IMS Health analysis of widely available consumer targeted healthcare apps

Some mobile apps enable the remote monitoring of vitals that can be communicated back to the healthcare practices.  This offers the potential to enhance the value of provided care by taking advantage of this patient reported data and embedding it into the clinical care plan:
if patients are regularly collecting health data they can, in consultation with their physician/nurse practitioner, use that information to modify their behavior and better manage their condition.
As such, healthcare apps have the potential to bring efficiencies into healthcare systems by reducing the frequency and cost of direct interventions by healthcare professionals with patients.
Monitoring of vitals can be done remotely, and communication with healthcare professionals – including pharmacists, physicians and nurse practitioners – can be done without the patient having to physically meet with them.

| Patient uses app to collect health data either by choice or on physician recommendation | Patient can transmit data to physician or take phone along to appt to show physician | Patient and physician together evaluate the data | Necessary  interventions made: behavioral  or medication changes |
|---|---|---|---|
| **Collect data** | **Share data** | **Evaluate data** | **Intervene**[10] |

Analysis of the widely available consumer healthcare apps on the iTunes app store shows that at present there are 159 apps which link to sensors.  However these are dominated by fitness and weight apps which monitor pulse rates when exercising and measure weight and body mass index (BMI).  Fewer than 50 of these 159 apps relate to actual condition management or provide tools and calculators for users to measure their vitals.  There is therefore considerable room for growth in this sector.

> "I am really interested in feedback loops and how instant data can change behavior.  I think apps give an opportunity for patients to have instant access to themselves"
>
> *Jim Cunnar, MD – DuPage Family Medicine*
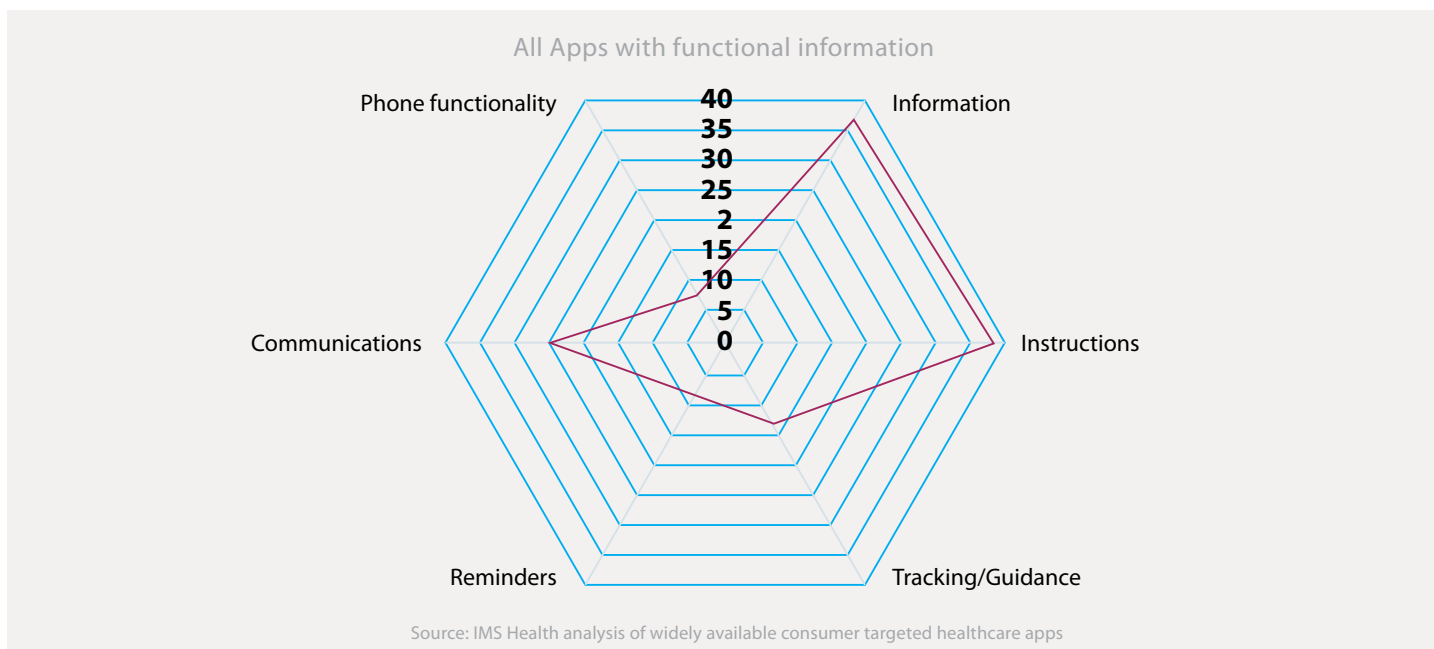
## IMS Health functionality scoring system

The IMS Health score for app functionality considers the results of 25 individual criteria assessed during the app review process.  These criteria include, but are not limited to, the type and quantity of information provided by the app, how the app tracks or captures user data, the communication processes utilized by the app, and the quantity of device capabilities included in the app. In addition to looking at this result, weightings are applied specific to the category of the app.  For example, in a condition management app there will be a higher value placed on results that focus on doctor communications than there would be for a reference app.

This scoring system was used for all consumer oriented healthcare apps with at least one assessed level of functionality as defined in Figure 4, and confirmed that the majority of apps have only simple functionality. This scoring system is based on our independent and objective assessment of the app functionality and does not reflect patient/user evaluation, physician evaluation, or evidence that users benefit from their use from an outcomes perspective. The maximum score achievable is 100. As illustrated in Figure 5, the distribution of the 16,275 reviewed apps skews toward the low end of the 100 point scale, with more than 90% of the apps receiving a score of 40 or less.

**Figure 5: IMS Health App functionality score distribution**



Number of apps

Functionality score

Source: IMS Health analysis of widely available consumer targeted healthcare apps
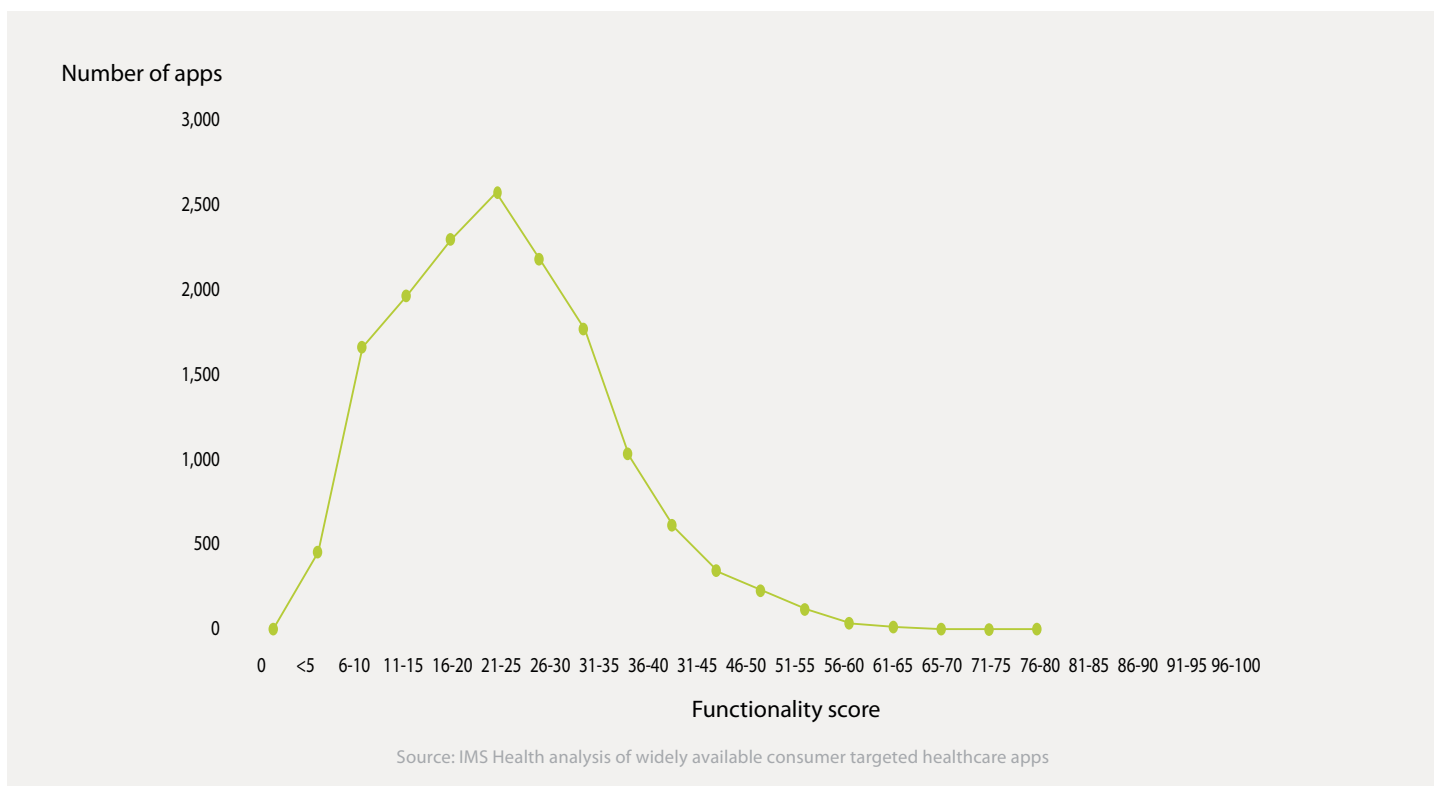
In looking across all apps at their individual functionality score (each of which has a maximum score of 100), the highest average scores accompanied the most prolific functionalities: information and instructions (see Figure 6). Despite the thousands of apps with these functionalities, few scored an excellent on this rating; instead average scores were only 40 out of a possible 100. This reflects the level of complexity of the app: the information score was assessed based on whether the app provided text, photo and video formats, and how the level of detail ranged from offering tips to detailed references. Therefore even though two-thirds of apps offer some form of information, for the majority this is simple content in a simple format. There are, however, significant scoring differences depending on the designed purpose of the app. Overall, when considering all 16,000+ apps, reminder functions only achieved an average score of 5 out of 100; however this varied dramatically. Those apps which are designed specifically as reminders to aid medication compliance and have a narrow purpose in this arena, saw scores reach as high as 100 for this marker.

## Figure 6: IMS Health App scores by type of functionality



All Apps with functional information

Phone functionality — Information — Instructions — Tracking/Guidance — Reminders — Communications

40
35
30
25
2
15
10
5
0

Source: IMS Health analysis of widely available consumer targeted healthcare apps

One of the most advanced apps for condition management and remote monitoring, approved by the FDA, is the WellDoc Diabetes Management software available through the app store with partner AT&T.  In the initial clinical trial of WellDoc (a 3 month non-blinded randomized controlled trial of 30 T2D patients aged 18-70 years old)  the average decrease in A1c values for intervention patients was 2.03% compared to 0.68% (P<0.02, one-tailed) for control patients.  Of the intervention patients 84% had medications titrated or changed by their HCP compared to controls (23%, P = 0.002).  The WellDoc group also demonstrated improved self-care in diet, medication, and exercise compared to that achieved by control patients receiving usual HCP care.[11] A key component of the software is the Guided Compliance™ tool which directs patients to test their blood glucose at optimal times to generate data for pattern analysis.  The software also acts as a coaching tool suggesting medication and lifestyle/self-management changes to patients (all suggested changes are also communicated to the HCP).  A follow-on trial consisted of a 12-month cluster-randomized study with 163 participants. The trial demonstrated that the average decrease in A1c values for intervention patients was 1.9% compared to 0.7% in the standard care control group (P<0.001).  The study therefore demonstrates that it is possible to improve treatment outcomes with mobile phone and web portal communications when used by both patients and their HCPs.[12]

## Business models for apps

The healthcare apps that are available to consumers today are produced by a variety of developers, from individuals with a novel idea to address unmet need, to large organizations with a commercial strategy involving an app. As such there is a wide range of scale, investment, and return in the current business models supporting consumer apps.

Examples of healthcare app developers:

### Table 1: Developers of mobile healthcare apps

| Developer | Motivation | Typical app functionality | Example apps |
|---|---|---|---|
| Individual app developers/ academic research groups | • Initially start out with small development to address unmet need out of interest or with ambitions to attract investment | Simple functionality designed for specific need | • Living Proof: Breast Cancer Survivor Stories<br>• Fat Burning Zone Calculator for Fitness |
| Patient organizations/ charities | • Creation of app products which aid users in condition management and provide emotional support and other patient success stories | Typically provide limited functionality, offering information, social media connections and physician recommendations | • Diabetes GPS<br>• Diabetes UK Tracker<br>• MyCancerManager<br>• PCR tracker |
| Corporate/ investment backed app developers | • Medium- to long-term financial returns as user base expands and revenue model grows | May span the full range of functionality:<br>• Display • Record<br>• Diagnose • Remind/Alert<br>• Communicate | • Calorie Counter by MyFitnessPal |
| Pharmaceutical manufacturers | • Increase awareness of condition<br>• Increase adherence to prescribed treatment | • Display health information<br>• Explain drug mode of action and side effects<br>• Remind/alert | • Afib Educator<br>• Hoop4Diabetes<br>• MyBETapp |
| Large consumer/ retailing brands | • Link app to present offerings, typically links to website<br>• Reach extended audience | • Display health information<br>• Record user entered data<br>• Provide reminders of service renewal | • Weight Watchers Mobile<br>• Walgreens<br>• Watsons Asia |
| Health insurance groups | • Inform members with general healthcare advice/condition management<br>• Enable HCP/facility search | • Display health plans<br>• Symptom checkers<br>• Physician locators<br>• Submit and monitor claims | • Medibank Australia symptom checker<br>• Singhealth HealthBuddy<br>• BUPA Mobile |
| National health systems | • Reach larger audience to influence healthcare management<br>• Lessen burden on clinical services | • Symptom checkers<br>• Physician locators<br>• Appointment reminders | • NHS Choices<br>• NHS Symptom Checker |

With such a variety of backing to apps development, there is unquestionably a range of financial models, which in turn affects the pricing of the available apps.  Of the 16,275 consumer healthcare apps available in the Apple app store, 7,717 are free, 7,689 are priced in the range $0.99 - $4.99, and 869 are more than $5 (of which 23 are more than $100).  Despite initial appearances, many of the 7,717 free apps offer paid content within the app.  In many cases, the free app is just a sample and the user needs to buy an upgrade or a subscription.

