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# mHealth: A Comprehensive and Contemporary Look at Emerging Technologies in Mobile Health

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# mHealth

# A COMPREHENSIVE AND CONTEMPORARY LOOK AT EMERGING TECHNOLOGIES IN MOBILE HEALTH





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# I. Abstract

#### What

The term "mHealth" stands for "mobile health" and is relatively ambiguous in terms of its definition. The definition as laid out by The University of Cambridge and China Mobile in their 2011 report on mHealth is as follows:

"An mHealth service or application involves voice or data communication for health purposes between a central point and remote locations. It includes telehealth (or eHealth) applications if delivery over a mobile network adds utility to the application. It also includes the use of mobile phones and other devices as platforms for local health-related purposes as long as there is some use of a network." (Leslie, Sherrington, Dicks, Gray, & Chang, 2011)

As it stands, mHealth is an umbrella term for a myriad of emerging technologies that leverage the reach and speed of mobile networks and mobile computing power in order to improve or widen the reach of healthcare delivery. The healthcare field is changing dramatically so technologies such as those of mHealth are of massive interest in the ways in which they can add effectiveness and efficiency to healthcare delivery.

This research aims to collect and synthesize information on mHealth and its application in the healthcare field in a comprehensive way. Operational definitions, constructs, and categorizations from previous literature are used and in some cases improved upon and new constructs or categories are developed. As well as a holistic view of mHealth's past evolution, current state, and future potential, this research aims to answer questions such as what technologies have been in use, which have seen success/failure, what technologies are currently being produced, and what the role of those technologies will be in improving the delivery of healthcare.

#### Why

Smartphones and mobile technologies have changed the way we communicate, spend our free time, shop, navigate, and interact with the world around us. Research shows that one in every five people globally own a smartphone and that ratio is expected to grow exponentially (Heggestuen, 2013). This technology has shaped how we interact with other goods and services and the same benefits can be applied to healthcare, as well. This translates into widened reach of healthcare services, decreased variability in the quality of healthcare by location, increased revenues for healthcare companies, and decreased costs for healthcare delivery and healthcare consumption. Literature in this arena becomes outdated extremely quickly due to the nature of the rapidly changing mobile networks and computing industry. Therefore, this area of study and commercial interest need constant oversight and monitoring as new applications and implications will continue to rapidly emerge.

#### How

This research will be conducted utilizing synthesis research methods in that multiple silos of research and literature will be compiled together for a comprehensive, contemporary look at mHealth. A 2011 comprehensive report on mHealth by The University of Cambridge in conjunction with China Mobile will be foundational to this research in its formalized categories of mHealth and constructs on its application. However, the landscape is quite different from even three-to-four years ago so they will be revisited and updated accordingly. Current news articles, technology expo events, conferences, and product reviews will also be consulted to gain an updated view on where mHealth is currently and what it is becoming. Qualitative interviews with healthcare professionals will also provide insight from the "front lines" as to what mHealth is immediately bringing to the table.

#### Results

Peripheral and sensor devices will see the largest immediate growth in the mHealth market as they are compatible with the existing smartphone and telecom infrastructure. These devices, be it medical devices, monitoring devices, or a mixture, will be paired with respective wellbeing applications which will provide intuitive user interfaces and robust analysis, incentives, and information regarding one's health. These devices are currently only subject to regulation if they take on the function of a currently regulated medical device and are easily accessible to consumers both in price and ease of procurement. These applications and devices can promote an interactive, incentives-based approach to personal health management which, on an aggregated level, can have larger population health implications and can open the door to more complex and expensive areas of mHealth. Hospitals can reduce costs, widen the reach of healthcare delivery, and help further improve overall health through the adoption of mHealth technologies. However, many mHealth solutions require patient participation so primary success in the consumer market will be better for the mHealth market as a whole. Areas of mHealth that will have to jump through regulatory hurdles involve using aggregated health data to better track health patterns, prepare for and quickly react to epidemics and disease outbreaks, and better map the health landscape for improved targeting of solutions. These types of applications bring with it privacy concerns both from the patient's point of view and from a legal standpoint. This type of application will also require data silos to be unified by a platform.

#### Implications

The widening reach and efficiency of healthcare delivery will increase revenues for healthcare providers while using technologies that will substantially reduce costs. Cheaper and more efficient ways of providing healthcare will be necessary in the current volatile healthcare climate. If mobile technology can create, for example, scenarios where remote diagnosis is feasible and preferred for a large proportion of the population, then the financial health of healthcare organizations will be improved, as well. A culture in which actively engaged and informed personal health management can create a collectively healthier society translating into improved productivity and a general boost in happiness. Information availability and real-time analytics on potential red flags can put the power of treatment for simple health problems into the hands of the patient thus a decrease reliance on physicians for small health concerns. Crowdsourcing health data and using aggregated data can allow areas to act proactively to

disease spread and better allocate resources to areas which are more afflicted than others. Big data can be brought to health in order to predict outbreaks on the population level and, given privacy resolutions, the individual level.

# II. Introduction, Literature Review, & Foundation<sup>1</sup>

Substantial research has been conducted in a global framework to show the current applications and implications of mHealth as of 2011 by the University of Cambridge in conjunction with China Mobile. Much of the framework presented in that report will be present in this research and built upon. It is important to recapitulate that framework in order to provide the foundation for the updated contribution. The framework presented is presented with a global market in mind and is not specific to any particular kind of economy. Both developing and developed economies are represented in the framework and certain elements of the framework may pertain to one type of economy more than another. It is also important to note that the context of this framework is, as stated, in 2010-2011.

#### **Overview of mHealth Market**

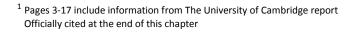
There are six main categories embedded in the broader mHealth market. These categories range from broad applications to very specialized, but do a decent job in summarizing the mHealth market. Figure 1.1 from the Cambridge report shows these categories visually.

#### **Public Health Research**

One of the broadest categories, and, arguably, the most beneficial to society as a whole is using the massive amounts of data collected via mobile networks to serve the public good. This could conceivably be applied to tracking disease outbreaks, epidemics, and pandemics, both for the sake of policy and healthcare intervention strategies. This was actually done in a disease surveillance project of Dengue Fever in Brazil. Questionnaires were distributed to health agents' mobile phones and through that data and GPS location data, the researchers were able to instantly analyze and map high infection areas.

Existing health data-collection platforms can also be augmented by mobile networks for the sake of public health research. Much of the health data available remain in silos and privacy concerns prevent much access to this data. This is also connected to the possibility of data mining eHealth records. These data must be appropriately anonymized and the data analysis

techniques must be properly authorized. Two companies of note that already employ this branch of mHealth are IMS Health and CVS Caremark.



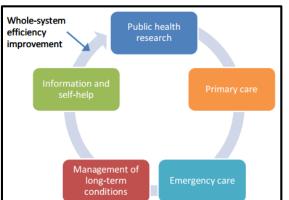


Figure 1.1 – Overview of mHealth Market

#### **Primary Care**

Primary Care applications for mHealth generally support the diagnosis of medical conditions and the provision of treatment by frontline local medical staff. The heaviest influence lies in bridging the gap between health resources and location. The scarcity of health resources in rural areas often require that patients be sent to specialists in larger metropolitan areas where most specialized health professionals opt to live. One app available in the Google Play Store, Sana, works to connect rural health workers to doctors in urban areas. Local health workers collect data including pictures and videos and send them to a data center where the data is reviewed and diagnoses are made. These results are then sent back to the health worker via SMS text. Another case example of this type of mHealth application comes from breast cancer screening in Tasmania. Image files were sent from rural, local health workers to larger assessment centers which decreased the need for extended travel to specialists saving the patients and specialists time and money.

Applications in this category can also be more direct than assessment centers through videocalling technology. The "3G Doctor" emerged in the UK to provide a low-cost consultation with a doctor via only a video-call. This showed that many visits to the doctor can be assessed and treated remotely without the need for a formal walk-in appointment.

#### **Emergency Care**

Applications of mHealth revolving around emergency care primarily deal with personal emergency response systems. Many devices are built with this in mind and offer one-touch access to emergency services. These devices are generally used for the elderly and those with conditions like Alzheimer's. These devices can also help in preventing falls or responding quickly to falls without the wearer having to do anything. Accelerometers and pressure sensors are connected to a mobile network and a person's gait is measured to predict the likelihood of a fall. Medical staff or loved ones can be instantly alerted of red flags or actual incidents.

