ABSTRACT

Long gone are the days when a patient visiting the doctor’s office comes out with a drug prescription paper handout explaining his or her conditions and dosage instructions. Today, the term mHealth (Mobile Health) has proved to be a game changer in healthcare, wherein mobile technology is used to assist patients and physicians for health services and information. The most visible aspect of mHealth is the usage of smartphones and tablets to run apps that virtualize them as clinical examination tools, as reference databases, as medical calculators or as technique guides.

MHealth has resulted in the evolution of a new delivery model focused on care that is patient centered and value based. The rate at which the mHealth apps are introduced into the app stores over the last couple of years is astonishing. According to a recent report there are presently 31,000 health, fitness and medical related apps on the market.

MHealth apps today can assist you to stay fit, track pregnancies, monitor moods, eat healthier, monitor blood pressure and sugar levels and even assist chronic disease management. From a clinician’s point of view, it assists them in real time monitoring of patient vital signs, sharing medical images and more. Apps like Medscape Mobile, Sermo, MIM mobile, and ICD 10 CM are already popular among the clinicians. According to ABI research [1], estimates predict that the mHealth apps market might see a revenue growth from $ 230 million currently to $400 million in 2016.

Unfortunately, this has also resulted in mHealth becoming a victim of its own popularity. This popularity has attracted not only the best and brightest but also the worst and the mere opportunist. Companies and individual developers see mHealth merely as a potential market to expand their business or get rich quick. Today there are mHealth apps in the market that are not only of no value but also potentially unsafe and dangerous. Consumers clearly lack the guidance of choosing a safe, secure and medically sound health app. This trend clearly puts the future of mHealth at stake. The purpose of this white paper is to explore the concerns and potential risks prevalent in the mHealth app market and identify what needs to change in order for mHealth to be a real game changer in healthcare.

Keywords: mHealth, FDA, HIMSS, mobile, healthcare, smartphone, medical, apps, fraud, security, regulation
INTRODUCTION

Earlier this year a significant impact to the healthcare industry was made by Kaiser Permanente, a major player in the managed care domain, by making its electronic health care system, which is considered to be one of the world’s most extensive electronic medical record systems, available via an Android app to its 9 million members. Trade analysts predict that the global sales of smartphones are expected to hit 1.5 billion units by 2016. Years from now every individual is expected to carry a smartphone, which would be exponentially smarter than smartphones are today. This would revolutionize the way healthcare systems engage patients by presenting information much more directly and comprehensively. The way healthcare is delivered and accessed is expected to radically change due to explosive growth in digital health apps.

A look into the diverse range of mHealth apps available in the market shows that we can broadly categorize them into:

<table>
<thead>
<tr>
<th>Applications for clinical, or assistance in, diagnosis</th>
<th>Applications for remote monitoring</th>
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<tbody>
<tr>
<td>• Symptom checkers</td>
<td>• LifeScan for patients with diabetes</td>
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<tr>
<td>• PHR access</td>
<td>• Remote heart monitoring</td>
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<td>• Digital imaging (MRI/X-Raying viewing abilities</td>
<td>• ECG viewer</td>
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<tr>
<td>• Electronic chart review</td>
<td>• Oxygen level remote check</td>
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<td>• Lab results review</td>
<td>• Telehealth services</td>
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<th>Applications for reminders and alters</th>
<th>Applications for references</th>
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<tr>
<td>• Prescription management</td>
<td>• ICD-9/10 reference guide</td>
</tr>
<tr>
<td>• Appointment reminders</td>
<td>• E&amp;M coding</td>
</tr>
<tr>
<td></td>
<td>• Specialized medical reference material</td>
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<table>
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<tr>
<th>Applications for healthy living</th>
<th>Applications productivity</th>
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<tbody>
<tr>
<td>• Pregnancy and baby development</td>
<td>• Remote dictation</td>
</tr>
<tr>
<td>• Diet assistance</td>
<td>• Surgery scheduling</td>
</tr>
<tr>
<td>• Exercise and fitness</td>
<td>• Interoffice communication</td>
</tr>
<tr>
<td>• Healthy eating</td>
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</table>

Not only has the rate at which mHealth apps are introduced into the market accelerated but the amount of innovation that these apps have brought in has been significant. A couple of mHealth apps that have been widely noticed for their innovative approach in the recent past are:

**DoctorMole** is an application based on ABCDE approach (Asymmetry, Border, Color, Diameter and Risk) for assessing skin moles. This app makes use of a smartphone camera to take pictures and then integrates them with augmented reality for processing results. [4]