Investment funding can be significant in the healthcare app space.  In August 2013 it was announced that Calorie Counter by MyFitnessPal, the most popular free calorie counter and fitness tracker on Google Play in the U.S. and the #2 on Apple App store in the U.S.[13], with both a website and mobile app covering 40 million users, had attracted $18 million of venture capital financing.  The app, which has always been free to users, achieved profitability through successfully advertising fitness and weight loss products and with the majority of revenues coming from desktop use. Future growth in revenue through partnerships with hospitals or health insurers is the aim and focus of the recent investment. Underpinning this investment by venture capital firm Kleiner Perkins Caufield & Byers and Accel Partners is a belief that insurers will pay for this app, or corporations will offer it as part of their employee health plans.[14]

## Apps placement on the patient journey

An entire continuum of healthcare needs can be addressed via apps, broadly in two main focus areas for healthcare organizations across the patient journey:

- Changing consumer/patient behavior in areas that affect health, particularly exercise and diet

- Improving the implementation of prescribed treatment regimens
  - Understanding physician instructions
  - Ensuring polypharmacy is appropriately managed
  - Medication compliance or adherence to physician instructions

A further detailed analysis of the consumer focused apps places them along a patient journey, consisting of overall wellness, diagnosis, HCP visit, further information, prescription filling and compliance.  A total of 14,243 apps  were placed on the patient journey, including those specific to a particular demographic group or disease area, which can be distributed across the full journey steps as displayed in Figure 7.

## Figure 7: Consumer healthcare app placement along patient journey

**The Patient Journey**

Therapy Area Specific: 1,980
Demographic Specific: 1,440

Number of apps

**Prevention/Healthy Lifestyles**

Healthy living, diet and exercise,
addiction quitting, stress, relaxation, and sleep          **8,786**

**Self-diagnosis**

Symptom checker and self diagnosis          **304**

**Finding a HC profession or facility**

Doctor reviews and referrals
Second opinions          **931**

**Diagnosis/ Education**

Medical information, condition management
information, emotional support post-diagnosis          **562**

**Filling prescription**

Finding a pharmacy, availability,
price and insurance coverage          **200**

**Compliance**

Persistence, Compliance          **225**

Source: IMS Health analysis of widely available consumer targeted healthcare apps

## Table 2: App placement on the patient journey

| Patient journey stage | Description | No. | Functionality | Example |
|---|---|---|---|---|
| Prevention/Healthy Living | Focus on factors associated with overall wellness:<br>• Healthy eating<br>• Weight management<br>• Fitness<br>• Tips for healthy living<br>• Smoking cessation<br>• Stress management<br>• Sleep | 8,786 apps | • Display information<br>• Display pre-loaded instructions for diet & fitness<br>• Record and display user entered data<br>• Track weight measurements over time | • CalorieCounter<br>• NikeTrainingClub<br>• OneSportsMan<br>• Weight and BMI diary |
| Symptomatic/ Self-diagnosis | • Reference for common symptoms/conditions<br>• Diagnosis based on data inputted/question answered<br>• Communication with medical professionals | 304 apps | • Display reference information<br>• Record users answers and display appropriate guidance<br>• Communication interface between patient and physician | • NHS Health and Symptom Checker<br>• SingHealth Health Buddy<br>• Medibank Symptom Checker<br>• Melanoma Visual Risk Checker<br>• Am I depressed?<br>• HealthTap |
| Finding a Physician | • Locate most appropriate physician or healthcare facility and find contact information<br>• Rate and review physicians<br>• Appointment reminders | 931 apps | • Display search results<br>• Display location information (and connect to GPS)<br>• Connect to phone function<br>• Display reviews<br>• Remind appointments | • BetterDoctor<br>• US Hospitals Lite<br>• Patient fusion<br>• Doctor visit manager |
| Education post-diagnosis | Provide health reference material:<br>• Drugs/medication information<br>• Emergency and first aid information<br>• Condition management information | 562 apps | • Display drug information<br>• Display condition information<br>• Record user entered data<br>• Can connect to healthcare professionals or emergency services | • Drug Guide for Consumers<br>• Family Drug Guide<br>• Pill identifier by drugs.com<br>• Health Handbook<br>• Emergency Info 4Family<br>• Medical Facts+ |
| Filling prescription | • Finding pharmacy<br>• Price scans for medications/special offers<br>• Refilling of prescriptions<br>• Drug interactions and side effects | 200 apps | • Display search results<br>• Display location information (and connect to GPS)<br>• Connect to pharmacy systems to register prescriptions<br>• Offer discounts on medications | • CVS Pharmacy<br>• Walgreens<br>• LowestMed Mobile |
| Compliance | Assisting the patient to act within the prescribed interval and dose of a dosing regimen:<br>• Pill reminders<br>• Medication trackers<br>• Alert support network if dose not recorded | 225 apps | • Provide reminders<br>• Display information<br>• Record user entered data (e.g. register dose was taken)<br>• Communicate with support network | • Medicine Reminder HD - with Local Notifications<br>• MediSafe – virtual pillbox |

The most dominant category on the journey is healthy living, while the least populated are self-diagnosis, filling prescriptions, and compliance.

**Healthy living:**  Earlier this decade Mokdad et al found that 40% of all premature deaths have to do with health behaviors. Specifically, the leading causes of death in the year 2000 were tobacco (435,000 deaths; 18.1% of total U.S. deaths), poor diet and physical inactivity (400,000 deaths; 16.6%).[15] Since then employee wellness programs in the U.S. have claimed that 70% of all healthcare costs are the direct result of behavior and have designed healthcare plans that reward healthy behavior.  For example at Safeway, employees are tested for tobacco usage, healthy weight, blood pressure and cholesterol levels and receive discounts off a "base level" premium for each test they pass.[16] As a result of encouraging healthy behaviors, the company saw its per capita healthcare costs remain flat while most American companies' costs increased by 38% over the same period.

With almost 9,000 apps available to help the population lead healthy lives there is a real opportunity to make an impact on overall health and wellbeing.  By far the largest category within this grouping of apps is diet and fitness, with more than 5,400 of these apps solely designed for the purpose of counting calories or tracking calorie consumption, providing fitness routines and monitoring weight or body mass index (BMI).  It has already been demonstrated that self-monitoring of physical activity and dietary intake are key components of behavioral weight loss programs.[17] Thus the variety of apps in this space could act to provide significant support and guidance for individuals to achieve their health targets and lessen the burden of behavior on overall healthcare costs.

**Self-diagnosis:** Although many apps provide symptom guidance and information, few propose an actual diagnosis to the end user and it is essential that those which do are approached with caution as not all are connected to a HCP.  Recent research evaluated smartphone apps that claim to detect cancer based on a picture of a mole.[18] Only one of the apps sent the picture of a suspected mole to a dermatologist. It was correct 98% of the time. Three others may have serious medical repercussions since they missed melanoma between 30% and 90% of the time, according to the report.[19]

The FDA released its guidance document on mobile medical apps on September 25, 2013. One of the areas that the FDA has been clear they intend to regulate is when mobile medical apps transform a mobile platform into a regulated medical device. As stated in the FDA guidelines *"When the intended use of a mobile app is for the diagnosis of disease or other conditions… the mobile app is a device"* [20] This means that apps which clearly serve the purpose of providing a diagnosis will be subject to FDA clearance as a medical device.  This should lead to a higher standard of diagnosis accuracy from the apps, and potentially increase the numbers of apps in this category now that developers have clear guidelines to work within.

**Filling prescriptions:** In the U.S., pharmacy apps provide weekly deals along with price comparisons, allowing pharmacists to attract customers. These apps typically provide pricing information for drugs sold at major retailers, and are intended to help both insured and uninsured consumers find the best deal on prescriptions by including pricing information for proprietary brands and generic drugs across the most commonly prescribed medicines.[21] These apps have the opportunity to be extended to the large audiences in emerging markets where smartphone penetration is growing rapidly, and where out-of-pocket costs are such a high proportion of healthcare expenditure and hence affordability is a key hurdle for access.  As such there is likely to be an increased number in this app category as target audience expansion occurs.

The U.S. market is also the most advanced market for chain pharmacy mobile apps.  Walgreens has developed an app which can be used to refill prescriptions and to remind patients when to take their medications; they claim the most popular feature of the app is the "Refill by Scan function", allowing patients to scan the bar codes on their prescription vials to order refills.  This  accounts for more than 40% of all online refills and generates more transactions than any other Walgreens app feature.[22] Similarly an app from CVS Caremark also enables patients to manage their prescriptions, with functionality that allows patients to fill prescriptions, access their prescription history, and transfer prescriptions between different CVS/pharmacy locations.[23] The company claims the app is used 1,000 times per day.  If these apps can be linked to improved medication adherence and customer loyalty, more extensive use of these sort of apps can be expected.

**Medication compliance:**  This may be defined as "the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen".[24] To date there are no public studies published in academic journals or whitepapers which demonstrate effective use of apps for improved compliance.  Indeed the only notable results have been released by app developers themselves. For example MediSafe Project has released a statement claiming that its mobile pillbox health app produced compliance rates of about 80% for patients taking type 2 diabetes medications, leading them to state that compliance was more than 26% higher for type 2 diabetic users when they used mobile technology.  However, neither the compliance rates for these individuals prior to using the app, nor the characteristics of this particular patient group, are reported for comparison.[25] It remains to be seen whether randomized trials of mobile apps for medication compliance can demonstrate a clinical benefit resulting from the use of these tools and hence show their value in the reduction of the multi-billion dollar non-adherence costs to the healthcare system. Such a demonstration of evidence of value would likely drive a surge of apps in this category.

## Apps specific to a demographic group or disease

Chronic diseases – such as heart disease, stroke, cancer, diabetes, and arthritis – are among the most common, costly, and preventable of all health problems.  Seven out of ten deaths among Americans each year are from chronic diseases, with heart disease, cancer and stroke accounting for more than 50% of all deaths.[26] About 1/4 of people with chronic conditions have one or more daily activity limitations.[27] Arthritis is the most common cause of disability, with nearly 19 million Americans reporting activity limitations.[28]

In addition to suffering early mortality, patients with chronic diseases also incur significant avoidable costs to the healthcare system through non-adherence to treatment.  In a recent IMS Institute report on avoidable healthcare costs in the U.S., it was demonstrated that six disease areas (congestive heart failure, HIV, osteoporosis, hypertension, diabetes and hypercholesterolemia) accounted for $105 billion in annual avoidable costs from non-adherence to medication treatment[29] (see Figure 8).

### Figure 8: Non-adherence avoidable costs by disease, US$bn

Avoidable costs by disease, US$Bn

**105.4**

44.0

24.6

18.6

15.5

1.8
1.0

● Congestive          ● HIV          ● Osteoporosis          ● Hypertension          ● Diabetes          ● Hypercholesterolemia
heart failure

Source: Avoidable Costs in U.S. Healthcare, IMS Institute for Healthcare Informatics, 2013
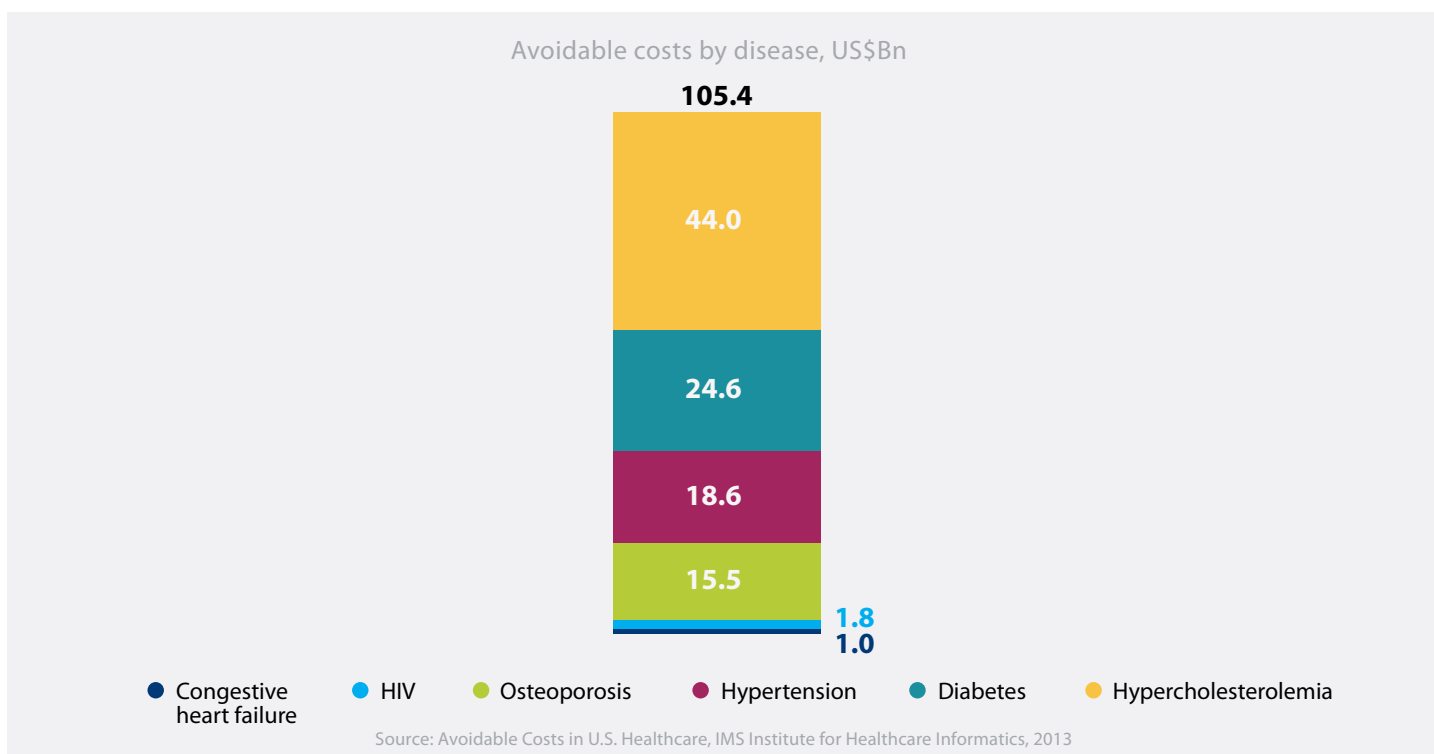
Of the 1,980 apps developed to date which relate to specific therapy areas, chronic conditions dominate.  However the areas of focus of these apps are highly concentrated and not related to leading causes of mortality or non-adherence. The largest category of apps for specific therapy areas is in mental health and behavioral disorders – with autism, anxiety, depression and attention deficit hyperactivity disorder (ADHD) making up 2/3 of apps available in that area (see Figure 9). Mental health and behavioral disorder apps also command some of the highest prices for apps. Of the 23 apps commanding prices in excess of $100, 16 of these are categorized under mental health and behavioral disorders, with autism again ranking highest with 12 of the 16.  These apps are predominantly communication solutions to aid with speech and provide pre-recorded messages.
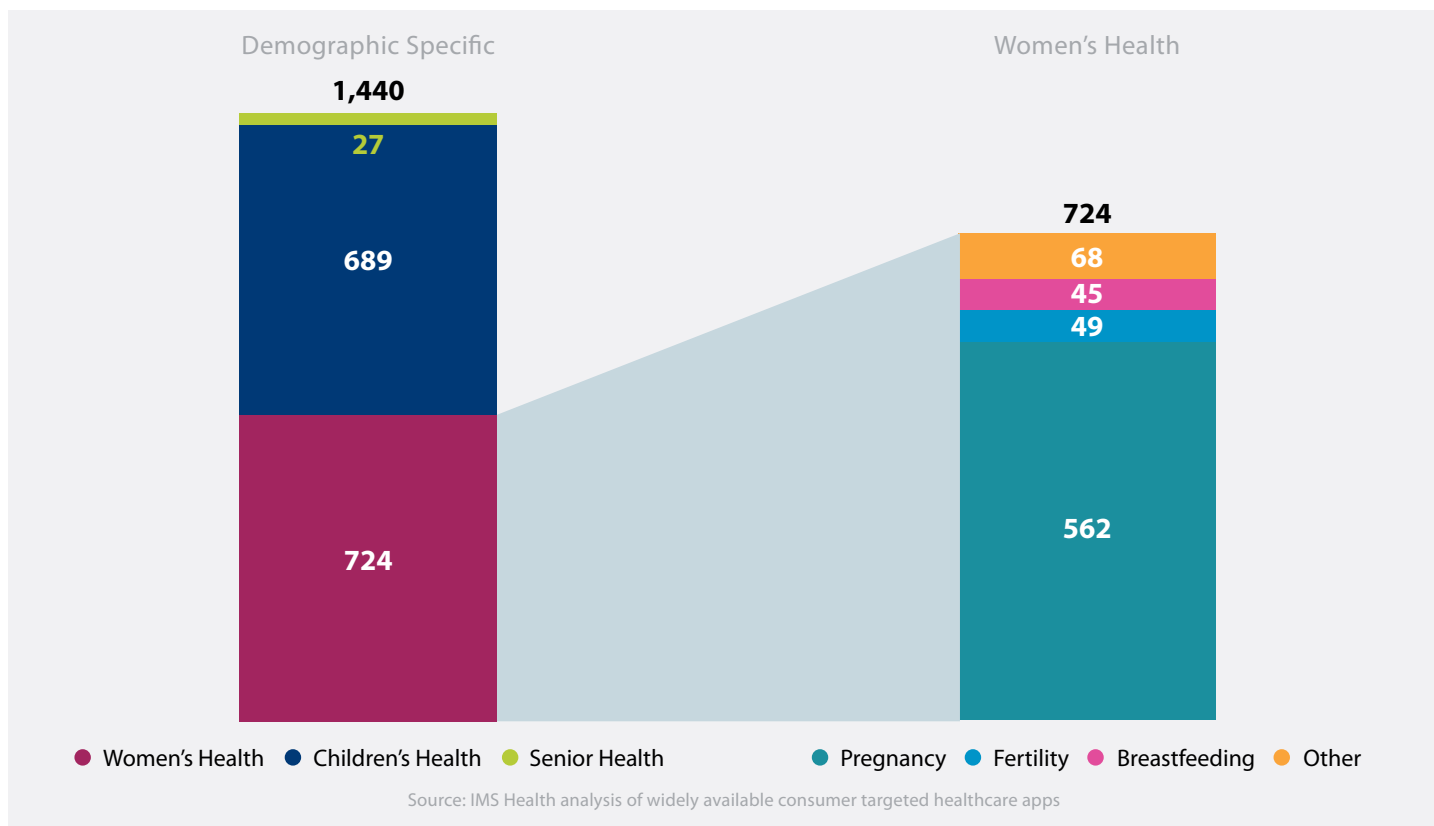
## Figure 9: Breakdown of apps by therapy area