Along with personal emergency care, mobile networks and technology can be leveraged to support victims in natural disasters. Responsiveness, as well as reach, can also be significantly increased. A company that provides an application of this nature is FrontlineSMS.

#### **Management of Long-Term Conditions**

Many long-term conditions require routine diagnostics and check-ups with very obvious red flags if there were to be any. Mobile networks help with decreasing the time spent on the management of these conditions where the condition is behaving normally. One application of this is self-management of diabetes where blood glucose readings and dietary info are sent off to doctors who can give remote, real-time feedback on the analysis of the data. Doctors can also have more of an impact on post-visit treatment or medication regimes. This is called Directly Observed Treatment (DOT) and can be done through motivational text

messages/reminders, video instructions on how to adhere to the regime, or through integrated device calendars to sync medication times and milestone dates.

#### **Information and Self-Help**

The quickest and easiest mHealth application to adopt is in the information and self-help category. This primarily consists of applications promoting wellness and incentivizing/encouraging individuals to improve their own health. These can include services that pull from informational health databases about symptoms and also services that provide an interface in which an individual can interact with their own health data. These are generally hands-off applications in regards to back-end infrastructure, but some, such as MiQuit, involve a more hands-on approach. MiQuit SMS System provides personalized encouragement and support to pregnant smokers attempting to quit smoking. An academic study showed that there was a statistically significant effect from the messages.

#### Whole System Efficiency Improvement

Applications under this category serve to improve the efficiency and effectiveness of existing processes within the healthcare system. Some of the most prominent and most successful applications serving this area of need are improvement on hospital appointment booking systems. Mobile networks can help foster the bookings themselves and they can serve as a vehicle to decrease the amount of absenteeism through SMS reminders or even push notifications. This category also includes any personal electronic health records that can be stored in, or accessed and updated through a mobile device and network. However, privacy concerns over personalized health data traveling over mobile networks are strong.

#### **Existing Applications**

The University of Cambridge identified four prominent types of existing applications spanning across the different broad categories of the mHealth market. Some of the applications noted are not new ideas and some are still seeing an influx in demand, today.

#### Mobile-Enhanced Appointment Booking/Reminder System

Mobile-enhanced appointment booking and reminder systems are systems allowing patients to make appointments to see doctors in primary care or hospital settings through mobile networks and devices. This application can be categorized in both whole-system efficiency and primary care categories of the mHealth market. While these systems exist without mobile networks through the internet or through telephones, mobility can be an arm to enhance the scope of such systems by enabling more effective "push notifications" to the patient related to the appointment.

Studies on these types of systems have shown there to be a statistically significant decrease in "do not attend" rates. The Royal Children's Hospital in Melbourne, Australia implemented a simple SMS reminder system for over 20,000 patients to test the effectiveness of mobility

integrated with the appointment booking process. The cost of sending the SMS reminders was also found to be outweighed by the increase in revenues and other intrinsic benefits to society. While appointment reminders are not a new phenomenon, including its benefits, the addition of mobility adds significant cost savings. A controlled trial at a health promotion center in Zhejiang, China showed that SMS reminders had the same effectiveness at reducing no-show rates at a significantly lower cost than phone reminders.

#### **Drug Authentication and Tracking**

A glaring problem in healthcare delivery is the integrity of the drugs being distributed to various pharmacies across the world. This is the result of widespread drug counterfeiting and trafficking which is a lucrative, illegal business. Mobile networks can be leveraged in these scenarios and applications can be built for tracking drugs through the supply chain which benefit stock control and inventory efficiency and integrity. Mobile networks allow these logistical processes to reach areas in which mobile network connectivity is the only source of contact with central drug databases as well as point of sale machines.

While this is an area which directly and profoundly affects healthcare delivery and services, it is not immediately thought of when viewing mHealth solutions and technology. The only connection these solutions have to health is the product that happens to be in the supply chain as well as the prevalence of black market activity with these products. This should be categorized as more of a supply chain management issue in which mobile networks can help manage inventory and product safety, but it is arguable whether or not this specific application should be categorized as mHealth specifically.

#### **Remote Diagnosis**

Remote diagnosis applications directly relate to the emergency care category of the mHealth market. They include the use of mobile devices to help health workers (usually non-specialized personnel in the health field) make diagnoses and treatment plans without the patient having to travel to specialists. These show up through the ability of workers to download or access databases or decision support material to or from their mobile devices in order to consult modern literature quickly and easily. Remote access via voice, text, or video communication also enhance services to more remote areas to widen the reach of care as well and bring in more revenue while cutting the cost per visit.

#### **Well-Being Applications**

Well-being applications have been and are still flooding mobile app ecosystems. These are simple, lightweight applications designed with the smartphone user in mind aimed at increasing the user's overall wellbeing. Several applications monitor in real-time vital signs such as heart rate and blood pressure as well as interesting information such as steps taken, distance walked/run, and other metrics. These often provide the user with an interface that allows them to monitor their data and make lifestyle improvements with tips and incentives from the

applications themselves. These applications illustrate the most pressing use of mHealth on personal smartphones and have the potential to collectively improve aggregate health patterns.

#### **Next Generation Applications and Uses**

The researchers at Cambridge suggested that the biggest potential for mHealth was in the next generation of applications which were in early stages at the time the research was conducted. These will most likely first surface in developed economies where the administrative aids in the delivery for health care are taken for granted or already established. Low-income economies will see them later but will immediately benefit from the robust administrative systems mHealth can bring to healthcare delivery.

#### Sensors and/or Other Peripherals

Applications leveraging the use of sensors or peripherals can measure vital health signs of an individual such as blood glucose levels for diabetics, pulse, blood pressure, and other metrics. These applications do not necessarily need to be reliant on a network for proper usage, but the data collected from the metrics measured can provide real-time analysis of the data with the increased computing power of smartphones. The future of this area lies in that regard. The real-time collection and analysis of data on a patient's personal smartphone is the greatest potential for this next generation application. The nature of these devices invites attention from regulators, however. The scope of those regulations and the ability to keep the prices for these sorts of devices low will be pivotal for the success of this type of mHealth application. Aside from those obstacles, this will most likely be the most commercially viable option as smartphones continue to penetrate the market.

#### Mobile Telecare

Mobile telecare applications directly provide support for assisted living. A mobile network can facilitate remote communication between carers (doctors or loved ones) and those being cared for. These applications may utilize sensors and peripherals, as well, but the data being entered will not be done so manually or even deliberately in the case of elderly patients. Growth in this application area has been largest in the United States due to the rising number of retirees and the number of private organizations serving that particular demographic. One criticism of this type of application is the potential reduction in demand of healthcare resources such as doctors, hospitals, and geriatric services. However, the benefit is that the reach of care and monitoring can be greatly extended allowing the elderly to remain in their own homes more easily.

#### Intelligent and Targeted Public Health Messaging

Public health messaging is an application of mHealth rooted in serving a broader societal need and is less of an immediate commercial success. Targeted messages can impact a large sample or even a population of afflicted individuals or an area where a health threat may be imminent. Populations already being treated for specific conditions can be administered through SMS text messages to support patients with long-term conditions and provide encouragement or help to maintain medication regimes. This communication can either be pushed to a patient's device or a system allowing two-way communication can be put in place. Thirteen out of fourteen studies on the effectiveness of intelligent and targeted public health messages demonstrate a positive impact.

#### Using Aggregated Private Data for the Public Good

Applications seeking to aggregate private data for the public good seek to build predictive models from the data. Simulation models can be created for disease proliferation, predictive models for individual health status, and predictive models for population-level health patterns. Data collected need to be anonymized but still complete enough to provide meaningful insights. Private organizations along with government-funded entities have shown success in building models based on anonymized health data such as IBM, University of Texas at Dallas, and Haifa University in Israel. The commercial incentive for these applications is not great on a large scale. Small scale implementation can gain the interest of private organizations.

