Mobile Health Application Solutions

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The tsunami of digital technology tools and solutions has revolutionized how the global population communicates and consumes. Social behavior, new business models, and on-demand access to information have converged to drive expectations of how to best provide services in the digital age.

In the United States, the Affordable Care Act and widespread adoption of the electronic medical record (EMR) provide the medical consumer with new financial accountability, the ability to access and digitally transfer medical information and to engage in their medical care in ways that were previously not possible. The impact on the American physician is equally profound and brings both unprecedented scrutiny into practice patterns and enforcement levers to control physician behaviors for compliance and reimbursement mandates. Most physicians recognize that active patient engagement in their healthcare improves outcomes, but many are concerned that digital patient engagement means a heavier workload and potential liability risk or payment penalties for not meeting meaningful use criteria. Physicians themselves use mobile healthcare applications (apps) mostly to access point of care tools, like risk calculators, treatment guidelines, or prescribing information. Nearly 90% of physicians report that they would recommend a mobile app to their patient but only 30% have done so, mostly because of a lack of knowledge or ability to adequately assess the quality of a medical application. Academic and nonacademic healthcare institutions often lack policies or procedures for vetting mobile health applications and do not provide support to physicians to identify applications across a spectrum of disease conditions.

Disruption of traditional health care has introduced new mechanisms for the medical consumer to access health care using digital tools in new and nontraditional venues. Large pharmacy chains, like CVS (Woonsocket, RI), Rite Aid (Camp Hill, PA), and Walgreens (Deerfield, IL), that already have contact with millions of patients daily, have created onsite health clinics and companion application solutions for their customers. Wal-Mart, Target, and other large retailers are also able to deliver medical care within their facilities. Target has partnered with Kaiser Permanente (Oakland, CA) to extend and expand the services offered in their onsite health clinics. Retailers are providing convenient care at a lower price than traditional healthcare delivery systems. Grocery store chains, like Kroger (Cincinnati, OH) and Whole Foods (Austin, TX), have health clinics or have announced they will soon offer them. These companies have robust consumer mobile health food content applications that can be easily integrated with existing health solutions. Self-insured businesses are increasingly aggressive in offering alternatives to traditional care for workers, including incentivizing workers for adopting healthy habits and other primary prevention measures that may keep them from becoming patients at all. Other than cost, other advantages that these new providers offer, compared with traditional healthcare providers, are convenience and an efficient service model. Because these providers also offer other products and services to consumers, they are enabling a cultural shift in healthcare delivery by integrating medical care into a retail service or employee experience. Many of the companion apps to these services offer consumers the opportunity to integrate the healthcare service experience with the ability to purchase other products or services from the retailer.

Global health and life insurers are also actively engaged, reaching out to their insured base with digital and nondigital tools, often enabled by wireless body worn activity sensors to motivate their subscribers to pursue health lifestyles and follow drug regimens and other secondary prevention treatments after a hospital stay. Subscribers receive benefits in the form of premium discounts and other perks for sharing information like cholesterol levels, fitness center visits and for sharing activity tracking data collected from body-worn sensors.