Source: IMS Health analysis of widely available consumer targeted healthcare apps
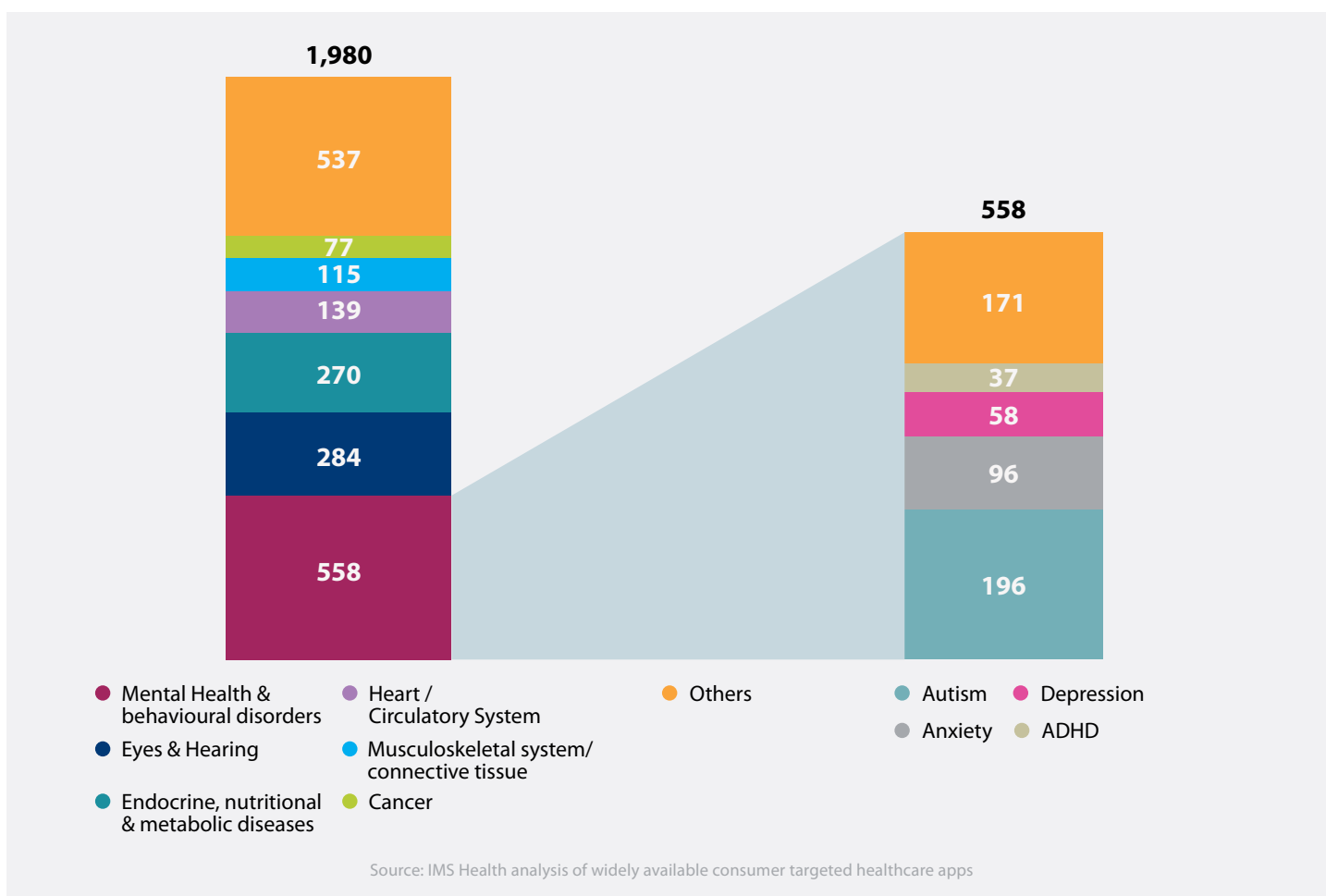
For other chronic disease areas, diabetes apps (categorized within endocrinology) account for 230 apps to date; 139 apps relate to the heart/circulatory system (of which only 12 target stroke) and there are only 77 apps for the other leading cause of death - cancer. Despite the fact that arthritis is the most common cause of disability, only 11 apps target rheumatoid arthritis, and 5 apps target osteoarthritis.  It would therefore appear that there is still unmet need in the therapy area space for apps which provide better condition management for patients living with the most disabling chronic diseases, such as cancer, stroke and arthritis. These apps could provide information for optimal condition management, the ability to track patient health levels over time (and record improvements in wellbeing or condition), and the ability to communicate with caregivers or other patients for motivation and the sharing of best condition management – the latter is likely to be particularly important in emotive diseases such as cancer.  One of the challenges will be how to motivate app developers to address these areas. Although a higher proportion of condition management apps are paid for than, for example, diet apps, only a small number cost more than a few dollars. As such, unless there can be paid content within the apps there is little financial incentive to address these key areas of unmet need and the duty is likely to fall back on pharmaceutical companies or healthcare providers themselves to generate the content.

Of the 1,440 apps categorized as being intended for demographic-specific target groups, women and children's health dominate.  Within women's health almost 80% of the apps are pregnancy oriented (see Figure 10).

Senior Health is at present a very small category, accounting for only 27 apps.  The main target audience within these apps however is not directly the patient, but the caregiver, with most of these apps targeting the carer network, enabling family members and friends to plan and coordinate their caring activities and tasks.  The 65+ age category is at present the group with the lowest penetration of smartphones according to the latest Pew Internet and American Life Project report on smartphone ownership.[30] It is therefore reasonable that apps directly targeting the patient within the senior health category would be lowest in number, and that instead the apps are designed for the caregiver base which is typically made up of younger, smartphone using family members.  In future years as smartphone penetration in the 65+ category increases there should be a concomitant increase in apps for this target audience.

**Figure 10: Consumer healthcare apps breakdown by demographic target groups**



Demographic Specific

Women's Health

1,440

27

689

724

724

68

45

49

562

● Women's Health  ● Children's Health  ● Senior Health          ● Pregnancy  ● Fertility  ● Breastfeeding  ● Other

Source: IMS Health analysis of widely available consumer targeted healthcare apps

## IMS Health ranking of top apps

Functionality scores were calculated for all apps which fall along the patient journey.  However, recognizing that the best apps have not only strong content, but are also user friendly and offer a positive user experience, the functionality score was combined with a user score.  The user score considers the number of reviews that an app has received in addition to its star rating.  As app use increases, and new sources of evaluation become available, rating scores will inevitably evolve beyond functionality and user scores.  In particular, it will be essential to also include physician evaluations and evidence of app efficacy in future scoring systems.

Combining the currently available functionality scores with the user scores provided an IMS Health App Score which has been used to identify the top apps in each category.  As such the IMS Health top apps by classification on the patient journey are listed here. These apps have strong functionality combined with ease of use.

## Table 3: Top apps by classification on the patient journey

### Patient Journey: Prevention/Healthy Lifestyles

| App Name | Developer | Description |
|---|---|---|
| Calorie Counter and Diet Tracker by MyFitnessPal HD | MyFitnessPal.com | Diet app featuring large calorie counting database and features such as food tracking, exercise and weight goals and links to friends |
| Calorie Counter PRO by MyNetDiary | MyNetDiary Inc. | Diet app featuring large calorie counting database and features such as food tracking, exercise and weight goals |
| Chest Trainer : powered by Fitness Buddy | Azumio Inc. | Weight training and fitness application which claims to mimic having a personal trainer in the home, requires no equipment |
| Cycle Tracker Pro - TrainingPeaks GPS | Peaksware, LLC | Converts phone into a GPS-enabled cycling computer, with a wide range of workouts, providing custom readouts and activity reports |
| Quit It 3.0 - stop smoking | Tommy Kammerer | A stop smoking motivational program, supporting and encouraging smokers to quit smoking, helping ex-smokers to stay quit; keeps track of the cigarettes not smoked and how much money saved as a result |
| Quit Smoking Now HD - Hypnotherapy with Max Kirsten | Max Kirsten | A four week quit smoking program with personal hypnotherapy sessions |

### Patient Journey: Finding a HCP or facility

| | | |
|---|---|---|
| Healow | eClinicalWorks | Lets patients communicate with their doctor's office and access up-to-date health records, includes visit summaries and appointment reminders |
| Vitals – Your top 10 doctors! | Vitals | Provides customized lists of the best local doctors, as rated by their patients, allowing for searches by symptom, condition or medical specialty |
| ZocDoc - Doctor Appointments Online! | ZocDoc | Tool to find and book doctor's appointments based on zip code searches |

| Patient Journey: Diagnosis/Education | | |
|---|---|---|
| **App Name** | **Developer** | **Description** |
| HealthTap - free doctor answers to medical and health questions | HealthTap | Provides health answers and healthy tips on any symptom, condition, medication, health concern, or even wellness topics from 47,000 U.S. doctors; provides current and vetted health information |
| iTriage | Healthagen LLC | Provides clear, concise, and useful information covering thousands of medical symptoms, diseases, conditions, procedures, medications and drugs |
| WebMD for iPad | WebMD | Provides mobile-optimized health information and decision-support tools including WebMD's Symptom Checker, Drugs & Treatments, First Aid Information and Local Health Listings |

| Patient Journey: Filling Prescription | | |
|---|---|---|
| GoodRx | GoodRx | GoodRx compares prices for prescription drugs and provides prices, coupons and savings tips for more than 6,000 drugs at most pharmacies in the U.S. |
| MyRefill Rx | Intelecare Compliance Solutions, Inc. | Order medications straight from the phone and get them delivered to the door, as well as medication reminders and appointment reminders |
| Walgreens | Walgreen Co. | Refill by Scan function, Points for Refills, Pill Reminders, Transfer Prescription feature, Refill Reminders, Health Reference encyclopedia |

| Patient Journey: Compliance | | |
|---|---|---|
| Dosecast | Montuno Software, LLC | Flexible medication reminder with customizable dose amounts and instructions, a large drug database and the ability to support multiple users |
| Pill Monitor Free – Medication Reminders and Logs | Maxwell Software | Prescription reminder that alerts the user every time they need to take a prescription. Allows user to enter all prescriptions, set up reminders, and track when they have been taken |
| RxmindMe Prescription / Medicine Reminder and Pill Tracker | RxmindMe, LLC | Prescription reminder that alerts the user every time they need to take a prescription. Allows user to enter all prescriptions, set up reminders, and track when they have been taken |

In addition to apps that relate to a specific step in the patient journey, apps with the highest IMS Health App Scores in specific therapy areas are as follows.