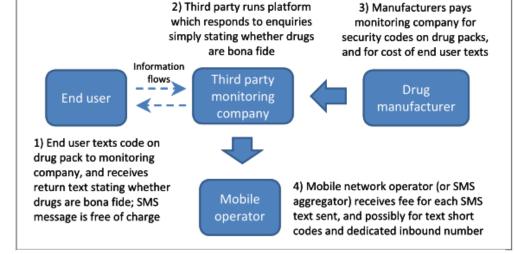
#### **Business Cases for mHealth**

Limitation of mHealth applications lie mainly in their inability to be justified from a commercial standpoint. Some services deliver indirect commercial value such as brand benefits from delivering a social utility. However, the potential for cost saving and/or revenue increases are also very strong for certain application types. The Cambridge report outlines three specific business cases from value chain, revenue and cost drivers, ROI factors, and market potential. These business cases are helpful to look at to see a framework of mHealth justification at work

to be potentially applied to applications and services in the future.

#### End-to-End Drug Monitoring Solutions

While mostly a supply chain issue rather than a direct, health related issue, drug trafficking and fraud is prevalent in many parts of the world. The use case scenario for this specific business case





involves the vendor of a drug to pay a third party providing security codes for each pack of

drugs through the supply chain. The end user of the drug can send the security code to the third party via a free text message and the third party will then send a follow-up message specifying the legitimacy of the drugs in question. The vendor pays for both the security codes, tracking, and the text messages. See figure 1.2 from the Cambridge report for a visual of the value chain.

The direct revenue potential lies in the operations of the third party monitoring company. The company can charge fees for the security codes and the text messages. These would be to support and improve the platform used to manage and validate the codes. Profit potential for these companies are a function of scale and market share increase is pivotal to market success.

The manufacturer's return on investment lies in avoiding lost sales due to counterfeit drugs. When counterfeit drugs enter the supply chain, the manufacturer loses the sale of the drugs those counterfeits replaced. Market share could also increase as a result of brand benefits from the trust incurred by the security validation. The presence of a security code could also make the manufacturer's products standout if other manufacturers are not using similar systems. A benefit is then reaped every time a consumer chooses a drug with a security code over one without a code.

This specific business case is more useful and plausible in developing economies where drug counterfeiting is a serious and costly issue. Developed economies with more sophisticated supply chains already have similar systems to this in place and drug counterfeiting is less of an issue than in developing economies. This specific solution hedges against the effect of rurality since the systems used can be accessed in most areas.

#### **Enabling the Remote Professional**

Applications within mHealth that leverage mobile phones and networks to foster the delivery of healthcare to remote areas create what is called the "remote professional." These include remote consultation, diagnosis, and decision support. The specific forms in which the remote professional is released depends on the state of

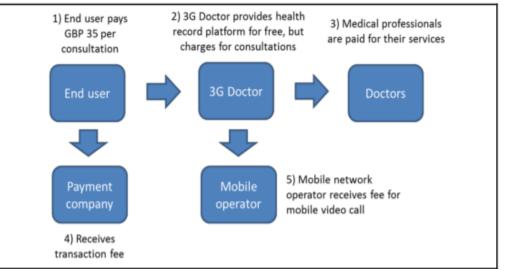


Figure 1.3 – "3G Doctor" Value Chain

the economy in the area it is utilized. The illustrative business cases for the remote

professional examine a use case in a developed economy versus a use case in a developing economy.

Video consultations are a perfect example of the remote professional in a developed economy. The 3G Doctor is an application utilized in the UK which shows its age with its title given that most mobile networks provide 4G LTE speeds. Two services were provided through this application of mHealth. Users/patients would create a personal health record hosted via the internet and able to be accessed through a computer or a mobile device. This would record the user's medical history and would be free aside from a service provider's or carrier's internet access fees. The second service allowed a video consultation with a doctor for a fee of 35GBP per consultation. 3G Doctor would pay physicians to participate in the service which would provide quick and convenient consultations where a formal doctor's visit may not have been possible at the time for the patient. Figure 1.3 from the Cambridge report illustrates the value chain for 3G Doctor.

The "Barefoot Doctor" is more applicable to developing economies where access to smartphones with 3G capabilities and sophisticated cameras may be harder to come by. For situations like this, the calculated distribution of those devices to local health workers in the community is an option. Organizations hold the capability to seek out and use expert resources instead of individuals. Several local factors go into this process, but figure 1.4 from the Cambridge report lays out a value chain and costs/benefits. A case study in the report states that over a five year period, based on the team at Cambridge's forecasts and assumptions, physicians would only need to increase the number of consultations by 5% to cover the initial capital investment in technology. Benefits of this system are more apparent in areas where the

means to travel to experts are scarce and/or the ratio of medical experts to those in need is very small. Benefits include time benefits, jobs created, and more high-impact work accomplished.

As economies develop further, the model outlined in figure 1.4 would evolve to one similar to the one outlined in figure 1.3. However, even in developed

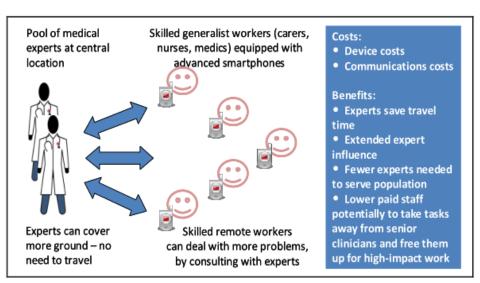


Figure 1.4 – "Barefoot Doctor" Value Chain & Costs/Benefits

economies, the "Barefoot Doctor" model can be applied to elderly patients where enabling remote access to specialists for consultations or empowering community workers with access to expert resources would provide a substantial benefit. The American Geriatrics Society estimates that by 2030 the United States will have a geriatric population of roughly 71 million in comparison to a severe shortage of geriatricians.

#### **Remote Monitoring Services**

This business case of mHealth directly relates to telecare and the use of mobile networks and communication to enable remote monitoring of the elderly or ill in the home. There are two potential value chains for these types of applications: one funded by the patients or their families and one funded by health institutions. In the first value chain, relatives or other loved ones pay a third party service provider to provide reminders, check-ups, and sensor-based

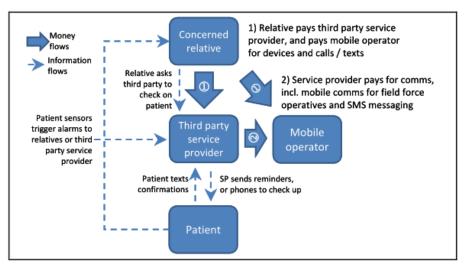
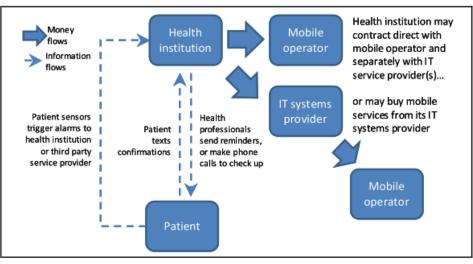


Figure 1.5 – Relative-funded model value chain

generated through subscription fees for the third party service since it is a managed service. The value proposition for individuals is peace of mind that their loved ones are being managed when they cannot be present. The institution-funded model can benefit from capital investments in facilitative monitoring technology by reducing admissions and reducing the cost of providing the services.

Studies have indicated that some circumstances result in in-house hospital treatments to be more expensive than at-home treatment plans.

Much of the value from this particular application lies in the proactive nature of the services. Not only are routine checks and procedures adhered to, but sensors and/or devices can



monitoring through a mobile network.

Insurance companies

may have incentives to

cover this scenario if it

can diminish or replace

bills. Figures 1.5 and 1.6

much higher hospital

from the Cambridge

value chains.

report illustrate these

In the relative-funded model, revenues can be

Figure 1.6 – Institution-funded model value chain

be leveraged to alert medical professionals or loved ones of potential problems before they occur or immediately as the occur thus potentially reducing the probability that the patient would need hospital intervention. The difficulty lies in the devices to use. Smartphones contain the necessary computing power but are expensive and not widely adopted by the qualified population for these services. Custom devices and/or software can serve this area but the road to profitability with this option requires scalability. Cheaper, passive sensors are also options which could be paired with more basic mobile phones to provide basic alerts. The most commercially viable option lies in custom devices/software solutions, however this would most likely need to be funded or subsidized by a large healthcare vendor where the societal and larger-scale health benefits justify the investment. Savings come from health institutions by becoming aware of potential episodes prior to the need for hospitalization and from individuals by enabling the elderly to stay in their own homes rather than paying for a nursing/care home. The market potential is perpetual since ageing is inevitable with all people worldwide. The execution of the application to bring it to the market is the difficult aspect.