Medical mobile applications are an important tool for the healthcare consumer and have the capacity to host a completely virtual healthcare experience that does not require the provider or patient to be present in the same place for diagnosis, treatment, or disease management to occur. Mobile health solutions should be expected to gain dominance over other less convenient and more expensive care that is confined to provider venues for many common medical issues. The global public already has increasing expectations for on-demand services provided over mobile devices from sectors as diverse as transportation (Uber, San Francisco, CA), lodging (Airbnb, San Francisco, CA), finance (Venmo, New York, NY), food (Yelp, San Francisco, CA), and entertainment (YouTube, San Bruno, CA). For medical information, diagnostics, and care, consumer desire for these products is high with 82% of consumers stating that they are open to and interested in nontraditional healthcare services.
Mobile Ubiquity
The computing power of current generation smartphones exceeds all of NASA’s (The National Aeronautics and Space Administration) computing resources used to land astronauts on the moon in 1969 and has more capability than a year 2000 era supercomputer.\(^14\) A mobile application is a software application designed to run on a smartphone or tablet computer or other mobile device. Globally, there are >5 billion mobile phones and 60% are smartphones, meaning that they have Internet access.\(^15\) In the United States, smartphones are owned by 73% of adults.\(^15\) A recent study found that the smartphone is the only Internet connection for ≤15% of smartphone owners.\(^16\) Smartphone owners use the phone to conduct a diverse range of activities that are essential to their daily life and >60% use the phone to access health information (Figure 1).\(^16\) These devices are so integral to the tasks of daily life that 87% of smartphone users report that they could not live without their smartphone.\(^14\) The majority of smartphone users also access social networks, video and music, or podcasting from their smartphone frequently. The types of use differ by age (Figure 2).\(^16\) These data suggest that medical solutions designed for mobile delivery can be heavily featured with content, social network support, and online care providers. For those >65 years of age, with chronic medical conditions and who represent the majority of hospital admissions and healthcare spending, smartphone penetration is lower compared with patients in the 45- to 54-year age range but used increasingly in all groups (20% versus 55%).\(^17\)

Inexpensive and expensive cloud-based data storage is another enabler for the creation of robust mobile healthcare solutions. Bluetooth low energy communication enables rapid communication between smartphone applications and body-worn or implantable sensors that can provide immediate diagnostic information to patients and providers. Global positioning sensors present in smartphones also allow integration of location data into mobile applications. All of these features provide a rich tool set for creating medical mobile applications that can facilitate patient-centered medical care that is inexpensive, immediately accessible, and tailored to patient-specific needs.\(^1\) Moreover, these solutions can be scaled to provide care to a smartphone-enabled global population.\(^18\)

Apple Versus Android Platforms
Mobile applications are made available through mobile application distribution platforms called operating systems (OS). There are 3 large mobile OS that support mobile applications, Apple iOS (Apple Inc., Cupertino, CA), Android OS (Google Inc., Mountain View, CA), and Windows (Microsoft Corp., Redmond, WA).\(^19\) Apple and Android offer the most mature applications developer and store environment. For smartphones, global market share is larger for Android and is estimated at 80% versus 14% to 18% for Apple and <3% for Windows.\(^20\) However, Apple has the majority share in downloads from its App Store, estimated at >60% of all app downloads compared with Android’s 37%.\(^21\) Application developers pay no fees to Apple for hosting their apps, and Apple has a vetting process that evaluates all apps submitted for content and functionality before the release of an app to the store. If the app is not offered free of charge, the developer keeps 70% of the revenue from the application. Apple has reported that it hosts 1.4 million apps in 155 countries and has paid out $25 billion in revenue to app developers with >75 billion apps downloaded from the App Store.\(^22\) Apple devices and iOS are the preferred platform for US physicians, but Android use is growing among physicians and is estimated at 30%.\(^23\) The majority of smartphone users have >20 apps on their devices, and most are gaming and social media apps.\(^24\)

Both Apple and Android provide application developers with application program interfaces (APIs), a set of routines, protocols, and tools for building software applications. The APIs govern how the software works and interacts with the user side of the software or graphical user interface.

The ability to integrate applications so that they can communicate or integrate on a single platform requires open APIs. Closed APIs allow users to use software that has been fully developed and that does not provide source code for developers.\(^25\)

Healthcare Consumerism, Social Networks, and Patient Engagement
Smartphone users check their smart phones 150x per day.\(^16\) Leveraging that behavior for health-related engagement to optimize disease management and outcomes is going to be a critical part of healthcare management going forward. Mobile social networking, that billions of people use daily, provides the platform to engage patients and their caregivers in a continuous care conversation. The ability to asynchronously communicate optimally uses the limited time resources of physicians and provides a mechanism for communication with multiple healthcare stakeholders in one conversation.\(^26\)

