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mHealth

Transforming Healthcare

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Introduction

This book defines the phenomenon of mHealth and its evolution, explaining why an understanding of mHealth is critical for decision makers, entrepreneurs, and policy analysts who are pivotal to developing products that meet the collaborative health information needs of consumers and providers in a competitive and rapidly-changing environment. This book examines trends in mHealth and discusses how mHealth technologies offer opportunities for innovators and entrepreneurs, those who often are industry first-movers with regard to technology advancement.

This book is relevant to administrators of hospitals and other inpatient facilities, physician practice personnel (both clinicians and managers), insurers and regulators, and other industry thought-leaders who are attempting to engage consumers in reducing costs and improving the health care encounter. This book is valuable to physicians and other clinicians, to patients and caregivers, to application developers and sales vendors—to all individuals who find their healthcare relationships, business or care-based, mediated by technology.

This book explores the changing dynamics and relationships among physicians, patients, insurers, regulators, managers, administrators, caregivers, and others involved in the delivery of health services. The primary focus is on the ways in which mHealth technologies are revising and reshaping healthcare delivery systems in the USA and globally, and how those changes are expected to change the ways in which the business of healthcare is conducted.

Technology-based business "solutions" emerge at an increasing rate, each touted as providing more value than the previous iteration, but few actually achieve the promoted outcomes. Consumers, whether they are technology-savvy business people or the general public, are beginning to view most technology products as transient. A "new and improved" version is always on the horizon. Thus, for staying power, a technology solution must evolve and continue to meet the changing needs and desires of the user. Our major point of discussion in this book addresses whether mHealth is a transient group of products and a passing patient encounter approach, or if it is the way much of our health care will be delivered in future years with incremental evolution to achieve sustainable innovation of health technologies.

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Overview

Introduction

"mHealth is the biggest technology breakthrough of our time [being used] to address our greatest national challenge," said US Health and Human Services Secretary, Kathleen Sibelius, in her keynote address at the 2011 mHealth summit held in the Washington DC area (Levy 2012, p. 3). Worldwide, the technology underlying mHealth and its potential to deliver information that can improve an individual's health as well as counter some health system shortcomings have moved from intriguing "apps" to a serious spot on the health-care agenda. With mHealth, the health-care industry is expected to transform into one that is personalized, participatory, preventive, and less expensive. This transformation is expected to have global implications as well—industry reports suggest that emerging markets are showing incredible strength and growth with mHealth (Levy 2012; West 2012).

Despite the increasing publicity hype, health-care consumers and providers do not have enough actionable information about mHealth to inform strategic utilization of mHealth products. mHealth has received little attention from academic researchers, and little to no efficacy testing of individual products or suites of products. Most "objective" information about mHealth is found in reports from various foundations, consultants, and private research firms. Unfortunately, much of what we read about mHealth in the public press is anecdotal or publicity hype, or is offered as speculative assessment. Nevertheless, Ms. Sebelius is correct in her assessment that mHealth is a big deal.

Although mHealth's trajectory along the "hype curve" may not yet have reached the maturity level of sustained productivity, as with the Internet, it is likely destined to become a ubiquitous entity in the near future. The technology hype curve shown in Fig. 1.1 is frequently used to illustrate the evolution of a new technology innovation over time, and may be applied to products and applications alike. The point at which the innovation is judged to be sustainably productive coincides to a great extent with achieving the majority of product users (Fenn and Raskino 2008; Levy 2012).

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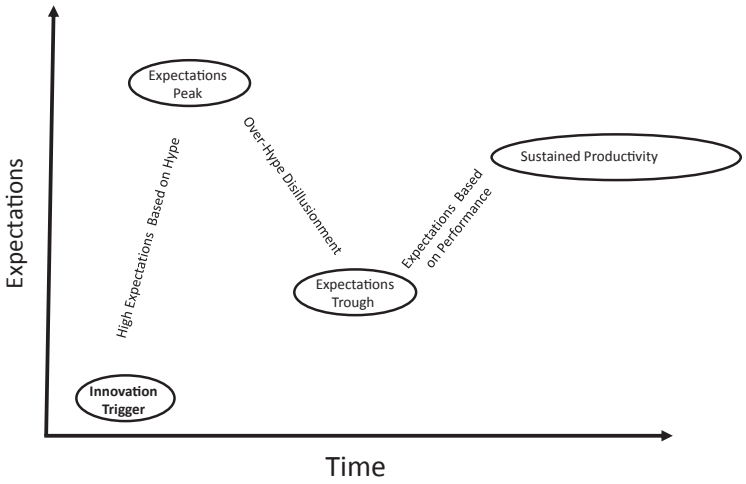

Fig. 1.1 Hype effect in emerging technology. (Adapted from Fenn and Raskino 2008. *Mastering the Hype Cycle*)

mHealth as a Transformative Agent

mHealth, may indeed, be discovered to have the power to transform key segments of the health-care industry, notably primary care and chronic care management. Further, it may be a pivotal force in improving the patient experience by engaging the patient in self-care to an extent not previously possible. The engaging questions related to the long-term sustainability of mHealth as a viable mode of health-care delivery will address the speed and scope of technology adoption, product life cycles, market competition, and even the fickleness of the end user, among many other topics.

Transformative agents can initiate both disruptive changes, those which upend institutions and processes and are highly visible to observers, and incremental changes, which often go unnoticed until cumulative events create a sufficient enabling impact that drives transformation. Sometimes small, seemingly insignificant changes can lead to other changes that enable substantial change. Conversely, sometimes disruptive changes overpromise and do not yield meaningful results. In China, for example, the ability to book medical appointments by mobile phone has led to huge efficiency gains, and the PatientLink program in Tianjin offers rural patients access to medical professionals. Even though neither of these changes on their own constitutes transformative change, they are producing cumulative effects that may ultimately transform segments of the Chinese health-care system (Levy 2012).

What is mHealth? Why is it Important?

Within the past decade in health care, we have seen the emergence of a phenomenon referred to as mobile health or mHealth. There is no standard or accepted definition for the parameters of the "health" component of the concept, but it is generally viewed as a driving force in transforming health-care delivery, making some elements of health care faster, better, more accessible, and cheaper (Levy 2012). But what exactly is mHealth? For this book, we have adopted as a working definition one offered by the American Health Information Management Association (AHIMA). AHIMA defines mHealth (mobile health) as:

> "the use of devices such as smartphones or tablets in the practice of medicine, and the downloading of health-related applications or 'apps' … [to] help with the flow of information over a mobile network and … improve communication," specifically between individuals and clinicians. (Source: AHIMA Guide 2013)

While we believe this definition offers a suitably comprehensive framework for examination and evaluation of such elements as product design and utility, provider acceptance, and data management, we recognize that with its focus on communication with a physician or other clinician, this definition fails to acknowledge the important role that mHealth applications play in self-care and self-management of health issues and the resulting information that is not intended to be reported to the individual's physician.

What are the drivers of mHealth aside from opportunities provided by the technology itself? Perhaps the most important driver in health care today is the aging population, especially in developed countries such as the USA. This trend has multiple consequences, including the increased incidence of chronic disease that requires continual care rather than episodic care. Mobile technologies offer the potential for managing noncritical care within the community, reducing the need for hospitalization, decreasing the cost of care, and improving the patient's quality of life (Norris et al. 2009).

The Mobile Phenomenon

Today, we live in a world in which mobile technology is ubiquitous. "Mobile" simply means that we no longer depend on hardwired connections to access and use computer systems, communication devices, and information resources. We can use smartphones, tablets, and other handheld devices to access information and communications anywhere, at any time for business, personal, or health reasons. We can watch a movie, order a latte, and get driving directions to a distant site—simultaneously if we choose—at any time of day or night. Many children and teens have never seen a landline phone with an attached handset and cannot imagine a world without wireless connectivity and continuous access to the Internet. Today's world is all they know; for them, history is a first-generation iPhone. And, because technology

enables us, we are connected to everyone, regardless of where they reside, whether across the street or across the globe. The world is literally at our fingertips.

When did the world become mobile in the current sense? We have lived with cell phones, or wireless telephones, since the 1980s. In 2007, Steve Jobs introduced a game changer, or pivot point, for mobile technology—Apple's iPhone. The iPhone was a "smartphone"—that is, a mobile phone with computer features. It was easy to use and reliable, and connected the user to the Internet, other computers, and large databases—and most importantly, it was highly portable and relatively inexpensive. With the smartphone, the consumer gained enhanced *mobility.* Consumers like mobility. They can have what they want when they want it—no plugs attached! And the fact that the smartphone was affordable meant that mobility was within the reach of the average person. The *sexy* aspect of the phone, its seductive multitouch screen computer interface, made it fun to use, too, which attracted the attention of young people (The Guardian 2010; Panzarino 2012). Interestingly, in the USA we refer to mobile phones as our *cell* or *cell phone,* focusing on the communication feature, whereas in European countries they reference the salient user feature of the device, referring to it as their *mobile*.

It is estimated that there are six billion mobile phones in use worldwide (International Telecommunication Union 2012), an amazing number considering that the total population is cited as approximately 7.1 billion (U.S. Department of Commerce). The number of mobile phones is expected to increase even more dramatically within the next few years, thereby ensuring a steady supply of users of mobile applications, likely including mHealth products. Mobile device sales in the USA alone are expected to grow from 172 million in 2009 to 215 million in 2015, a 25% increase (Zimmerman et al. 2012). And, revenue from mobile data usage is expected to increase from US $ 35 billion in 2008 to US $ 180 billion in 2016, a dramatic 514% increase (Verma et al. 2012). Trend analyses project there will be 1.4 mobile devices per capita by 2016 (Cisco 2012). It is a good thing to have two hands!

However, despite this rapid growth in both users and available devices, not everyone recognized this transformative shift to smaller, more mobile technology as a stable trend. While early adopters of technology innovations were abandoning their laptops for smaller mobile devices and were downloading apps especially designed for small touch screens, some users and vendors remained committed to large screen convenience. Facebook founder and CEO Mark Zuckerberg admitted, "It's probably one of the biggest mistakes we've ever made." Six years after Facebook was founded, it had no wireless strategy and it had yet to embrace the apps culture. However, by December 2011, Facebook was reorganized to embed mobile engineers in all product teams. They retooled their development processes, embraced apps, and set a priority of becoming a mobile company (Hempel 2013b).

The Pew Internet & American Life Project conducts survey research in the area of mHealth, producing several reports documenting mobile phone users and usage among US adults. Their findings identified that fully 85% of US adults own a cell phone. Of those, 53% owned smartphones, and half of those smartphone owners use their devices to get health information. And, 20% of smartphone users have

Table 1.1 Types of health apps used and % of users (N=254). (Source: Pew Internet/CHCF Health Survey, August 7–September 6, 2012; reported in Fox and Duggan 2012)

Type of app used	Percent of users
Exercise, fitness, pedometer, or heart rate monitoring	38
Diet, food, calorie counter	31
Weight	12
Menstrual or period cycles	7
Blood pressure	5
WebMD	4
Pregnancy	3
Blood sugar or diabetes	2
Medication management (tracking/alerts, etc.)	2
Mood	Less than 1
Sleep	Less than 1
Other	14

health apps on their phones. As reported by this study, the most popular types of health apps are used to monitor exercise, diet, and weight (Fox and Duggan 2012).

In earlier research, Pew reported 17% of cell phone owners had used their phones to look for health advice, but by 2012, that number had almost doubled the previous figure to 31%. Furthermore, nearly all demographic groups surveyed reported significant increases in this activity, with the exception of those over 65 and those who did not complete high school (Fox 2010; Fox and Duggan 2012).

Types of health apps and purported usage have been identified by researchers according to what the app users are tracking. As Table 1.1 shows and is affirmed in the literature, health, exercise, and diet are among the most used. In light of the incidence of diabetes, estimated by the Centers for Disease Control at approximately 7.7 per 1000 in 2011, we find the low number of users of blood sugar or diabetes monitoring apps particularly interesting. The number of medication management app users seems surprisingly low as well, as chronic disease management is primarily pharmaceutical.

Owning a smartphone rather than another type of mobile phone clearly makes a difference. Among smartphone owners, 52% gather health information on their phones, compared with only 6% of non-smartphone owners. Cell phone owners who are Latino, African-American, between the ages of 18 and 49 years, or hold a college degree are also more likely to gather health information via their phones (Fox and Duggan 2012).

Mobile technology has expanded our expectations and available options, and has significantly changed the way we search for information, pay for products, and relate to friends and retailers alike. However, the technology has yet to bring serious innovation to health-care delivery models to date. That statement may become false in the aftermath of the Affordable Care Act (ACA), which is poised to power an information technology transformation in health care in order to achieve goals of efficiency, convenience, affordability, and quality.

Even though it is quite reasonable to assume that mobile devices will be an important component of the technology solutions deployed, serious challenges to the proposed transformation must be acknowledged. The US health-care system is fragmented, disconnected, inefficient, and inaccessible for many individuals because of their personal income or geographic location. Furthermore, health care is a complex industry in which service delivery and business models are increasingly challenged by conflicting incentives, cost constraints, and assertive payers and consumers seeking value and satisfaction from their encounters. Whether robust technology will be sufficient to overcome such obstacles is truly an important issue.

The Emergence of the Apps Culture

As mobile technology has grown, so have the development of apps and the emergence of an "apps" culture. This trend demonstrates a shift from using voice communication devices to mobile computing devices. Fully 59% of US adults are currently mobile Internet users; that is, they access the Internet wirelessly using a laptop, tablet, or cell phone. As mobile computing and Internet use become the new normal mode, cell phones are being used more and more for the work previously done on laptops and desktop computers. Furthermore, cell phones represent the only source of accessing the Internet and participating in online activities for many low-income and nonwhite adults (Purcell et al. 2010). Federal programs such as Lifeline Assistance offer financial assistance to purchase and maintain cell phone service contracts to these categories of adults. Recent research has revealed that mobile technologies are often used at much higher rates within communities of color. Meanwhile, as the technology continues to evolve, policymakers, clinicians, and academics appear to be lagging further behind in assessing the potential effects of mobile technologies on reducing racial disparities and improving health outcomes (Martin 2012).

What is an app? As with the abstract concept of mHealth, there is also no standard definition for the term "app." Accordingly, we have adopted the definition provided in the 2010 report *The Rise of Apps Culture* as "end-user software applications that are designed for a cell phone operating system and which extend the phone's capabilities by enabling users to perform particular tasks" (Purcell et al. 2010, p. 9). Cell phone "apps" are distinct from cell phone "functions," which are hardware-enabled activities such as taking pictures and recording video that run on systems software. Apps are an important component of mHealth, but currently, the majority of apps are primarily used for purposes of entertainment. Children as young as 3 or 4 can be observed to be engaged with their parents' cell phones, either playing simple games or watching videos. Using computer devices as a toy is not limited to children; adults, even older adults, enjoy the many game and entertainment options available. The higher value of apps lies in maximizing the host devices as a tool (Purcell et al. 2010).

