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Improving Health Care through Mobile Medical Devices and Sensors

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Health care access, affordability, and quality are problems all around the world. There are well-established disparities based on income and geography, and the high costs of health care present affordability challenges for millions of different people. Large numbers of individuals do not receive the quality care that they need.

Mobile technology offers ways to help with these challenges. Through mobile health applications, sensors, medical devices, and remote patient monitoring products, there are avenues through which health care delivery can be improved. These technologies can help lower costs by facilitating the delivery of care, and connecting people to their health care providers. Applications allow both patients and providers to have access to reference materials, lab tests, and medical records using mobile devices.

Complex mobile health applications help in areas such as training for health care workers, the management of chronic disease, and monitoring of critical health indicators. They enable easy to use access to tools like calorie counters, prescription reminders, appointment notices, medical references, and physician or hospital locators. These applications empower patients and health providers proactively to address medical conditions, through near real-time monitoring and treatment, no matter the location of the patient or health provider.

In this paper, part of our Mobile Economy Project, we look at specific applications and inventions, and discuss how mobile is transforming health care in the United

States and around the world. We argue that mobile health helps frontline health workers and health care providers extend their reach and interactions – enabling them to be more efficient and effective in their provision of medical assistance. And in the conclusion, we recommend several steps that will speed the adoption of mobile technology in health care.

Innovations in Mobile Health Care

Applications such as the iWander app for Android devices are being used for patients suffering from Alzheimer's disease or dementia. It makes use of the GPS function of smart phones to track patient locations. If the individual travels away from their home or other known locations, it triggers a signal to the person's family or caretaker to check on their status. Through geo-location coordinates, the person can easily be found and returned to the care setting.[1]

Social media sites are also helping patients cope with specific diseases. For example, diabetes-related complications represent a major source of emergency room visits. A study of the site at www.TuDiabetes.org had around 500 patients report their experience with hypoglycemic events, age, gender, use of insulin pumps, and health issues. The average person said they had suffered six insulin-related problems.[2] From sharing their experiences, viewers could see what others had experienced and ways to cope with particular health emergencies.

Some of these applications have been developed for the cloud. A problem in the health care area is difficulty in connecting different devices. These "interoperability" challenges arise in multiple ways. In some cases, information systems are not able to communicate with one another. At other times, there are incompatibilities in terms of data files, semantics, or file sharing protocols. Placing the wireless solution on a cloud storage system helps with connectivity issues and makes it easier to communicate across different information regimes.

The Electronic Medical Information Exchange (known as eMix) represents an example of a cloud-based system. It allows health care providers and patients to access medical reports wherever they are. People can see medical imaging reports, lab tests, and medical background in a secure distribution system that helps people gain access to their records regardless of where they are located.

Another system is the 2net Platform developed by Qualcomm Life. This system transfers, stores, and helps convert and display electronic medical device data. It is a cloud-based system designed to be interoperable with different kinds of medical devices and applications.[3] Patients as well as care providers have access to their information around the clock. This is a tremendous benefit, especially during times of medical emergencies.

With the development of many new mobile applications, it is important to determine which ones are most helpful. iMedicalApps (www.iMedicalApps.com) is the leading outlet for medical personnel. Its analysts offer reviews and commentary on mobile medical technology. Readers can see which applications receive the most positive reviews and which ones do not. It offers recommendations on the top health care applications available on the market.

Invention plays a role in all of these mobile applications. It takes time, talent, and ingenuity to devise effective mobile health apps. Inventors have to combine knowledge of software and hardware, as well as the intricacies of the health care system to build products that help people and providers address health issues. Some of these are of low complexity, while others represent much bigger undertakings. Operating in an environment that encourages and facilitates invention is a vital part of the mobile ecosystem.

Remote Testing and Diagnosis

There has been a growth recently in "wearable sensors" and remote monitoring devices. Some of these products have been listed with the FDA, while others are off-shore devices that are not for sale in the United States. For example, researchers have developed a portable electrocardiogram (ECG) system for high-risk cardiac patients. It uses smart phones attached to heart monitors to transmit heart rhythm data to health providers. Software analyzes the ECG waveforms for possible abnormalities.[4] Those requiring special attention are notified of possible problems that need to be addressed.