#### **Macro-Environmental Factors and Trends**

A driving force behind the acceptance and implementation of mHealth applications is tied to macro-environmental effects. In other words, mHealth is emerging not because of innovation for innovation's sake, but because large global factors are placing pressure on current healthcare delivery systems which need to change. The Cambridge report lays out eight interrelated Millennium Development Goals (MDGs) drafted by the United Nations which address macro-environmental factors and the effect mHealth could have on them. For the sake of brevity, four of the eight are chosen which greatly pertain to the United States.

#### **Increasing and Ageing Population**

This trend is currently a large issue in the US with the influx of Baby Boomer retirees. The large demand for healthcare, especially those with diseases pertaining to old age, is increasing the cost of providing that healthcare. Applications of mHealth that could address this trend are applications reducing cost such as remote treatment and empowering the remote professional. This substitutes expensive resources and manual processes (hospitals, medical professionals, etc). Along with empowering the remote professional and providing expert resources to local health workers, applications supporting carers outside the healthcare profession is also pivotal to mHealth's curbing of the problems associated with this trend.

#### **Rising Income and Dietary & Lifestyle Changes**

American lifestyles, including those detrimental to one's health, have grown in popularity on a global level. As more "Western" lifestyles emerge, long-term conditions associated with these lifestyles could accrue more widespread concern such as heart disease, diabetes, and certain cancers. mHealth has a role to play through leveraging rising income as a potential vehicle for change. Well-being applications, information provision and self-help, intelligent public health

systems, and remote monitoring of long-term conditions can all help to curb the effects of "Western" lifestyles. One could argue, however, that these types of lifestyles are evolving into ones more conducive for healthy living.

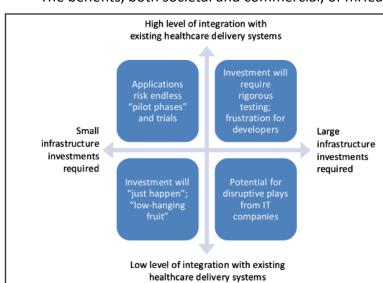
#### Advancement of Medical Technology and Rising Personal Expectations

The supply curve along with the demand curve are both shifting in relation to healthcare delivery. Medical technology is becoming more advanced and access to said technology is becoming easier and more widespread (enter mHealth). This also carries with it a growing demand for more advanced treatment methods. Economically speaking, when supply and demand both rise, prices rise in unison making health more "industrial" than before. Applications matching resources to needs more effectively can help create a sense of order amidst rapidly changing technology and needs. Information for health professionals as well as the public is also an important variable in addressing this trend.

#### **Population Mobility**

As people move locations, any health conditions unique to their local environment may travel with them. This is especially true with movement between countries. An increased risk of epidemics, pandemics, and pressure on centralized health systems exist as people move around and populate cities. Given the pressure put on centralized health systems in more populated cities, mhealth applications supporting local healthcare and local healthcare personnel can be very important to alleviating that pressure. Increasing efficiency of the larger institutions is also pivotal, but this is a standard business practice when times get tight. A more controversial, yet potentially powerful use of mHealth is for data collection to be used in epidemiological research. Predictive models could be produces mapping the spread of any disease, especially caused by high rates of migration.

#### **Deployment of mHealth Applications**



The benefits, both societal and commercial, of mHealth applications have been conveyed by

now. However, as with all business models, execution is 90% of the battle. There are two main dimensions of segmentation when it comes to the deployment of mhealth: the level of interaction required for existing health delivery systems and the extent of additional infrastructure and investment needed to deliver the application. Figure 1.7 from the Cambridge report shows these dimensions on a strategic map of

Figure 1.7 – Segmentation of mHealth opportunities

mHealth deployment opportunities. The easiest applications to deploy are "plug-and-play" applications utilizing sensors and peripherals interacting with a smartphone or tablet. Those require very little infrastructure investments and are at low levels of integration with existing healthcare delivery systems. If these applications were to be used by healthcare professionals within a hospital setting, the disruption would be greater to existing systems, but infrastructure investment would remain on the low end.

More complex mhealth applications which require large infrastructure investment regardless of the level of integration with existing systems will be the most difficult to deploy. The Cambridge report asserts that applications of this nature require larger platforms such as a large cloud computing platform to provide a foundation. These applications do not completely rely on a mobile phone but rely on potentially computationally intense processing. The Cambridge report argues for the merit of publicly available platforms provided by existing or new cloud computing providers. The two important results cited in the report are the decrease of upfront investment required to deploy new applications due to an established foundational platform and the standardization of services due to a standard, generic foundation thus curbing the effect of information silos. Incentives for cloud computing companies to create and provide such a platform come from the ability to enter the healthcare environment with managed exposure risk. The reputation of the platform provider is safer due to merely *enabling* the health sector application business and not *entering* it. However, revenues are not alluring enough and public/societal benefits are harder to define thus less compelling a reason for implementation. Lack of trust with personal health data is also cited as an obstacle for larger platforms.

#### **Recommendations for Players**

The Cambridge report lays out specific recommendations for what are considered the major players in the mHealth environment. Those recommendations are laid out below directly from the report.

#### **Policy-Makers**

- Policy-makers should ensure that their policies and priorities for healthcare are complemented by financial incentives that reward those who deliver outcomes, particularly inn disease prevention
- Policy-makers, healthcare agencies and professional healthcare bodies should provide guidance for assessing the healthcare and public financial benefits from emerging applications in a manner that can be understood by application providers, and create an expectation that such assessment should be an integral part of provision.
- Public health authorities and agencies should engage in assessing the benefits and costs of acquiring information – whether as "by-products" or directly – from mobile applications, either to replace existing data gathering or to gain new knowledge. This requires clarity of ownership of, and access to, personal information.

- Regulatory regimes and the medical establishment's guidance setting need to strike an appropriate balance between the risks and benefits of specific mHealth applications, distinguishing between those apps for which a light touch or a market-based approach is appropriate (i.e. those that pose no risk to health and may be effective, and which typically have little or no interaction with the established health delivery system) and those which have the potential to bypass or substitute other healthcare systems (i.e. those that might pose a risk to health unless properly regulated, or which might need to be robustly evaluated if health system money is to put into them.)
- Telecommunications regulators should review any constraints that existing regulations may place on the deployment of mHealth applications. In particular they should consider allowing mobile operators to operate as micropayment banks, i.e. directly handling small financial transactions.

#### **Telecommunication Operators**

- Operators should have clear strategies which might be different in different markets for how much of the value chain (basic services, generic platforms, application provision) they wish to operate, balancing investment, financial return, reputational risk and the presence/absence of other players operating parts of the value chain.
- Mobile operators should promote their networks as platforms for innovation and small-scale application deployments, and should invest in the provision of generic service platforms for this purpose. They should facilitate the use of the platform for domain specific innovation (here healthcare, though the recommendation is more generally applicable) by third parties, recognizing that, even if they choose to operate some applications directly, some applications will be too small (or present excessive risk) for the operator to provide.

#### Systems Integrators, Manufacturers, and Technology Providers

- Mobile operators should promote their networks as platforms for innovation and small-scale application deployments, and should invest in the provision of generic service platforms for this purpose. They should facilitate the use of the platform for domain specific innovation (here healthcare, though the recommendation is more generally applicable) by third parties, recognizing that, even if they choose to operate some applications directly, some applications will be too small (or present excessive risk) for the operator to provide.
- There is an opportunity for technology providers to provide the tools for creating or running managed services related to mHealth, which will in turn enable operators to provide generic service platforms. Technology providers need to decide whether their strategy is (a) to build and sell or (b) to build, sell and operate, perhaps in direct competition with operators.

#### Healthcare Providers (Including Insurers)

- Healthcare providers should examine mHealth applications as a means of managing exposure to costs e.g. through the use of in-home monitoring to avoid hospital or residential stays. This might allow reduced charges or premiums, or increased profits.
- Healthcare providers should consider how they might use data generated by mHealth applications to monitor and optimize the healthcare delivery chain itself, e.g. by improving the management and efficiency of expensive assets, or by better understanding the patterns of use.

#### Gaps and Dimensions of Note for Further Investigation

The Cambridge report while in-depth and very comprehensive addresses certain areas in which further investigation is needed. Many of these gaps remain interesting today despite the time difference and increase in technological availability.