Increasingly, many adults in the USA expect and in some cases actually need their phones, especially in the case of low-income adults and those who live in remote or rural locations, to have more functionality and capability than was possible prior to the "smart" generation of phones. Trying to figure out who app users are appears to be complicated by a variety of factors such as social media use, as well as use of the Internet and other mobile technologies and devices. In fact, not all adult cell phone users are aware that activities they perform on their phones are actually app enabled. What has been established, however, is that there is a strong correlation between app use and a variety of online activities, cell phone activities, and technology use in general (Purcell et al. 2010, p. 19).

A 2010 Tracking Survey conducted by the Pew Research Center's Internet & American Life Project, which included 1917 US adults with cell phones, revealed that only 29% have personally downloaded or installed an app to their phone, while 38% have purchased a phone with preloaded apps. In terms of "active" app use, only 24% of US adults describe themselves as active app users. Overall, the survey showed that while apps are popular among a segment of cell phone owners, a notable number of cell phone owners are not yet part of the emerging apps culture. One in ten adults with a cell phone, about 11%, is not even sure if their phone is equipped with apps. In particular, many older adult cell phone users apparently do not even use the apps that were preinstalled on their phones. Clearly, having apps and using apps are not the same thing. Of those who have apps on their phones, only about two thirds of this group actually uses them. Taking pictures and texting are far and away the most popular non-voice cell phone data uses, with more than seven in ten adult cell phone users embracing these features on their phones (Purcell et al. 2010). Based on our earlier definitions, these actions are powered by computer functions, not separate applications.

Overall, mobile app users are younger, more educated, and more affluent than other cell phone users or the adult population as a whole. App users have a distinct demographic profile when compared with other cell phone-using adults and when compared with the entire US population of adults. App users skew male, and are much younger than the broader population. The app-using population also skews slightly Hispanic when compared with other cell phone users and adults (Purcell et al. 2010).

The mobile applications industry is responsible for an estimated 466,000 US jobs and US $ 20 billion in annual revenue (Rockwell 2013). Because app development for health care has not yet reached a mature stage compared with the popular apps used for entertainment, shopping, banking, and games, health-care apps represent opportunities for innovators and entrepreneurs. Even though costs for developing an application can range from relatively low-cost to significant investment—estimates range from US $ 8000 to more than US$ 100,000—it can be quite challenging to monetize that application. Most users are not willing to spend much on apps, and mobile advertising has not proved to be lucrative (Rockwell 2013). In addition, there are web sites such as ibuildapp.com that enable users to develop a variety of apps for personal, business, and health—at no charge—for their mobile devices.

There are some widely recognized apps with large markets such Blue Button, used by the Veterans Health Administration (VHA). Blue Button is touted as driving a patient-centered revolution in health care because it offers the consumer the ability to download their personal health data and take control of their own health and health-care decisions (Downs 2011). With more than six million downloads, iTriage, a product offered by Aetna, one of the nation's largest health insurers, is one of the most consistently popular health apps in Apple's iPhone App Store. iTriage allows the consumer to do research on a variety of health conditions, find local practitioners, and learn more about their medications (Hempel 2013a). But there are also niche market and social media apps such as PatientsLikeMe where patients, caregivers, and others can join a community of people to both gain and share information about particular diseases (Bradley 2013).

Challenges, Limitations, and Barriers to Diffusion of mHealth

Even though mHealth has the potential to transform health care in domains ranging from service delivery to patient care to reimbursement systems to global outsourcing of both clinical and financial services, it faces serious limitations. For example, there are no proven business models to guide entrepreneurs and investors, and little evidence of monetization. Furthermore, we do not know if consumers want and will use mHealth technologies, or if vendor hype is driving observations and speculation at this point. In fact, the increase in the number of US adults who had ever downloaded a health app for their phones has been shown to be insignificant (Levy 2012). There is also no evidence of efficacy; we do not know if mHealth is effective on a large scale.

Perhaps what is more worrisome are the high dropout rates that suggest weakness in the market for health apps. "Dropout" means that the app is deleted from the phone or other mobile device because the user no longer wants it. Research has revealed high percentages of dropouts for health wellness or fitness apps (Levy 2012). Drew Sievers, CEO of mFoundry, the company that helped Starbucks develop its popular mobile app, believes that consumers can become overwhelmed by the technology and confused into doing nothing (Helft 2012). This may well be the case with health consumers and with providers and health professionals as well.

Difficulties also arise from the fact that the health-care industry has a long history of resisting disruptive change. In fact, health care is viewed as among the most entrenched and change-averse industries in the USA (Christensen et al. 2007). The culture is conservative, and the core driver of health-care culture is physicians. Physicians remain a powerful stakeholder, and they uphold the status quo and exhibit resistance to change. For example, about 62 % of physicians do not use email with their patients. Furthermore, the time it takes for a significant health-care innovation to become standard clinical practice is on average 17 years, illustrating the impact of physician resistance to changes in practice behaviors (Winslow 2013).

Health care traditionally has not been an early adopter of information technologies. Computers were first used in hospitals for financial applications such as billing, and not in conjunction with clinical services until many years later. There are several reasons for this late adoption, including a perceived lack of benefit at the point of care, the expense of IT projects, and past failures (Norris et al. 2009).

Despite hospitals' laggard approach to allocating capital for information technology, medical technology innovation has historically been a very important factor in the delivery of health-care services. In fact, the development of health technologies such as X-rays had transformed hospitals into modern scientific institutions by 1910, where surgeries were performed and patients were cared for using scientific principles. Physicians gained authority over the patient and the practice of medicine in large part because of their control of technology. Physicians' orders were required by the patient in order to gain access to diagnostic testing such as X-rays and laboratory work or to use hospital facilities for such testing and for surgeries (Starr 1982).

However, 100 years later, the situation has radically changed. Clinical technologies continue to advance the practice of medicine and clinical workflows, but it is the health information technologies that have dramatically affected patients, physicians, nurses, and other clinicians the most. Indeed, during the past 20 years, much of the information previously communicated on paper has gone electronic such as orders, diagnoses, test results, and consultation notes from a variety of providers. The method of electronic communication has continued to evolve as we moved from mainframe and minicomputer systems to networked computers, and more recently to mobile as smartphones, tablets, and other wireless devices are increasingly used in health-care organizations (HCOs).

Diffusion of mHealth is viewed as a challenge in part because it is believed that physicians will not use mHealth tools and apps if they are not reimbursed for doing so. This is intuitive from a historical perspective and even reflects recent trends in which physicians began to adopt electronic health records at a faster rate after government subsidies were provided to incentivize their adoption. Survey research also suggests the possibility that physicians' lack of support of mobile health may have less to do with reimbursement and more to do with issues of patient empowerment, that is, patients taking on responsibility and accountability for their health and care. Physician resistance to the disruption of their traditional authoritative roles in health care as reported shows that 42 % of physicians surveyed worry that mHealth will make their patients too independent of them. Only 27 % of physicians reported encouraging patients to use mHealth applications in order to become more active in managing their health with 13 % actively discouraging the use of mHealth applications. And, among younger physicians with less than 5 years of experience, 24 % of this cohort were actively discouraging patients from using mHealth applications to manage their own health (Levy 2012).

While further examination of such information is essential for the future of mHealth diffusion, it also signals a potential power struggle for control over patients. The physician's greatest source of power over the years has been their relationship with the patient. Physicians used the relationship to escape corporate control and to retain professional independence and authority (Starr 1982). Even

though their control has waned in recent years, especially with the emergence of the ACA and a trend toward practice consolidation and hospital-based employment of physicians, physicians still remain incredibly powerful. Patient empowerment and self-care enabled by mHealth represent enormous challenges to physician authority. Whether physicians will ultimately agree to embrace such changes is unknown. What we do know is that technology such as mHealth ultimately may serve as an equalizer and shift some control over health care to the consumer. For the consumer, acceptability of the technology, especially with respect to consumer empowerment and convenience, probably will help patients overcome their concerns and lower resistance to use.

The diffusion of mobile health technologies begins with the experts and enthusiasts who widely promote and communicate to others the benefits of use. This group is followed by proactive early adopters. As their experience spreads news of success and satisfaction, late adopters will follow. Consumers are more likely to adopt mHealth technologies if the application improves on their existing technology. If the application enhances convenience, expands the capabilities, or reduces health-care costs, it is more likely to be adopted (Norris et al. 2009).

How can we assess diffusion of mHealth? One indicator might be looking at the written policies of HCOs. According to the Amcom Software Survey (2012), there was little evidence of mHealth documentation. Key findings from this survey included the following:

- Of the facilities surveyed, 34.1 % have a written policy.
- Thirty-one percent had a policy under development.
- Twenty-two percent reported using a verbal policy.
- Thirty-seven percent had no plans to implement a mobile strategy.
- Reasons cited for lack of a documented strategy include lack of awareness, not a high priority, or no one to take a leadership role.

Ethical issues surrounding the electronic storage and transmission of private health-care data and the potential for misuse have not been discussed in detail, but are likely to emerge once exchanging personal health data becomes routine. Similarly, issues such as Bring Your Own Device (BYOD), whereby clinicians and other health-care workers are encouraged to bring their own mobile devices to work, probably will gain future attention. It has been suggested that BYOD is a facilitator in that physicians are more likely to use technology they are familiar with and use on a regular basis. There are also system cost savings projected if the facility does not have to pay for the cost of mobile devices for employees. But there are drawbacks to BYOD, including security challenges and problems with integration if types of device are not standard among users (Intel White Paper 2013). In addition, what about infection control if mobile devices travel freely outside the facility with individual employees?

Both doctors and payers list privacy and security concerns as leading barriers to greater use of mHealth, and only around half of doctors believe that mobile Internet facilities at their workplace are reasonably secure. Only 53 % of doctors reported that the mHealth applications and services they use personally work with

their organizations' information technology. Even fewer say that they are integrated with technology in other parts of the health system. As noted previously, culture is perceived as a formidable barrier for implementation**.** In fact, 27% of doctors and 26% of payers cite a conservative culture as a leading barrier to diffusing mHealth (Levy 2012).

Meanwhile, government regulation is emerging that may discourage or at least slow down mHealth innovation. Providers and payers search for measures of mHealth to assess productivity and evaluate the true productivity or cost impact and return on their investments. Thus, there is a critical need to examine the topic of mHealth to determine whether it will lead to transforming health care or it will leave the marketplace at a standstill.

Currently, mHealth is fragmented and disconnected much like the US healthcare system itself, which is greatly in need of transformational change. Because mHealth is occurring in a piecemeal fashion, with incompatible applications or apps that serve narrow interests and reflect little coordinated development, there is a need for collaboration and integration in developing apps and other mHealth tools (Estrin and Sim 2010; Chen et al. 2012). The call for and support of the development of mHealth open architecture by the Robert Wood Johnson Foundation and others offer the promise of a more collective and expansive approach toward mHealth product development. mHealth has the potential to transform health care globally and to expand public health surveillance beyond the USA so that pandemics and other health issues of global significance can be addressed holistically and managed successfully. But to do so, mHealth must avoid further fragmentation and focus more on collaborative integration.

High Hopes and Some Realities

Expectations run high for mHealth, both within the USA and globally. A recent global study showed that roughly 50% of patients reported their belief that mHealth would improve the convenience, cost, and quality of their health care in the next 3 years. Six in ten doctors and payers surveyed have expectations for widespread adoption of mHealth in their countries in the near future. But experts interviewed for the study predicted that mHealth adoption would be slowed by strong resistance to change from powerful stakeholders such as physicians (Levy 2012).

Even with the growth of mobile and online opportunities, most adults continue to search for health information by turning to a health professional, friend, or family member when they have a health question. The Internet plays a growing but still supplemental role for most people to seek access to health information. Mobile connectivity has not changed that (Fox 2010). Studies have shown that consumer literacy skills, including reading ability, limit their capacity to use online health information. In addition, the online materials are often too complex, poorly written, or contain too much medical jargon (Agarawal et al. 2013; Tu 2011). The mHealth transformation must deal with such challenges in order to advance.

In today's US culture, transparency is a given, that is, except in health care. And this recognition is critically important in the evolution of mHealth. To move beyond the development of diet or exercise apps, which have yet to capture sustainable market share, developers must figure out how to assure privacy and security. One of the foremost experts in the area of wireless technology in the delivery of health care, Eric Topol, M.D., believes that the future of mHealth lies with digitized medicine. Biosensors will assess physiologic metrics such as blood pressure and glucose levels and transmit them wireless through smartphones to physicians who will gain a more comprehensive view of the patient and use this information to more effectively assess and manage the patient's care But currently, there is a chasm between the world of available technology and the clinical practice of medicine, and physicians continue to maintain the status quo (Winslow 2013).

Topol also expects that consumers will be the drivers of mHealth, and will use the power of social networks to bring about significant change (Winslow 2013). Support for this prediction is found in niche social networks such as PatientsLikeMe. Patients with serious diseases and their caregivers use this site for help and information that they are not getting from mainstream medical care. Such social networks tell their members that their data will be shared, and members do not mind sharing because they perceive a benefit to them in doing so that outweighs their fear of exposure. But whether larger social platforms such as Google or Facebook can gain the trust of members when it comes to assuring privacy of personal health data remains to be seen (Bradley 2013; Kuratis 2011).

In the USA, health care is big business, representing 18% of gross domestic product (GDP). Increased productivity gains from mHealth are predicted to save as much as US $ 305 billion over the next 10 years due to reduced travel time and expenses, faster and improved communications and decision-making, and other improvements. Remote monitoring alone is expected to save close to US $ 200 billion over the next 25 years by managing chronic diseases in the USA (Levy 2012). However, these predictions are just that—predictions. No one has yet developed a robust and reliable business model that shows how to make mHealth a successful venture on a large and sustainable scale. There is a great need for knowledge and insight about mHealth so that insurers, entrepreneurs, app developers, the government, and others who have vested interests in both making and saving money can move mHealth along the transformation trajectory. Table 1.2 summarizes the knowledge needs of various key stakeholders in making mHealth a sustainable mode of healthcare delivery.