Propeller Health has developed an inhaler with an asthma sensor built into it. The sensor tracks environmental conditions that pose possible dangers to asthma sufferers. By keeping track of external conditions as well as how often the person is taking medicine, the device helps manage asthma and keeps health providers informed about disease management.[5]

AirStrip was co-founded in 2005 by web developer Trey Moore and Texas obstetrician Cameron Powell. It uses wireless software AirStrip OB to monitor fetal heart rhythms and

send that data about pregnant mothers to their physicians. The entrepreneurs also have developed AirStrip Cardiology which monitors heart data and AirStrip ICU for intensive care or emergency room patients.

Its research has found improvements in physician satisfaction following deployment of these mobile health applications. Surveys of obstetricians found "mean overall satisfaction scores are 4.5 to 10.9 percent higher at AirStrip hospitals than their regional and national peer group counterparts."[6]

In China, Life Care Networks and the Community Health Association of China have pioneered an initiative called Wireless Heart Health to help those suffering from cardiovascular diseases. Around three million people die from that cause every year in China. Patients are equipped with remote monitoring smartphones that record electrocardiogram data through purpose-built sensors. That information is sent electronically via the 3G network to 24-hour call centers for rapid monitoring by cardiac specialists. Those with abnormal readings receive special consultations and referrals to hospitals if warranted.[7]

Research by Suneet Chauhan demonstrates the value of electronic fetal monitoring. Using a sample of nearly 2 million infant birth and death records, he and his colleagues found a 53 percent reduction in mortality based on monitoring devices.[8] Having real-time data on possible abnormalities helps health care providers identify who is at risk and what can be done to prevent more serious conditions from developing.

Turkish researchers Oguz Karan, Canan Bayraktar, Haluk Gumuskaya, and Bekir Karlik have combined smartphone technology with software algorithms to create "pervasive healthcare services".[9] Their system allows users to enter data such as their age, physical activity, whether they are pregnant, whether they have diabetes in the family, body mass index, skin fold thickness, cholesterol, diastolic blood pressure, serum insulin, and plasma glucose concentration into their smartphones. Along with personal medical history, this information is transmitted in real-time to health providers with decision-making support that tells them whether the readings are normal or abnormal. Those with abnormal signs are advised to seek medical assistance.

Zephyr is a firm founded in 2003 that offers a heart rate monitor enabled through a mobile device for use by consumers, soldiers, first responders, and athletes. It tracks heart activity, breathing rate, electrocardiogram signals, stress levels, posture, activity level, and peak acceleration. The tool straps onto the chest and records data on physiological status. It gives consumers and professionals a powerful tool for monitoring their own health status.[10]

These products represent just a few of the new services and monitoring devices designed to help people with particular illnesses. There has been an explosion of innovative approaches that have come to the marketplace. With health care systems needing to improve access, affordability, and service delivery, inventors have turned to mobile devices to provide better health care.

Empowering Frontline Health Workers with Medical Knowledge

In many places around the world, frontline health workers have difficulty accessing medical information or learning from the experiences of health colleagues. Often times, they don't have common medical reference materials or basic knowledge about diagnosis, treatment, and prescriptions.

A project called "mPowering Frontline Health Workers" is addressing this problem by using mobile devices to provide the latest medical information to frontline health care providers. Through a digital repository provided by health experts, people such as midwives, nurses, and community health workers can use cell phones, smart phones, tablets, and laptops to get information on neo-natal care, immunization, and childhood diseases. This helps them become more effective in delivering health care and reducing the death of children and mothers in developing nations.[11]

In South Africa, as an example, health providers use mobile devices with a library of clinical resources. Nurses and physicians can access the latest in medical information concerning diagnosis, treatment, and medication. They can look up data on drug interactions as well as ways to treat particular illnesses.[12]

And in Japan, the Wireless Health Care@Home program allows residents living in remote areas to send critical health information to doctors via a wireless network. Allowing people to manage their own health while also receiving timely treatment helps them prevent illnesses from becoming more serious.[13] It is a way to empower patients by giving them greater responsibility for their own medical treatment.

These are just some of the ways that mobile devices improve health care by providing timely and up-to-date information at people's fingertips. If health providers can check on adverse side effects that arise from certain treatments or how particular medications affect patients, those are tremendous benefits for the health care system. They help to reduce costs while also improving the quality of medical care.