- **A.** Assessment of how well mHealth applications perform in terms of the correctness of the diagnosis or recommendations, in particular the real-time analysis of inputs without having to send data off-device for analyzing
- **B.** Crowdsourcing of private data for the public good with aggregate modeling and realtime information and analytics
- C. Sensors and peripherals, in particular wearable tech and the commercial viability, IPOs, and financial performance of these solutions (Leslie, Sherrington, Dicks, Gray, & Chang, 2011)<sup>2</sup>

For the purposes of this research, the most interesting items for further investigation are the sensors and peripherals, how the introduction of easily accessible "plug-in" sensors and peripherals with accompanying well-being applications is shaping how we view and interact with our own personal health management, and crowdsourcing of private data for the public good.

# III. Peripherals, Sensors, and Well-Being Applications

An area of mHealth which is getting substantial media and commercial attention currently is peripherals, sensor devices, and well-being applications. These are mainly devices which interact with a smartphone through Bluetooth connectivity, Wi-Fi connectivity, or through direct plug-in to a headphone jack or charging port. These devices often correspond with a proprietary smartphone app which collects data from the peripheral device or sensor and provides analytics, insights, or suggestions depending on what data is collected and what the purpose of the device is. There is a flood of "wearable tech" in the market currently which aims to make these types of devices seamlessly integrate into our everyday lives such as smart watches, fitness bands, and even "smart" clothing like shirts, sports bras, and socks. (Sensoria, n.d.)While products and companies are entering this market rapidly due to low entry barriers, five current products with the most popularity and/or potential future value to mHealth will be highlighted for this research.

#### Fitbit

Fitbit Inc. provides products and online services to aid people in becoming aware of their fitness status and everyday activities while encouraging them to set goals and improve their performance. Their flagship product released in October of 2013 is the Fitbit Force which is a

<sup>&</sup>lt;sup>2</sup> Direct citation of the Cambridge report ends on this page. Any mention further is directly attributed to the report within the text

Bluetooth connected wristband which sends data to a connected smartphone in real time. The success of their fitness tracking device has allowed the company to move into a holistic product offering for connected health. The product offerings allow users to track everyday activity such as steps, distance, caloric intake, stairs climbed, and active minutes along with food logging tools and sleep analytics (how well you sleep and how long). Through a separate Wi-Fi enabled scale, users can also send important weight, BMI, and percentage body fat data to a smartphone to be included in a user's health data (Fitbit Inc., n.d.).

Fitbit Inc. is an example of the marriage of well-being applications and peripherals/sensors. While in the Cambridge report the two were mostly separate, smartphone health devices usually interact with proprietary smartphone applications to create a whole package.

#### **Kinsa Smart Thermometer**

The Kinsa Smart Thermometer is a thermometer which plugs into the headphone jack of a smartphone (iPhone or Android device) and then transmits temperature data to the smartphone. From the initial reading, a user can save and share symptom history, have access to illness forecasting that alerts a user when they are sick and when they are likely to get better, have access to one-touch calling for nurses, have access to urgent care scheduling, and have the ability to share pictures and videos with a doctor. Along with those immediate features, users can track the health status of their area using Kinsa Groups (Kinsa, n.d.).

#### **Kolibree Toothbrush**

The Kolibree toothbrush is a Bluetooth connected electric toothbrush which tracks users' brushing data and transmits it to the Kolibree smartphone application. This data includes brushing time and percentage of teeth properly brushed. The accompanying smartphone application allows families to track each other's brushing habits and provides users with rewards and points for progress to incentivize proper brushing. This data can be shared with other family members or even dentists should the user choose to do so. The feedback is reported in real-time so users can track immediately how well they brushed (Kolibree, n.d.).

#### **MobiSante Ultrasound**

The MobiSante MobiUS SP1 portable ultrasound system represents a once highly sophisticated and expensive piece of medical equipment being reinvented to leverage the computing power of smartphones and thus bring ultrasounds to rural and/or impoverished areas. The portable ultrasound is lightweight and very mobile in that it can fit in most pockets. The device works together with a smartphone application to send ultrasound images to the display of the smartphone. This device can be used for primary care, OB/GYN, emergency medicine, and vascular uses. Local health workers in rural areas can now provide these services without the need for the patient to travel to a hospital. This can also be revolutionary in impoverished areas receiving health aid, especially in low-income economies (MobiSante, n.d.).

#### iBGStar Glucose Meter

The iBGStar Glucose Meter is a device which connects via the charging port of an iPhone 4s and earlier and reads a test strip to reveal data on glucose, insulin, and carbs. The device syncs automatically with the accompanying iBGStar Diabetes Manager smartphone application to provide longitudinal charts of data over time as well as immediate analysis of a reading. These results can be shared with healthcare providers through email, as well should the user choose to do so. The portability of the device allows a user to take readings at any time and any place allowing better diabetes management and more informed decision making. This device is a prime example of leveraging mobile networks and mobile computational power to manage long-term conditions (BG Star, n.d.).

#### Teddy the Guardian

Teddy the Guardian is a connected medical device disguised as a plush teddy bear to create a more inviting health experience for children. The teddy bear contains medical sensors which measure heart rate, oxygen saturation, body temperature, and stress levels. This data is sent wirelessly to a tablet, smartphone, or web application making information sharing with a pediatrician much simpler. This particular sensor product is specifically designed to curb skewed vital measurements of children when visiting a pediatrician. Children often get stressed or nervous when visiting the doctor which can affect the measurements the doctor must make to assess health. The teddy bear reduces this effect while leveraging open source data platforms, advanced analytic capabilities, and mobile networks (Teddy The Guardian, n.d.).

#### **Commercial Viability and Market Implications**

Peripherals and sensors have the greatest chance for profitability in the immediate future of mHealth. In the strategic map of the market (Figure 1.7), these products would fall in the bottom left and investments will "just happen" with the nature of being "low hanging fruit." Very little infrastructure is needed and the existing healthcare system will not be disrupted in most cases as these devices are mainly personal devices. While this makes these products attractive in the short term, a cultural shift has to occur if these devices are going to be very successful while other quadrants require more capital investment and process altering. However, we have seen the consumer market change the way things are done in business and other professional fields. For example, widespread adoption of iPhones and Android devices have pushed many companies to participate in a bring-your-own-device policy for company cell phones (CIO, n.d.). These types of devices which connect seamlessly to a smartphone could aid low-budget hospitals or healthcare facilities worldwide. This will, of course depend on commercial performance of these devices and proof that it isn't simply a fad.

In 2013, NPD Group reported that the overall fitness device market, in which Fitbit Inc. is included, was worth \$330 million. This data only reflects point-of-sale sales data and does not include direct-from-manufacturer sales. One could argue the market is even larger in that light. Fitbit devices accounted for 68 percent of devices sold in this category giving them essentially \$224.4 million of the market. As previously stated, products like these are "low hanging fruit"

and will attract attention from investors and consumers alike. Devices like these which easily introduce consumers to personal health management will prove beneficial to more sophisticated peripherals. A cultural mindset shift has to occur if more peripheral devices are to make a meaningful impact on the market (Dolan, 2014).

# IV. Personal Health Management

The rise of portable and powerful peripheral medical devices for smartphones has given consumers/patients and healthcare providers an entirely new way to think about health. The old paradigm of yearly checkups being the best method of personal health management is transitioning into a new paradigm of always connected personal health management. Devices such as the ones laid out in chapter three allow users to be in constant connection with vital health data about themselves which can help them keep better track of their own health, but can also be used to facilitate a remote monitoring program with doctors. While seemingly an annoyance to be constantly faced with health data, practices like this can have lasting effects on individuals, businesses, and our healthcare system as a whole. Michael Critelli, CEO of the personal health records company Dossia, laid out four implications of individuals adopting personal health management systems.

# Personal Health Management Systems Help Us Manage Health the 99% of the Time We Aren't Patients

A personal health management system should be built to gather "comprehensive and cumulative information." This includes health history like what conditions a user has had in the past, but also current biometric data which can often indicate larger issues. This data can then be used to alert patients of risk factors for certain conditions and remind patients of necessary actions to take such as immunizations or other preventative steps. Access to expert advice can also be leveraged through mobile networks.