Conclusions

Is mHealth a hyper-innovation or a hyped innovation? There is a lot of activity, but much of it seems to be unfocused and little time or effort appears to be invested in strategic planning. According to survey research, providers often lack goals, plans, budgets, business drivers, or leadership for their mHealth initiatives (Medullan

Table 1.2 mHealth information stakeholders

Stakeholder	Information needs
Consumer/patient	Understand the technological shift to mobile and that even though shopping has been revolutionized by the technology; health care is more complicated and has additional challenges of privacy and security. Examine a variety of current mHealth apps and consider how mHealth can empower patients, save money, time, and improve health outcomes and patient satisfaction. Examine the trend toward self-care and patient's role in app development
Health-care providers/ physicians and other clinicians	The technological shift to mobile has the potential to upend the patient's relationships with providers, especially physicians. Recognition that the interaction with the patient does not end with the payment of the fee or discharge document. Instead, it is continuous. Identify how mHealth can help providers do their work more efficiently and enhance quality outcomes and patient satisfaction
Health-care providers/ institutions (hospitals, physician practices, urgent care, and retail clinics)	Recognize the trend toward self-care, which is further enabled by mHealth. Identify mHealth strategies that facilitate in managing the patient as an asset across an integrated network and in directing patients to the most appropriate source of care at the right time and most affordable price. Identify incentives for clinicians and patients
Health-care executives/ CEOs, CIOs, and other top management	Understand the impact of the technological shift to mobile. Identify security, privacy, infection control, and other challenges to implementing mHealth strategies. Recognize the limitations of BYOD programs. Understand what truly motivates clinicians and patients to adopt mHealth and how mHealth can be used to achieve goals of ROI, efficiency, patient satisfaction, and health outcomes
Insurers/payers	Who will pay matters. Right now, payers are key drivers in using mHealth to achieve efficiencies, lower administrative costs, improve customer service, and assure quality outcomes. This book will affirm their important role and direct insurers/payers toward opportunities to "mobilize" patients and providers and create strategies to meet challenges, including regulations, in adopting mHealth strategies
Innovators, entrepreneurs, and app developers	Gain greater insight about mHealth and its transformative potential. See beyond the technology to the end user of the product and the implications of self-care for a variety of key stakeholders, including payers. Understand that health care has complexities, including workflows and clinical requirements Identify key drivers and barriers and challenges of monetization and business models, and the limits of development of mobile health apps that exhibit no proof of concept and undergo no pilot testing. Understand the role of games for app development
Politicians and policymakers	Understand the implications of the technological shift to mHealth and its potential role in achieving health reform goals and in transforming health care in the USA and globally. Create reimbursement mechanisms to assist in diffusion of mHealth. Work to eliminate barriers. Fund mHealth research efforts and encourage collaboration with key stakeholders

Table 1.2 (continued)

Stakeholder	Information needs
Academic researchers	Identify areas of mHealth research and potential collaborators and granting sources to fund such research. Integrate mHealth into the teaching of both undergraduate and undergraduate courses
Health professions educators	Assure that health professionals are equipped with skills to succeed in the mobile age and beyond. Design and offer training for students, alumni, and community partners who need to gain access to mobile technologies. Work with the private sector to assure relevancy of training programs

2012; Shaw 2012). But those who want to succeed in mHealth have to perform their due diligence if they are to understand the big picture, especially knowing what matters to the end user. The challenge of mHealth will be even greater for innovators because the improvements that mHealth can bring, such as patient-centric care and a greater focus on prevention, will involve disruption in how health care is provided.

Consumers have high expectations for how things should work in the mobile world. Most consumers are comfortable using their mobile phones for shopping, checking in at the airport, and online banking. They have an expectation that their personal devices should work with minimal effort. If they do not, they go elsewhere (Slabodkin 2013). In health care, consumer expectations reflect the impact of the mobile world. Mobile technology has upended an 1850s' premise on which health care has been based: that service delivery must occur in a face-to-face setting (Dishman 2011). Mobile technology is also revising consumer expectations for the patient–physician relationship. For over 100 years, the patient's relationship with the physician was transactional; it ended when the bill was paid (Flexner 1910). But now, that relationship is moving toward one that is continuous and is characterized by real-time, virtual service delivery.

The following vignette illustrates a possible future for mHealth. Whether this future materializes is dependent on a variety of factors, including satisfying key stakeholders that have the potential to delay or obstruct transformative change. As discussed in this chapter, health care is more complicated than shopping and as such requires technologies that offer connectivity, interoperability, and integration of information all the while assuring the end user of security and privacy.

The physician walks into the examining room with a smartphone in one pocket and a tablet in the other. She pulls up laboratory results on the tablet with its larger and clearer interactive touch screen. She switches windows to look at the results of the pathology report, including photos of the tumor and the specialist's notes and recommendations. The physician begins to discuss various options with the patient, who is using his smartphone to email his wife with the news of diagnosis while simultaneously recording the physician's explanation and instructions. He will play these back later. The physician meanwhile sends her staff a request to schedule a follow-up appointment for the patient and to check her schedule for openings for

surgery. The physician leaves the room and ducks into her office. There she pulls out her smartphone and begins to use Dragon, a voice transcription program, to dictate her notes and complete the electronic health record for the patient.

mHealth has the potential to address four key aspects of health care: (1) prevention: public health and lifestyle awareness; (2) monitoring: pre-disease screening and assessment; (3) treatment: providing efficient and effective care; and (4) support: for patients along with caregivers. In addition, mHealth has the possibility to address both clinical and business applications as well as enable a variety of telemedicine efforts to collect and share patient data with clinicians (Norris et al. 2009).

Over the past 20 years, increasingly sophisticated mobile technology has transformed how people communicate, do business, and engage in their social environment. The immediate future offers exciting promise for this industry, as health care is viewed as one of the top three fields likely to drive mobile device growth over the next 5 years (Greenspun and Coughlin 2012). And, a strong majority of consumers surveyed (74%) seem receptive to new models of mobile service delivery, such as virtual physician visits (Cisco Press Release 2013). Sustainable innovation and adoption of mHealth technologies not only has the power to transform the healthcare experience in the USA but also can drive expansion beyond the US borders to create new global health-care markets.

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Chapter 2
From Telemedicine to Telehealth to eHealth: Where Does mHealth Fit?

Overview

Diabetes, high blood pressure (BP), and other chronic diseases can cut years from a person's life and reduce the quality of life during those years. Sadly, despite the state of our medical knowledge, these diseases are on the increase in the USA, fueled by the growing obesity epidemic among children. Treatment for chronic diseases accounts for a significant portion of our health-care dollars and has hidden costs to individuals and to the system. Chronic care is by definition long term, often lifelong, and often involves complex self-care protocols that are difficult and time consuming for patients, especially children and the elderly, to follow. Because the consequences of changes in relevant health markers can be life threatening in some chronic illnesses, the supervision of self-care by a trained clinician is essential. For example, a rise in blood glucose for a diabetic can signal the need for additional insulin. If the insulin is not administered in time, the person can become unable to deliver the needed treatment independently. Remote monitoring, tracking health data from afar, can help doctors and nurses intervene when needed to save lives, prevent hospitalization, and decrease costs associated with inpatient care.

When the field of telemedicine (literally, "medicine at a distance") emerged more than 40 years ago, it was principally focused on providing diagnostic and health monitoring services to patients living in remote or rural areas. Early telemedicine programs were predominantly hospital-based, and telemedicine effectively expanded the market area it served and increased referrals to the sponsoring hospital. The most widely used data transmission technology at that time was hard-wired telephone lines, with some opportunities for video interfaces. For patients, the greatest benefits of early telemedicine programs were reduced travel time and costs, and access to specialist consultation services not available locally. Technology innovations supporting high-speed communications and more robust computer processing coupled with reform initiatives have enabled the migration of telemedicine over the past decade to a mainstream health-care delivery mode supporting a broader array of health-care services and benefits for both providers and individuals (Galewitz 2012; Brown 2013). Data from a *Hospital & Health Networks* survey has shown

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that 70 % of the "most wired" US hospitals offer some form of telehealth (Jackson 2011; Page 2011).

Currently, there are two drivers for the rapid expansion and adoption of computer-based health-care products and services—the availability of affordable technology and the changing health-care delivery environment. Since the necessary technology has been available for some time, why has technology alone been insufficient to drive significant industry changes? The short answer is "money." Prior to health-care reform, there was little financial incentive for providers to develop telemedicine beyond its basic remote monitoring programs unless it served a specific organization strategic goal. But money is a powerful motivator in health care. Newly implemented readmission penalties for providers serving Medicare and Medicaid patients are expected to drive hospitals to develop telehealth programs that monitor and manage postdischarge treatment to prevent unplanned readmissions. And, as health-care delivery is distributed more fully along the continuum of providers and facilities, these applications will diffuse more broadly as well.

As this chapter will show, remote monitoring of important health indicators such as BP and blood glucose and transmission of relevant information are key elements of telemedicine services that can be well met by mHealth apps. Current technology makes this type of monitoring easier and more convenient than early systems and expands the process from one-way information transmission to information exchange between patient and provider. mHealth products will help to transform telemedicine from a provider-driven tool serving selected patient populations to one that facilitates patient engagement and empowerment across the continuum of health-care services.

What Is Telemedicine?

For this book, we will rely on a modification of the definition developed by the American Telemedicine Association (ATA), which defines telemedicine as

> the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology (ATA website).

When the term "telemedicine" entered our vocabulary several decades ago, the health-care industry operated very much in a medical model of "sick care," and the concept was used to describe information transmitted for diagnosis or treatment of specific conditions. As our medical model has grown more inclusive of managing health as well as managing disease treatment, the term "telehealth" has emerged and the terms are used interchangeably, just as we use medicine and health in our daily language. The distinction is not precise; both refer in general to using telecommunication devices to transmit information related to health care. As our focus is explaining how mHealth applications can extend and add value to information and services delivered through telecommunication devices and computers, we prefer

Table 2.1 Services provided via telehealth. (Source: American Telemedicine Association website www.americantelemed.org/)

Service	Description
Primary care and specialist referral services	May involve a primary care or allied health professional providing a consultation with a patient or a specialist assisting the primary care physician in rendering a diagnosis. This may involve the use of live interactive video or the use of store-and-forward transmission of diagnostic images, vital signs, and/or video clips along with patient data for later review
Remote patient monitoring, including home telehealth	Uses devices to remotely collect and send data to a home health agency or a remote diagnostic testing facility (RDTF) for interpretation. Such applications might include a specific vital sign, such as blood glucose or heart ECG or a variety of indicators for homebound patients. Such services can be used to supplement the use of visiting nurses
Consumer medical and health information	Includes the use of the Internet and wireless devices for consumers to obtain specialized health information and online discussion groups to provide peer-to-peer support
Medical education	Provides continuing medical education credits for health professionals and special medical education seminars for targeted groups in remote locations

the "telehealth" label. Thus, we propose to modify the ATA definition as *the use of information exchanged from one site to another via electronic communications to monitor, maintain, or improve an individual's health status*.

The ATA website, http://www.americantelemed.org/learn, lists an array of services considered telehealth that include transmission of published health information, continuing medical education programming, patient portals, and call centers for real-time clinician consultations. The services typically provided using a telehealth model fall into four broad categories. Table 2.1 lists and describes each of the four categories.

So many information-based services are labeled telehealth by virtue of the digital transmission factor that it is necessary to make the distinction that the technology itself, while a necessary element, does not constitute a telehealth application. Generally speaking, health information technology (HIT) enables telehealth, which is the actual delivery of a health-related service from one site to another site remote from the first.

In addition to categorizing the types of services provided, the ATA has classified the most commonly used design models for telehealth programs. *Networked programs* link tertiary care hospitals and clinics with outlying clinics and community health centers in rural or suburban areas. The links may use dedicated high-speed lines or the Internet for inter-site communication links. The ATA estimates

the number of existing telemedicine networks in the USA at about 200, providing connectivity to more than 3000 sites.

Point-to-point connections use private high-speed networks. This type of system is used by hospitals and clinics that deliver services directly or that outsource specialty services to independent medical service providers. Examples of outsourced services include radiology, stroke assessment, mental health, and intensive care services. *Monitoring center links* are the model of choice for cardiac, pulmonary, or fetal monitoring and for care and services provided to patients in their home. Often regular landline telephones or wireless connections are used to communicate directly between the patient and the center although some systems use the Internet. *Web-based e-health patient service sites* provide direct consumer outreach and services over the Internet. Under telemedicine, these include those sites that provide direct patient care.

Impact of Health-Care Reform: The Affordable Care Act (ACA)

The market for remote monitoring technology, especially for home telehealth care and disease management, is predicted to reach US $ 295 million by 2015. And, as the market for telemedicine grows, it is expected to shift away from traditional services toward consumer-focused products, too. Some experts anticipate that growth will also occur in remote monitoring of intensive care units (ICUs). The eICU is seen as a viable way to reduce costs and respond to physician and nurse shortages associated with staffing ICUs 24/7 (Caramenico 2012). However, these applications can be costly—eICU units can cost US $ 6–8 million to establish, not including staff salaries.

The ACA creates a variety of financial incentives for hospitals with Medicare patients to use remote monitoring. For example, patients with chronic diseases such as congestive heart failure (CHF) are expected to increase significantly, especially with the trend toward an aging population, and facilities with extensive inpatient stays and readmissions are being penalized by new reimbursement programs. Thus, the ability to remotely measure the patient's weight, BP, and oxygen levels to monitor changes and ultimately reduce or avoid hospital admissions becomes a driver for hospitals under ACA incentives (Lowes 2013).

Mario Gutierrez, executive director of the Center for Connected Health (CCH) Policy, suggests that the ACA is creating the "perfect storm" for expansion of telehealth as a delivery mode. In his opinion, expanded insurance coverage will increase service demand to an extent that cost control will require virtual patient engagement (Bowman 2013).

Telehealth Research

Research in the early telemedicine era had a strong focus on cost effectiveness and patient satisfaction, and results were inconsistent among studies. Generally speaking, clinical outcomes differed among the various programs as did cost savings,

and patients typically based "satisfaction" on the ease of use and personal time and money savings. Using the *Journal of Telemedicine and Telecare* as an industry indicator, the volume of research on patient satisfaction appears to have declined in recent years. Possibly, the pervasiveness of computers in an individual's work and personal life make computer-assisted health care more acceptable and satisfaction is a less relevant concept than when the technology was unfamiliar to many people. Conversely, the number and variety of applications seems to be increasing. Again, the pervasiveness of computers in business and society, and the advent of mobile computing, are easy explanators for this observation. Research topic trends aside, robust research offers important information to guide product development and to establish care protocols.

The Whole System Demonstrator (WSD) program, sponsored by Britain's Department of Health, is the largest randomized control trial of telehealth and telecare in the world. The intent of the study was to quantify the impact of telehealth to inform investment decisions in programs that could enable people to live independently and to take control and be responsible for their own health and personal care. Data collected for this study showed that remote monitoring decreased patient deaths by 45 %, reduced emergency visits by 15 %, and reduced associated costs for health-care services. As a result of these findings, Britain's Department of Health embarked on a project known as 3 Million Lives to install remote monitoring devices in the homes of 3 million patients (Britain's Department of Health 2011).

A Swedish study found that mobile phones provide a fast and safe method of reporting pain postoperatively in real time. This finding is important because early pain management is a key factor in treating postoperative pain to prevent postoperative emergency department visits and also in reducing the risk of developing a chronic pain syndrome that can affect the quality of life and prove costly in recurrent treatment. However, because the study sample was small (37 participants), further studies are required to better inform policy (Stomberg et al. 2012).

A recent telehealth study found that 7 % of US physicians are using videoconferencing chats with patients, and they use them more often for routine follow-up visits than for urgent care or acute care conditions. This approach is less costly and more convenient for patients, which leads to improved patient satisfaction with the overall encounter. It is also a clear shift toward using telehealth technology for the convenience of local patients, in contrast to the earlier model of providing specialty services to remote patients. The study also found that psychiatrists and oncologists are more likely to use video chats than other physician specialties (Manhattan Research 2011). In these specialty areas, the need for quick response to patient needs may be a key driver over convenience.

According to a 2013 study, follow-up telephone calls to postambulatory surgery patients can safely substitute and be as effective as face-to-face visits in selected low-risk cases. From the patient perspective, this telehealth approach decreased travel time and expense while improving patient satisfaction. From the provider perspective, the telehealth calls freed up time in clinics to see new patients (Hwa and Wren 2013).