## Table 4: Top apps by therapy area

| Therapy Area Specific : Diabetes | | |
| --- | --- | --- |
| **App Name** | **Developer** | **Description** |
| Daily Carb - Carbohydrate, Glucose, Medication, Blood Pressure and Exercise Tracker | Maxwell Software | Tracks daily nutrition intake of food, carbs, fiber, fat, tracks quantity of water intake, readings of glucose, HbA1c, blood pressure, heart rate, weight, exercise, medications and insulin |
| Glucose Buddy - Diabetes Logbook Manager w/syncing, Blood Pressure, Weight Tracking | Azumio Inc. | Designed as a data storage utility for people with diabetes. Users can manually enter glucose numbers, carbohydrate consumption, insulin dosages, and activities |
| GoMeals | Sanofi-Aventis U.S. LLC | Food, activity and glucose tracker designed to aid the user make healthy lifestyle choices |

| Therapy Area Specific : Mental health & behavioral disorders | | |
| --- | --- | --- |
| ADHD Angel | Daniel Anderton | Reminders to take medication, a process for sending reports ahead of physician visits, ADHD information/reference, advice on the 8 main ADHD 'Tipping Points' |
| Live OCD Free | Pocket Therapist, LLC | Claims to reduce OCD symptoms by 34% in 8 weeks; includes video tutorials as well as extensive user guide |
| T2 Mood Tracker | The National Center for Telehealth and Technology | Allows users to monitor their moods on six pre-loaded scales (anxiety, stress, depression, brain injury, post-traumatic stress, general wellbeing). Custom scales can also be built |

| Therapy Area Specific : Musculoskeletal system and connective tissue | | |
| --- | --- | --- |
| Office-Fit | Medicus 42 GmbH | Provides exercises against work-related pains and stress |
| WebMD Pain Coach | WebMD | Offers a holistic approach to balancing lifestyle with chronic pain conditions.  In particular provides help for those suffering from back pain, neck pain, nerve pain, fibromyalgia, migraine, osteoarthritis and rheumatoid arthritis |
| Zimmer Arthritis 411 | Zimmer, Inc | Patient education resource for people who suffer from osteoarthritis. Can be used at home to learn more about arthritis pain and treatment options |

| Therapy Area Specific : Oncology | | |
|---|---|---|
| Dr K's Breast Checker | Lingopal Holdings Pty Ltd | Designed to help women keep track of change in breasts using interactive tools, provides practical information and reminders |
| PCR Tracker | Cheryl-Anne Simoneau | Specifically designed by CML patients for CML patients, allows user to track and graph results from lab tests, treatment reminders, understand treatment milestones, access educational tools and videos, reference to a glossary of terms used |
| SkinKeeper | The Health Safari Pty Ltd | Enables user to monitor moles, capture important personal and family skin cancer risk factors, and  share this information with their doctor |

| Therapy Area Specific : Nervous system | | |
|---|---|---|
| Noteness (Multiple Sclerosis) | Martin Hartl | Is a multiple sclerosis diary app. Monitors injections and symptoms, and provides reminders |
| Parkinson Diary | Health Wave Signals, LLC | App for patients and caregivers to record, report and review symptoms easily. Features symptom logger, graphical representation of changing symptoms, animation to visually see how symptoms have changed over time |
| Young Epilepsy | Young Epilepsy | Designed for young people with epilepsy, and parents or carers of a child with epilepsy. Contains an up-to-date information portal, video and diary that helps track and manage seizures and symptoms |

Top-rated apps that are specific to women's health or children's health are as follows:

## Table 5: Top apps by demographic

| Demographic Specific : Women's Health | | |
| --- | --- | --- |
| **App Name** | **Developer** | **Description** |
| Ovulation Calendar Ladytimer Free | Vipos.com | Tracks and predicts menstrual cycle days, helping women to become pregnant or avoid pregnancy |
| Period Diary (Period, Fertile & Ovulation Tracker) | nanobitsoftware.com | Fully animated  period and ovulation tracker. Monitor  menstrual symptoms, body weight, temperature,  and add notes |
| Pregnancy Tracker from WhatToExpect.com | Everyday Health, Inc. | Guides women through pregnancy day-by-day. Based on entered due date user receives personalized content, gets access to the latest parenting news and health information, and can be connected to a community of other expecting moms |

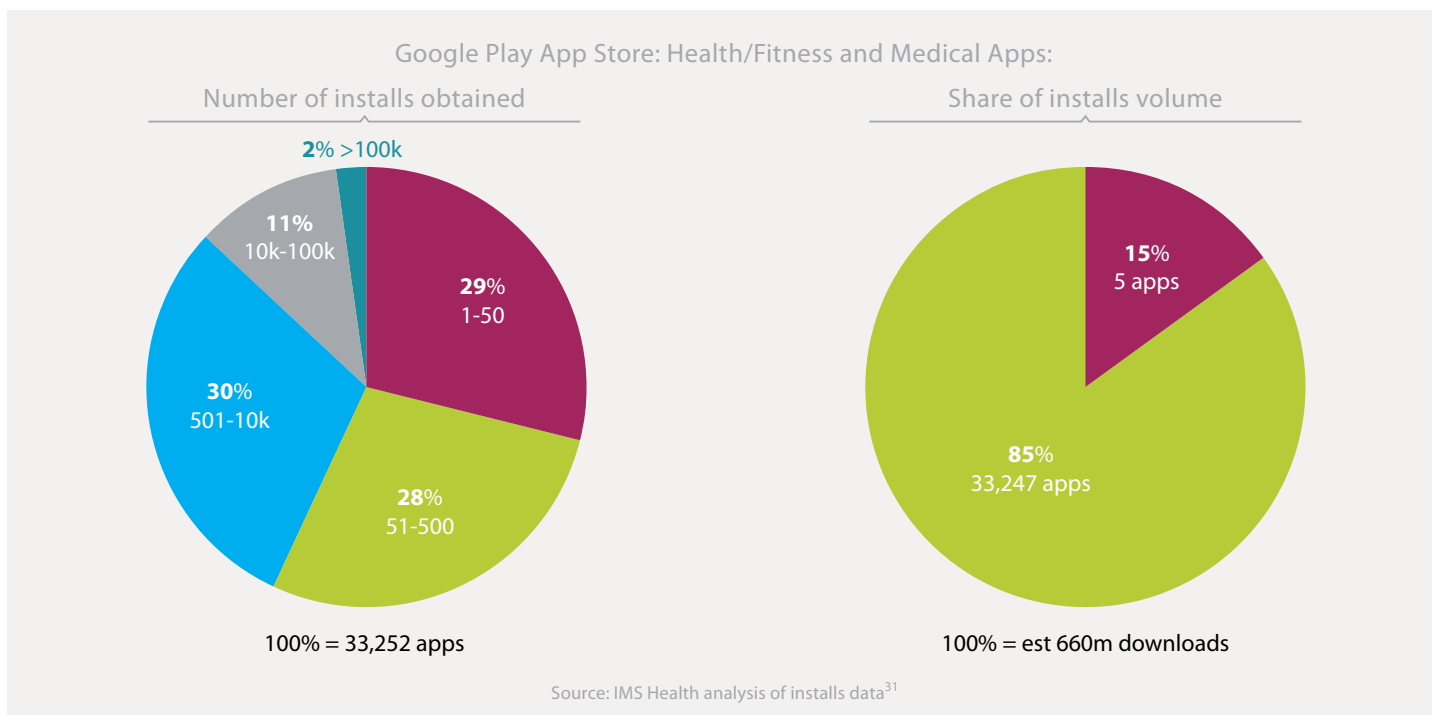| Demographic Specific : Children's Health | | |
| --- | --- | --- |
| Baby Connect (Activity Logger) | Seacloud Software | Baby tracking application which provides graphical reports and trending charts, weekly averages, medicine, vaccine and growth tracking, timers, notifications, reminder alarms |
| Baby Food Pee Poo Free | Colorful Drop | Combines baby logger/tracker, reminders (feeding, diaper change, and sleep) with built-in alarm sound or human voice, as well a white noise recorder/player |
| Total Baby | ANDESigned | Baby logging and tracking function which covers:  Diapers, Nursing, Pumping, Bottles, Solids, Sleeping, Bath, and Other (timing and tracking), Diary, Milestones, Doctor Visits, Growth, Vaccines, and Allergies (logging) |

# Achieving greater uptake of healthcare apps

**Patients, physicians and payers all face obstacles in accessing or supporting the use of apps, providing barriers to their greater use and usefulness across healthcare**

- Despite the thousands of healthcare apps available, downloads are heavily skewed toward a small number of apps

- Barriers to wider uptake and use of healthcare apps span all stakeholders

- Patients currently face a maze of healthcare apps with little guidance on quality although this is starting to be addressed in the U.K. and U.S.

- The demographic skew of smartphone users makes it more difficult to reach those who are the most expensive users of the healthcare system

- Physicians see six key hurdles to the widespread recommendation of apps to patients

- Payers expect to see evidence of improved outcomes and reduced hospitalizations before they will reimburse mobile apps

## Assessment of app functionality

Installs data from the Google Play (Android) app store shows the skew in download volumes for healthcare apps. The majority of these healthcare apps receive very few downloads: more than 50% of the apps in this category receive less than 500 downloads, with only 2% receiving more than 100,000 downloads.  In fact, 5 apps account for 15% of an estimated 660 million downloads in this category (see Figure 11).[31] It would therefore appear that despite the choice available the market is already very concentrated and consumers are consistently choosing the same apps. Since analysts' estimates for downloads of apps in 2013 across all geographies and categories range from 56 to 82 billion, this shows the current limitation of healthcare app use.[32]

## Figure 11: Android healthcare apps installs from the Google Play store

Google Play App Store: Health/Fitness and Medical Apps:

Number of installs obtained

2% >100k

11%
10k-100k

29%
1-50

30%
501-10k

28%
51-500

100% = 33,252 apps

Share of installs volume

15%
5 apps

85%
33,247 apps

100% = est 660m downloads

Source: IMS Health analysis of installs data[31]

There are many reasons for both the skew and the limited number of downloads observed, and they span all stakeholders.  These barriers result in a current lack of incentive to recommend and use mobile apps in healthcare and hence the full potential of apps is far from being reached:

• Patients have to navigate a maze of healthcare apps with little guidance, meaning those apps with the most downloads are considered best and continue to receive the most downloads – a self reinforcing cycle

• The demographic skew of smartphone users makes it harder for the most expensive healthcare system users – the elderly suffering multiple chronic conditions -  to be targeted

• Prescribers are faced with the same widespread choice of apps as patients and with limited information regarding app performance and benefits may be wary to choose an app to recommend to their patient

• Payers are unwilling to consider providing reimbursement for mobile apps without evidence that they bring clinical or cost benefit - and to date there are minimal studies demonstrating efficacy

## Challenges for patients using healthcare apps

With more than 16,000 healthcare apps in the Apple app store alone to choose from, the choice for consumers is confusing.  Healthcare app developers include pharma companies, retailers, national health systems, insurance companies, as well as small businesses and individuals.  There is a recognizable split between those apps which are developed as part of a commercial strategy, and those which are developed simply to try and cover an area of unmet need.  For a consumer approaching an app store, at first glance it would appear that healthcare apps are in a state of chaos with little structure or order to help the patient determine the optimal app out of the thousands available for their particular needs.

In March 2013 the National Health Service (NHS) Commissioning Board in the U.K. unveiled a library of NHS-reviewed health apps intended to help people manage their health. The apps are produced by a variety of developers and then reviewed by the NHS to ensure they are clinically safe.  At present the library is a working project with more apps being added over time.  Apps in the library to date include those which provide advice on specific medical conditions (such as mental health or diabetes), allow users to book repeat prescriptions, access test results, and find the most appropriate NHS service.  The library has been designed by the NHS to put patients in control, in the hope that giving patients easy access to information will encourage them to participate in their care.  This initiative by the NHS is also in response to the large number of apps available that are of varying levels of quality with respect to the medical advice provided. It is intended to provide an NHS stamp of approval so users know the apps are safe.[33]

Progress is also being made in the U.S. HealthTap has developed a product called AppRx, which enables its 40,000 physician users to evaluate health and medical apps. Doctors in the network review the apps on a high level, based on three questions.[34]

- Is the app medically sound?

- Is the app useful?

- Is the app easy to use and understand?

Doctors have the option to write a review to explain their choice, and their reviews do not enter the system until at least 30 reviews have been made and the HealthTap medical review board has approved them.  These reviews are then available to all of HealthTap's non-doctor customers – patients will be able to see the reviews and see how many/which doctors recommended the app. Separately, patients will also be able to recommend the app with the "applaud an app" function.

More recently in the U.S. the "Go You Cigna Marketplace" was launched providing a landing site for members that features certified health and wellness apps.  As development continues the aim is to certify additional health improvement apps that receive positive customer feedback.[35]

These first steps towards healthcare app-verification are essential for consumers to have trust in the app they are using.  Without such measures consumers are reliant on numbers of downloads and individual reviews as a guide to usage by the wider public, and hence become involved in a self-reinforcing cycle of most downloads continuing to inspire further downloads.
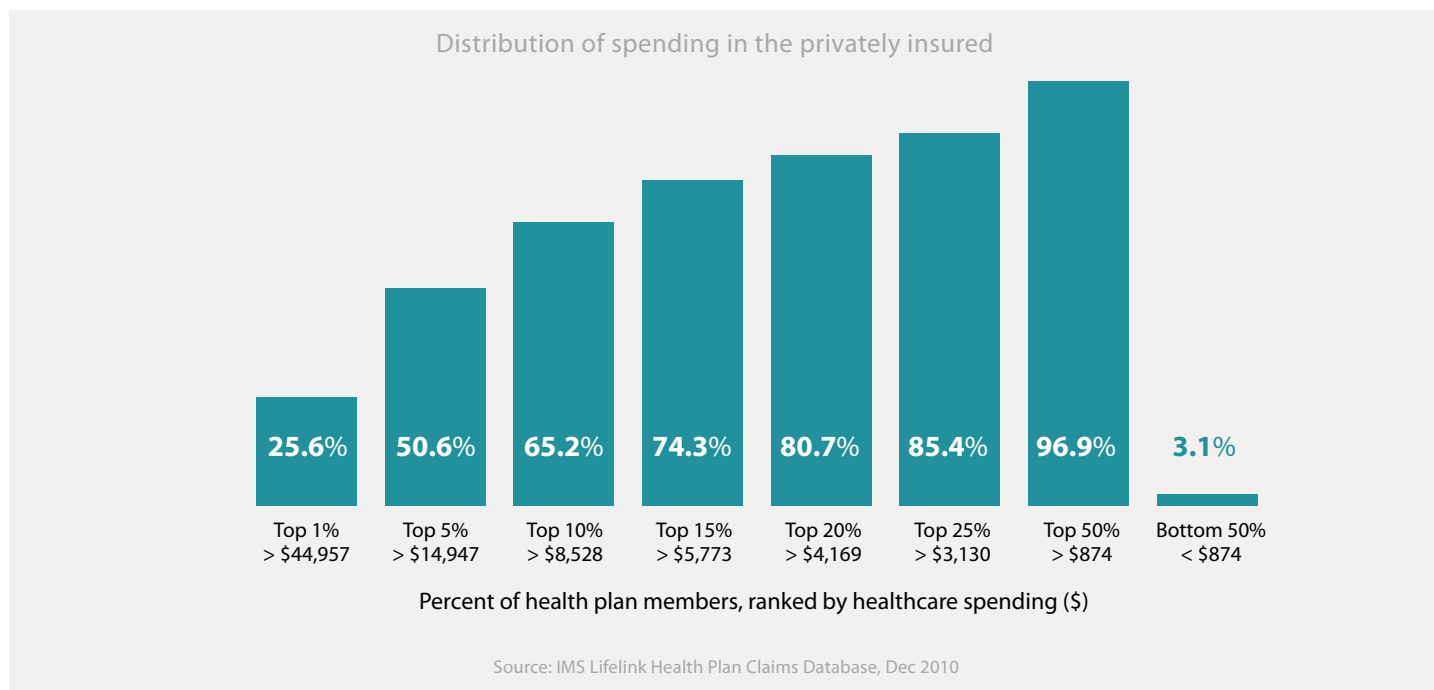
## Smartphone penetration vs healthcare expenditure

The 2012 Pew Internet and American Life Project report on cell phone activities showed that 31% of cell phone owners in the U.S. use their phone to look for health/medical related information.[36] With the increasing number of healthcare apps and their uptake by the general population, technology is providing the opportunity for individuals to be at the heart of their own healthcare. In moving to a situation where patients/consumers have increasing personal responsibility for their own health, there is the potential to move towards a society focused on overall wellness and preventive measures rather than reactive measures.