Facilitating Mobile Health Innovation

Invention has aided the development and deployment of the applications and systems described here. Those who build medical devices and develop software applications need an environment that encourages discovery and creation. This includes a culture that facilitates invention and rules that help inventors make money from their various creations.

Medical device inventors Howard Levin and Mark Gelfand describe how they operate.[14] Levin is a heart transplant cardiologist, while Gelfand is a systems engineer. In thinking about health problems, they start with a list of up to 30 ideas and then whittle them down. Using fellow experts and the medical literature, they analyze factors such as whether the product would meet an unmet need, pose a technical risk, be used on patients, and whether it produces any adverse side effects.

In the United States, there are also a number of issues that need to be addressed regarding government regulation of mobile medical devices. One topic is the question of whether to regulate particular products. Some devices are marketed for health and fitness monitoring and therefore are not subject to device regulation. Calorie counters or activity monitors fall within this category. As consumer items that have no discernible risks and are non-invasive in nature, there is no reason for the U.S. Food and Drug Administration (FDA) to oversee them.

Those that are thought to pose some patient risks are subject to regulation. FDA's Center for Devices and Radiological Health groups 1,700 medical devices into 16 medical specialties. It focuses specifically on "radiation-emitting electronic products" used in diagnosing or treating diseases in the United States. Companies must register as manufacturers, and list their products and potentially need clearance through a premarket notification 510(k) process or premarket approval, in addition to meeting appropriate labeling requirements, institute good manufacturing practices and report adverse events through the Medical Device Reporting system.

Each device is assigned to one of three regulatory classes based on intended use and possible risks to patients.[15] Stethoscopes represent an example of a Class I devices. It is subject only to general controls since they pose lower risks to patients. Class II devices such as scanners are considered higher risk and general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and require premarket notification through the 510(k) review process. Brain stimulators and cardiac

defibrillators are examples of the highest risk devices that support or sustain human life and are of substantial importance in preventing impairment of human health represent a potential, unreasonable risk of illness or injury. Class III devices call for clinical studies demonstrating safety and effectiveness.[16]

Other countries vary considerably in how they handle medical devices. The European Union, for example, allows the marketing of mobile devices across all member countries once they have been approved as "Conformite Europeenne" in any one of its nations. It uses four categories of devices (Classes I, IIa, IIb, and III) based on risks and intended usage.

Medical devices are approved if "the device successfully performs as intended in a manner in which benefits outweigh expected risks."[17] Class III devices in Europe require clinical trials, but their details are not made public and are not binding on manufacturers. Information on serious adverse events must be reported to the relevant government authority but are not publicized to the general public.

Some commentators have expressed concern that European regulators are paid directly by device sponsors and that they are focused most on whether medical tools work as intended as opposed to their impact on public health. Medical researchers Daniel Kramer, Shuai Xu, and Aaron Kesselheim say the European process is faster and requires less detailed clinical studies. They claim European regulators have approved monitoring devices for coronary artery interventions based on 22 subjects, compared to 800 people for the same device in the United States.[18]

Others have suggested the value of postmarket oversight of medical devices. Under current law, patients, physicians, and manufacturers convey device failures or adverse impacts to the U.S. Medical Device Reporting system. Although that database receives more than 100,000 complaints each year, less than 0.5 percent involve medical device failures.[19] Yet with the FDA approving more and more devices through substantial equivalence of predicate device in the 510(k) clearance pathway as opposed to premarket approval requiring detailed analysis, these authors feel the needs for better oversight.

Still others have expressed concern about the level of medical device user fees. The U.S. Food and Drug Administration first started collecting fees in 2002. Device manufacturers pay fees when they register as manufacturers and list their particular devices for marketing with the FDA. Assuming that Congress does not kill the device fee as part of a budget agreement, the federal agency plans to collect around $595 million between 2012 and 2017 through this means.[20]

The FDA recently published its final "guidance" on mobile medical apps that outlines its "current thinking" and approach to mobile medical applications.[21] The guidance defines mobile applications and mobile platforms, and explains what is subject to agency oversight. For example, government officials do not include electronic copies of medical textbooks or reference materials as subject to regulation. Apps that distribute educational materials for patients or provide suggestions regarding general health and wellness are not included. The same is true for mobile apps that help with general office operations such as billing, appointments, medical claims, business accounting, medical reminders, or insurance reimbursements.[22]