Creating in-depth healthcare content, diagnostic tools and treatments using mobile platforms enable a level of continuous consumer service and engagement that does not currently exist in the traditional healthcare system. Building the right application that serves individual patients with highly specific needs, provides a continuous service model, and engages caregivers and providers is as much creative as technical
challenge. Leveraging popular uses of smartphone features, such as messaging, social networking, photo, video, and music, into medical applications has the promise of increasing the likelihood of consumer engagement and retention.27 There is also the promise of physician disintermediation from time-consuming routine tasks. Task automation enhanced by tools, such as machine learning and artificial intelligence, will help provide physicians the decision support tools needed to scale these solutions.28

Eliminating gaps in healthcare communication that are responsible for many healthcare errors is easily accomplished with commonly used mobile capability.29 For example, at the University of Southern California, we recently developed a mobile application to facilitate the outpatient care of ventricular assist device (VAD) recipients. Before developing the application, we mapped the number of caregivers and providers who are involved in the care of a single VAD patient. There are at least 6 persons surrounding the patient who requires access to critical data (1–3 family members, 1–2 referring physicians, a VAD surgeon and coordinator, a heart failure physician, and coordinator). In addition, there is the need for multiple communications between these individuals on an ongoing basis for information related to anticoagulation status, VAD driveline site issues, symptom status, and VAD performance. We created a mobile application that enables delivery of this information to the patient, caregivers, and providers related to these issues. Resources on the smartphone, including photo, text messaging, and Bluetooth low energy communication, to other connected devices, such as a scale and blood pressure cuff, were integrated into the app. All information from the app is stored on a HIPPA (Health Insurance Portability and Accountability Act) compliant data storage platform (Medable Inc., Palo Alto, CA) that can be shared to the EMR (Figure 3).30 The application will undergo clinical testing this year to assess use and the ability of the solution to prevent common VAD-related morbidities that result in a high rate of rehospitalization after implant.31 After preliminary data are obtained and if the application provides value, the app can be offered to other VAD implanting institutions. The opportunity to accelerate learning and the identification of solutions to improve workflow, communication, and to reduce national readmission rates for this costly therapy are extraordinary.32

Medications are a mainstay of chronic disease management. For patients and providers, they are often a major source of confusion, medical errors, and dissatisfaction with the
medical care delivery system. Particular areas needing better solutions include prescription renewal and clarity around medications after hospital discharge. A coherent and consistent method of communicating medication and medication adherence information to patients, caregivers, and providers is also lacking. The Walgreens mobile app, launched in 2013, provides users with medication refills that are ready within 1 hour, medication reminders, photo printing services, shopping rewards and coupons, live chat with a pharmacist, and appointment capability with an in-store Walgreens clinic. The application has >40 million users.

One powerful application launched last year by the nonprofit organization Pulsepoint (PulsePoint Foundation, Pleasanton, CA) alerts cardiopulmonary resuscitation–trained citizens that paramedics are called for a sudden cardiac arrest in their immediate vicinity. The app only alerts if the arrest occurs in a public place and provides the location of the victim so that early citizen performed cardiopulmonary resuscitation can be initiated until emergency personnel arrive in response to the initial call. This app brings cardiopulmonary resuscitation–trained individuals to actual events. It is estimated that 57% of Americans have had basic cardiopulmonary resuscitation training but only 11% have ever had to use their skills. The app has been offered nationwide and is affiliated with local emergency medical service providers. Participating Emergency Communication Centers communicate with the app through a cloud service. The app also alerts users to the location of the nearest automatic external defibrillator in their vicinity.

Mobile applications of the future will use the ubiquity of mobile and cloud computing to integrate data collected from people and the objects they encounter throughout their daily lives. This will provide a contextualized, continuous, and deeper understanding of health events. In this scenario, specialized, networked sensors attached to people and things will provide intelligence to manual processes and are deployed pervasively. Applications will provide the integrated infrastructure and notification for users. This integrated digital environment is often referred to as the Internet of Things.