However, it is important to recognize that apps are not a panacea and optimal deployment does not mean for every individual, in every situation.

> "There is a tendency among certain populations to over analyze… there is always a limitation when you're designing an app of how much raw data  you want the consumer to know versus  having a built-in back end where there is somebody with a medical background, some kind of structure or framework, where the data that's being collected can be interpreted and analyzed for the consumer."
>
> *Alisa Niksch, MD – Tufts University School of Medicine*

Although for many people apps in healthcare have progressed from being a novelty to a mainstream tool the fundamental question remains: can healthcare apps really improve healthcare efficiency and lessen healthcare costs?  In the U.S. it is estimated that 5% of the population account for 50% of all healthcare expenditure; 20% of the population account for 80% healthcare expenditure[37] (see Figure 12).  The pertinent issue then is whether apps can really turn the dial for the 20% of the population who are the nation's top users of healthcare services.

## Figure 12: Percent of total healthcare expenditures for percentiles of the U.S. population[37]

Distribution of spending in the privately insured

| Top 1%<br>> $44,957 | Top 5%<br>> $14,947 | Top 10%<br>> $8,528 | Top 15%<br>> $5,773 | Top 20%<br>> $4,169 | Top 25%<br>> $3,130 | Top 50%<br>> $874 | Bottom 50%<br>< $874 |
|---|---|---|---|---|---|---|---|
| 25.6% | 50.6% | 65.2% | 74.3% | 80.7% | 85.4% | 96.9% | 3.1% |

Percent of health plan members, ranked by healthcare spending ($)

Source: IMS Lifelink Health Plan Claims Database, Dec 2010

The elderly (age 65+) are much more likely to be among the top healthcare spending percentiles.  A principal reason for this is that a much higher proportion of the elderly than the nonelderly have expensive chronic conditions.  However, those over the age of 65 are least likely to own a smartphone or to have downloaded an app, according to recent surveys (see Figure 13).

## Figure 13: Smartphone penetration and app download by age group[30,36]

Smartphone Penetration by age group (%), USA

| Age group | |
|---|---|
| 18-24 | 79 |
| 25-34 | 81 |
| 35-44 | 69 |
| 45-54 | 55 |
| 55-64 | 39 |
| 65+ | 18 |

% US phone owners who have downloaded an app

| Age group | |
|---|---|
| 18-29 | 65 |
| 34-49 | 53 |
| 50-64 | 25 |
| 65+ | 8 |

Sources: Pew Internet and American Life Project: Smart phone ownership June 2013, Cell phone activities Nov 2012
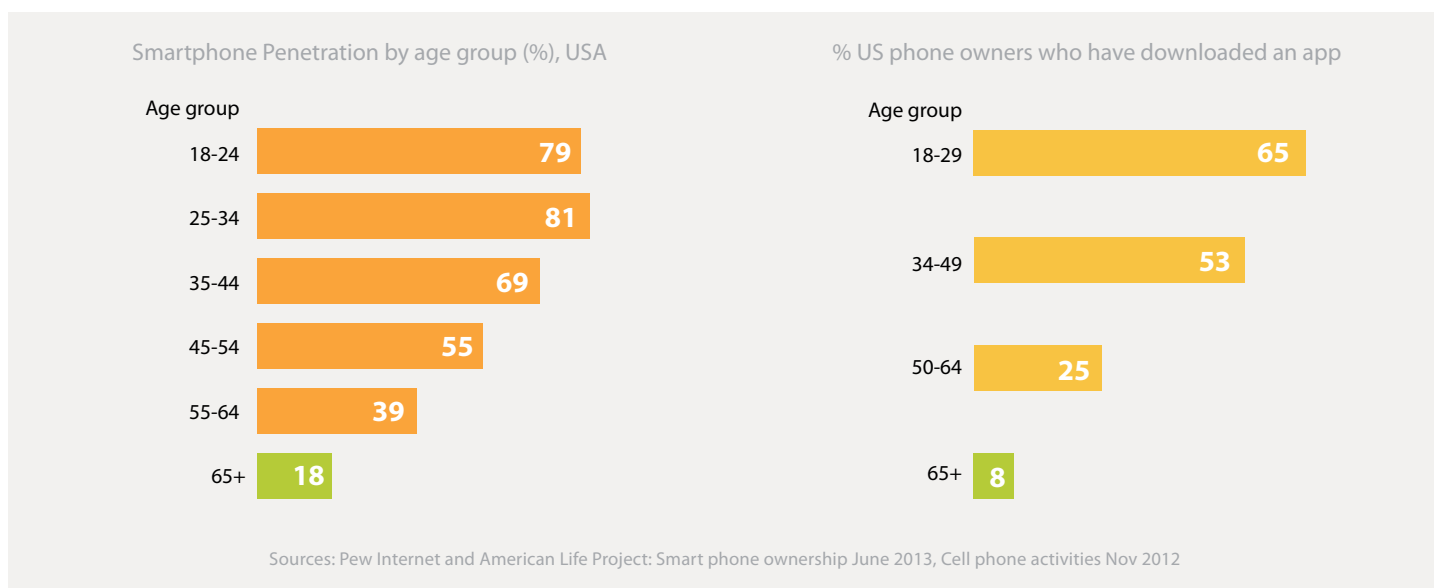
"The challenge we face as practicing physicians is that we have an aging population who can be very savvy with a smart phone and tablets but may not view these technologies as an essential part of their life.  And then you have the millennials who were born after the internet was created, and that is the life they know, the connected life.  So, from an enterprise standpoint, we  have to figure out a way to engage both these patient  groups"

*Sameer Badlani, MD – CMIO, University of Chicago Medicine*

Methods for increasing smartphone penetration and app downloads amongst the elderly are essential to unlock the full potential of mobile apps in healthcare efficiency improvements. An alternative approach is to consider family and caregivers of the elderly and the role they can play, supported by specific apps.  For example, the hundreds of apps developed to help patients find an appropriate medical professional/facility can also be used by family; obtaining a prescription refill simply by scanning the current product barcode can be done by friends and family members who can ensure from a single visit to the patient that their medications remain well stocked.  When it comes to medication adherence, several apps serve not only as pill reminders, but allow the patient to nominate a "support network" who will also receive notifications if a medication dose has been missed or not entered into the system.  In this way the carer network is using healthcare apps to become or remain involved with healthcare management plans for elderly patients.

In the case of older patients with multiple medical problems, it would not necessarily be beneficial to use apps that are narrowly focused on one disease area, and instead it would be optimal for these patients to be supported in taking their multiple medications that their physician has prescribed, and to be supported in remembering the combination of diet tips suggested as a reasonable fit for their preferences and combination of medical conditions.  The burden on the patient if every specialist seen decided to recommend or prescribe their own preferred app for adherence would quickly lead to app overload, similar to that experienced by patients receiving uncoordinated guideline-recommended care for multiple co-existing chronic conditions.[38,39]

"There's a group [of patients] who each have several medical problems and often they have several specialists, all making recommendations.  It's often overwhelming for the patient and for the caregiver.  They get overwhelmed by the number of pills and the number of recommendations that they have been given, so I feel that if everybody starts prescribing apps it could quickly lead to app overload"

*Leslie Kernisan – Geriatrician and caregiver educator*

It is feasible that with increasing smartphone penetration amongst the elderly – the 18% of Americans age 65+ who now own a smartphone compares to only 13% in 2012[30], and high smartphone penetration amongst the younger generations who are likely to make up the caregiver base, mobile healthcare apps can begin to make an impact on healthcare efficiency in the highest healthcare-spending group.

Finding appropriate medical attention promptly, enabling caregivers and family members to access further detailed information on the condition, order prescription refills and receive their own notifications if the patient has not taken their medication, enables a more solid support network than might otherwise be envisioned and can lead to avoidance of costly complications arising from delayed access to healthcare or non-adherence to treatment. However it is important to note that most patients and families have only limited time available for daily healthcare management tasks and while apps can help people to manage a medical plan, not all patients or carers will be willing to try, or will respond, to mobile apps. Technology is an enabler, but the challenge remains in changing a patient's behavior.

In fact it is changing a patient's behavior that may well hold the key to healthcare savings in the future. Younger people are prolific users of apps on smartphones and apps related to diet/fitness/weight management account for half of all apps on the healthcare app store and are the top ranking apps within the category.   Over time, the positive influence these apps have in changing behavior and attitudes toward wellness, exercise, diet and health could potentially have a very significant impact on future levels of chronic disease and the associated healthcare burden.

## Six key hurdles for widespread physician app recommendation

At present, physicians do not recommend apps as standard practice, though they show strong interest and the current level of activity looks set to change in the near future as the infrastructure and evidence for use becomes more widespread.  The pioneer in this space is Dr. Erik Topol MD, a practicing cardiologist with Scripps Clinic, who has said in interviews that he prescribes more apps than pills.[40] A near-term opportunity exists for other physicians globally to become confident in going beyond an ad hoc assessment of the ratings of individual apps and actually recommend or even prescribe to their patients the use of such a tool to monitor behavioral patterns, to access information and to monitor their treatment remotely or provide extra data to the healthcare professional.
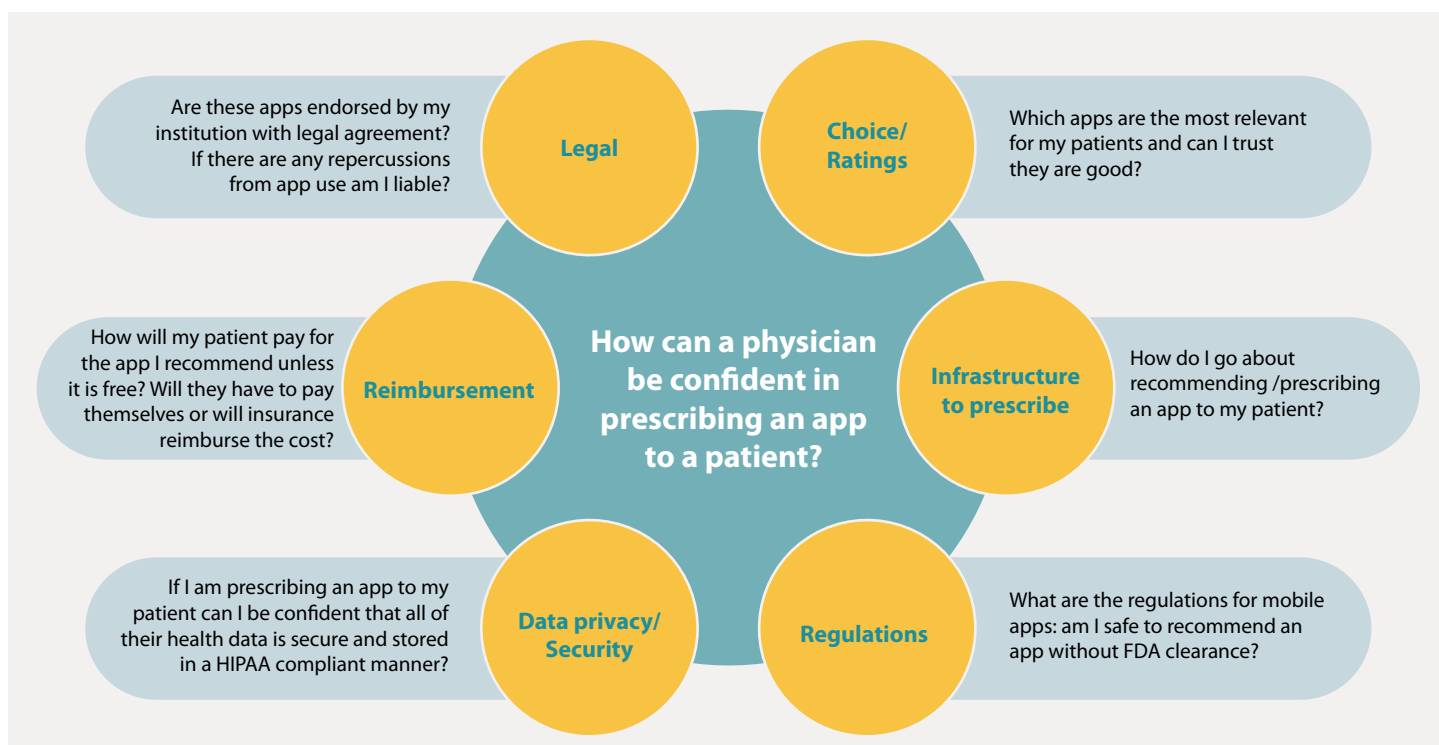
> "I conceptually love the idea of apps in engaging our patients.  As a physician, if I could get this fantastically digestible data that allows me to better care for them, that's the Holy Grail.  But I think we're, as we all know, a long way from there"
>
> *Michael Docktor, MD – Boston Children's Hospital*

In-person discussions with leading physicians and opinion-leaders in the U.S. suggest a diverse set of hurdles for widespread app-prescribing currently exist (see Figure 14):

- Choice of apps and evidence behind them
- Infrastructure for app prescribing
- Regulations
- Data privacy and security
- Reimbursement
- Liability

## Figure 14: Hurdles to widespread physician recommendation of apps



Are these apps endorsed by my institution with legal agreement? If there are any repercussions from app use am I liable?

**Legal**

**Choice/ Ratings**

Which apps are the most relevant for my patients and can I trust they are good?

How will my patient pay for the app I recommend unless it is free? Will they have to pay themselves or will insurance reimburse the cost?

**Reimbursement**

**How can a physician be confident in prescribing an app to a patient?**

**Infrastructure to prescribe**

How do I go about recommending /prescribing an app to my patient?

If I am prescribing an app to my patient can I be confident that all of their health data is secure and stored in a HIPAA compliant manner?

**Data privacy/ Security**

**Regulations**

What are the regulations for mobile apps: am I safe to recommend an app without FDA clearance?

**Choice of apps/lack of evidence:** In the same manner that the sheer volume of available apps can be confusing to patients, physicians face the same challenge.  When a patient is seeking a recommendation, the physician has limited resources to help guide their choice and may fall back on personal preference or peer recommendation rather than the specific needs of the individual patient.  Physicians more than patients are likely to look for evidence that apps work and can demonstrate improved outcomes,  hence apps which have evidence to demonstrate their efficacy are more likely to stand out and be recommended.