**AirStrip Technologies’ AirStrip Cardiology** is for a patient who has just suffered a heart attack. The physician needs up-to-the-minute information. This app is designed to provide near real-time electrocardiogram data to the physician directly via his iPhone/iPad. [4]

**vCath** is an app developed by Bangor University in the UK. It is designed to teach neurosurgical trainees the art of cannulating the lateral ventricles of the brain. [4] [5]

With the inflow of such innovative apps, mobile technology is expected to create a big impact on the healthcare field, significantly in the service delivery model and the overall medical treatment experience.
HOW THESE mHEALTH APPS ARE PREDICTED TO TRANSFORM HEALTHCARE

1. Improved access to care to care

These developments seem to eliminate the requirements for patients and doctors to be present physically at the same location. Any patient from a rural area will be able to virtually consult with a specialist half a world away from his/her home.

2. Improved patient engagement

One of the primary concerns in today’s healthcare system is the lack of patient engagement. This can be addressed through these apps.

Apps can notify you if the consultant is running late rather than you having a long wait in his office. Medication reminder apps can keep track of your dosage of pills and remind you promptly for the next turn, notify you if running low on the pills and/or automatically ask if want to pick up the prescription at the nearest store since it is aware of your location and your prescription records. [6]

3. Define new provider business models

The explosion of inbound data from these devices will create healthcare professionals with new opportunities. Being a system dominated by an influx of patient data, the current healthcare services do not suit this model. This could give rise to opportunities for a new set of companies that would be focused on the inbound data management.

4. Contribute to patient understanding of their health

Healthcare will be safer when patients are given tools to manage their own health by means of these digital apps.

"Our journey," an app used by the Phoenix Children’s Hospital, is a classic example in this case. This app is used to guide the parents through the care process that their child will go through while at the hospital. The app also suggests questions that the parents should ask the doctors. [7]

Another example would be Endomondo, an app for motivating patients to exercise and to track fitness goals such as time, speed, calories burnt and heart rate.

5. Facilitate the tracking and management of chronic illnesses

The people who are expected to benefit the most from these apps are the patients with chronic conditions such as asthma and diabetes. These apps can monitor the vitals and symptoms of the patients to ensure that worsening conditions are caught early on.

The iBGStar iPhone glucose meter is a forerunner in this category. Irrespective of the patient’s location, this app allows patient to monitor his or her glucose, insulin and carbs anytime. It also charts the patient’s glucose pattern over time, which can be shared with the consultants, aiding in making informed decisions. [7]

6. Reduced Medicare Fraud

Fraud in Medicare is progressing hand in hand with the healthcare advancements. Several laws have been implemented to protect the integrity of healthcare. Digital apps can play an important role in this regard.

People and their transactions in space and time can be tracked by digital apps. This would facilitate Medicare’s correlation of claims data with location and time data from the digital health systems.
apps, to look for fraud. An interesting example quoted by Rock Health founder is that while patients are visiting a pharmacy, scanning their Medicare card and conducting the purchase digitally would allow instant tracing of the transactions by Medicare. [6]

CURRENT MARKET TRENDS
Mobile network infrastructure provider Aruba Networks, during the latest HIMSS healthcare IT conference in Las Vegas, released results of a recent survey showing that: [8]

- 85% of hospitals are currently providing access to personal mobile devices
- 83% of healthcare IT professionals allow iPads on their enterprise networks
- 65% support iPhones and iPod Touch devices
- 52% of hospitals currently support BlackBerry devices
- 46% usage of the Google OS on personal phones and tablets

Another interesting result published by Juniper research states that the download of mobile healthcare and medicals apps will increase from 44 million this year to 142 million by 2016 globally. [9]

![Adoption of mHealth Initiatives Around the Globe](Source: How mobile devices are transforming healthcare, Technology Innovation, 2012)

Despite these tremendous predictions and trends, what’s the reality of mHealth apps?

**Apps + Market ≠ Downloads**
MHEALTH: A POTENTIAL GAME CHANGER

REASON?

The mindset behind the apps usage among the population has been the following.

Of 235 million U.S. smartphone owners (source: Business Insider citing ComScore, September 2012):

- 70% want their apps for free or < $7.50 per month – (Source: ABI Research, May 2012)
- 68% open only five or fewer apps at least once a week – (Source: USA Today citing Pew, January 2012)
- Only 10% have downloaded health apps – (Source: Mashable citing Pew, July 2012)
- 17% don’t use any apps – (Source: USA Today citing Pew, January 2012)
- 2-3 minutes is the average time spent with an app – (Source: Internal industry report, February 2012)
- 80% to 90% of apps are eventually deleted

Despite an explosion in the number of mHealth apps available in the Apple App Store—from 2,993 in February 2010 to 13,619 in April 2012—a major concerning factor has been that the majority of these apps are focused on tracking fitness or diet. Every month, the app store sees a release of two or three new BMI calculators. The true health problems, such as chronic conditions or chronic condition management, have been focused on by far few apps. The following table, which shows percentage distribution of app types, clearly indicates the focus on reference, educational and tracking support more than decision support.