FDA Regulation and Privacy

The first Food and Drug Administration (FDA) guidance document for medical mobile applications and indications for regulatory approval was issued in 2011, and the document was most recently updated in February 2015. In general, the FDA regulates those applications that meet the definition of a medical device and that pose a risk to patient safety if they do not function as intended. Medical applications that provide medical information or content are generally not required to seek regulatory approval and those that incorporate diagnostics or primary prevention disease prevention recommendations are generally subject to individualized FDA enforcement discretion.

The FDA provides lists of examples of applications that have received 510(k) clearance. Time to regulatory approval for mobile application 510(k) clearance has not proven to be a significant barrier for mobile medical app developers. Analyses have shown that compared with the overall average time to clearance for medical devices, mobile apps are approved in much shorter time intervals. In 2013, between 95% and 97% of all 510(k) submissions cleared within 1 year.

Medical Research Platforms

In May 2014, Samsung Electronics (Suwon, Gyeonggi Province, South Korea) entered the open source digital health marketplace with the release of Simband, a wrist wearable health tracking device, and Samsung Architecture for Multimodal Interactions, a cloud-based open software platform that allows app developers and researchers to access data from Simband’s built-in sensors. Embedded sensors that detect bio-impedance, heart rate, ECG, steps walked, and galvanic skin response enable health data collection. The platform API has been released to the public, but Samsung has not released apps for Simband to date.

The Apple ResearchKit was released in April 2015 and launched with 5 research studies from separate US academic institutions (Figure 4). The kit is an open source software framework for collaborative medical research that allows researchers and developers to create mobile apps exclusively for research. The platform not only allows researchers and developers to create apps but also parts of the kit can be added to apps that may already be in use. ResearchKit works with Apple’s own health application, HealthKit. HealthKit was released by Apple with the release of iOS version 8 in June 2014. HealthKit can also bring in data from motion coprocessors built into iOS devices and allows users to aggregate non-Apple health and fitness devices with compatible Bluetooth LE. Apple has created 2 separate databases to store demographic and operational data. Health data are encrypted and shared with iCloud or iTunes when the user unlocks the smartphone. Access of aggregate information is protected from the use by third party participants. To date, >900 applications have already been developed for integration with HealthKit.

ResearchKit contains 3 customizable modules to enable a clinical study: informed consent, qualitative data (surveys), and quantitative data (active tasks). Studies must be submitted with sponsoring site Institutional Review Board approval or documented exemption, and applicants must attest to the intent to publish the data. Only research institutions or companies with established research programs are eligible for submission of studies. Apps developed with ResearchKit can use sensor and coprocessors in the iPhone, such as the accelerometer (and global positioning sensors), barometer, and gyroscope. Data collected from ResearchKit studies reside in an encrypted form on the smartphone until purged to a secure data platform. It is the responsibility of the research sponsor to identify the data storage platform and to meet the needed security to store patient research data.

Mobile Medical Application Landscape

Mobile medical applications targeting patients and consumers are built and offered by a variety of traditional and retail healthcare providers, payers, pharmaceutical, and device manufacturers. Approximately 500 apps have been developed by providers, such as Kaiser Permanente and Mayo Clinic, as a
means of reaching out to patients and physicians. Goals of apps include referral facilitation and other logistical support, such as appointment management. Medical content delivery, marketing, and documentation of meaningful use requirements are other goals. These tools provide providers with a means to reach out and engage patients and physicians directly and to extend their product from a service, payment, pill, or device to a digital platform for disease prevention and management.4 Pharmaceutical companies, such as Novartis (New York, NY), Pfizer (New York, NY), GlaxoSmithKline (Middlesex, United Kingdom), Merck (Kenilworth, NJ), Sanofi (Paris, France), and others are also developing hundreds of apps to achieve greater direct patient exposure for education and tools for disease management and drug adherence, market access, and branding. Medical payers like Humana (Louisville, KY), Aetna (Hartford, CT), and Cigna (Bloomfield, CT) are investing heavily in app development to promote disease prevention and management and to provide logistical support, such as provider directories and explanation of benefits. However, the bulk of medical applications developed and released to date, numbering >150,000, have been created by mobile health (mHealth) developers for a variety of health and chronic disease management indications. Approximately 20% of mHealth app developers also sell body-worn sensors or sensors embedded in scales or blood pressure units. The main source of revenue for developers of mHealth apps is service revenues like those resulting from the ability to share a photo or scan of a fetus with friends. This contrasts to other nonmedical apps that earn revenue from in-app purchases like game enhancements.44