"It goes without saying that 40,000 apps within any store is the definition of poor design, because you know that 90% of them are terrible designs and I would say that's the number one cause of lack of adoption"

*Israel Green-Hopkins, MD – Boston Children's Hospital*

Some physicians also expressed a downside potential in that apps may create "data overload" that leaves a physician awash in data but nothing fundamentally useful to make important decisions. If apps start overwhelming physicians with data to interpret, there will be a need for "data triage" to separate the important signals from the noise of information overload.  There is a risk in the short term that recommending a patient use an app could lead to longer, not necessarily shorter and more meaningful patient encounters.

**Infrastructure to recommend:** At present, the infrastructure necessary for physicians to formally recommend apps to patients is limited and many instead resort to writing down an app name and giving it to the patient during their consultation. To address this challenge for physicians, in 2012 testing of an app formulary was undertaken by Happtique, but to date there has been no public release of results from that test.[41]  App formularies could be a significant asset to physicians if they contain simple functionality such as grouping apps by type, rating their functionality and ease of use as well as their medical content, and displaying the frequency of recommendation so that physicians can see which apps are recommended the most by others in their profession. Formularies will need to be designed such that physicians can directly send the app recommendation securely to the patient's phone for them to download and be able to follow up as to whether the app was in fact downloaded.

Seamless integration with other health information technology systems including electronic health records (EHR) will be a necessity for any system designed to provide a means for physicians to recommend apps to their patients, as they – or the chief information officer of their provider organization - will likely resist a stand-alone IT system at a time when so much effort and attention is being placed on implementing or upgrading EHR systems.  Large provider networks or integrated delivery systems are also likely to require apps to contribute to patient engagement, consistent with the Meaningful Use requirements under the 2009 Health Information Technology for Economic and Clinical Health (HiTech) Act.  The overall goal of the Meaningful Use program is to promote the widespread adoption of EHR systems, ultimately creating an infrastructure that improves the quality, safety and efficiency of patient care.
To qualify for Meaningful Use incentive payments, eligible providers must not only adopt an EHR, but also show that they are "meaningfully using" their EHR by meeting a number of objectives designed by the Centers for Medicare & Medicaid Services (CMS) to have a positive impact on patient care.

**Regulations:** The FDA recently released its guidelines for mobile medical apps stating clearly that the two groups of apps it will regulate are those which are intended to be used as an accessory to a regulated medical device and those which transform a mobile platform into a regulated medical device.  To date, the FDA has approved  about 100 mobile medical apps - including 40 in the last year - most of which are focused on chronic condition management including diabetes, asthma, and blood pressure management.[42] However the FDA has also made clear that it intends to exercise discretion in regulating apps that provide patients with simple tools to organize and track their health information, such as apps that enable patients with specific conditions or chronic diseases to log, track, or trend their events or measurements and share this information with their HCP as part of a disease-management plan, and also apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.  With the issuance of this guidance, physicians can be confident going forward that the apps they are likely to be recommending to their patients are receiving appropriate levels of regulatory scrutiny.

**Data privacy and security:** It is essential that there is both transparency and awareness of how data entered into the app is used and that patient consent is obtained for use of that data. If a healthcare app collects, stores, and/or transmits information that constitutes Protected Health Information (PHI) it is essential that it does so in full compliance with the Healthcare Information Portability and Accountability Act (HIPAA), and any other applicable laws or regulations of the country concerned. Any app that is intended to connect to an Electronic Health Record or Personal Health Record (PHR), enabling users to send and retrieve patient information between a mobile device and the EHR/PHR, must do so in a secure manner and all stakeholders involved must accept their stewardship role for protecting the data contained within.

> "Doctors have to be able to trust the app and the data that it's collecting and distributing"
>
> *Creagh Milford, DO, MPH – Massachusetts General Physicians Organization*

**Reimbursement:** How the patient will pay for the app is a concern for many physicians. Although almost half of healthcare apps available to consumers can be downloaded for free, the other half range in price from $0.99 to more than $100. In particular, therapy area specific apps are more likely to only be available with a patient charge. At present patients need to cover the cost of the app directly although as evidence emerges for efficacy there is likely to be a push for reimbursement. WellDoc's BlueStar diabetes management system is now available to employees at a number of Fortune 500 companies who have decided to offer it as a reimbursed program for their employees and their dependents with diabetes.[43] The product is on prescription benefit plans, requiring a healthcare professional to prescribe BlueStar to one of these employees before they can use it. WellDoc is pursuing a new path to condition management with its reimbursed mobile software and it is likely that this will be mirrored by other developers in the future. Reimbursement for physicians to review remotely generated patient data via apps is also seen as a consideration prior to recommending such an app, particularly for physicians operating on a fee for service basis.

**Legal:** Discussions with leading physicians make clear that taking the leap from recommending an app to a patient to officially prescribing an app would add a whole new dimension to the process. Chief medical information officers (CMIO) would recommend the prescription of a subset of apps by that institution's physicians to their patients only after receiving the endorsement of their organization's legal team. Liability from any medical repercussions as a result of app use is also a concern for physicians.

> "When an individual physician says 'I like this app, you should use it', it is very different from the CMIO or the Associate CMIO saying 'These are the endorsed apps from the organization, we have evaluated the app and physicians are welcome to use them'. Now you are putting an institutional stamp on an app and you have to have supporting evidence for use, liability, and technical support amongst many aspects."
>
> *Sameer Badlani , MD – CMIO, University of Chicago Medicine*

## Payer requirements for app reimbursement

Before payers will be willing to reimburse mobile apps, encouraging uptake by both patients and physicians, there will be a need for evidence which shows the benefits of using apps as part of standard healthcare management. The evidence requirements will vary depending on the intended utility of the app (see Figure 15).

**Figure 15: The app evidence divide**

| **Critical need for evidence** | | Self-Diagnosis Apps |
|---|---|---|
| Clinical trials to demonstrate efficacy | Regulation to verify safety of diagnosis | |
| **Need for evidence to demonstrate benefits to all stakeholders** | | Condition Management Remote Monitoring |
| Observational studies to demonstrate efficacy | Need for regulation when apps link to device or sensor | |
| **Need for evidence for reimbursement** | | Prevention/ Healthy Lifestyle Compliance Rx filling |
| Observational studies necessary to improve uptake | No foreseen need for regulation | |
| **Download popularity/3rd party ratings suffice** | | Finding HCP Education post-diagnosis |
| Ranking by professionals likely to aid consumer confidence | Download volume likely to be influencing factor for choice | |

**Self-diagnosis apps:** These apps are likely to require the highest level of evidence and the results from evaluating several apps intended to diagnose melanoma suggest this is an urgent and critical need.[18] Diagnosis apps may be less likely to be reimbursed by payers in mature markets where there is an expectation that a HCP will be undertaking the diagnosis, but the FDA will be regulating such apps as medical devices and hence will be expecting to see evidence of their utility before approval. There is a strong likelihood of self-diagnosis apps becoming widely used in emerging markets where access to physicians can be severely limited in remote locations, and yet where smartphone penetration is continually increasing. As such patients should be reassured of the accuracy of such applications through thorough testing and regulation by the FDA or other agencies.

**Condition management/remote monitoring apps:** The largest trial carried out to date in the condition management/remote monitoring area is the WellDoc diabetes management software trial.[11,12] As well as demonstrating improved A1c levels in patients, feedback from physicians was also very encouraging. The product is now reimbursed by several large corporations' healthcare plans. However reimbursement for other medical apps, including others approved by the FDA, has not been secured and many questions remain for reimbursement. For condition management medical apps, payers are likely to expect to see evidence of a defined improvement in specific outcomes measures, whether this be therapy area specific measures such as A1c levels or blood pressure levels or an overall defined improvement in adherence to prescribed treatment as a result of remote monitoring, medication reminders and healthcare task management.

**Wellness apps:** A recent RAND report estimated that approximately 50% of employers with more than 50 employees offer wellness programs. Although only about half of all employers offer wellness programs, more than 75% of employees working for companies with more than 50 employees have access to a wellness program, because large employers, who account for a greater share of the workforce, are more likely to have such programs.[44] With many corporations in the U.S. and Europe enrolling employees in wellness programs, and with measures such as those in the Affordable Care Act encouraging employers to set aside premiums for wellness based incentives, there is growing interest in how apps may support patients in this manner.

It is likely that to fully realize this potential, payers of wellness programs will want to see meaningful evidence of the efficacy of relevant apps. Evidence for apps in a wellness setting is much more likely to come from real world use than an randomized clinical trial, and to date few studies have analyzed this. A pilot study by Carter et al followed 128 overweight volunteers over a time period of 6 months, comparing the outcomes of a group of patients randomized to self-monitor weight management via a mobile app against patients using either a website or a paper diary.[45] The pilot trial was not statistically powered to detect change in anthropometric measures; however trial retention was 40/43 (93%) in the smartphone group, 19/42 (55%) in the website group, and 20/43 (53%) in the diary group at 6 months. Adherence was statistically significantly higher in the mobile app group with a mean of 92 days (SD 67) of dietary recording compared with 35 days (SD 44) in the website group and 29 days (SD 39) in the diary group (P<.001).

Larger scale real-world trials such as this are likely to be conducted in the future to satisfy the requirements of payers in a wellness setting. However it remains to be seen if there will be a "class effect" and whether one large trial with a specific calorie counting app or a fitness app will be seen as sufficient to cover all calorie counting and fitness apps, or whether ease of use and individual functionalities of the app will lead to a more individual evidence scenario. If that is to be the case then there will inevitably be a fall out from the smaller app developers who are

unable to afford such an extensive analysis of their user base.  Evidence that is collected by the use of apps in such Wellness programs could also be used by physicians and payers looking for outcomes evidence before widely adopting such technology.

**Finding a HCP/healthcare information apps:** These apps serve to provide the consumer with information on relevant healthcare services and their condition management/medication regimen "on the go", providing a convenience factor, and do not sit on a part of the patient journey that is ever likely to see reimbursement or recommendation.  As such apps are downloaded on the basis of consumer interest, and download popularity or reviews from other users are likely to suffice, formal evidence of utility is unlikely to be required in the future.

# Call to action

**For mobile apps in healthcare to move along the maturity curve and become a fully integrated component of healthcare delivery, all stakeholders must be engaged and evidence developed**

- The app maturity process will be driven by four key elements which involve all stakeholders
  - Payer and provider recognition of the potential role of apps in healthcare management
  - Creation of a standard benchmark for security/privacy guidelines that protects PHI globally
  - Curation and evaluation of healthcare apps
  - Integration of apps with other health IT systems

- Systematic development of credible evidence of the value derived from using healthcare apps will also be necessary

For app use in healthcare to evolve across the maturity spectrum from present day novelty factor and ad hoc use, to become a fully integrated component of healthcare delivery with widespread recommendation by healthcare professionals and reimbursement from payers, there are four key issues to address on the model to app maturity (see Figure 16). There are a range of stakeholders which form the "app ecosystem" and each of the four steps requires collaboration between these stakeholders: the app developer, the regulator, the provider, the patient and the payer (see Figure 17). Additionally underpinning the entire maturity model will be increasing evidence of app effectiveness.
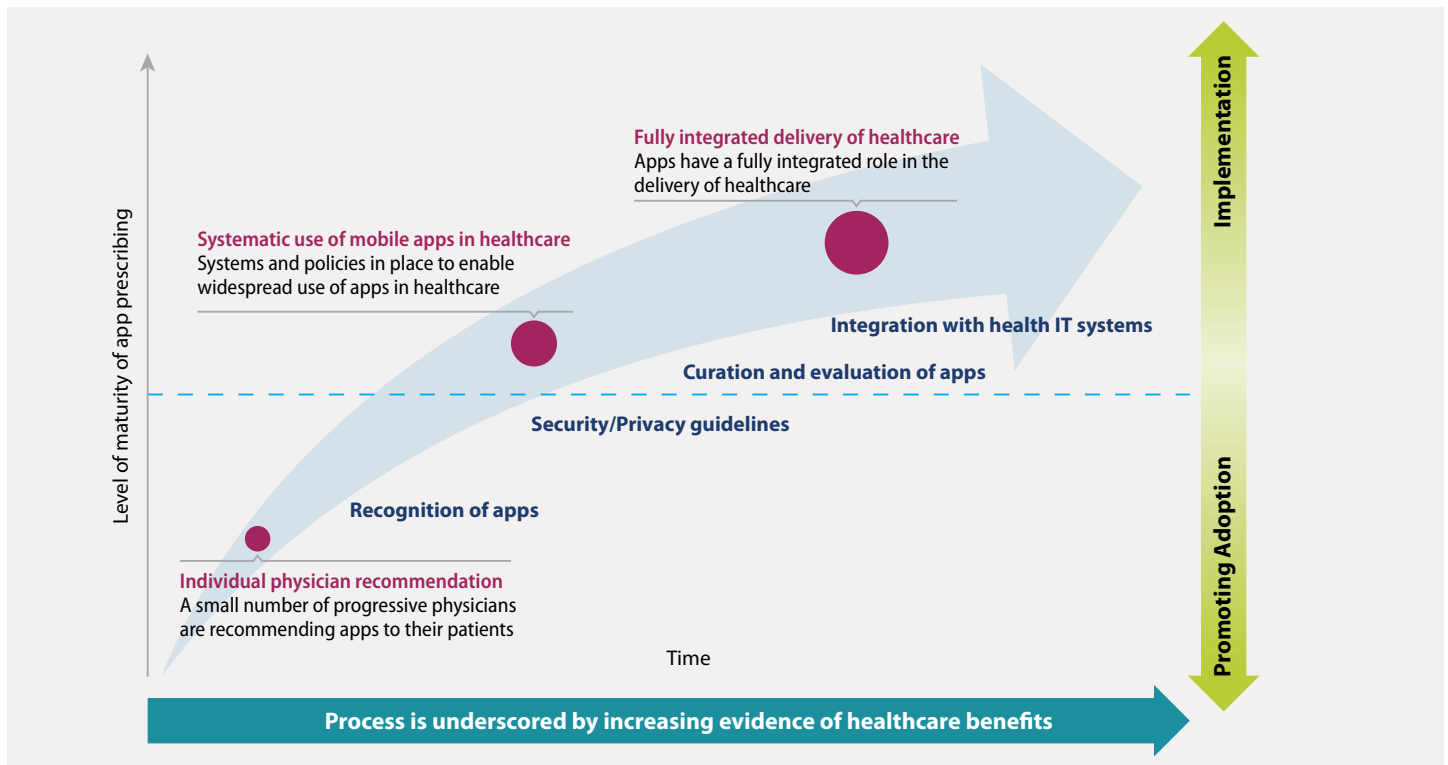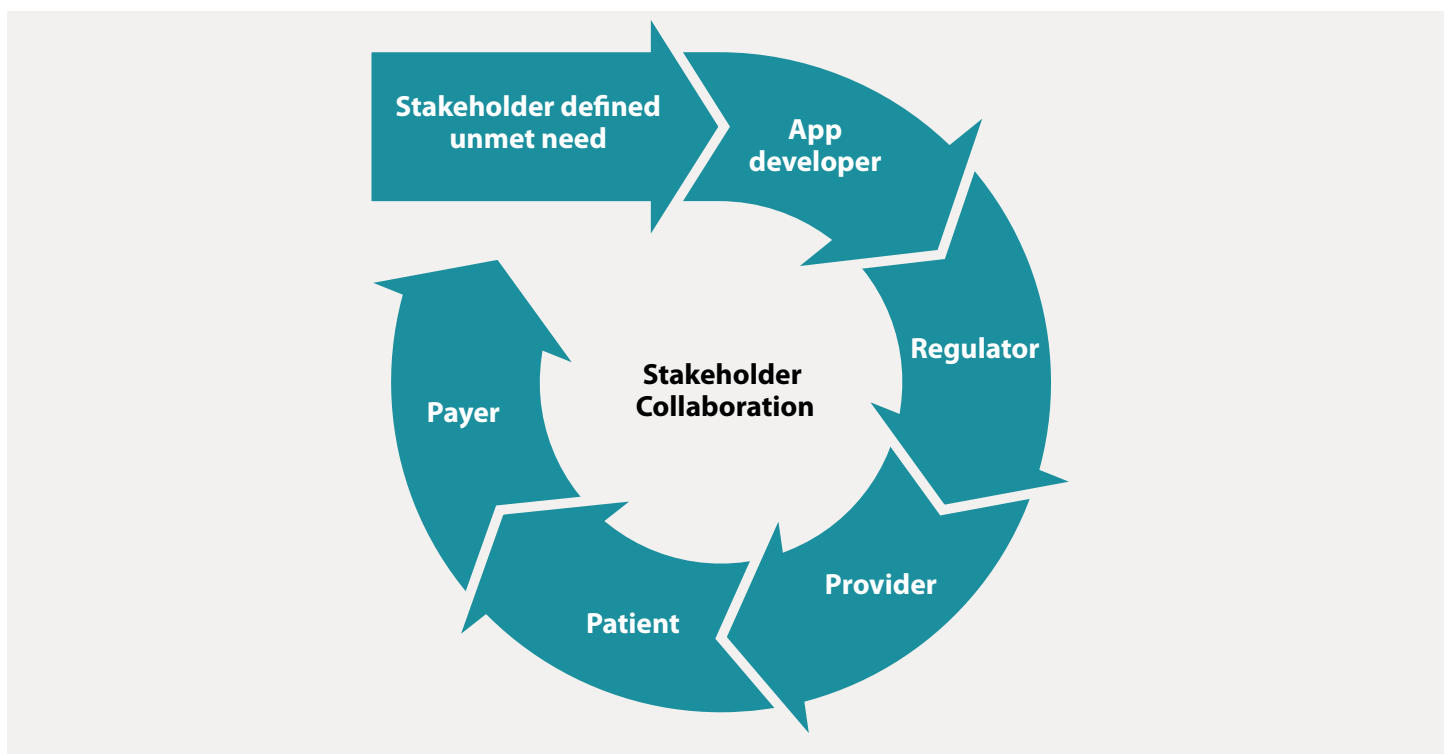
## Figure 16: The app maturity model