Because less than 50% of patients with high BP in the USA have their BP under control, telehealth represents a practical and cost-effective method to improve BP management for these patients. A 12-month study conducted by researchers at HealthPartners Research Foundation in Minnesota used home telemonitoring combined with actual pharmacist case management via phone conversations to improve BP management. Home BP monitoring, in which patients routinely measure and transmit their BP measurements, was found to improve patient satisfaction too. Home monitoring offers advantages over face-to-face traditional office visits in which misclassifications often result from white-coat hypertension, a situation where the patient's BP increases simply because it is being measured in a clinical setting, which causes anxiety in some patients (Margolis et al. 2013).

Studies of telemonitoring interventions for patients with chronic diseases have increased within the past decade. Moreover, the evidence produced by these studies has become more and more important to a wide range of policy makers, clinicians, insurers, and other key health-care stakeholders. Despite the importance of this research, little formal assessment of these studies in the aggregate has been conducted. One recent study of methodological quality calls into question the research methods used. There appeared to be a lack of scientific rigor used in evaluating the claims of reduced costs and improved quality for home telemonitoring (Kitsiou et al. 2013).

The VA Story

A total of 289 hospitals made the *Hospitals & Health Networks* 15th annual "most wired" list, including the Veterans Administration (VA) hospital network. Moreover, the VA, which is the nation's largest health delivery system, with 152 medical centers and 1400 outpatient clinics and other facilities, was recognized for taking technology "beyond the four walls of the hospital" and for ambitiously using telemedicine to assure that veterans get care as close to home as possible, and often at home (Weinstock 2013).

So far, the biggest use of telemedicine has been by the military and the VA (Baum 2012). In fact, the VA has used home telehealth services to manage chronic conditions at an unprecedented scale when compared with other health services organizations (Broderick and Lindeman 2013). And, the VA uses aggressive approaches to increase the number of veterans who benefit, such as the Federal Ruling issued on March 06, 2012 that waived co-payment charges to veterans for home video telehealth services (VA Final Ruling 2012). This exemption opens the telehealth program to all veterans, including those who previously could not afford to participate because of co-pay barriers.

The US Department of Veterans Affairs signed a 5-year, US $ 28.8 million contract with AMC Health, a New York-based provider of telehealth solutions and services. VA telehealth programs reach approximately 500,000 veterans and are expected to extend that number to 800,000 by the end of 2013. A total of 1.3 million consults were reported for 2012. AMC Health represents an outcomes-based approach to telehealth that aligns with the VA's telehealth goal to actively engage

patients so they proactively self-manage chronic conditions (AMC Press Release 2013). In addition, the VA is committed financially to expanding its telehealth programs into other areas, including palliative care and dementia care. In April 2011, the VA awarded US $ 1.38 billion in national contracts for home telehealth devices and services over a 5-year period. Well over 90,000 veterans were expected to enroll in its home telehealth program by the end of 2012 (Broderick 2013b).

The VA's commitment to telemedicine is long-standing. Since the 1990s, information and communications technologies, including telehealth, have been at the center of system-level transformation to furnish continuous, coordinated, and comprehensive primary and specialty care for its veteran population. The VA Office of Telehealth Services houses a program called Care Coordination Home Telehealth (CCHT), established in 2003 targeting chronic conditions such as diabetes and hypertension and posttraumatic stress disorder (PTSD). CCHT uses remote monitoring devices in veterans' homes to communicate health status and to capture and transmit biometric data, which is monitored remotely by care coordinators, who are usually nurses or social workers, but can also include physicians, pharmacists, dieticians, and occupational therapists (Broderick 2013b).

Promising results from program efforts have been reported, including reduced hospital admissions and high rates of patient satisfaction. Decreases in health resource utilization were largest in highly rural settings (50.1%) and urban locations (28.2%), and patient acceptance was high, with only 10% of patients declining participation in telehealth home services (Broderick 2013b). The technologies used most in CCHT are messaging and monitoring devices (85%), videotelemonitors (11%), and videophones (4%). The messaging devices ask patients questions that assist in monitoring their health status. Monitoring devices record vital sign data. Videophones and videotelemonitors are used in audio-video home consults (Broderick 2013b).

In 2011, American Well teamed with the VA to provide online behavioral health services to patients in Minnesota and remote oncology consultations to patients in Nebraska. These types of collaborations are decreasing facility-level costs to the benefit of the system as a whole. A single VA hospital in rural Oregon saved more than US $ 88,000 in travel expenses alone during the FY 2011 by shifting 3224 patient encounters from traditional face-to-face visits to telehealth services (Cerrato 2012).

The VA has reported reductions in emergency visits and hospital admissions using remote care coordination at its Clarksburg, West Virginia hospital. About 95% of patients accessing services remotely from the Clarksburg hospital live in rural areas. Increasingly, the VA is using home monitoring for care coordination of patients diagnosed with chronic diseases such as diabetes, CHF, pulmonary disease, or hypertension, and those who are living in Ohio, Delaware, Pennsylvania, or West Virginia are monitored remotely by the Clarksburg facility. Patients routinely send readings from a device that is connected to a wired or cellular phone. A nurse monitors the submissions and makes follow-up calls to patients and a physician when readings are abnormal (Charleston Gazette 2010).

The VA's telehealth program includes home monitoring, video consults, and "store-and-forward" telehealth, which refers to the capturing of digital images, video, audio, and clinical data and storing this information on a computer or mobile device for forwarding at a convenient time to caregivers (AMC Press Release 2013).

Meeting the Needs of Rural and Underserved Populations

Telehealth has the potential to bring health-care services, especially specialty medical care consults, to rural, remote, and underserved populations in the USA. But if those populations do not have access to affordable broadband services on which mobile technology relies, how will telehealth programs fulfill these expectations? The Federal Communications Commission (FCC) established the Rural Health Care Program 16 years ago, with the goal of securing funding for broadband infrastructure and services for rural and underserved areas. To date, the FCC has fallen far short of this goal. Government oversight has criticized the FCC for lack of progress and failing to adequately develop assessment programs and measurement goals. Meanwhile, the ATA complained that the FCC annually reserves more than US $ 300 million in funds that could be used immediately to help improve Americans' access to health services and help reduce the cost of health care (Wicklund 2011). Growth markets in telemedicine include both rural and underserved areas. California became a first mover with the Telehealth Advancement Act of 2011 that expanded access to health care in rural areas and inner cities by offering more telehealth services (Telehealth 2011).

The CCH, a nonprofit division of Boston-based Partners Health care system, employed nontraditional interventions aimed specifically at altering behaviors in underserved populations. The center has primarily connected with the underserved through text messaging, mostly because of its simplicity and availability to this population group. Text messaging interventions have focused on prenatal and addiction patients. Prenatal care works well for program evaluation because start and end dates are clearly established. Seventy-two percent of women involved in prenatal programs reported feeling more connected with their OB/GYN physician and the physician practices had better show rates for appointments. The center is in the process of building apps to use for pain management (Perna 2013).

UnitedHealthcare joined with Cisco in implementing its new "Connected Care" program which connects patients in underserved areas with primary care physicians, specialists, and hospitals by using telehealth applications. Physicians conduct virtual patient examinations in real time using a two-way video screen and also interact with the patient and an on-site nurse at the point of care performing the actual medical tests (Keller 2010).

Increasingly, individuals in small rural areas are being treated by doctors and nurses using webcam-enabled telehealth. Approximately 25 % of the US population resides in rural areas that are medically underserved. Furthermore, the need for care will increase as the population ages in remote areas such as South Dakota where the

proportion of people over the age of 65 is 72% higher than in the rest of the USA and is expected to double by 2020 (Abrams 2012).

Avera Health Network, which began in 2009 with a US $ 13 million start-up grant from the Helmsley Charitable Trust, is believed to have the only long-distance critical care program in the USA and perhaps the world. The nonprofit network provides a range of telehealth services such as high-definition two-way video consulting that make it possible for experts to be available 24/7 in locations throughout the Dakotas (North & South), Minnesota, Iowa, Wyoming, and Nebraska. Four main services provided by the network include eConsult, eICU Care, eEmergency, and ePharm. As of October 2012, Avera Network, based at Avera McKennan Hospital in South Dakota, reported an 18% decrease in ambulance and helicopter transfers to major hospitals, resulting in approximately US $ 6.6 million saved and keeping health care in local communities (Abrams 2012).

Telehealth gives hospitals the opportunity to provide specialty medical care that is cost effective and convenient to rural patients. In sparsely populated western states such as Washington, travel time for specialty care at an urban medical center can take up to 10 hour round trip. In addition, telemedicine can build referral patterns for transport of critical patients. Especially important is that telemedicine services can improve clinical outcomes for discharged patients, which contributes to a hospital's effectiveness ratings and reimbursement and contributes to sustainability and growth (Page 2011).

The Business of Telehealth

In addition to the partnerships forged in meeting the needs of the rural and underserved populations, opportunities for business development and relationships exist in other health markets. The development of many personal use mobile health apps are conceptualized around the device itself such as cell phone or tablet. The question has become, *What can we do now that the consumer has a smartphone?* Meanwhile, the evolution of telemedicine represents using the mobile device as a means to solve a variety of problems, including decreasing costs, increasing access to care and services for patients, and ultimately improving the quality of care and health status. Smart clothing that integrates wearable electronic sensors into clothing is in the works for remote patient monitoring (RPM). With a smartphone, the individual often is required to manually enter the data, whereas smart clothing would track and report vital signs automatically—without needing the wearer to do anything. John Vu, CEO of Misfit Wearables, a core start-up company that looks to integrate wearable sensors into everyday clothing is realistic about the challenges of developing smart clothing, including battery life and complete invisibility. But the savvy CEO also sees the potential impact of smart clothing on remote monitoring (Farr 2013).

In 2012, Sprint launched a new gateway device with the veteran home monitoring company Ideal Life of Toronto, Canada. The product is similar to what Verizon and Qualcomm offer, a series of at-home remote monitors for BP, weight, glucose

readings, mobility, and other vital sign data. Data are collected from monitors using wireless technology and stored in a cloud database that can be accessed by physicians and caregivers. Alerts are sent when readings exceed normal ranges. Well-designed home monitoring systems make integrating remote monitoring data easier for a hospital or other care provider (Jackson 2012).

In 2011, Walgreens partnered with the IT giant Cisco to furnish telehealth and on-site clinical services for more than 40,000 Cisco employees and their family members at the company headquarters and the Cisco campus in North Carolina. Walgreens will run Cisco's LifeConnections health center, the brick-and-mortar clinic at the company's headquarters in San Jose and also provide telehealth services, including virtual physician visits, at the North Carolina campus. Both Cisco and Walgreens have previous telehealth collaborative experience. Cisco is already involved in a joint effort with the health insurer UnitedHealth Group. The two created a nationwide network to enable video medical imaging, audio communication, and health record information to be exchanged between health-care providers and patients from remote locations such as retail stores and office settings. Cisco and UnitedHealth Group successfully tested the telehealth program in a pilot study with more than 300 Cisco employees in San Jose over a 7-month period in 2009 (Mearian 2011).

Physician entrepreneurs are in the telehealth game as well. A 37-year-old cardiologist with an MBA founded Telemed Ventures and became CEO of Smart Care Doc, a telehealth business with the goal of providing affordable health care in areas underserved by providers (Baum 2012). However, most companies involved in telehealth are venture-backed start-ups. Walmart had a poor experience in their 2005–2007 efforts, and if (when) Walmart gets involved in telehealth in a big way, it will probably be with an established health-care partner. The struggles with telehealth are not unique to Walmart as many plans of the large, established insurers such as UnitedHealthCare and Blue Cross have also struggled with telehealth services (Cannon 2012). The critical question for entrepreneurs, investors, and insurers is whether pilot projects and partnerships, which can be successful at the local level, will translate effectively and profitably to a much larger national scale.

Benefits, Disadvantages, Challenges, Barriers, and Opportunities

Benefits

According to the ATA, the growth enjoyed by telehealth ventures to date has occurred because of four main drivers—access to needed services, cost savings, improved quality, and patient interest. From its inception more than 40 years ago, telehealth applications have been promoted for their ability to bring health-care services to patients in distant locations. Not only does telehealth improve access for patients but it also allows physicians and health facilities to expand their reach, beyond their own offices. Given the provider shortages throughout the world—in

both rural and urban areas—telehealth has a unique capacity to increase service to millions of new patients.

Reducing or containing the cost of health care is one of the most important reasons for funding and adopting telehealth technologies and has received as much attention in the literature. Telehealth research has shown reductions in the cost of health care and increased efficiency through better management of chronic diseases, shared health professional staffing, reduced travel times, and fewer or shorter hospital stays.

The third focus of the familiar health-care trilogy—quality—has received its own share of investigation. Studies have consistently shown that the quality of health care services delivered via telemedicine is as good those given in traditional in-person consultations. In some specialties, particularly in mental health and ICU care, telemedicine frequently delivers a superior product, with better clinical outcomes and patient satisfaction.

Finally, considering demand, it is clear that consumers want telehealth products. For the individual patient, the greatest impact of telehealth is personal—how it directly benefits the patients, their families, and their communities. Using telemedicine technologies reduces travel time and related stresses for the patient. Over the past 15 years, study after study has documented patient satisfaction and support for telehealth services. Such services offer patients the access to providers and medical services that might not be available otherwise, without the need to travel long distances (ATA website).

A major benefit of remote monitoring in particular is the potential cost savings to the system, especially as we move toward covering the previously uninsured and the growing number of seniors. Remote monitoring is especially critical in reducing readmissions, both hospital and emergency department. Dramatic decreases in hospital readmissions (75%) have been seen in a 2-year pilot program conducted with Indianapolis-based St. Vincent Health, using remote videoconferencing between nurses and discharged patients. Johns Hopkins is using remote patient training and education, including on-demand videos, streamed to patients' hand-held devices that answer patients' questions about postoperative care (Slabodkin 2012)

Technology Barriers

Currently, remote monitoring systems generally do not feed data directly into electronic health record (EHR) systems. Because of this lack of interoperability, physicians may be forced to either view and manage two separate sources of patient information or reenter remotely captured data into the EHR. However, vendors are working to eliminate this barrier (Lowes 2013).

One of the key challenges of remote monitoring is standardizing the data streams from various remote monitoring devices and systems. While most vendors provide some type of proprietary web interface for clinicians to interact with the data they collect, few clinicians have the time to learn the nuances or to log into multiple proprietary systems to view data. What clinicians require is product standardization so they can access needed data from any system on any type of device (Jackson 2012).

Challenges

Telehealth is not without challenges. Perhaps the biggest challenge is logistics; that is, arranging to have a physician or qualified individual online at the very moment a patient is ready to ask a question. There is no available pool of primary care physicians to standby because these physicians are in short supply and high demand, especially under health-care reform guidelines. Other challenges include patient acceptance, privacy and security concerns, reimbursement ambiguities, and provider liability issues (Cannon 2012). These issues have been acknowledged since the early days of telemedicine, and resolution does not appear imminent.