The rapidly growing digital wellness and disease management culture is supported by robust venture funding in digital

<table>
<thead>
<tr>
<th>App Name</th>
<th>Academic Research Institution(s)</th>
<th>Industry Partner(s)</th>
<th>Research Subject</th>
<th>Research Goal</th>
<th>iPhone Sensor Attribute(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Health</td>
<td>Mount Sinai</td>
<td>LifeMap*</td>
<td>Asthma</td>
<td>Gain greater insight into triggers for asthma; monitor symptoms, medication adherence, &amp; steps</td>
<td>Accelerometer, GPS, Weather app</td>
</tr>
<tr>
<td>mPower</td>
<td>University of Rochester</td>
<td>Sage BioNetworks†</td>
<td>Parkinson’s Disease</td>
<td>Measure data dexterity, balance, memory, and gait</td>
<td>Gyroscope, Accelerometer, GPS, Touch screen monitor, Voice recording</td>
</tr>
<tr>
<td>GlucoSuccess</td>
<td>Massachusetts’s General Hospital</td>
<td>N/A</td>
<td>Diabetes</td>
<td>Understand how diet, physical activity and medications affect blood glucose levels</td>
<td>Gyroscope, Accelerometer, GPS</td>
</tr>
<tr>
<td>Share the Journey</td>
<td>Dana-Farber Cancer Institute</td>
<td>Sage BioNetworks†</td>
<td>Breast Cancer</td>
<td>Learn long-term effects of chemotherapy used in treating breast cancer</td>
<td>Gyroscope, Accelerometer, GPS</td>
</tr>
<tr>
<td>MyHeart Counts</td>
<td>Stanford Medicine</td>
<td>University of Oxford</td>
<td>Cardiovascular Disease</td>
<td>Evaluate how activity and lifestyle relate to risks of cardiovascular disease.</td>
<td>Gyroscope, Accelerometer, GPS</td>
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* LifeMap Solutions (San Jose, CA) develops big data analytics algorithms.
† Sage BioNetworks (Seattle, WA) builds platforms and services for undertaking research.

Figure 4. Apple ResearchKit: participating centers research application summary. Information derived from Apple Inc., 2015. GPS indicates global positioning sensors.
health companies expected to exceed $4 billion in 2015, eclipsing venture investment in the traditional medical device sector. Early published data indicate that patient engagement in disease management applications can result in improvements in healthcare outcomes and hospital readmission for chronic diseases, such as coronary artery disease, heart failure, and diabetes mellitus. The ability of mobile applications to improve outcomes, enhance patient education, reduce costs, and improve patient and physician communication and experience are the areas of greatest interest to mHealth investors and developers. Although there have been >1000 apps developed for diabetes mellitus, <2% of diabetics use these apps because many apps are only compatible with more expensive glucometers than patients currently use. Remote monitoring, remote consultation, and diagnostic apps are viewed as having huge growth potential over the next 3 years.