The types of mobile devices it seeks to regulate include the following:

- "use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart,"
- "use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself (e.g., microphone and speaker) to electronically amplify and 'project sounds associated with the heart, arteries and veins and other internal organs,'"
- use sensors to measure "physiological parameters during cardiopulmonary resuscitation," "analyze eye movements for use in the diagnosis of balance disorders,"
- use sensors that examine "degree of tremor caused by certain diseases," "electrical activity of the brain," "blood oxygen saturation," or "blood glucose levels,"
- "connecting to an existing device type for purposes of controlling its operation, function, or energy source," or
- "transform a mobile platform into a regulated "display, transfer, store, or convert patient-specific medical device data from a connected device."[23]

Finally, there were a variety of mobile apps for which the FDA said it would exercise "enforcement discretion (meaning it will not enforce requirements under the Federal Drug & Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers."[24] This included things such as the following:

- devices that "provide periodic educational information, reminders, or motivational guidance to smokers trying to quit,"
- devices that "use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms," or
- "mobile apps that use video and video games to motivate patients to do their physical therapy,"
- mobile apps "that aggregate and display trends in personal health incidents."[25]

Recommendations for Future Action

Mobile technology offers interesting ways to help with health care access, affordability and service delivery. Through mobile applications, sensors, remote monitoring devices, and reference materials, there are numerous avenues through which health care delivery can be improved. Invention is a big part of this ecosystem because it is hard to build new hardware or construct software applications without a broader environment that encourages and rewards inventiveness.

In order to encourage mobile health, we recommend several actions designed to improve the adoption of mobile medical devices and applications. Policymakers should encourage the use of mobile devices for health care. Smartphones and tablets have spread rapidly in developed and developing nations, and this represents a major opportunity to transform the manner in which medical care is delivered. Moving to electronic systems for service delivery will save money, improve access, and provide higher levels of quality.

Chronic diseases are a costly part of the current system. Nearly three-quarters of medical expenditures takes place on a small number of chronic illnesses. They include cardiovascular disease, cancer, diabetes, and asthma. We should encourage the use of mobile systems that monitor patient symptoms and provide real-time advice on treatment and medication because they have the potential to control costs, reduce errors, and improve patients' experiences.

There now are mobile applications that aid in chronic disease management, sensors and remote devices that monitor patient physiology, and electronic libraries that bring the latest knowledge to health providers around the globe. These materials represent a quantum leap forward in offering quality health care. We should work to remove barriers to adoption and make these tools much more widely available.

The same is true for clinical decision support for health care providers. With growing knowledge about diseases, genetics, and pharmaceutical products, the practice of medicine has become far more complicated. Physicians are expected to know the latest advances in medicine and apply that information to their patients. Software that helps health providers understand how to deal with particular symptoms and what drug interactions they should avoid are increasingly being viewed more like a reference library than a medical device, calling into question how they should be regulated. Health providers need access to as much accurate data as they can get on how to treat various ailments.

In addition, one of the barriers to cost containment and quality service delivery has been the continued reliance in many locales on paper-based medical systems. Physicians prescribe medicine through manual forms, lab tests are reported on paper or film, medical records are stored in filing cabinets, and insurance claims get paid through reimbursement requests sent through the mail. In a digital world, one cannot imagine a costlier way to run a health care system.

On the issue of government regulation, the FDA has finalized its guidance on how mobile applications and regulated mobile medical devices are to be treated in an effort to clarify some of the ambiguities and help further innovation. Having clear rules that encourage desirable behavior is the best way to move forward in mobile health.

Conclusion

In short, many countries including the United States are challenged to provide adequate health care. Difficulties include physical distance between doctors and patients, too few skilled health care professionals and the extraordinary complexity between insular medical systems and costs of health care equipment and infrastructure. In addition, the current epidemic of chronic illnesses, in both developed and developing economies, illustrates the need for innovative, efficient, technology-supported interventions.

Mobile technologies offer the ability to connect patients with their doctors, care-givers and loved ones and enable timely health monitoring which suggests improved patient engagement and better health outcomes. Mobile technology can aid in providing access to information, helping to lower costs, facilitating remote care and increasing efficiencies by connecting patients to their providers virtually anywhere. Mobile health applications and services are becoming an essential tool in extending health care resources around the world.

Endnotes

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