## Figure 17: Stakeholders in the app maturity model

**Recognition of the potential role for apps:**  Apps should not be used as a replacement for human care, rather they should provide a strengthening of the care provided. Across the patient journey mobile apps have the potential to empower patients to live a healthier lifestyle, and to ensure adherence to prescribed treatment.
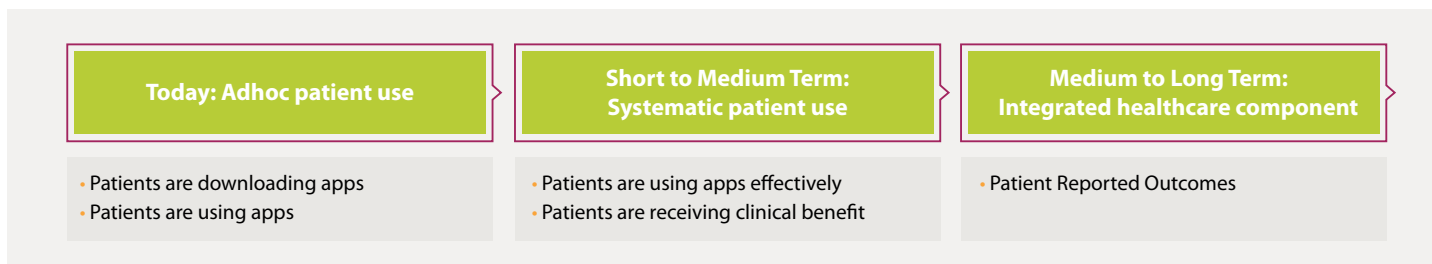
In the U.S. the Patient Protection and Affordable Care Act is driving dramatic changes in healthcare.  Improving the quality of care and treatment outcomes is one of the priorities of healthcare reform. Delivery of care changes center on the patient and creating connections between all settings of care; an additional component of healthcare delivery reform is preventative healthcare.  Payers and providers should recognize the potential of mobile apps in this setting.  A key benefit to the physician in charge of the patient's healthcare management is the remote monitoring of vitals which can be communicated back to the healthcare practice. Alongside patient logging of healthcare activities this can help to improve continuity of care in cases where there is a transition of care management after hospital discharge, avoiding the penalties that will be introduced for hospital readmissions.  Public health literacy can be improved through use of informational apps and patient awareness of preventative healthcare services can also be targeted.

> "There is a big desert that you enter once you leave the hospital or the doctor's office.  So that is where I really see a lot of opportunity and personal excitement around using an app as a tool to help fill that space"
>
> *Jonathan Birnberg, MD – North Shore University Health System*

A further aim of the healthcare reform is to encourage the meaningful use of EHRs in order to enable information-sharing between healthcare stakeholders and across settings of care.  Apps also have a potential role here with providers offering apps from which patients can directly access their EHR, and with the potential for patient-reported healthcare measures being transferred from the app to the EHR.

For providers and payers to recognize the potential value of apps to healthcare efficiencies they will also be looking for evidence that the patient is actively engaging with the technology (see Figure 18).

## Figure 18: Evolution of evidence of app implementation

| Today: Adhoc patient use | Short to Medium Term: Systematic patient use | Medium to Long Term: Integrated healthcare component |
|---|---|---|
| • Patients are downloading apps<br>• Patients are using apps | • Patients are using apps effectively<br>• Patients are receiving clinical benefit | • Patient Reported Outcomes |

**Security/Privacy:** The main risks posed to data protection by apps at present stem from the consumer's lack of awareness or understanding of the types of data collected and a failure to obtain the consumer's consent for the processing, storing or accessing of any personal data on their smartphones.  As such, a typical privacy policy for mobile applications (not specific to healthcare) would contain as a minimum four published elements:[46]

- The categories of personally identifiable information (PII) collected and the types of third parties with whom the information is shared

- A description of the process for users to review and request changes to their PII that has been collected

- The process by which material changes to the privacy policy will be communicated

- The effective date of the policy

With healthcare apps it is essential that any information that constitutes PHI is treated in full compliance with HIPAA, and any other applicable laws or regulations of the country concerned. The challenge for app developers today is there is no published standard which shows that an app is in fact HIPAA compliant and different regions globally are at different stages of mobile app privacy guideline design.

In a time of rapidly evolving technology, industry self-regulation is the most effective way to maintain the balance between consumer confidence in privacy and continued innovation. As such the mobile healthcare apps industry should itself define a standard which ensures that all healthcare apps adhere to the highest privacy standards.  This standard should include, but not be limited to, the following points:[47]

- App developers should request consent before the app starts to collect data from the device or place data on the device: this consent should be informed and specific

- Apps should only collect data that is strictly necessary for the app to perform the desired functionality

- Developers should define a reasonable period of time for data retention. Dormant apps should be treated as expired and the data should be deleted

- HIPAA standards should be translated into a global benchmark which forms the basis for privacy and security of all PHI data transmission, encrypting data and making efforts to de-identify user data before sharing it with another party

Once mobile healthcare app developers have designed their global privacy standard, providers and patients can be reassured of the benefits of apps in healthcare rather than detracted by their concerns over protection of personal information.

**Curation and evaluation:** Systematic curation and evaluation of apps that can provide both physicians and patients with summarized content to aid decision-making regarding the appropriate app choice will be an essential step towards promoting the widespread adoption of healthcare apps.  There are initial steps being taken in the U.S. and the U.K. but new services with widespread medical endorsement that ensure this information is made available in the proper format and context to support patient care will be required in future.

Evaluation services must group apps by functionality, and contain user evaluations, physician evaluations and evidence to support the use of the app in the context for which is was designed. Professional healthcare societies, such as the American Medical Association or other similar organizations, should be involved in the process endorsing the apps with the highest evaluation rating for use by their members since credibility and trust are a strong factor in who curates.

**Integration of apps:** The integration of mobile apps with other aspects of patient care including use of electronic health records and patient portals requires the least collaboration between stakeholders but will be one of the pivotal steps on the app maturity journey to facilitate the widespread prescription of mobile healthcare apps.  This requires consideration by provider organizations, EHR software vendors, and the support of the Office of the National Coordinator for Health Information Technology (ONC) and CMS regarding meaningful use.

**Stakeholder collaboration:** Across these four steps different stakeholders have different roles to play.  In addition to the main stakeholders there are professional service enablers who also need to contribute to the process.

## Table 6: Stakeholder call to action

| | Recognition | Security/Privacy | Curation/ evaluation | Integration |
|---|---|---|---|---|
| App Developer | ✔ | ✔ | ✔ | ✔ |
| Regulator (Approver) | | | ✔ | |
| Provider | ✔ | ✔ | ✔ | ✔ |
| Patient | | ✔ | ✔ | |
| Payer | ✔ | | | |

The call to action is therefore clear: app developers and healthcare providers need to be the main drivers of progress for app maturity. As the key starting point in the process, app developers have the power to drive recognition through the design of apps which a) satisfy key areas of unmet need (such as condition management in leading chronic diseases or disabling conditions), b) clearly address elements of healthcare reform, c) have a clear value proposition backed up by evidence of effectiveness which can be used in the evaluation of the app and d) which respect the data protection rights of the user and ensure all sensitive information is handled appropriately. App developers must also be willing to work with other developers of healthcare IT system infrastructure to ensure that there can be a seamless integration of systems.

A fundamental challenge here is the range of app developers. App developers range from National Health Systems and large retailing brands with sufficient resources to tackle all of the above calls to action, to individual app creators with no financial backing and no resources available to collect outcomes evidence. A consortium of app developers needs to be formed which represents equally the interests of all app developers, and which lays out a clear plan to overcome the hurdles on the app maturity curve. Providers also need to work together to share best-practice on app policies and to design national guidelines for the systematic use of mobile apps in health delivery.

App developers and providers must then work together to ensure maximum benefit and cost efficiencies for the healthcare system.

# Evidence

There is a pressing need for credible evidence of value derived from the use of healthcare apps that will meet the needs of physicians and payers. This evidence will inevitably evolve and become more sophisticated over time.  Although at present observational studies are accepted as the best available, it will be essential that over time randomized trials are conducted with the long-term goal being outcomes based evidence.

> "Patient reported outcomes, or whatever term you want to use - those will be the future that we, as providers and health systems, will be measured on"
>
> *Creagh Milford, DO, MPH – Massachusetts General Physicians Organization*

There are at present opposing sides of the debate as to the necessity of conducting randomized clinical trials (RCT)with mobile apps but these arguments tend to be based more on logistics than evidence requirements.  Those against performing randomized trials typically argue that the cost would prevent small app developers from conducting them, and that the time taken to generate results is too slow considering the pace at which technology evolves.  It is also argued that since multiple medical devices marketed with FDA approval do not have randomized trials to back them up simply because they are unlikely to cause harm, there is no reason for apps to be treated any differently, especially now that the FDA has stated it is likely to exercise discretion for the majority of mobile apps.[48]
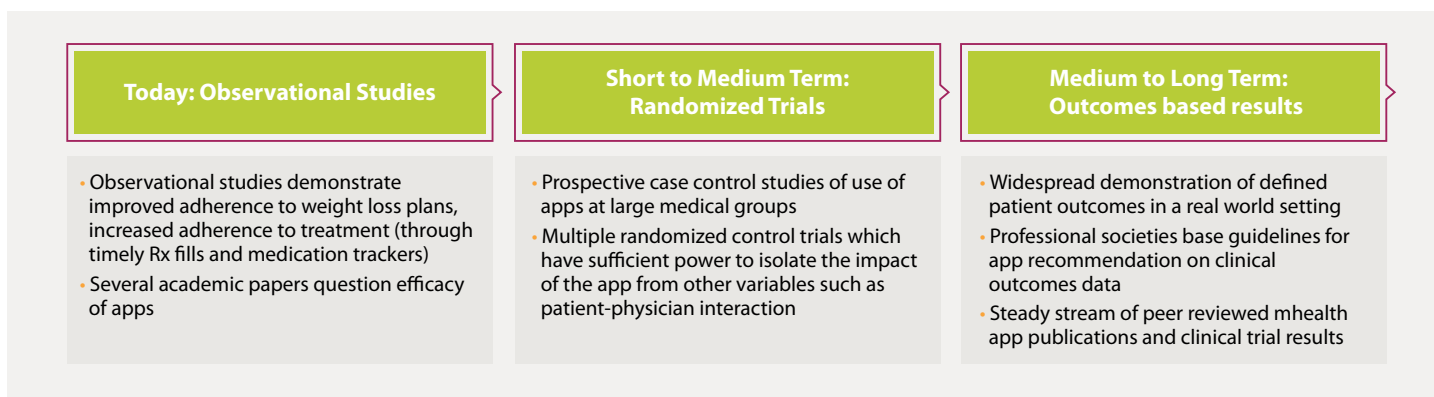
However, these arguments are looking at the process of the randomized clinical trial purely from a development and approval perspective.  The call to action for evidence generation from randomized trials and outcomes based results is based on the belief that without this evidence there will not be widespread uptake by providers and payers, making apps a fundamental component of healthcare delivery and instead skepticism will remain amongst these key stakeholders. Since at present there is almost no scientific evidence published in peer-reviewed journals regarding defined benefits of mobile app use, it is necessary to approach the evidence evolution in stages.

> "I am not aware of any scientific literature that proves the benefit [of mobile apps]. While there are a lot of industry sponsored white papers we really need to see randomized control studies - which is the gold standard for calling an intervention evidence based.  Even a prospective case control or cohort studies would be a good start."
>
> *Sameer Badlani, MD - CMIO – University of Chicago Medicine*

Observational studies are appropriate for comparing the effectiveness of apps within a given classification (e.g. diet and fitness, compliance) and for encouraging uptake, whereas RCTs should be used to demonstrate improved healthcare outcomes from an mHealth strategy (hence not app specific). In the future since providers will be measured on patient reported outcomes, it will be essential to have data providing evidence conducive to outcomes based results (See Figure 19).