**Wearable Sensors, Biometric Data, and Medical Applications**

Wearable sensing devices to track activity and other health metrics, like sleep and calories expended, has created a consumer health tracking and wellness culture that has been embraced by a wide demographic of Americans. It is estimated that 64 million Americans have a connected wearable device and that number is expected to increase to 130 million with the introduction of the Samsung Simband (2014) and, most recently, the Apple Watch (2015). The wrist is the most common location for body-worn sensors and will most likely be the dominate location with the introduction of the Apple Watch. The global wearable sensor market is expected to rise from 17 million device shipments to 187 million units annually by 2020 (Figures 4 and 5). Use of consumer body-worn sensors in hospitalized and recently discharged patients after cardiac surgery has been studied, and sensor activity data pre and post discharge has been shown to predict readmission to the hospital. Sensors used after myocardial infarction, as a means to extend and promote cardiac rehabilitation activity regimens, have also been proven effective. One recent study found that the accuracy of step counts, that is, used to derive other metrics like calories expended, was highly accurate for smartphone-based sensors and a good approximation for most, but not all, wrist-worn sensors.

Accompanying mobile applications provide users with continuously updated information about activity and sleep and often provide additional content about benefits of exercise and a supportive social community, also tracking their health. Most sensors capable of obtaining heart rate are optical and calculate heart rate from frequency measures. The error of these devices, particularly at high heart rates, can be as high as 68%. Most recently, Google announced that they have developed a medical grade sensor wrist wearable that will monitor ECG and activity and ambient environmental conditions. The intended purpose of the device is to provide value to clinicians by providing contextualized, continuous medical grade diagnostic sensors and decision support.

Much of the hardware and validation data supporting sensor-derived biometrics have been developed for elite athletes. In elite athletics, wireless body-worn sensors collect heart rate, skin temperature, respiratory rate, body position and movement, deriving measures like peak oxygen consumption, heart rate variability, and body mechanics are currently in use. Body position and gravitational forces on the body can be accurately measured from body-worn sensors. In addition, the National Basketball Association and National Football League have the ability to track all movement during game play and derive biometrics from motion sensor data. The National Basketball Association, the National Football League, and many elite soccer clubs worldwide use some or all of these sensors, but rules and practices vary as to how they are used for in game play versus training. Athletic clothing is now embedded with electromyography sensors that provide real-time feedback on muscle group activity and is being used for training and to assess and guide recovery from injury. All of these commercially approved sensors have potential applicability and use for chronic disease management and rehabilitation. Sensors that assess head injury and cumulative head trauma are commercially approved for athletic use and have been built into helmets and mouth guards.
Wireless diagnostic ECG can be recorded from a number of body-worn athletic sensors on the chest or upper torso. In addition, there are several FDA-approved patch sensors that can monitor real-time ECG, thoracic impedance, and activity. These have been studied to manage chronic diseases, and several have a companion application. The AliveCor (San Francisco, CA) smartphone enabled ECG, provides the user with the ability to collect and save a 30 s, Lead I ECG by touching 2 sensors attached or adjacent to the phone. The saved ECG is then stored in a secure cloud and available for download. The application also provides FDA-approved diagnostic algorithms for ECG interpretation, including the diagnosis of atrial fibrillation. The ability to record ECG on-demand has proven use for the public, athletic screening, and patients with known heart disease and has been shown to detect atrial fibrillation in patients without a history of arrhythmia when used in large-scale screening.

Proteus Digital Health (Redwood City, CA) has created a new sensor-enabled model for medication and healthcare management. The company hosts a disease management system that is triggered by an ingestible sensor that is integrated into a single pill or encapsulated with a mult drug regimen. When the pill is ingested, the sensor emits a signal that is detected by a body-worn patch that can be worn for up to a week. The patch also has microelectromechanical system sensors that track activity, respiratory rate, temperature, and ECG. The application allows for patients, clinicians, and patient identified caregivers to view medication compliance and activity data daily through an accompanying app. The system also allows for integration of other important metrics, such as weight and blood pressure, from Bluetooth LE devices. The system was FDA approved in 2012 and is currently being used in the United States to manage chronic diseases, such as heart failure, hypertension, and psychiatric disorders (Figure 6). The Proteus system has the potential to significantly affect avoidable costs incurred in patient non-adherence to medical therapies, estimated to account for $105 billion annually in the United States alone.