#### When Illness Occurs, We Become Better and More Informed Patients

Mobile networks can be leveraged to obtain the lowest price physician for any specific condition as well as information on the quality of any facility. Once the initial person and place of care is decided, the doctor or physician can utilize the data obtained through any personal health management system to see trends over time and fill in gaps where a patient may not recall a specific event making the treatment plan more informed and effective.

#### Incentives or Rewards from Health Plans or Employers Increases Health Engagement

Health data can be easily transferable through mobile networks meaning multiple parties can have access to it. Employers can incentivize progress with a specific regime through financial incentives or extra days off. The healthier the employees, the more productive they are.

Health care providers can also provide support and monitor progress. Increased engagement with individual health can decrease overall healthcare costs over time.

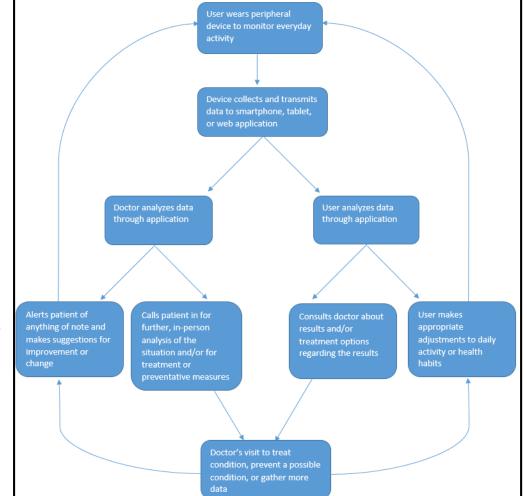
#### Shareable Personal Health Records Can Aid Remote Health Management

Remote patient monitoring can give patients peace of mind that red flags will be caught before hospitalization is necessary. Also, healthcare professionals can deliver more effective care at a much lower cost. Keeping patients out of hospitals reduces the strain on the overall healthcare system. Catching conditions or warnings early can prevent reactive health measures which are

often more expensive and less effective than preventative measures (Critelli, 2011).

### Flow Chart of Personal Health Management and Larger Implications

Figure 2.1 illustrates the flow of events from peripherals facilitating personal health management to possible treatment. The process moves in a cycle of continuous improvement thus enhancing the effectiveness of the overall healthcare system. The obstacles with this are the same as any other marketing



problem: adoption. Something as intrusive to daily routines as constant health management needs to be approached carefully for widespread adoption. Device and platform makers must make their respective products unobtrusive, simple to use, and seamless to integrate into standard daily activity. A cultural shift of health engagement must occur for systems and processes like these to succeed and become a part of the greater healthcare system. Widespread adoption of personal health management practices not only gives us an overall healthier society and a more efficient healthcare system, but it brings with it multitudes of data which is a brand new phenomena. The data itself is massive, but the transferability is very powerful. This data aggregated has large implications for how society as a whole approaches health.

# V. Big Data in mHealth

Unprecedented amounts of data about our health is continuing to be amassed as more and more people begin to use and adopt peripheral medical devices and personal health management practices. This data, when aggregated, can help healthcare professionals and scientific researchers build predictive models for specific conditions on an individual level and a population level. The ability to map disease outbreaks is also a possible outcome of the use of aggregated private data. More individuals are also becoming more engaged with their health which is fostering an increase in crowdsourced health solutions. Mobile networks are also allowing healthcare professionals to participate in crowdsourcing, as well. These initiatives, however, face obstacles in terms of privacy concerns, financial feasibility, and participatory shortcomings.

#### Predictive Models & Disease Mapping

The use of sensors or peripherals interacting with smartphones, tablets, and mobile networks provide detailed and complete data over an extended period of time with consistent intervals. This data can be used to identify risk factors for diseases on a population level, sub-population level, and even an individual level. Large enough datasets can provide insight into situations where the average effect of a certain drug, for example, may be null but different people will have positive or negative reactions (thus the average being null). Individual models would allow individuals to obtain more meaningful health information based on their own situation.

#### Case Study 1 – Fitness Tracking

Fitness trackers such as the Fitbit Flex mentioned earlier capture physical activity data withoutthe bias and validityFigure 2.1 – Personal Health Management Flow Chartproblems of

questionnaires. If this data were to be paired with corresponding EHRs, studies could be conducted linking physical activity to certain health scenarios as well as identifying social and environmental impacts on physical activity. This also gives researchers the power to negate the "null-average" problem as mentioned above in that people in different settings and with different health histories may respond differently to varying types of fitness routines. Population health initiatives could also be produced if social factors play a large role in a lack of physical activity and obesity. Models could also be produced to identify a particularly "lazy" day and communicate this information to a user as an encouragement to maintain physical activity daily. (Barrett, Humblet, Hiatt, & Adler, 2013)

#### Case Study 2 – Asthma

Leveraging the power of sensors and peripherals, researchers have been able to get a better hold on asthma and "spatial predictors of asthma exacerbations." (Barrett, Humblet, Hiatt, & Adler, 2013) Asthma was cited with \$56 billion in healthcare costs in lost productivity in 2007 and that number is on the rise. A new device, the Asthmapolis sensor, passively captures time, location, and GPS coordinates of the inhaler use through communicating with its smartphone application and connecting to an existing inhaler. Users can provide additional contextual information such as symptoms and environmental conditions. Studies have found that users of the Asthmapolis sensor experienced a reduction in asthma symptoms and a perceived improvement in control and awareness over a 4-month use period.

The data generated by the passive data collection of the sensor coupled with participatory data entered by the user can be used in much the same way aggregated data from Fitbit sensors can be used. Unidentifiable data can be used from this sensor to identify "asthma hotspots" in a given area. This data can also be coupled with contextual environmental data allowing researchers to study links between asthma attacks and things such as air quality, traffic conditions, and weather conditions. This allows public officials to better address asthma in their respective areas (Barrett, Humblet, Hiatt, & Adler, 2013).

#### Disease Mapping

Developments in advanced spatial statistics coupled with the influx of health data is allowing researchers to map diseases much more easily. Previous disease maps have shown maps not in real-time causing expedited obsolescence. This is usually done through reported cases of a disease vs non-reported cases of a disease. Real-time data transfer from peripheral devices and passive sensors could be used to create real-time maps of conditions. Advanced statistics with large amounts of real-time data and advanced computer science would make this possible and would have a large impact on resource allocation for times of crisis as well as practical resource allocation for dealing with diseases. The Kinsa Smart Thermometer mentioned earlier has a feature in its smartphone application which allows users to opt-in to sharing illness occurrences. The software then maps these occurrences as well as tracks the history (like "health weather" as the company proclaims) (Barrett, Humblet, Hiatt, & Adler, 2013).

#### Crowdsourcing

Crowdsourcing is when "an organization communicates a problem or challenge to participants in an online community" (Brabham, Ribisi, Kirchner, & Bernhardt, 2014). This technique of eliciting solutions to complex problems through the power and scale of collective intelligence is being used by healthcare professionals as well as patients. This can be through online forums or other direct forms of communication, but this can also be accomplished through less direct means. Google Flu Trends is an example of crowdsourcing based on Google searches in order to map the spread or score the risk of a flu outbreak in different areas. While not perfect, this method is quicker than traditional studies done to map disease spread and is well correlated with actual flu outbreaks. Usually, however, crowdsourcing refers to participatory events. Mining of either of these types of crowdsourcing techniques can produce meaningful results. An article from the American Journal of Preventative Medicine lays out four types of crowdsourcing:

- 1. Knowledge Discovery and Management
- 2. Distributed Human Intelligence Tasking
- 3. Broadcast Search
- 4. Peer-Vetted Creative Production

Each of these types uses crowdsourcing to elicit different types of information to solve different types of problems. All of which, however, have practical applications in public health (Brabham, Ribisi, Kirchner, & Bernhardt, 2014).