Do we need healing hands? The laying on of hands has been a long-standing tradition in the delivery of health care. And, there is extensive research demonstrating the value of "touch" in medicine. A simple pat on the back can calm cardiovascular stress, reduce anxiety and depression, and make the patient feel safer. But with patients who are in underserved or remote areas or who cannot afford travel costs or time off from work, in-person contact is not possible or feasible. Thus, telehealth may represent a viable alternative for them (Cerrato 2012). Dr. Eric Topol, a cardiologist and the chief academic officer for Scripps Health, a San Diego-based nonprofit health care network, acknowledges that something will be lost when most face-to-face visits with physicians are replaced by telecommunication data exchanges. However, he says that we are getting "virtual touch" rather than actual touch. While technology can create anxiety in some dimensions, it can also empower patients to assume more control and responsibility for their health (Simon 2011).

Opposition to telehealth is also coming from physicians. The promise of better service is a real threat to traditional physician practices, which often have inefficient systems that cause patient dissatisfaction. Retail clinics became tough competitors for physician practices because they offer patients convenience, including extended hours, good service quality, and lower costs. Telehealth can go beyond those benefits, helping consumers stay healthy anywhere at any time courtesy of smartphones, tablets, and PCs. Studies have shown that consumers like and often prefer virtual visits. A major study by Cisco found that fully 74 % of consumers are "open to virtual doctor visits" using technology to improve access and convenience, especially when the e-visit with an online physician is followed by a telephone or e-mail "check-in" a few days later to see how the patient is feeling (Brown 2013; Cisco Press Release 2013). When was the last time your primary care doctor or their office staff called to inquire about your status following an in-office visit?

A recent study showed that there are notable impediments blocking extensive physician use of telehealth. In particular, the major impediments include HIPAA security issues, reimbursement, and physician liability for telehealth-enabled care (Manhattan Research 2011). Some of the barriers to telemedicine have absolutely nothing to do with technology. Instead, they are about money and regulations. The single biggest impediment to the development of telemedicine is reimbursement. As with many aspects of health-care delivery, the payment policies of the public insurance programs, Medicaid and Medicare, are key drivers in the deployment and ac-

ceptance of telehealth applications nationally. Although the federal Medicaid statute does not recognize telehealth as a distinct service (Medicaid.gov website), Medicare's definition of telehealth (42 CFR 410.78) recognizes the use of interactive telecommunications, audio and video at a minimum, to improve a patient's health.

With regard to Medicaid, states have the flexibility in covering and reimbursing for telemedicine services. In general, telehealth is viewed as a cost-effective alternative to the more traditional face-to-face way of providing medical care (e.g., face-to-face consultations or examinations between provider and patient), and states have a great deal of prerogative or flexibility to determine the scope of their telehealth programs, including:

- Whether (or not) to cover telehealth at all
- What types of telehealth to cover
- Where in the state telehealth can be covered
- How telehealth is provided/covered
- What types of telehealth practitioners/providers may be covered/reimbursed, as long as such practitioners/providers are "recognized" and qualified according to Medicaid statute/regulation
- How much to reimburse for telehealth services, as long as such payments do not exceed Federal upper limits

If the state decides to cover telemedicine, but does not cover certain practitioners/providers of telehealth or if its telehealth coverage is limited to certain parts of the state, then the state is responsible for assuring access and covering face-to-face visits/examinations by these "recognized" practitioners/providers in those parts of the state where telehealth is not available (Medicaid.gov website).

Some states do not license telehealth providers, or they place restrictions on how providers interact with telehealth patients. In Maine, a telemedicine visit is billed the same way as a traditional doctor's visit, and Maine law requires private insurers to pay for telemedicine e-visits just as they would for traditional office visits (Tice 2011). However, when it comes to eICU visits, the reimbursement is not there and without reimbursement, eICU visits are proving to be financially unsustainable. However, the eICU concept, which was introduced in 2004 at Johns Hopkins, remains a viable method for many facilities to extend resources to smaller hospitals, especially in rural areas (Abrams 2012).

MaineHealth's VitalNetwork is an 8-year-old critical care monitoring platform that collects vital signs and other medical information from patients in hospital ICUs. This information is shared with eICU specialists in a "command center" in Portland who then consult with clinicians at the point of service and also interact via video connections at the patient's bedside. The network serves Maine's more remote hospital locations that do not have access to expensive resources such as ICU specialists on staff. MaineHealth announced that it will shut down its eICU service on October 1, 2013 claiming lack of reimbursement and budget constraints (Wicklund 2013b).

Some physicians question why their profession is being asked essentially to provide services over the phone for free. They point to lawyers, accountants, and others

who routinely bill for phone consultations (Cohen 2013). If you contact your lawyer by phone to obtain advice, the expectation is that the meter is running and you will receive a bill for the time spent on the phone with the lawyer. Moreover, asking physicians to provide free telephone consults may be a marketing tool for insurers rather than a method for increasing remote access (Cohen 2013).

However, there is some evidence that reimbursement for telemedicine may be changing. Virtual doctors' visits appear to be attracting large insurers and employers. An example is NowClinic online care, a subsidiary of UnitedHealth Group, which is the parent company of the largest US health insurer, UnitedHealthcare, which offers patients web and phone primary care medical services that are both inexpensive and available 24/7. NowClinic began in 2010 and currently operates in 22 states. Other large insurers such as Aetna and Cigna, as well as large employers including General Electric and Delta Airlines, are signing on. In addition, drug stores such as Rite Aid have begun using NowClinic in selected stores in Michigan and Pennsylvania because it is a less expensive option to hiring either physicians or nurses to staff store clinics (Galewitz 2012).

Legal Issues

As it becomes increasingly a more common practice for physicians to do telehealth consults, there needs to be clear guidance about specific situations that may be deemed inappropriate and subject to sanction. While the practice of telehealth may be legal as a delivery option in a given state, it does not mean that there are no restrictions that necessitate guidance to eliminate confusion among physicians (Bompey 2010). State medical boards make it difficult to practice telemedicine, especially if the care is delivered interstate. Many state boards require a prior doctor–patient relationship or even a previous medical examination, which effectively prevents telehealth from being a stand-alone option for care delivery. However, some medical boards are loosening requirements. Nine states, mostly rural, such as Tennessee, Nevada, and New Mexico have eased the process (Galewitz 2012). The Governor of Pennsylvania, Tom Corbett, has also signed legislation to expand telemedicine's use for Medicaid patients. At least 36 other states provide reimbursement for Medicaid patients (Baum 2012).

In 2011, California enacted the Telehealth Advancement Act that eliminated the need for in-person visits as a precursor to receiving telehealth services. Under previous law, telehealth providers had to have at least one in-person visit with a patient before initiating any virtual visits. They also had to obtain special written consent from the patient to allow telehealth care. The new law permits verbal consent and notification instead. In addition, the law eliminates the requirement that telehealth visits be provided in a doctor's office or hospital (Jackson 2011c).

In addition to these state-level actions, the CMS removed credentialing barriers to telemedicine. Medicare's new telehealth credentialing policy permits the hospital receiving telemedicine services to grant privileges to the telehealth physicians using information provided by the physician's home hospital. This means that the hospital

receiving the telehealth services no longer has to conduct separate credentialing investigations and approvals, both of which were time consuming and costly and put an undue burden on smaller hospitals that could not afford the vetting process (Lowes 2011).

In addition, malpractice insurance will also need to change if telemedicine is to grow. This includes permitting physicians to make treatment decisions over the phone rather than restricting physicians to phone triage. Triage services are limited to determining the time frame within which patients need to be seen in person, now versus later, and whether they should be seen at the emergency department or the physician's office (Cohen 2013).

Opportunities

Ultrawideband technology, which is not new, has the potential to expand the market for advanced remote patient care by providing continuous real-time health diagnosis. Even though the technology has been around for over a decade, it has been used mostly in military radar applications. But the capacity to transmit enormous amounts of data quickly, using little energy, could prove extremely useful for telehealth applications. A study done by Oregon State University (OSU) researchers suggests that a patient's body heat could actually provide the power for the sensors. They envision a network of tiny wireless sensors, possibly embedded in a Band-Aid or similar-sized patch, which could monitor vital signs and more. The measurements could be transmitted to a PC or smartphone. As described, this would be a noninvasive, inexpensive way to monitor risk factors and possibly prevent life-threatening events such as a heart attack. The study suggested that the product could be commercialized and made publicly available within the next few years (Jackson 2011b; OSU News Release 2011).

According to Dr. Ido Schoenberg, chairman and CEO of American Well, a well-known telehealth services vendor, and other experts, there are limitations to what can be done online—but you can do a lot (Cerrato 2012). Insurers have identified telehealth's potential for better management of their policy holders' risk factors. For example, Blue Cross Blue Shield of Louisiana and Blue Cross Blue Shield of Massachusetts joined with American Well to provide physician consultations to policyholders of those companies using iPads, iPhones, Android devices, and web-cam-equipped PCs. American Well also works with WellPoint, one of the largest US insurers. In short, insurers are eager to pilot test telehealth projects that enable better chronic disease management (Golia 2013).

WellPoint also is using the CareMore model, a coordinated care approach to caring for seniors that includes remote monitoring. WellPoint acquired CareMore, a company whose clinics serve seniors across the southwest and whose care model routinely achieves impressive patient outcomes while saving money. The CareMore model focuses on managing chronic diseases and prevention and uses telehealth applications such as wireless scales to alert clinicians to sudden weight gains that might be warning signs of dangerous fluid buildups for patients with CHF (Main and Slywotzky 2011).

Focused Collaboration

The world-renowned Joslin Diabetes Center, an affiliate of Harvard Medical School, announced that it would begin offering telehealth services nationally in conjunction with American Well. This means that countless patients will have easy access to world-class endocrinologists (Cerrato 2012). The large insurer, Humana, and Intel are working together on a pilot project to monitor vital signs of patients with CHF. Because chronic illness accounts for 75 % of health-care costs, insurers are looking for new ways to monitor high-cost patient populations. Patients use an Intel Health Guide, an electronic computer device to measure and submit their weight, BP, and other health data. Nurses with Humana track the information and interact virtually with the patients using web video, phone, and e-mail (Keller 2011).

In 2010, the California Telehealth Network (CTN) was launched with goals of increasing patient access to specialists while reducing costs and improving patient outcomes. CTN is a peer-to-peer network where providers can share X-rays and other diagnostic tests simultaneously and also view procedures and treatments from remote surgical centers and emergency rooms in real time. CTN is expected to become the largest telehealth system in the USA with approximately 850 facilities linked. Sixty percent of network providers will be rural although the network could also be used to reduce waiting times for urban patients seeking specialty care. CTN is jointly funded with US $ 30 million from the FCC, the University of California, and other private and public entities. The network is supported by AT&T, which is providing infrastructure and network services as part of a 3-year, US $ 27 million contract (Yin 2010).

AT&T also partnered with St. Joseph Health System in Orange, California to create a series of clinic-based telehealth kiosks that function as self-serve health care. The kiosks contain vital sign monitoring equipment, conferencing capability, and other information transmission functions. The kiosks are located at both physician and patient sites and can be accessed by phone (Jackson 2011a).

Outlook for Physicians

Physician support for remote diagnosis depends to some degree on their medical specialty. Primary care specialists and internists report being more optimistic about the potential for diagnosing patients virtually, especially with the quality of cameras now built into most PCs. On the other hand, specialists such as neurologists see limitations to virtual visits and consultations because of the inability to get feedback from requisite hands-on assessments, including palpation and direct testing of motor resistance and reflexes (Cohen 2013). However, the shortage of neurologists is pushing telemedicine into emergency rooms. A number of teleneurology companies offer videoconferencing equipment and emergency neurological consults for acute stroke, which is the third leading cause of death in the USA (Jenks 2010).

Seniors and Telehealth

Remote care technology has the potential to help seniors manage their care effectively and stay connected to their health-care team. Despite common perceptions that people over the age of 65 either cannot learn how to use technology or refuse to use it altogether, recent studies demonstrate that seniors are quite "tech savvy." In fact, one 9-month study showed that even the frail elderly were able to use a web-portal telehealth service (Finklestein et al. 2011). Moreover, older populations have adopted remote care technology in order to take better care of themselves (Madden and Zickuhr 2012; Older Populations 2013). Seniors may be less experienced with technology when compared with younger adults and it is recognized that the declines in perceptual, motor, and cognitive functions that come with growing older can affect their ability to use technology (Smith and Zickhur 2012). But this does not mean that new product designs and training cannot overcome such obstacles.

Recent studies report that more than half of seniors are active online, and approximately 70 % use the Internet daily. Furthermore, seniors are integrating technology into their daily lives and 40 % identify themselves being extremely to very comfortable using the Internet (Koppen 2010; Madden and Zickuhr 2012). Older adults are more likely to use technology when the perceived benefits are apparent and assist them in accomplishing goals (The SCAN Foundation Technology Summit 2010).

Thus, the opportunity for mHealth entrepreneurs and developers is to recognize that the trend of older adults using technology is expected to increase. Seniors represent an untapped market segment with growth potential, especially as the 78 million baby boomers age and continue to redefine the next decade much as they did the 1960s. Baby boomers want to stay active and healthy during their retirement years. Baby boomers use technology for accessing news, online banking, social networking, and entertainment almost twice as much as the current older generation and just as much as the young adults. Furthermore, baby boomers are also emerging as early adopters of eHealth options. They are 98 % more likely to visit health websites compared to the average Internet user. In addition, they are increasingly exposed to online health-care services at their workplace (Greying Gadgets 2009; Hesdanun 2004; Older Populations 2013). Finally, independence is a critical concern for seniors. They want to remain in their own homes, and in control of their own lives, as long as possible and remote care technologies offer the possibility that they will be able to do so.

Lessons Learned: Early Adopters

The Commonwealth Fund, a highly visible and well-known private foundation whose stated goal includes working toward a high performance health system, published case study research results for several major telehealth projects of early adopters, notably the VA, Partners Healthcare (Partners), and Centura Health at Home (CHAH). The findings of this research showed that remote patient monitoring

(RPM), including home telehealth and telemonitoring, can help improve care coordination, patient experience, and reduce hospital admissions and costs. These technologies remotely collect, track, and transmit health data from the patient, who is at home, to a provider. The technology also can be used to facilitate communication among patients and providers and engage patients in management of their own health care (Broderick and Lindeman 2013).

Partners is a large integrated health system in Boston. Partners' programs in home telehealth have been driven by its CCH, which has pilot tested and implemented telemedicine and remote monitoring solutions that have demonstrated a positive impact on patient engagement in self-care, which has resulted in improved care and clinical outcomes. In 1995, Partners established Partners Telemedicine to use consumer-ready technologies to deliver remote care. This entity evolved into CCH, which focuses on applying technologies to conditions that have clear measures of success, either in terms of clinical outcomes, such as reduced infection or mortality, or financial returns, such as cost savings or return on investment (ROI). An example is the heart failure program. The Medicare payment reductions for 30-day readmissions associated with poor heart failure outcomes translate into negative financial outcomes. Partners' Connected Cardiac Care Program (CCP), which has enrolled more than 1200 patients since its inception in 2006, connects heart failure patients to providers through remote monitoring and has seen significant reductions (50%) in heart failure hospital readmission rates. Cost savings from the program are estimated to be more than US $ 10 million (Broderick 2013a).