<table>
<thead>
<tr>
<th>No.</th>
<th>Class</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drug or medical information database</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>Medical information reference</td>
<td>33.75</td>
</tr>
<tr>
<td>3</td>
<td>Decision support</td>
<td>3.75</td>
</tr>
<tr>
<td>4</td>
<td>Educational tools</td>
<td>23.75</td>
</tr>
<tr>
<td>5</td>
<td>Tracking tools</td>
<td>8.75</td>
</tr>
<tr>
<td>6</td>
<td>Medical calculator</td>
<td>3.75</td>
</tr>
<tr>
<td>7</td>
<td>Others</td>
<td>16.25</td>
</tr>
</tbody>
</table>

Table 1. Distribution of app types in the medical category
(Source: Status and trends of mobile-health applications for iOS devices: A developer’s perspective, The Journal of Systems and Software)

SO WHY DO MHEALTH APPS FAIL?

1. Misguided motivation for app development

A health app would not be considered useful if it did not address a specific problem regardless of its elegance, experience, ease of use or any other appeal. The main recipe for failure is just monitoring a physiologic parameter or simply collecting data without purpose. The data collected must be filtered in a way that translates a message to the end user.

2. Lack of clinician involvement

The mHealth apps that are being developed lack clinician input. These applications need to be redesigned around the healthcare technology, by defining a set of rules or processes with appropriate inputs from the clinicians or their respective bodies. Another important aspect would...
be the connectivity of mHealth tools. This would necessitate data workflow and patient-clinician interaction.

3. Poor attention to usability
An in-depth consideration of the user experience of the app also plays an important role equivalent to that of the app functionality. HIMSS defines the usability of medical apps as “the effectiveness, efficiency and satisfaction with which specific users can achieve a specific set of tasks in a particular environment.” (Source: mHIMSS)

4. Not building to regulatory specifications
Despite an excellent user experience, if the app does not meet the regulatory requirements such as from HIPAA (Health Insurance Portability and Accountability Act) or FDA (Food and Drug Administration), it gives rise to safety concerns and hence will need to be reworked at a significant cost. App development would be significantly affected based on the regulations. [11], [12]

LOOKING FORWARD
Having looked at the current trend of mHealth apps, one can infer that though mHealth is seen as a game changer in the healthcare industry, it currently lacks rules in its own game. There is a lot of rush in the development of these apps, and many are just seen as a mode to get rich quick without exploring the domain or the potential that mHealth has to offer. This leads to concerns of the app’s safety and security as well as its future. Navigating the health app craze without direction can be painstakingly difficult. However, the motivating factor is that mHealth is still in its infancy, and if we provide proper directions to the mHealth app development, it indeed will transform healthcare. So what do we need to focus in mHealth app development to make the transformation a reality?

1. FDA Approval for Mobile Healthcare Apps
The FDA is responsible for scrutinizing and approving medical devices. In July 2011, FDA issued draft guidelines due to the increasing use of mobile apps within the health arena.

Not all mHealth apps would require FDA approval. Apps that promote wellness and good health, such as those that: [13]

- monitor eating habits or exercise by logging, tracking or recording
- provide “copies” of reference materials such as textbooks or teaching aids
- track general health and wellness or make recommendations
- provide office function assistance for billing, appointments, or insurance transactions
- function as “generic aids” but are not for a specific medical purpose

would not require FDA approval.

However, apps that are used as an accessory to a regulated medical device or transform a mobile device (smartphone) into a regulated medical device such as: [13]

- Any mobile medical app that transforms the mobile platform into a class II PACS (picture archiving and communication system)—for example, apps that display radiological images for diagnosis
- Apps which lets clinicians view full-resolution medical images such as Mobile MIM [14]
- Apps which displays real-time fetal heart rate monitor data such as AirStrip OB [14]

must have FDA approval.
There is much debate going around in the internet space as to whether mobile medical apps need FDA approval or not—whether they would make it impossible for developers to bring valuable products to the market by acting as barriers to innovation. [15] If we take a closer look at what exactly FDA is proposing, we would find that they do create barriers to entry as they set a high bar. But in doing so, they ensure consumer safety, credibility and proven effectiveness. Mobile health has the potential to get out of hand if not regulated. For example, there is an app that will generate insulin dosage suggestions based on self input of one’s carbohydrate count. Clearly this could be dangerous to patients if it’s not approved.