The same Proteus Digital Health patch sensor that measures medication compliance is also purposed in a separate athletic application (Proteus Recover). In this scenario, athletes’ heart rate and body position are used to indirectly assess sleep quality and athletic recovery. It is currently being used to measure athletes’ recovery status in between game or practice play. The patch also assesses subjective symptoms of fatigue and symptoms in between athletic events. The software app reports a recovery score that is used by athletes and trainers. This example of an FDA-approved medical sensor used for an athletic application speaks to the versatility of sensors and applications and the ability of these technologies to provide value across patient and consumer groups. Another biometric monitoring patch, initially developed and marketed for athletic, military, and emergency medical service monitoring, was subsequently FDA approved for patient monitoring (Zephyr Technologies, Annapolis, MD). Zephyr Technologies was acquired by Covidien, Ltd (Dublin, Ireland) in May 2014. Subsequently, in January 2015, Covidien was acquired by Medtronic Inc. (Dublin, Ireland). The opportunity for non-regulated and highly regulated companies to leverage body worn or implantable sensors across patient and consumer communities for different use cases, defined by the software offering, is considerable. Also, the opportunity to gain further understanding, through analysis of the large elite athletic data sets, into the mechanism of and risk factors for sudden cardiac death is significant.

Implantable Devices and Mobile Applications

Most cardiac rhythm management companies have applications that physicians and device technicians can access to track their patients with pacemakers and implantable cardioverter-defibrillators that are enrolled in remote patient management programs. All current generation cardiac rhythm management devices are capable of remote transmission but ≤50% of physicians do not refer their patients to remote follow-up after implant, despite robust data indicating that patient outcomes are improved. This percentage may increase as a result of recently updated guidelines recommending remote management for all implanted patients. Patient applications and web portals, if they exist at all, provide limited information to patients. This has been a source of consternation within the cardiac rhythm management patient community that has demanded full access to their device data. Newer pacemakers and implantable cardioverter-defibrillators have Bluetooth LE transmission capability that will create a straightforward way to share device data to patient-centered applications. As all cardiac rhythm management companies have built secure data platforms to receive remotely transmitted implanted device data, there is the opportunity to expand these platforms and include patient facing software applications. Services, such as medication or activity trackers or reminders, access to medical content or a broader patient community could be made available and have been developed as demonstration projects and clinical trials. The main impediment to progress in building these platforms had been uncertainty and inexperience on the part of device manufacturers as to how to provide a meaningful, compliant, and valuable digital tool for patients and physicians. Many companies are also hesitant to reach directly to patients with device data and services because they feel that are at risk of alienating their physician customer base.

The new generation of implantable hemodynamic sensors for management of heart failure provides web- and app-based data to physicians to allow for physician-directed patient self-management of remotely transmitted intracardiac pressures. The LAPTOP (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) trial provided heart failure patients with direct access to their left atrial pressure readings and a daily fixed and flexible prescription as to what heart failure medications to take based on left atrial pressures. This trial was terminated before completion, but clinical outcome tracking for primary end point assessment continued until study closure in April 2015. The results of the trial are pending. The FDA-approved CardioMEMS pulmonary artery pressure sensing device provides daily pressures to physicians via an application, but does not provide data to patients directly.
Assessing Applications for Patient Use

Providing a prescription for a mobile app solution for a patient is a daunting task, given the large number of mobile medical applications in the Apple App store and the commercial availability of >1000 wearable devices. There are several new companies that provide an end-to-end solution for physicians to assist them in recommending the right app to the right patient. One company, IMS Health (Danbury, CT), vets apps based on 6 criteria that include physician and patient ratings, app functionality, professional organization endorsement, developer ratings, and clinical use data. A score is developed that rates the app to help guide physicians. Prescribing physicians can then manage and view their app prescriptions, and patient use through the IMS Health AppScript application. Most companies in this area also offer or plan to offer a consumer version of their service.