Meanwhile, CHAH looked to build on its success in employing telehealth in decreasing preventable readmissions by expanding its services to home-based Medicare beneficiaries. CHAH is the first home health agency in Colorado to implement a telehealth system that was based on two-way video technology supporting virtual visits for patients with a very high acuity level. In expanding efforts to include the routine monitoring of patients with chronic conditions, CHAH's traditional clinical call center was broadened to include 24/7 telephonic telehealth services staffed by RNs. This extended model enabled better continuity of care and more effective use of health-care resources. The changes permit a limited nursing staff to manage a larger number of patients on a daily basis and provided different levels of monitoring depending on patients' needs, from acute to chronic care. Successful integration of telephonic telehealth included working with vendors to select solutions that scale while meeting the broader patient population's needs (Broderick and Steinmetz 2013).

Telehealth and Transformation of the Delivery System

Is telehealth a key enabler for transforming the US health-care delivery system? Because we are living longer, the number of patients with chronic illness is growing. Caring for these patients will be costly unless technology enables new channels for delivering telehealth services. The Internet, computer tablets, smartphones, remote

monitoring, and wireless applications and devices, including wearable devices such as a wrist watch or a small bandage that can monitor patients continuously (Brown 2013), all contribute to the phenomenal technological capability in the telehealth infrastructure. Meanwhile, the telehealth growth curve has accelerated rapidly in the past few years due in large part to technological advances, more applications, and the emergence of wireless connectivity. In particular, consumer familiarity and acceptance of technology is an important part of telemedicine's accelerated progress. Reportedly, 6 billion people on the planet have access to cell phones (Brown 2013), which creates a world marketplace beyond our imaginings.

Of the health-care decision makers responding to a 2010 survey by Intel Corporation at the Annual Meeting of the ATA, 89% reported an expectation that telehealth will transform health care in the next 10 years (Intel Press Release 2010). Furthermore, they expect telehealth will have a major role in improving the quality and delivery of care to an increasingly chronically ill and aging population. In addition, clinical decision makers believe that the adoption of technology and telehealth solutions will cut costs and improve patient outcomes. Top perceived barriers to implementing telehealth solutions included third-party reimbursement for services provided and fear of technology (Intel Digital Health Survey 2010; Intel Press Release 2010). Table 2.2 highlights significant findings from the survey. Particularly noteworthy is the expectation that legislation will be needed to facilitate the expansion of telehealth in the USA.

Mobile technologies, including smartphone apps, wireless sensors, and other innovative tools, demonstrate transformative potential. The technology can not only improve diagnosis and treatment but also change the way both doctors and patients think about health care. Mobile technologies allow both patients and clinicians to monitor vital signs, note changes, and verify that medications have been taken—all without ever having a face-to-face meeting (Simon 2011).

What Is Trending in Telemedicine?

From SoloHealth's stations, slated for installation in 2500 Walmart and Sam's Club stores, to video consultations with doctors, to smartphone apps that track BP and heart rate, consumer health technology is attracting big-name backers such as retailer Walmart, health insurers Wellpoint and UnitedHealthcare, and companies that make or distribute medical products, such as Johnson & Johnson and Cardinal Health (Appleby 2013). Walmart's interest is especially significant, given the giant retailer's reach, the growth of its pharmacies and retail medical clinics, and its willingness to explore and use alternative delivery methods such as telehealth.

UCLA Health System partnered with CVS MinuteClinics, the largest national retail clinic chain with nearly 600 clinics in CVS pharmacies nationwide. UCLA physicians will serve as off-site medical directors for 11 in-store clinics in Los Angeles County. David Feinberg, president of UCLA Health System, reported that if the partnership with CVS is successful, there could be a possibility for UCLA specialists to evaluate patients remotely at a MinuteClinic. Currently, CVS MinuteClinics

Table 2.2 How health-care and IT professionals feel about telehealth. (Source: derived from Intel Digital health Telehealth in the US Health Care System Preliminary Topline Survey findings (May 2010), A phone survey conducted between April 29 and May 10, 2010 of health-care and IT professionals in the USA)

Category	Findings	Percentage
Aging population	Telehealth has the potential to be widely used among baby boomers	75%
Aging population	Perception that the US health-care industry will rely heavily on telehealth practices to address the aging population over the next 10 years	60%
Quality	Telehealth will improve health-care quality because physicians will have better access to patient data through ongoing monitoring	87%
Barriers	Reimbursement is a barrier to implementing telehealth	29%
Barriers	Fear of technology (e.g., lack of buy-in from clinical staff or concern about how patients will be able to use the technology)	20%
Advantages	Improved quality of care is the biggest perceived advantage to telehealth adoption	42%
Expectations	Telehealth is going to dramatically change the way we manage patient care in the US over the next 10 years	89%

will be referring those patients requiring specialty care or a permanent primary care physician to other local providers including those at UCLA (Terhune 2012).

Mount St. Mary's Hospital and Health Center launched the first telehealth group medical practice in the USA using the innovative "Online Care" platform. This extends access to high-quality medical services throughout Mount St. Mary's communities, including poor and vulnerable populations, and into the homes of local residents. The telehealth group medical practice will use participating doctors, associated medical providers, and their staffs for online visits, thereby giving patients the opportunity to interact with them much in the way they do in person. The Online Care practice is a collaborative effort among Mount St. Mary's, Blue Cross Blue Shield of Western New York, and Ascension Health, the nation's largest Catholic and nonprofit health system, of which Mount St. Mary's is a member. Online Care is a telehealth service provided by Blue Cross Blue Shield and powered by American Well™ technology (Jacobs 2011).

Conclusions

This chapter describes the evolution of telemedicine from a provider-driven tool to an enabler of patient engagement and empowerment. Telemedicine began in the USA more than 40 years ago with goals of extending access to individuals living in remote and rural areas. Rural providers would send X-rays and other tests to specialists and hospitals and communicate using technology, including satellite and video transmission. There were financial challenges, both related to reimbursement and

the cost of providing the service. And, there were licensure issues, especially when physicians were diagnosing and treating patients across state lines. Meanwhile, the technology has advanced, and the cost of telemedicine services has declined with the advent of digital communication and the emergence of mobile computing. And health-care reform is expected to move more care online to expand access and reduce costs.

While we now are capable of delivering telehealth services anywhere, we are not doing so in large volume because we have not figured out how to pay for it through insurance, and we have not produced new business models to support development (Brown 2013). Most health-care experts are in agreement that telehealth represents great potential for improving patient access and reducing labor costs, especially in rural and remote areas where there are physician shortages, particularly specialists (Cannon 2012).

Because of the trend toward adoption of mobile products and services, telehealth has become a part of the evolving self-care revolution. Examples of this include the unmanned self-service health kiosks, developed by SoloHealth with planned deployment in 2500 Walmart stores. As Americans gain insurance coverage under the federal health law, thereby putting increased demand on primary care doctors and spurring interest in cheaper, more convenient care, more examples will emerge. When an additional 30 (or 40?) million Americans get in line for a doctor's appointment, consumers may look to alternatives such as retail clinics located in Walgreens, CVS, or Walmart to get their checkups. In California, our largest state, an estimated 4 million additional people will receive health coverage under the ACA (Appleby 2013).

Are mHealth and telehealth becoming obsolete concepts? It looks that way to Jonah Czerwinski, senior advisor to the Secretary of the US Department of Veterans Affairs and who also serves as leader of the VA Center for Innovation. Even though the two terms are clearly popular in health care, Mr. Czerwinski believes that wireless connectivity is rapidly becoming the *new normal* for health care and that "connected" health care is emerging as the standard of health care for the VA (Wicklund 2013a).

Or is it a case that telehealth is becoming so commonplace that it is actually accepted as a component of the medical workplace; that clinicians expect to use telemedicine in their daily routine of treating patients and patients expect to access health care anywhere at any time? Doing what we *can* with mobile is not the same as doing what we *should* with mobile. As we saw in Chap. 1, goals of benefit, usability, and consistency are driving mHealth and the development of telemedicine reflects the impact.

Is telemedicine sustainable? Thus far, the biggest use of telemedicine has been by the military and VA. A key reason for this fact is that the VA is a single payer system with the infrastructure to facilitate technology diffusion. Although the number of people who would use telehealth on a broad scale if it were offered to them is unknown, some telehealth companies have focused on specialty areas such as strokes because of concerns that there are not currently enough people using it for primary care (Baum 2012). However, as the technology advances, it is anticipated

that telemedicine will go mobile in a big way and will eventually reach out and touch all of us—virtually.

> A busy telecommuting Mom sits at her laptop with her screaming 2-year old son on her lap. It is 2:30 p.m. on a Tuesday afternoon. She is in the middle of drafting a press release for her boss and participating in a virtual consult with a physician from her pediatrician's virtual on-call system. Late Monday evening, using the laptop's webcam, she sent her pediatrician a photo of her son's rash, which has been rapidly spreading over his body. Her son is clearly in distress even as she attempts to comfort him on her lap. The on-call pediatrician is evaluating her son's vitals, which were exchanged at the beginning of the consult via a mobile app. A nurse and a pharmacist join in the virtual consult. By 3:00 p.m., a prescription has been ordered and is scheduled for delivery within the hour. At 4:30 p.m., Mom is back at work on her laptop; her son dozing nearby. An e-mail from the physician appears in her inbox—just checking in. The busy telecommuting Mom smiles and hits the reply button.

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Chapter 3
mHealth Regulation, Legislation, and Cybersecurity

Introduction

The rapid evolution of mobile technology and its growing impact on health-care delivery is shifting public and media attention from the "capture, store, and communicate" functionality of mobile technologies to the more provocative issues of regulation and consumer protection. With awareness that regulation is pervasive in the health-care industry, legislative action to regulate mHealth technologies was inevitable. Deloitte executives acknowledge that "networked medical devices and other mobile health devices have the potential to play a transformational role in healthcare, but also may be a vehicle that exposes patients and health care organizations to safety and security risks" (Deloitte Center 2013). Simply put, despite all of the benefits of using mobile devices for health-care delivery the perceived potential for harm to individuals creates a fertile environment for ensuring inclusion of mHealth technologies in existing protective legislation and for promulgating additional regulation. From another perspective, legislation and regulation can be viewed both as a facilitator to increasing technology usage through structured guidelines and as an impediment or barrier to developing and deploying innovative mobile technologies. Ryan Minarovich, chief executive officer (CEO) of the Tenzing Group, plans to promote "regulatory strategy alongside business strategy" in his address at the December 2013 HIMSS mHealth Summit (mHealth News 2013).

With regard to the perception of individual harm, the greatest concerns revolve around the security and privacy of personal health information used and stored on mobile devices since the physical devices are at great risk for being stolen, and for stored data to be accessed improperly by an unauthorized user, infected with malware, or hacked to accomplish identity theft. Certainly, information security is not a new concept emerging as a result of mobile computing. The distinguishing factor with regard to mHealth information security is that the most attractive feature of these devices, their mobility, is also the greatest challenge to protecting the data and information stored on or accessed with the devices. Analysis of 538 publicly reported security breaches of health information found that 38 % of the

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breaches involved unencrypted laptops and other portable devices (Redspin, Inc. 2013). These 538 breaches involved a frightening number of patient records—more than *21.4 million*. Even more astounding is that a single breach involved 780,000 records.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its subsequent modifications created the most noticeable and pervasive regulation of electronic health information through its Privacy and Security Rules. Within the parameters of the HIPPA legislation, "privacy" refers to the protection of an individual's personal health information by limiting its use and disclosure to third parties. "Security" refers to physically protecting health information stored or transmitted electronically. As regulatory guidelines for various sections of this law have been implemented sequentially, HIPAA legislation often is viewed as the "gift that keeps on giving." Organizations can be fined as much as US$ 100,000 for data breaches in addition to the costs of restitution to affected individuals.

While the HIPAA legislation is prominent among health IT legislative and regulatory requirements, several government agencies play important oversight roles with regard to mHealth applications and mobile devices. In addition to an organization's legislated responsibility to protect the security and privacy of health information no matter the storage or transmission medium, developers and vendors of mHealth apps, organizations that engage in mHealth delivery of services, and individual users of mHealth are well advised to monitor current and pending legislation.

Key Players in mHealth Legislation

There is plenty of evidence that mHealth and mobile devices have an increasing economic impact. Thus, it should be expected that legislation will follow the money trail. The rapidly evolving environment of wireless communications has enabled equally rapid transformation of the mobile health industry, producing astounding growth in the number of users. The Cisco VNI Global Mobile Data Traffic Forecast (2013) showed a 70% increase in mobile data traffic worldwide in 2012 to a traffic volume 12 times larger than existed in 2000. Smartphone usage increased 81%, and mobile-connected tablets grew to 36 million. The number of mobile devices is expected to exceed the number of people on earth by December 2013. Faster network communication capability spurs development of newer smartphones, tablets, and other mobile devices in a seemingly endless cycle of "more speed leads to more devices."

Although all types of mobile devices can potentially host mHealth applications, smartphones and tablets are noticeable favorites. Predictions into 2017 suggest that 50% of all smartphone and tablet users will have accessed an mHealth application and that the number of available mHealth applications is just less than 1 million, with 62 different app stores functioning as software distributors (Research and Markets 2013). The Apple iTunes App Store markets more than 43,000 apps, just over 23,000 of which are categorized as health-care apps (IIHI 2013). With these

many applications already available and companies regularly investing millions of dollars to secure additional market opportunities, industry standardization and regulation are needed.

Federal Communications Commission

The Federal Communications Commission (FCC) is an independent government agency established by Congress in 1934 to oversee and regulate "interstate and international communications by radio, television, wire, satellite, and cable" (FCC n.d.) in the USA. Among the functions and responsibilities of the FCC, in addition to its regulatory and licensing roles, are "encouraging the development of innovative services" and "consumer information and education." One important contribution in these areas was the "mHealth Summit to Foster Innovation in Wireless Health Technology," sponsored by the FCC in 2012. The summit brought together health information technology (HIT), industry, academic, and government leaders to discuss ways to increase adoption of mHealth by decreasing such barriers, for example, regulatory approval, reimbursement issues, and privacy and security concerns (FCC 2012).

Specific actions taken by the FCC to further mHealth include allocating dedicated spectrum for Medical Body Area Networks (MBANs), which continuously transmit health data from body sensors to medical providers; the Rural Health Care Pilot, which provided funding for a nationwide broadband for health-care transmissions; and adoption of new rules to enable Medical Micropower Networks (MMNs), which are ultralow power wireless medical devices implanted in the body to replace damaged nerves.

Federal Trade Commission

The Federal Trade Commission (FTC) was established in 1914 to protect consumers and to promote a strong competitive economy by curtailing unacceptable business practices related to false product claims and monopolistic mergers. Perhaps the most visible of the FTC consumer protections are the truth in advertising guidelines and regulations intended to prevent fraud and deception by companies providing goods and services to the public. The FTC's second mission focus is to promote market competition by enforcing antitrust laws (FTC n.d.), federal and state legislative acts intended to prevent market consolidation resulting in monopolies that thwart market-driven pricing. Monopolies may also limit technology innovation by removing incentives to develop new or improved products to gain or keep market advantage.