#### **Limitations and Concerns**

The most glaring limitation in using aggregated data is privacy. Even in situations where the data is anonymized and seemingly unidentifiable, security is always a risk when transferring data through mobile networks and the cloud. Merging data from varied and secured sources while protecting patient privacy is not easy and that kind of data is necessary for building sophisticated predictive models. The silos involved with this data is also a huge obstacle. Patients who switch providers frequently will have their information scattered across multiple databases likely with different EHR providers each with their own nuances. A larger cloudbased platform would be ideal for this type of problem (Barrett, Humblet, Hiatt, & Adler, 2013). However, a report on precision medicine by the National Research Council cites complex issues of consent, confidentiality, patient access, and oversight need to be addressed when looking to merge data and/or develop an overarching platform

# VI. Regulatory Landscape Overview and Policy Implications

The future of mHealth growth and expansion remains closely tied to regulation. The Food and Drug Administration (FDA) released its final guidance on mobile medical apps in September of 2013 and it has received mixed responses. Some believe that the lawfully unbinding guidance simply creates more confusion about what is or is not worth creating while others believe that some guidance is better than none. The FDA has expressed that it does not want to hinder the advancement of mobile medical technology and has limited the potential regulations to a minimum. There are three type of mHealth apps that the FDA considers to be subject to regulatory oversight.

Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.

- Apps that display medical device data to perform active patient monitoring
- Apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform
- Apps that are intended to display or store medical device data, without controlling or altering the functions or parameters of any connected medical device constitute a Medical Device Data System

Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Mobile apps that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform.

- Apps that use hardware attachments or interface to a monitoring system (blood glucose reader and meter; electrocardiograph electrodes to measure ECG signals)
- Apps that use external or internal sensors (electronic stethoscope)

Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved. (Food and Drug Administration, 2013)

- Apps that perform patient-specific analysis
- Apps that use patient-specific parameters and calculate dosage or create a dosage plan
- Apps that leverage Computer Aided Detection software (CAD)

#### Implications of FDA Final Guidance Report

The FDA has made it clear that it only wishes to apply its regulatory authority to a specific subset of mHealth apps that transform a smartphone or other mobile device into a historically-regulated medical device or a platform facilitating diagnoses and/or treatment recommendations for diseases and other conditions. However, many are worried of any sort of FDA regulation because complying with FDA standards often adds years and more money to the cost of developing any new service or device stifling potential innovation with red-tape. To the contrary, many developers and health professionals believe that the FDA did a good job of divulging what is open to regulation, but acknowledge that there are still many gray areas. Others believe the release of an unbinding guidance report would create more confusion than anything else. "It doesn't create legal obligations and we thought it would create confusion. The FDA doesn't get to decide what it regulates – Congress does," said vice president of

governmental affairs for Athenahealth Dan Haley. Congress is set to review the FDA's guidance report and decide on official regulations soon (Vesely, 2014)

#### **Initial Congressional Reaction**

While congress as a whole is waiting for the official congressional review, members of congress have already begun to act against FDA regulatory power of mHealth applications. A bipartisan group of lawmakers came together led by Representative Marsha Blackburn of Tennessee to try and curb regulations in the realm of mHealth that might stifle innovation in a time of great growth and evolution. The SOFTWARE Act was introduced in October 2013 to address these issues. The Act identifies three areas of mHealth apps: medical, clinical, and health. Only medical apps/software ("software that directly changes the structure or functioning of the body or includes the use of a regulated medical therapy without physician involvement") would require FDA approval under the SOFTWARE Act. The Act has come under scrutiny for its oversimplification of the mHealth market, especially in a time when rapid technological advancement can rapidly alter to makeup of the mHealth market (Graham, 2013).

#### **Implications in Context**

The areas of mHealth the FDA has identified as possible regulatory areas are the area which have the capability of making a large difference in not only personal health, but also health in rural and impoverished areas. If peripherals that turn a smartphone or tablet into a sophisticated medical device have to wait for years before approval, the marginal benefit of their inception decreases and less people are effectively impacted by the innovation. This is especially the case in situations where the medical devices or sensors are tied to a certain operating system or device. Mobile technology is changing at such a rapid pace that regulatory slow-down would perhaps be financially detrimental to mHealth device manufacturers and their platforms. While there are categories of apps in mHealth, they all intertwine and build off of one another as is seen with peripherals, personal health management, and leveraging big data in mHealth.

The regulation, in this case, needs to be very cautious and allow itself to be shaped by the technology and not vice versa. This would require, however, minimal regulation or very rapid adjustments to existing regulation which is not an expedited process in any context. While regulation will slow the growth of these types of products and services, it will not halt mHealth altogether. It is an inevitable trajectory even if the market looks very different in the future.

# VII. Thinking Ahead for mHealth

Mobile technology is evolving at an extremely rapid pace and at a large scale. There are over one billion smartphones in use globally, there are now roughly seven billion mobile subscribers worldwide, and there are over 81 billion mobile app downloads per year (Ruder Finn, 2012). Mobile technologies have continued to innovatively evolve and, as such, adoption has skyrocketed. Changes in this technology from a hardware/software standpoint and from a network/platforms standpoint will continue to pave the way for more innovations in the mHealth market. Analysts suggest that the market will grow exponentially. However, this largely depends on consumer adoption of mHealth applications and technologies. While some mHealth applications rely on physician adoption, such as those assisting local healthcare workers or remote professionals, the commercial mHealth apps, such as peripherals and sensors, will rely on consumer-driven demand.

#### What the Analysts Say

Market analysts have a vested interest in knowing which industries are commercially viable and potentially profitable. As such, their predictions for the financial performance of mHealth and its predicted adoption amongst professionals and consumers have a definite impact on the level of investment that can be expected to be observed. Analysts predict the market for mHealth applications and devices to grow at a 61% AGR through 2017. The market is also expected, by some, to see \$26 billion in revenue by 2017 and grow to \$58.8 billion by 2020, globally (Terry, 2013). Other analysts are predicting more modest gains to about \$10.2 billion by 2018 (Ruder Finn, 2012). The opportunities for the mHealth market vary largely because of established health infrastructures and the health of the respective economy. Therefore, specific markets may see more explosive growth then others while some may experience modest to negligible gains in the same time frame. While analyst predictions may drive the investment climate and activity, the knowledge of future mHealth performance may be better extracted from healthcare consumers themselves.

#### What the Consumers Say

According to market research conducted by Ruder Finn, 91% of healthcare professionals own smartphones. These types of professionals often tend to adopt new technologies quicker than the general public. Tablet adoption amongst physician almost doubled from 2011 to 62% ownership in 2012. One of the questions asked by Ruder Finn was what mobile technologies and/or apps would allow for more efficient and effective patient care in the eyes of the patients themselves. The top three responses were remote access to test results (43%), monitoring devices to remotely alert a health emergency (33%), and remote access to patient health records (30%). This implies that the shareability of health data and the fostering of remote emergency alerts are what healthcare professionals are demanding most from the mHealth market. However, while still a minority, 13% of respondents indicated that they did not think mHealth applications nor mobile technologies would allow for more efficient and effective patient care. Patients largely believe that leveraging mobile technologies and devices can aid in the delivery of cheaper, more effective healthcare. The thoughts on the most effective application possibilities do not necessarily mesh with apps that are of most interest to consumers, however.

The three types of apps most in use are social media apps, games, and news apps. People like achieving/attaining something, sharing those among other things with friends, and being informed. These trends can be seen in the results for the top health apps of interest to consumers. The top three apps of overall interest, spanning gender differences, are calorie counting apps, fitness/training apps, and healthy eating apps. People tend to like achievement (reaching health goals through these apps) and information (self-information gathered). While these indicate what interest is in the market, not all consumers have an interest in adopting health apps with the fifth most frequent response was no interest.

Of the consumers surveyed who did not wish to use mHealth, the top three cited reasons are a lack of need to access health related apps, a preference of consulting with healthcare professionals in person about any health related question, and the unwillingness to share personal health information through mHealth apps. Other reasons included not finding health apps helpful, "other" reasons, and a lack of awareness that health related applications are available on mobile devices. The survey also found that patients between the ages of 18-44 are the most likely to adopt mHealth apps along with patients with chronic conditions over non-chronic conditions and patients with children over no children. The concerns vocalized by patients and consumers should catch the attention of mHealth providers, innovators, and investors because consumer adoption of these technologies is key to its success (Ruder Finn, 2012).

#### The Digitized Self and the Future of mHealth

Much of the future of mHealth depends on consumer-driven demand, regulations, and available platforms. Without a centralized platform, mobile operating systems remain the platforms of note and they are volatile as updates occur frequently and carry with them notable changes with most iterations. However, the Ruder Finn study suggests that there is no significant difference in usage patterns of mHealth applications between different mobile operating systems. The breakdown of ownership of the operating systems was 45 percent Android, 33 percent iOS, 8 percent BlackBerry, 3 percent Windows Mobile, and 3 percent other (Ruder Finn, 2012). Information technology and privacy regulations pertaining to mHealth will also determine its future outlook. These concerns are not likely to halt the trajectory of mHealth, but the mHealth market as categorized today and the types of solutions and applications may be very different.