2. Rigorous Validation
Not a large majority of current health apps have been rigorously evaluated. In fact, many of the apps these days have a disclaimer that they have not been validated through rigorous research and hence have been left to individuals’ perspective. Both mHealth app providers and developers need to be proactively prompted to validate their apps, to ensure patient safety. Orthopedic surgery currently claims the greatest number of validated apps, most of which are directly related to goniometric calculations.

Fortunately today several healthcare research groups seem to have realized the importance of this. One among them is Johns Hopkins University’s Global M-Health Initiative. They are making quality research on mobile apps including ones related to obesity, EHRs, child health and immunization, HIV, and maternal health. Their results should eventually help consumers and clinicians make informed choices. [16]

Similarly, Sensiotec, a player known for providing non-contact patient monitoring, has come up to perform clinical trials on its Virtual Medical Assistant (VMA), a wireless monitoring solution based on noncontact vital signs, to determine if it improves patient outcomes. [14]

3. Engagement
One of the primary problems with most of the health apps is that, after downloading, they are at most used once or twice and then uninstalled or forgotten. The reason being, there is no engagement. Health apps need to be engaging and motivating and also offer a coaching component.

A classic example for this feature would be Medscape Mobile app, one of the most popular apps for the iPhone, iPod Touch, BlackBerry, and Android. It became the #1 downloaded free medical app in 2010. One of the primary reasons for its success was cited as its ease of use, news and navigation features. In the Apple App Store, the current version of Medscape Mobile rates 5 stars among users. [14]

For the apps targeted towards healthcare professionals:

- An exciting feature that can be provided in the app alongside its primary functionality could be mobile CME (continuing medical education). “Continuing medical education (CME) refers to a specific form of continuing education (CE) that helps those in the medical field maintain competence and learn about new and developing areas of their field. These activities may take place as live events, written publications, online programs, audio, video, or other electronic media.” [17] Professionals can earn Credits on-the-go and then track them automatically via the app’s on-site CME Track.

- Provide the ability to share clinical images, perform live medical consultations, have discussion forums and share ideas and insights on clinical cases and more.
For the apps targeted towards patients or general users:

- A lot can be done with the health data gathered from the users, but in order to get that data you need something compelling that will convince the users to provide their health information in a consistent way. Techniques such as building in the ability to set specific goals and then track the activity necessary to get to that goal (such as running a marathon) will provide even more incentive for people to use the app.

4. Effective but Smart Design

To meet the expectations of the user, development teams today are required to design and deliver better applications and application interfaces.

But what goes into making an extraordinary mHealth App?

Consistency, efficiency, navigation, focus, context, anticipation and, last but not least, just make it simple.

The efficiency factor plays a crucial role in differentiating the app as an ordinary or an extraordinary one; hence you need to know your user’s context, and be efficient with the limited space, attention, time and focus available within it.

Features and focus—be ruthless while selecting features for the product, as there is no point in providing features or data that are irrelevant to the context.

Space and attention—given the reduced screen size and reduced attention, one needs to put less on each screen.

Time and effort—one of the biggest complaints among users of mobile healthcare apps is the difficulty in entering structured data. Hence in order to overcome this, users need to be provided with at least one feature, or a combination of features, such as speech recognition, smart defaults, guided entry, anticipation or the ability to reuse information wherever possible.

5. Privacy and Security

How secure is your data? This is the question that arises in the mind of the consumer. The constant mobility and often-required Internet connectivity might compromise the privacy and confidentiality of health information.

Consumers lack guidance on choosing a safe, secure, medically sound health app. Today maybe consumers find it easy to trust and download apps associated with players like Cleveland Clinic, Nike Fuel Band, American Red Cross, and Walgreens since they are known in the space.

However, in the long run, it is the responsibility of every mHealth app provider to ensure and entrust the data security to its consumers by adapting a highly secure encryption technique in their solutions, allowing users to safely obtain health information.

MHealth apps have several layers of security concerns such as personal information management, secondary use of personal information, improper use of personal information, and errors with stored personal information. Usage of cryptography is one solution to guaranteed data confidentiality and protection. DE4MHA (Data Encryption Algorithm for Mobile Health Apps) encryption is one such example to look forward to. [18]
CONCLUSION

The mHealth app world needs guidance. The vast amount of apps available in the market makes it difficult for consumers to navigate. Bottom line: Consumers need to be provided with safe, reliable, approved and engaging apps that will enable them to guide their health. A greater involvement of the healthcare regulatory bodies, professionals, developers and healthcare providers in the creation of these apps is crucial to push the mHealth app world forward. The future is optimistic.
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ABOUT THE AUTHOR

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