An exciting development where the FTC has significant potential to influence the evolution of mHealth is the Internet of Things (IoT; Ashton 2009), meaning

"the connection of physical objects to the Internet and each other" (Shapiro and Chadwick 2013). Simply put, this means that "smart" *devices* such as body sensors capture and transmit data over the Internet independently as opposed to *people* establishing a computer or wireless device connection to communicate or complete a transaction. To achieve the IoT vision described by Shapiro and Chadwick (2013) as "jaw-dropping in its expanse and in its potential," manufacturers and service providers must earn the trust of consumers as well as meet user needs and provide real benefit to the consumer. As with many mHealth applications, smartphones and tablets will be pivotal to exploiting the enormous capability of the IoT. The number of devices connected to the Internet has surpassed the number of users of the Internet, a growth trend that is expected to continue in the near future. As this connectivity explosion continues, consumers must be vigilant about managing the risks of privacy and security breaches that are ubiquitous with these devices. The FTC can play a strong role in consumer education about self-protection practices as well as pursuing their oversight responsibilities for assuring that device manufacturers and service providers represent their products and services accurately.

Food and Drug Administration

Some mobile medical applications themselves may be subject to regulatory oversight by the Food and Drug Administration (FDA; Barton 2012; Melnik 2011), the federal agency established in 1906 to oversee and regulate safety standards for food, medication, and health products to protect individual consumers.

One of the many responsibilities of the FDA is assuring the safe, beneficial, and appropriate use of medical devices. "Medical device" is very broadly defined by the FDA, using such language as "an instrument, apparatus, implement, machine… including a component part or accessory which is intended for use in the diagnosis…or the cure, mitigation, treatment or prevention of disease…" (FDA 2012). The key in applying this definition to mHealth devices is the concept of "intended use" (Thompson 2013). For a device to be considered subject to FDA regulations as a medical device, it must have an "intended" medical purpose. So, is a tablet computer used to transmit a patient consultation report from one physician's office to another physician's office a medical device? The short answer is "It depends."

A mobile device such as a smartphone or tablet can be viewed as either an accessory or a component of a medical device depending on the mHealth application being used and how a patient or consumer is using the device and app, and what information is being transmitted (Thompson 2013). If the device is deemed to be an accessory of a medical device or a component of a medical device, then it is regulated as a medical device under the FDA guidelines. A mHealth app and smartphone can be viewed as a means to deliver health care to a consumer because an app can be utilized to aid in diagnosis, treatment, prevention, or management of care. And, just like any health-care device or piece of medical equipment, it can pose a threat of harm or fail during use.

The Medical Device Amendment in 1976 authorized the FDA to monitor and regulate medical devices as defined above. The FDA proposes to extend this authority to regulate any mobile device and/or mHealth software application that acts as a component or accessory of a medical device that enables someone to display, analyze, or transmit patient specific data. Developers of devices and mHealth applications must demonstrate that the product is safe and effective for consumer usage. For example, under the 1976 Amendment, the FDA regulates blood pressure cuffs for safety and accuracy. Because blood pressure now may be measured and monitored with a smartphone or tablet using an mHealth app, the FDA will need to monitor and regulate these devices and software applications in addition to conventional blood pressure cuffs. An important exclusion to this extension of authority is devices and/or mHealth applications used by a consumer for educational purposes, such as seeking medical information about providers, medications, or current treatments for a condition.

In addition to devices and applications, the FDA refers to an app store as a virtual retail store that sells mHealth apps. Examples of these virtual retail stores include iTunes, Google Play, and Blackberry App World. App store distributors and retailers will be expected to utilize good distribution and marketing practices, and will be responsible for facilitating a product recall or to initiate corrective action if an app is discovered to put consumers at risk for harm with continued use.

Conversely, concerns have been raised as to whether the FDA's resource base and capabilities are adequate to oversee the myriad components of health IT safety on a national scale (Terry 2011; Wicklund 2013). In addition, the emergence of global markets and HHS expansion into global public health that relies heavily on mobile devices may further strain the resource capabilities of the US government to monitor and regulate mHealth products.

Department of Health and Human Services

The Department of Health and Human Services (HHS) has a long history of implementing and regulating programs and services intended to protect the health of all Americans. In 1965, with the passage of Medicare and Medicaid, HHS became an insurer as well as a regulatory body. The full scope of HHS health-care programming is well beyond the scope of this chapter, but interested readers are invited to explore the HHS website at www.hhs.gov.

The HHS established its mHealth initiative with a goal of improving the delivery of health services and population health. The goal is pursued by partnering with professional health associations to encourage the development of apps to help consumers self-manage health-care conditions or make better lifestyle choices. Elements of this initiative and example projects are discussed in a later chapter. However, it should be noted that any recommendations coming from professional associations are voluntary and as such do not carry the weight of law.

Key Legislation Affecting mHealth

Two of the most important federal legislative acts to affect health information generally and electronic information specifically are the HIPAA and the Health Information Technology for Economic and Clinical Health Act, referred to commonly as the HITECH Act. Both acts are far-reaching in their implementation. Privacy and security of transmitted information, frequently referenced as the primary concerns related to mHealth, are governed in large part by these two laws. Technology developers as well as health-care organizations are required to abide by these data privacy and security laws that provide federal protection of health data and personal health information.

HIPAA Privacy Rule

The HIPAA Privacy Rule, implemented in 2003, protects all "*individually identifiable health information*" held or transmitted by a covered entity (organization, provider, health plan, etc.) or its business associates, in any form or medium, whether electronic, paper, or verbal (USDHHS 2013a). The Privacy Rule calls this information "protected health information (PHI)," and defines it as:

Individually identifiable health information, including demographic data, that relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,

and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) (HHS.gov n.d.).

As with many other related concepts, the PHI acronym has been modified, using ePHI to distinguish PHI stored or transmitted in electronic format. The Privacy Rule is intended to be both flexible and comprehensive, striking a reasonable balance that permits use of information to provide and promote high-quality health care and to protect the public's health and well-being, while concurrently protecting the privacy of people who seek care and healing.

The Privacy Rule outlines the circumstances under which PHI can be used and disclosed with and without the patient's authorization. The Rule states that an organization or provider is permitted, but not required, to use and disclose protected health information without an individual's authorization for the purposes or situations identified in Table 3.1. Organizations may rely on professional ethics and best judgments in deciding which of these permissible uses and disclosures to make without securing authorization from the individual.

Table 3.1 HIPAA Privacy Rule: uses and disclosures permitted without patient authorization. (Adapted from http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/)

Permitted use/disclosure	Example
Individual	An individual may wish to maintain a personal health record in his or her home computer
Treatment, payment, and health care operations	One provider may transmit an individual's PHI to another provider who provides subsequent care
Use/disclosure events with opportunity to agree or object	Facilities may include patient information in a directory to respond to guest/visitor queries by name. At the time of admission to the facility, an individual may request to not be included in the directory
Incidental use or disclosure	A hospital visitor may see the name and room number of another patient on a nurse staffing board
Public interest and benefit activities	Funeral home personnel may be provided with health information about a deceased person that would serve to protect the health or safety of funeral home staff
Limited data set	After removal of direct identifiers, data could be used in a research database if the researcher commits to data safeguards for the included data

An important component of the HIPAA Privacy Rule is the principle of "minimum necessary" use and/or disclosure of PHI, which must be applied in any and all instances of use or disclosure. This would mean, for example, that a provider who needed to view reports of previous diagnostic imaging to properly diagnose or treat a patient should not request a copy of the patient's complete medical record of all past episodes of care. Health-care organizations are charged with the responsibility of making reasonable efforts, usually demonstrated by implementing appropriate policies and procedures, to use, disclose, and request only the minimum amount of PHI needed to accomplish the requestor's intended purpose (HHS.gov).

HIPAA Security Rule

The HIPAA Security Rule, which was also implemented in 2003, addresses five important elements of assuring the security of electronic health information, defining standards, procedures, and tactics for protecting ePHI (USDHHS 2013b). These protection measures apply to information as it is stored, accessed, transmitted, and audited. The five elements are listed and described in Table 3.2. While the labels are intuitive and conceptually simplistic, operationalizing the requirements has proved daunting for many facilities.

Paper-based patient records, and even electronic records on a mainframe computer, were relatively simple to protect; the key was a physically secure location with controlled access. The complexity of the current health information management environment would be almost beyond comprehension to health-care personnel in the mid-nineteenth century. Not only are data in multiple formats and location, but also they are transmitted—often wirelessly—across great distances and shared

Table 3.2 Elements addressed in the HIPAA Security Rule. (Adapted from http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html)

Element	Description
Administrative safeguards	Analysis of risk to facility electronic data resources; security measures to reduce risks; ensuring access based on "need to know;" personnel training regarding security policies and procedures; periodic evaluation of effectiveness of policies and procedures
Physical safeguards	Control of physical access to facility; assurance of proper use and access to workstations and electronic media
Technical safeguards	Access limited to authorized users; hardware, software, and procedural controls for systems with ePHI
Policies and procedures	Policy and procedural compliance with security rule provisions; periodic review and update of documentation
Organizational requirements	Oversight and management of business associates' access to and use of PHI; compliance with contract regulations of HITECH Act of 2009

with many other entities, including peripheral business partners. Security breaches can occur at any number of points along the nonlinear continuum of data capture, processing, transmission, storage, and access. Mobile devices, wireless and shared networks, public access portals, and other functionalities of modern computing create data security concerns previously unimagined (Luxton et al. 2012).

In addition to demonstrating compliance with the five security elements outlined in the HIPPAA Security Rule, organizations are required to perform a risk analysis to identify areas of vulnerability and to utilize risk management methodologies to anticipate and manage identified risks. Among items that are facility specific, organizations should verify adequacy of the basic security practices shown in Fig. 3.1, as recommended in a white paper prepared by BEI Healthcare IT (BEI 2011).

Robust operational practices are needed to protect the confidentiality, integrity, and availability of patient information, regardless of the format or information system design. Among the options for physical security, organizations should definitely have a robust hardware firewall in place. The transmission of personal information should be encrypted and comply with HIPAA rulings. Policies should be applied for updating of hardware, firmware, operating systems, and applications, and these policies should be routinely evaluated and modified as needed.

The organization must also have a security risk management process in place with appropriate metrics for measuring the organization's performance on relevant dimensions. The organization must not only perform the risk assessment but also develop a prioritized plan for addressing security risks, demonstrate progress on that plan, and integrate the security risk assessment aspects into their policies and procedures. This is extremely important as CMS will conduct a sampling of post-payment audits of the organizations that have applied for meaningful use (MU) funds, and if they have failed to meet even one item, they must repay all of the funds received and face the possibility of fraud charges (CMS 2013).

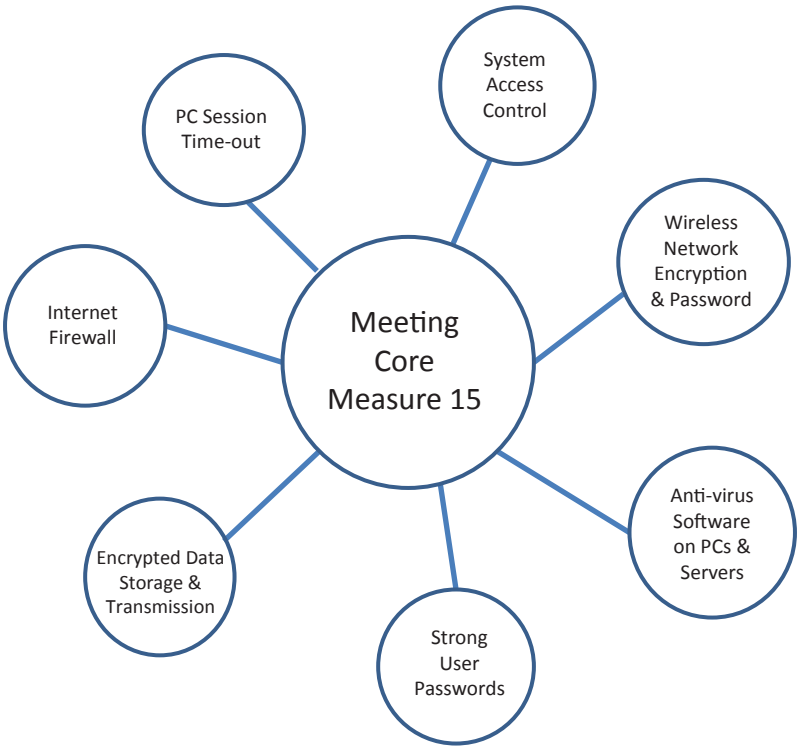

Fig. 3.1 Basic ePHI security practices

Meaningful Use

"Meaningful use" is the common name given to the standards established by the Centers for Medicare and Medicaid Services (CMS) to drive widespread deployment of the electronic health record (EHR) among US health-care providers (HealthIT.gov n.d.). An expected benefit of increased reliance on EHRs is improved health-care generally, and ultimately population health, as providers would have better access to complete and accurate information for medical encounters. The MU standards emerged from the HITECH Act, which is based on the premise that strategic investment in health information technology will drive improvement in health-care delivery and patient care. The CMS, charged with managing the incentive programs expected to stimulate facility investment in needed technologies, will deploy the MU standards in three stages over a 5-year period culminating in 2016. The broad focus areas of the three stages are shown in Fig. 3.2.

Of the requirements for MU Stage 1, Core Measure 15, protection of information in an EHR, has been challenging for many organizations. The measure requires conducting a security risk analysis in compliance with the HIPAA Security Rule, and to

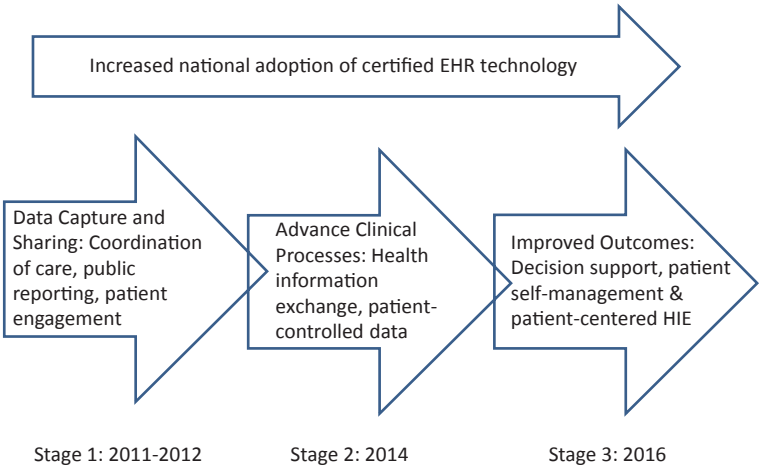

Fig. 3.2 Stages and objectives for CMS meaningful use

correct deficiencies identified through the assessment. One problematic area where remediation has been required for many organizations is policies and procedures for the organization's business processes. Standardized or generic policies and procedures that do not reflect current or actual practice do not meet the mandates of the measure.