What some are calling "The Digitized Self" coupled with "The Internet of Things" is what many purveyors of mHealth see as a large part of the market's future. Being able to collect and share all aspects of our health and connect devices to each other and to the cloud is the power of what will drive consumer demand for mHealth. Devices such as smart pills which monitor your health internally to wearable devices, peripherals, and sensors are all helping pave the way for the rise in popularity of what has been dubbed as "Little Data." Contrary to "Big Data," Little Data refers in this case to the data generated by individuals about themselves and the world with which they interact. This is the pivotal shift from passive health management to active health management. This shift is being championed by mHealth applications and the power of mobile technologies (Ruder Finn, 2012).

Nobody can know for sure what is in store next for the mHealth market. Most experts agree and consumers seem to acknowledge that it will continue to grow and become a part of the healthcare infrastructure (Ruder Finn, 2012). However, what that infrastructure or market will look like is a mystery. The important thing for purveyors of mHealth solutions to be cognizant of is what consumers are looking for and what they want. Healthcare needs and trends, demographics, and the state of the global economy will all play a role in which solutions are brought to the surface, but consumer demand and consumer needs will drive the innovation in the end.

# VIII. Telehealth and Kaiser Permanente: An Inside Look with Jody Crane

Jody Crane is a director of acute care, urgent care, and emergency room operations along with innovation at Kaiser Permanente. Kaiser is an integrated healthcare provider in which they



provide the insurance but also owns the means of healthcare delivery by employing physicians. There are roughly 50,000 total employees with revenues of about \$50 billion last year. Mr. Crane joined Kaiser in April 2013 and has since been leading its dive into mHealth via remote consultations with patients. Patients can make appointments through a mobile app or a call to Kaiser's call center. Since the system is integrated, call center employees are able to screen patients prior to an appointment with various scripts that are made available. Some Doctors work with the call center to screen more complicated calls and evaluate what is needed. Kaiser's previous attempt at mHealth resulted in a failure due to the technology divide between doctors and patients. The call center would qualify patients for a video consultation and the patient could be directly connected with a doctor. However, most of the time available in these consultations was spent coaching patients through the video call technology and attempting to establish a working connection. Mr. Crane implemented a system utilizing receptionists who will ensure patients are ready to go prior to the video consultation with a doctor so the connection and technology will be set up and ready. Figure 2.2 illustrates this process. This decreased customer frustration and used doctors' time much more efficiently. Within a few months of implementation, video consultations were taking place 24/7 averaging around 500 calls per month. One hundred percent of patients stated that they would use the service again. This system allowed Kaiser to provide a convenient and effective service to its patients saving patients money through the free video consultation and eliminated need to travel. This also saved Kaiser money in terms of the overhead cost involved in each visit. It is not a profitable service, but it is an efficient service which cuts cost for the patient and the healthcare company (Crane, 2014).

### IX. Conclusion

The continued evolution of mobile networks and technologies will lend itself to more innovation within the mHealth market. These types of applications and solutions will become a part of our lives more and more as smartphones become staples in our lives, as well. The mHealth market not only represents a market or investment opportunity, but rather it represents a fundamental shift in how health is approached: from passive health management to active health management. However, it represents a business problem more so than a science, technology, or health problem because of the consumer-facing nature of the market. If mHealth fails to make it past the commercialization phase of its life cycle, it will have difficulty integrating itself into the treatment infrastructure of healthcare.

#### **Most Promising Areas**

The most exciting and commercially promising areas of mHealth solutions lie with peripherals/sensors which will help facilitate active personal health management through "The Digitized Self" as well as the leveraging of data to build models for individuals and populations. These peripheral and sensor devices will need to be compatible with smartphone hardware and the respective software in order to have market share and will need to be coupled with some sort of proprietary well-being application with a friendly user interface and incentives for results. App usage trends suggest that app users like to play games, share things with friends/family, and be informed. Developers of mHealth applications need to keep these trends in mind as consumers will be the ones adopting most of these technologies and applications.

Once the idea of smartphone-enabled health devices has proven itself in the consumer market, the transition into using such devices for treatment plans will be much more seamless than if consumers were largely skeptical of the idea. These devices and solutions do not disrupt existing healthcare infrastructure but rather create an extension of that infrastructure. The initial capital investment is also relatively low depending on the device and software meaning that if/when these solutions are integrating into treatment plans or monitoring regimes, the costs for all parties will be significantly decreased.

#### **Implications and Final Thoughts**

Healthcare costs are not only on the rise, but are becoming increasingly complicated under the political spotlight. The adoption of mHealth will not only provide a way in which costs for all parties can be reduced, but it also champions a fundamental shift in social attitudes towards healthcare and health management. Active health engagement creates a culture of healthminded decisions which benefits us all in the long run. Commercially, mHealth represents a brand new market in which to innovate and provide either frontline solutions in the form of devices and applications or provide back-end support in the form of platforms and network support.

The future of mHealth depends on platform availability/compatibility, regulatory action, and consumer attitude/adoption. The obstacle is more of a marketing problem than anything else and should be treated as any other product entering an untapped market. If these types of applications can be successfully implemented in individuals' lives and the larger healthcare infrastructure, society will see a reduction in healthcare costs, a boost in productivity due to active health management, and new technologies which can improve healthcare worldwide.

#### Bibliography

- Barrett, M. A., Humblet, O., Hiatt, R. A., & Adler, N. E. (2013). Big Data and Disease Prevention: From Quantified Self to Quantified Communities. *Big Data*, 171-173.
- BG Star. (n.d.). *Our Products: iBGStar*. Retrieved from Developing Integrated Diabetes Solutions BGStar.com: http://www.bgstar.com/web/ibgstar
- Brabham, D. C., Ribisi, K. M., Kirchner , T. R., & Bernhardt, J. M. (2014). Crowdsourcing Applications for Public Health. *American Journal of Preventative Medicine*, 179-187.
- CIO. (n.d.). All About BYOD. Retrieved from CIO.com: http://www.cio.com/article/705880/All\_About\_BYOD
- Crane, J. (2014, April 18). Kaiser Permenante Telehealth Program. (K. West, Interviewer)
- Critelli, M. (2011, May 5). The Consumer Case for Personal Health Management Systems. Forbes.
- Dolan, B. (2014, January 15). Fitbit, Jawbone, Nike had 97 Percent of Fitness Tracker Retail Sales in 2013. *mobihealthnews*.
- Fitbit Inc. (n.d.). The Fitbit Story. Retrieved from Fitbit Official Site: http://www.fitbit.com/home
- Food and Drug Administration. (2013, September 25). Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff.
- Graham, J. R. (2013, November 9). Mobile Health Apps: Blackburn's SOFTWARE Act Would Limit FDA's Power, Ensure Regulatory Restraint. *Forbes*.
- Heggestuen, J. (2013, December 15). One In Every 5 People in the World Own a Smartphone, One In Every 17 Own a Tablet. *Business Insider*.
- Kinsa. (n.d.). *Home: Kinsa*. Retrieved from Kinsa World's Smartest Thermometer: https://www.kinsahealth.com/
- Kolibree. (n.d.). *Home: Kolibree*. Retrieved from Kolibree World's First Connected Electric Toothbrush: http://www.kolibree.com/
- Leslie, I., Sherrington, S., Dicks, D., Gray, N., & Chang, T.-T. (2011). Mobile Communications for Medical Care.
- MobiSante. (n.d.). *The MobiUS SP1 System*. Retrieved from Portable Ultrasound Machine | Mobisante: http://www.mobisante.com/
- Ruder Finn. (2012). mHealth Report.
- Ruder Finn. (2012). mHealth Report.
- Sensoria. (n.d.). Sensoria Home Page. Retrieved from Sensoria Fitness: http://www.sensoriafitness.com/
- Teddy The Guardian. (n.d.). *Home: Teddy The Guardian*. Retrieved from Teddy The Guardian: http://teddytheguardian.com/
- Terry, K. (2013, July 30). Mobile Health Market to Reach \$26B By 2017. Information Week.
- Vesely, R. (2014, January 21). mHealth Regulations: What's in Store? *iHealthBeat*.