**Figure 19: Evolution of evidence development for efficacy**

| Today: Observational Studies | Short to Medium Term: Randomized Trials | Medium to Long Term: Outcomes based results |
|---|---|---|
| • Observational studies demonstrate improved adherence to weight loss plans, increased adherence to treatment (through timely Rx fills and medication trackers) <br> • Several academic papers question efficacy of apps | • Prospective case control studies of use of apps at large medical groups <br> • Multiple randomized control trials which have sufficient power to isolate the impact of the app from other variables such as patient-physician interaction | • Widespread demonstration of defined patient outcomes in a real world setting <br> • Professional societies base guidelines for app recommendation on clinical outcomes data <br> • Steady stream of peer reviewed mhealth app publications and clinical trial results |

**Observational studies:** Although observational studies may not be the gold standard when it comes to making statements of fact about safety, efficacy, or effectiveness, they provide valuable data on "real world" use and practice, and help formulate hypotheses to be tested in subsequent studies.  In the current situation where there is a complete absence of evidence, beginning with observational studies which are feasible and affordable to push on what is known in the world of mobile health apps is a strong start, and these observational studies will be a useful way to generate empirical evidence for testing in RCT.

**Randomized Controlled Trials:** In the short to medium term, work needs to commence on the design and recruitment for an RCT to demonstrate the overall health outcomes associated with using mobile apps. To design such a trial there needs to be a consensus on the criteria for evaluation of apps, with researchers, clinicians, and entrepreneurs freely sharing and debating their work. A 3-4 year RCT as seen in the development of drugs is wholly unnecessary for mobile apps, but evidence of behavior change or change in defined health measures in an appropriate time scale are essential to ensure the effectiveness of the mHealth approach.  The trial must be designed with the appropriate power to isolate the impact of the app from other variables such as the quality of the patient-physician interaction.

Further it must be recognized that a patient may be using their own online tools regardless of physician recommendation and hence if one arm is the "app intervention" arm and the other a "current care" control arm, the control arm must acknowledge that people are likely to passively use open websites and mobile tools themselves. The key is to know how information, support, and communication impacts on the patient's wellbeing and, as such, these longer term RCTs should be formulated in terms not of a specific app but in terms of a functional assessment of what is needed, for example, different ways of providing information, support and communication.[48]

> "Right now there is scant scientific evidence that apps work.   The main, respectable journals have not published any 'interesting ' peer-reviewed and reproducible results. When they do, you will have the attention of the medical community. We are taught to trust our journals. Sadly, medical research has not embraced the technologies that are out there and continue to focus on basic research and meta-analysis studies - which they should.   Doctors are not techno-phobic, they're just afraid of new applications without a demonstrable ROI on time and outcomes."
>
> *Jordan Shlain, MD, FACP – HealthLoop Inc.*

# Conclusion

As evidenced by the most detailed analysis of widely available consumer healthcare apps to date, there has been a tremendous development of mobile apps to assist consumers and patients in every step of their healthcare management - from preventive measures that encompass overall wellness, through to adhering to a prescribed treatment regime. The apps developed to date are supported by a wide range of backers and have very different business models and propositions. They also vary widely in their functional capabilities.

One of the main challenges stemming from the wide variety of mobile healthcare apps available is the confusion amongst consumers regarding the most appropriate app to meet their needs, resulting in a significant download skew whereby the most downloaded apps continue to receive the most installs as a result of high review numbers and ratings. Physicians face the same challenge when they try and recommend an app to a patient.
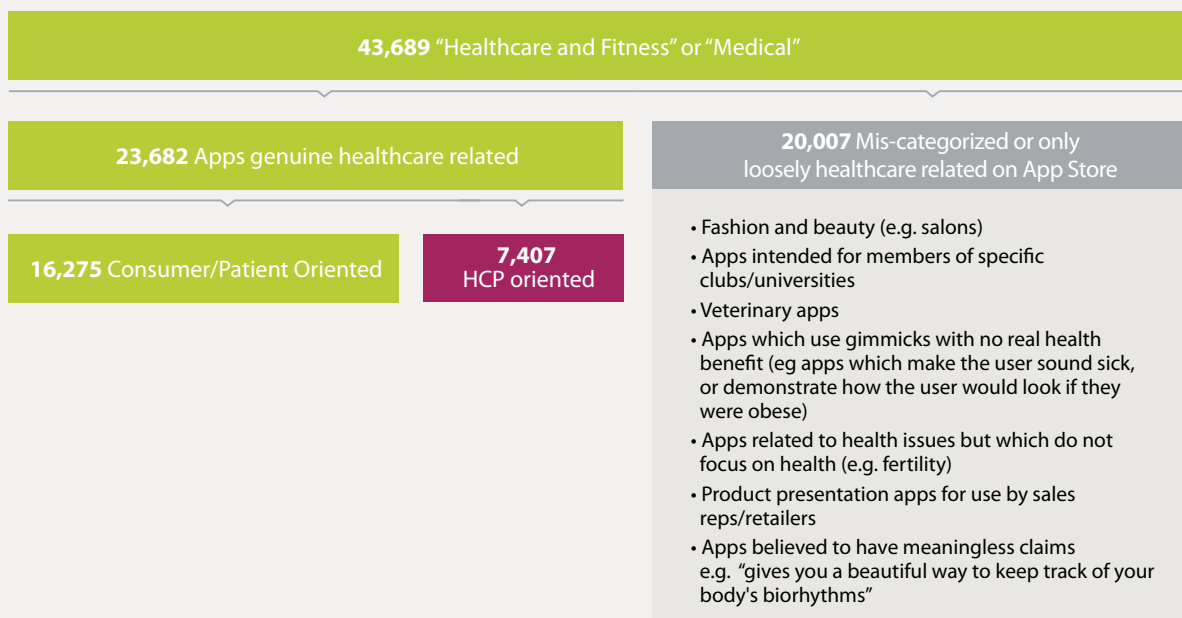
For healthcare apps to move through a maturity cycle from being an ad hoc recommendation to a systematic, integrated component of healthcare delivery, all stakeholders will need to work together. Healthcare payers and providers will increasingly recognize the potential benefit apps can bring, app developers will ensure privacy and security of patient data, and a concerted effort will be made to evaluate healthcare apps and to integrate them with other health IT offerings. Moreover, significant investment will be made in evidence generation to demonstrate that mobile apps can lead to defined improvements in health outcomes. Many of these steps will require considerable upfront investment – meaning there must be an incentive to move apps towards maturity.

One such incentive in developed markets is the ongoing shift to patient centered care models. Stakeholders need to see patients as responsible and capable partners in healthcare management - and patient engagement through mobile apps is an exemplary first step in this process. Some of the areas where substantial gains can be made in the healthcare system involve exciting an interest in healthy lifestyles through diet and fitness apps, combined with the potential for remote monitoring and patient collected data being used to develop the healthcare management program. This could lead to fewer people contracting chronic conditions and actively adhering to treatment recommendations - improving patient outcomes at lower overall cost.
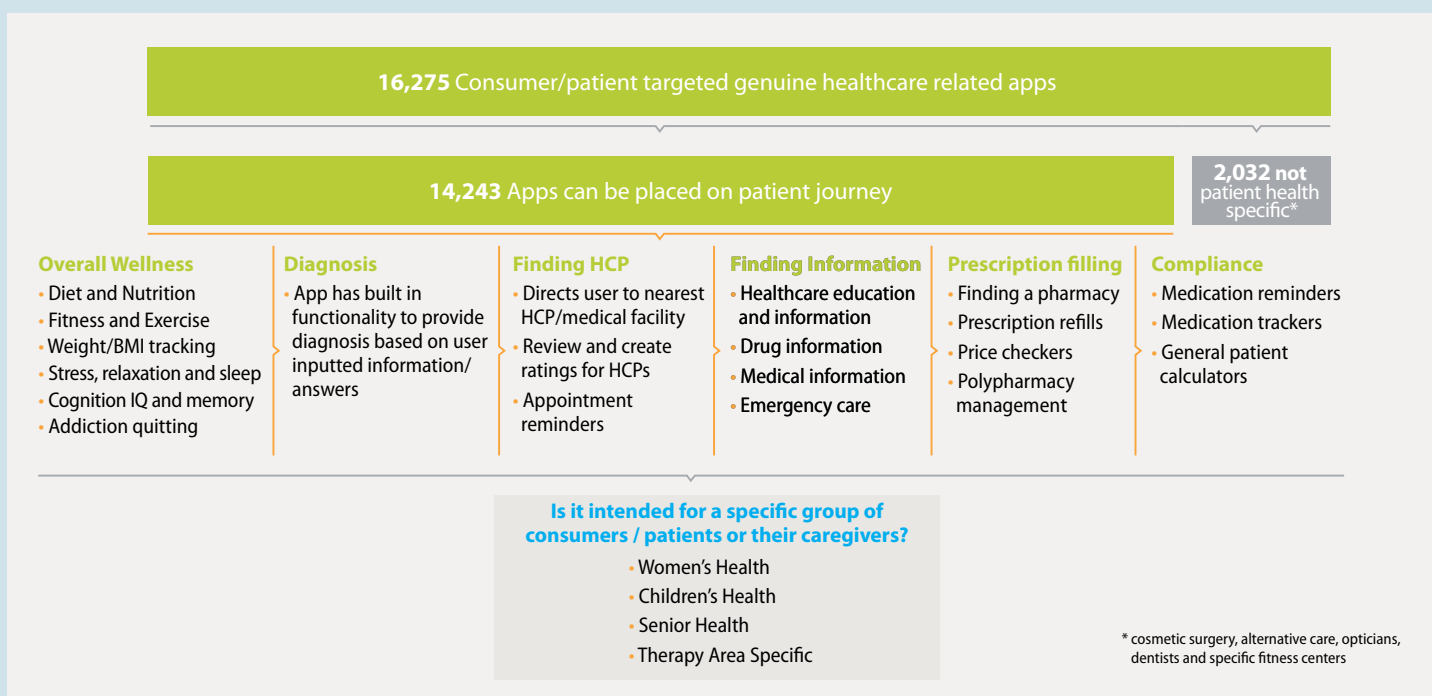
# Methodology

## Count of widely available consumer healthcare apps

All 43,689 apps available for download from the Apple iTunes App store as of June 2013 were scraped from the store and analyzed. A thorough examination of the content of these apps led to the exclusion of 20,007 apps from further analysis since these were considered not truly related to healthcare (e.g. salons, apps with gimmicks). Of the remaining 23,682 apps considered genuine healthcare apps, further content analysis categorized 16,275 apps as consumer/patient oriented and 7,407 apps as HCP oriented. A full analysis was only conducted on those apps targeting consumers/patients.

**43,689** "Healthcare and Fitness" or "Medical"

**23,682** Apps genuine healthcare related

**16,275** Consumer/Patient Oriented

**7,407**
HCP oriented

**20,007** Mis-categorized or only
loosely healthcare related on App Store

- Fashion and beauty (e.g. salons)
- Apps intended for members of specific
  clubs/universities
- Veterinary apps
- Apps which use gimmicks with no real health
  benefit (eg apps which make the user sound sick,
  or demonstrate how the user would look if they
  were obese)
- Apps related to health issues but which do not
  focus on health (e.g. fertility)
- Product presentation apps for use by sales
  reps/retailers
- Apps believed to have meaningless claims
  e.g. "gives you a beautiful way to keep track of your
  body's biorhythms"

The intention of this analysis was to categorize apps along the full patient journey, as opposed to other reports which simply grouped apps based on target audience (women's health, fitness etc). As such a further detailed analysis of the 16,275 consumer focused apps sought to place them along a patient journey consisting of overall wellness, diagnosis, HCP visit, further information, prescription filling and compliance; recognizing also that some apps cover the full patient journey and are intended for specific groups of patients (demographic specific or therapy area specific).

A further 2,032 apps were therefore excluded at this point, although they relate to healthcare they would not sit on a patient journey (e.g. finding an optician or dentist, specific fitness centers class timetables, cosmetic surgery). This left 14,243 general consumer healthcare apps which belong on a typical patient journey.

**16,275** Consumer/patient targeted genuine healthcare related apps

**14,243** Apps can be placed on patient journey

**2,032 not** patient health specific*

**Overall Wellness**
- Diet and Nutrition
- Fitness and Exercise
- Weight/BMI tracking
- Stress, relaxation and sleep
- Cognition IQ and memory
- Addiction quitting

**Diagnosis**
- App has built in functionality to provide diagnosis based on user inputted information/ answers

**Finding HCP**
- Directs user to nearest HCP/medical facility
- Review and create ratings for HCPs
- Appointment reminders

**Finding Information**
- Healthcare education and information
- Drug information
- Medical information
- Emergency care

**Prescription filling**
- Finding a pharmacy
- Prescription refills
- Price checkers
- Polypharmacy management

**Compliance**
- Medication reminders
- Medication trackers
- General patient calculators

**Is it intended for a specific group of consumers / patients or their caregivers?**
- Women's Health
- Children's Health
- Senior Health
- Therapy Area Specific

\* cosmetic surgery, alternative care, opticians, dentists and specific fitness centers

Quality control was built into the mobile app review process. After each app was reviewed, it underwent a second round of examination by a separate group of reviewers, verifying the results of the first review, even if the app was rejected initially. A smaller random set of apps were selected for a weekly or monthly review. Since each app's reviewer and date of review was recorded, any misclassification trends uncovered during the reviews were linked to a specific individual or time frame and these affected apps were sent for reclassification in their entirety.

## Functionality assessment score for consumer healthcare apps

The IMS app functionality score is calculated for the 6 key areas of information, instruction, tracking and guidance, reminder, communication and use of phone functionality.  Each app undergoes a rigorous assessment for each function.  Apps are assessed within use case.

The following criteria are considered:

**Information**

- Level of detail of information
- Provides information as text
- Provides information as picture
- Provides information as video
- Provides audio information

**Instruction**

- Provides instructions to the user

**Tracking and guidance**

- Ability to track and capture user entered data
- Graphically displays user entered data
- Outputs user data
- Can link to sensor
- Provides guidance based on entry

**Reminder**

- Built in reminder function

**Communication**

- Uses email
- Uses SMS
- Provides secure communication
- Provides link to social networks

**Phone functions**

- Use of phone's GPS
- Use of phone's camera
- Use of phone's scanner
- Use of phone's voice recorder

The user rating score considers both the number of reviews the app has received on the iTunes app store and the Google Play store, and the star rating assigned to the app.

## Android data download analysis

Data for downloads of Android apps was purchased from AppMonsta in July 2013. This data provided information including AppID, App name, Category, App URL, Description, Publisher, Release Date and Downloads, where downloads were quoted in the following ranges: 10 million to 50 million; 5 million to 10 million; 1 million to 5 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 therefore taken for each range from which a total number of downloads was estimated.

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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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