Over two-thirds of consumer healthcare apps provide medical information aimed to inform users. These applications have no other functionality, such as instruction, recording ability, guidance, alerts, or other communication functions. Examples include those apps that provide information about sleep or accompany baby monitors. The vast majority target women’s or children’s health apps, and most women’s health apps relate to pregnancy. Only 10% of consumer medial apps are reviewed by an external source.

Electronic Medical Record Integration

Most US medical centers have or will soon implement an EMR because of the Affordable Care Act mandates and financial subsidies totaling nearly 27 billion dollars. The EMR market is dominated by 10 major vendors and most offer an application for physicians and patients. There is still much uncertainty about how competitive the EMR vendors will be in providing applications that serve patients and physicians and how they will accept data from other applications. Ease of integration will also depend on whether or not specific apps have open APIs.

Data Platforms and Analytics

Mobile applications, whether stand-alone or in association with a sensor, generate huge amounts of data. Providing secure data platforms and analytic support is critical to assure patient privacy and scalability. Because mobile application content...
can be easily changed, there is also an enormous opportunity to create versions that better suit patient and physician needs and to do so with great efficiency. Partnerships with data analytic experts to accomplish these ends are not only critical to the learning cycle of use but also to providing close looped systems and decision support tools that do not require physician mitigation. Ideally, the analytics should be exception-based, concise summaries that augment the physicians’ and the patients’ knowledge base, allowing both to practice and live more efficiently and deliver care at a reduced cost. Many new digital health companies are being created to provide data analytic support to medical companies and providers, but few provide decision support via mobile tools. Recent announcements of partnerships between EMR vendors, data analytic companies (like IBM), and device makers have been publicized and are expected to grow.⁹¹

App Enabled Virtual Health Care

The major technological, economic, and cultural forces that are motivating global populations to have a greater awareness and take a more active role in their health or that of a loved one are converging on the service-oriented platform of mobile applications resident on mobile devices. There are several new companies that focus on providing patients with applications that support on-demand content and live physician advice and disease management.⁹²–⁹⁵

The use of virtual humans agents, extensively studied in the treatment of post-traumatic stress disorder in returning military personnel, have shown to be as effective or superior to clinicians in their ability to retrieve quality information from subjects.⁹⁶ Virtual characters can be programmed to provide healthcare services. Virtual human agents are also attractive in that they can be customized for the user and are indifferent to the location of the user. Virtual agents deliver consistent information and demeanor and can benefit from machine learning to become better at providing medical information. Recently, the author has created her own virtual character by processing the patients’ knowledge base, allowing both to practice and disease management.⁹²–⁹⁵

Conclusions

Most medical apps are consumer focused and provide information or medical content but possess little functionality. Medical apps that possess functionality tend to target women’s health and behavior. Apps that manage chronic conditions and include diagnostic sensors require regulatory approval for disease management and represent <10% of all apps. New application platforms for conducting large-scale research projects can integrate sensor data and attributes of the smart phone (global positioning sensors, activity tracking, video, photo, and touch screen features) are now available to the medical academic community. These features may prove critically important to maintain patient adherence to digital medical care platforms. Digital medical application platforms that aggregate multiple app APIs and sensors and provide decision support, and patient engagement tools are critical to widespread use and benefit. Medical applications have enormous potential to solve multiple problems for healthcare providers and patients. Current efforts to assess and rate medical application content and quality are underway, and these efforts can provide physicians and patients with standardized direction as to what apps to select. Physicians can work with the developer community to target those conditions that have greatest need for digital support and use of digital tools that can reach patients anywhere, anytime. Essential to the long-term success and growth of virtual management solutions for chronic disease include the ability to analyze large amounts of data, provide artificial intelligence, and machine learning to provide decision support. The global mHealth app market is expected to grow to over $26 billion by 2017. Although this only represents 0.5% of global healthcare spending, estimated at $6 trillion, the potential reach of these solutions to provide and augment current global healthcare delivery is staggering.⁹⁴

Disclosures

Dr Saxon has stock ownership in Medable Inc. and Proteus Digital Health.

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Is Healthcare Ready for Empowered and Digitally Demanding Patients?


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