These security practices are not new as control systems typically evolve along with operational systems. However, the application of these regulations to mobile devices is less robust as many organizations have not systematically modified their policy structure to incorporate use of mobile devices. If they have not already done so, organizations should revisit their policies and procedures to require the same security aspects for mobile devices as they would their "hardwired" systems. This is extremely important as a 2013 survey of IT and security professionals found that "almost 60% of respondents…believe that mobile devices present more risk [to their organizations] than in 2012," and about half expect to devote "more resources—money and staff hours—into mobile application security in 2013" (Richards 2013).

Cybersecurity

Deloitte Center for Health Solutions executives, in their 2013 Issue Brief "Networked Medical Device Cyber Security and Patient Safety: Perspectives on Health Care Information Cyber Security," stated that "networked medical devices and other mobile health devices have the potential to play a transformational role in health care, but also may be a vehicle that exposes patients and health-care organizations to safety and security risks." Thus, despite all of the benefits seen with the

utilization of mobile devices, the biggest concerns revolve around the security and privacy of personal health information used and stored in these devices since these devices may be stolen, accessed improperly by an unauthorized user, infected with malware, or hacked.

The Deloitte report defines cybersecurity (information security) as "the protection of information and informational systems from intentional or unintentional unauthorized access, use, disclosure, disruption, modification, or destruction in order to preserve their confidentiality, integrity and availability." This conceptualization of information security is not new. It is consistent with the overarching framework of the Privacy and Security Rules issued with HIPAA and its subsequent modifications described previously. Where the Privacy Rule is targeted at controlling access, and limiting the use and disclosure of PHI generally, the Security Rule defines technical standards for the physical protection of ePHI.

Common Challenges to Assuring Information Security

Key problems leading to security breaches as identified through a benchmark study with data reported by 80 organizations (Ponemon Institute 2013) included "inadequate funding, solutions, and expertise" to protect an organization's information resources. Additionally, the technologies that were expected to deliver greater productivity and convenience, such as mobile devices, file-sharing applications, and cloud-based services, have proven difficult to secure; thus, the number of breaches associated with these technology solutions is growing. The mobile component is made further complex when organizations allow a "bring your own device" (BYOD) policy, enabling employees to access company systems with their own tablets or smartphones which may lack adequate security features (Kaspersky n.d.; TechTarget 2013). The Ponemon study found that 81% of reporting organizations permitted employees and medical staff to use their own mobile devices to access company systems, with 51% of the employees or medical staff bringing their own devices to the health-care facility. The scope of the security breach problem can be measured in dollars; the average cost to the organization for data breaches reported in this study averaged US$ 2.4 million over a 2-year period.

Many data privacy risks stem from unencrypted data transmissions and connection to third-party sites (Privacy Clearing House 2013), often without the user's knowledge that these risk-prone activities occurred. Perhaps intuitively, free apps often present greater risks of privacy and security breaches than paid apps. This increased risk caused by less robust security features may be due in part to the reliance on paid advertising to support the costs of development and dissemination.

Managing Mobile Device Data

Recognizing the security challenges inherent in mobile computing, Burgess (2012) suggests a couple of simple practices that can have a big impact on an organization's efforts to properly secure mobile devices while enabling a clinician's access to patient information. First, encrypt all data transmitted and store the data on a dedicated secure server. Second, develop robust acceptable use policies and consistently employ password requirements and access control software. A third approach, one that most organizations employ in some form, is a documented proactive strategy for security of mobile devices. The intent of such a strategy is to optimize the functionality and security of a mobile communications network while minimizing cost and protecting against downtime and security breaches. In addition to the techniques described, other common elements of a data security plan include:

- Device access protection: passwords and user authentication, secured wireless networks, and remote wiping capability for mobile devices such as tablets and smartphones
- Physical access protection: secure facilities for equipment and data storage, data and media destruction protocols, and data backup and contingency plans for natural and man-made disasters
- Administrative controls: routine monitoring of audit logs, quick action in response to unauthorized access or nonadherence to protocols, and ongoing training and reminders about security practices

Most importantly, the organization must foster a culture of PHI protection and appropriate access and use. A breach reporting system that employees understand and use is essential to investigating issues and correcting system problems to forestall future breaches.

Security Insurance

Costs associated with security breaches have reached incredibly large numbers, reported by some sources as averaging US$ 6.75 million per incidence (Ponemon 2010). These high-dollar losses coupled with the increasing frequency of breaches—with some organizations reporting as many as five incidents in a 2-year period—have created an environment where some organizations are considering investing in cybersecurity insurance (Horowitz 2012; Herrin and Jones 2011; Ponemon 2013).

While most policies include coverage for hazards such as data privacy loss and repairs to company databases, broader policies also include coverage for costs of notifying customers in the event of a breach and loss of income from site failure, or crisis management coverage, including hiring an emergency public relations team and monitoring potential credit risks for affected persons. Organizations may choose to secure coverage for employee acts such as release of PHI, whether

inadvertently or maliciously. With strong risk prevention strategies and financial protection through cybersecurity insurance, health-care organizations can effectively decrease the likelihood of breaches while decreasing the impact of costs and penalties associated with these breaches should they occur.

Cloud Computing

Cloud computing, a relatively recent form of distributed network configuration, allows users wireless connectivity to remote computing services and data storage, typically via the Internet. As defined by the National Institute for Standards and Technology (NIST), cloud computing enables "convenient, on-demand network access to a shared pool of configurable computing resources (networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction" (NIST 2009). Simply put, users can enjoy computing resources without having to purchase or maintain the technology. A user, whether an individual or a company, purchases access to the needed resources through a vendor, or cloud service provider (CSP), and pays for the resources actually used, typically processing time or storage capacity. Amazon Simple Storage Service (Amazon S3) is an example of a CSP that has become big business, with a Morgan Stanley report projecting revenue at US$ 24 billion by 2022 (Darrow 2013).

Cloud computing has many advantages, including scaled fee structures and decreased reliance on capital investment in computing technology (Glandon et al. 2013). However, it is not without concerns, particularly with regard to data security, a factor that inhibited early adoption of cloud computing by health-care enterprises as a major component of their network architecture. However, a June 2013 survey of 50 senior-level health-care executives suggests that the cloud is gaining their trust, albeit slowly. The survey data showed that 58% of respondents rated their "confidence in using cloud computing to access information from disparate locations" as 4 or 5 on a 5-point scale, with only 4% rating at level 1 (Covisint Corporation 2013).

There are three basic cloud types (Dinh 2011). A *private cloud* consists of processing or storage space dedicated to the user, and not shared with other users. The private cloud may be physically located behind the user's own firewall or dedicated space in a cloud provider's data center. While this option provides greater security, it loses some advantage of scaled pricing. However, private cloud options are likely the best option when the need to protect PHI is paramount. A *public cloud* is just that, access to a virtualized data center that is shared with other users on demand. The demand sharing option enables the vendor to maximize the processing and storage utility of their distributed network. Thus, users benefit from the lower prices a high-volume provider can offer, though the price often comes with increased risk of data security breaches. A *hybrid model* is designed to harness the advantages of both public and private cloud computing, allowing organizations to use a public cloud

service for some needs, while enjoying the enhanced security of a private cloud or internal computing resources for other, more sensitive, types of data.

Cloud computing has also spawned new acronyms into computer language. Three acronyms are particularly important in describing the services purchased and subsequently the scope of cloud computing an organization will employ: IaaS (infrastructure as a service), PaaS (platform as a service), and SaaS (software as a service). As suggested by the acronyms and labels, a user can purchase one or more options from a range of available services to supplement existing internal resources, or to operate completely in the cloud. If the user wants to avoid the capital costs associated with computer hardware, an IaaS option may be preferred. If hardware currently exists, the user may choose a PaaS option that will provide software, tools, and utilities to support a desired information application. A SaaS option creates an operational application support environment. While cloud computing is not the best information technology strategy for all companies, for small and start-up companies developing mHealth apps, cloud computing and purchased CSP services can provide good alternatives when seeking the most cost-effective IT approaches.

However, whether cloud computing services provide adequate privacy and security capabilities to protect PHI is debatable. The ability to meet the requirements mandated for data privacy, such as those for the Payment Card Industry Data Security Standard and HIPAA, will be dependent on the technical expertise of individual CSPs. The security issues and legal concerns inherent in cloud computing are complex, and users must make deliberate decisions in formulating a cloud computing strategy. Technology is such that any computer function—capture, processing, transmission, storage, etc.—*can* be performed in a cloud environment. The relevant business decision is what *should* be relegated to the cloud, and to what type of cloud.

Choosing a CSP must be a thoughtful, sound business decision. Organizations must employ due diligence in vetting vendors for assurance that the vendor has the needed technical capabilities and applies robust security practices before entering contracts. When evaluating CSPs, it is extremely important to determine whether the provider offerings can meet the business needs in light of the criticality or sensitivity of the data. Many components of a due diligence investigation will be facility or user specific, but certain key attributes should be assessed for all CSPs (QuinStreet 2013) and evaluated with regard to security needs and business objectives. As illustrated in Fig. 3.3, a "good" CSP will score well on ratings of the following five attributes: (1) transparency, (2) risk mitigation, (3) proof of capabilities, (4) integration capability, and (5) relevant experience.

Transparency is vital in cloud computing services, particularly when the data to be processed or stored are sensitive or create a risk for loss of individual privacy if breached. CSPs must provide information and assurances about their custodial obligations, including storage location, security practices, and access controls. Strong security strategies include risk analysis and planning for alleviating to the extent possible the effects of a detrimental event such as improper access or a security breach. The CSP should be able to provide documentation of security strategies employed and discuss events where mitigation practices were invoked. Proof of

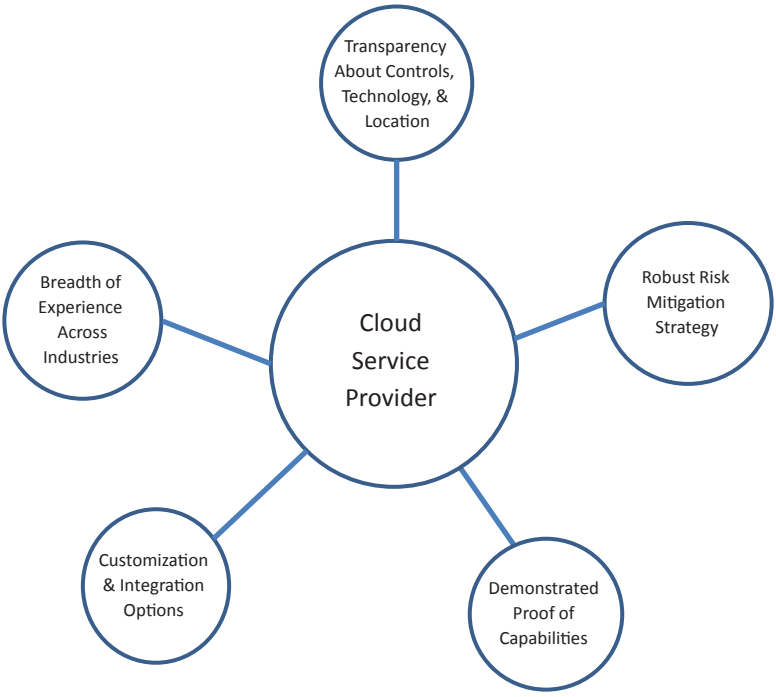

Fig. 3.3 Desirable cloud provider attributes. (Adapted from QuinStreet Executive Brief, 2013)

security control can be established in part by achieving security certification by an external entity, such as the International Standards Organization (ISO) or NIST. If the user will require the cloud services to be integrated with on-site systems, the vendor's ability to meet integration and customization requirements is an important consideration, and may be a deciding element for choosing between a public and a private cloud. Finally, users should consider the CSP's experience not only in the user's industry but also in other industries. This is important for many reasons, but specifically with regard to security controls, as the more experience a vendor has in multiple environments, the greater the likelihood of stronger and more varied control protocols.

The adequacy of an information system vendor's security measures may well be the deciding factor in vendor selection, and cloud computing services may require additional scrutiny in light of their distributed networks. Holmquist (2013) framed 20 questions to include in an assessment of a CSP's risk management and data security processes. The questions are straightforward and specific, assessing components such as system architecture, text and encryption protocols, access policies, and risk analysis and mitigation practices. The most important categories and components of the CSP's security features are shown in Fig. 3.4.

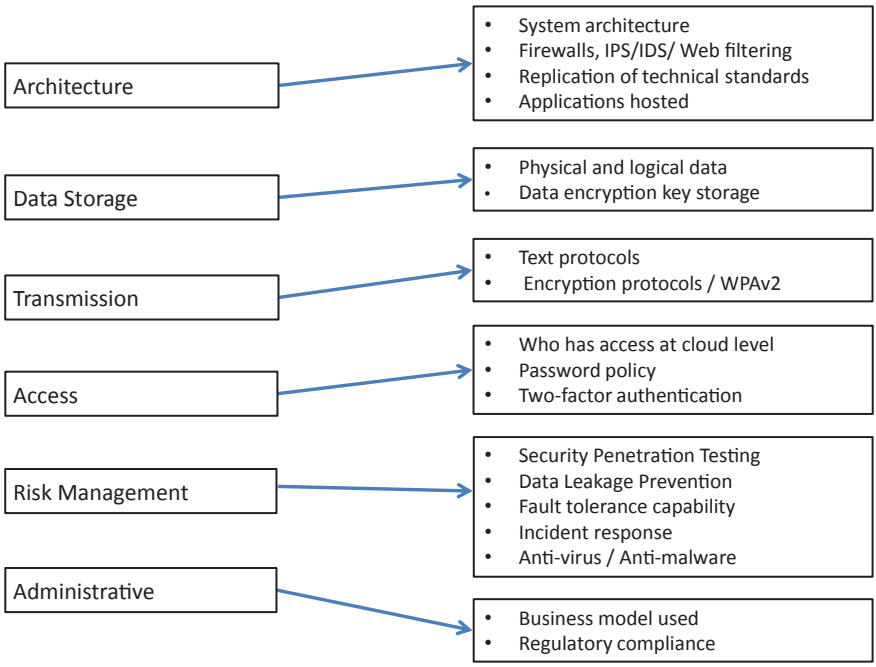

Fig. 3.4 Essential cloud security features. (Adapted from Holmquist 2013, Risk Management Frameworks for Cloud Security)

Health-care information and delivery applications are moving to mobile technologies rapidly, and electronic data need to continue to expand. Further, the Office of the National Coordinator for Health IT (ONCHIT n.d.) and the CMS are expanding requirements for organizations to demonstrate they are using electronic health information in meaningful ways, especially through exchanges of health information between facilities. Thus, many organizations are seeking solutions for data management in cloud services. This driver toward cloud computing is mitigated, however, by the heavy fines organizations face for data privacy and security breaches. Despite the need for less expensive and efficient information processing, storage, and transmission, organizations are reluctant to share control over their information systems with third-party computing vendors and their multiple and invisible storage sites.

Conclusions

Patient privacy and security remain a top concern when sharing patient information, regardless of the medium being utilized or the recipients of the transmission. This fact is as true for mHealth applications as for traditional health-care delivery modalities. As technology continues to evolve, enabling new capture, transmission, and access options with PHI, comprehensive training will be required to ensure that all

health-care personnel are knowledgeable and informed about the heightened risks to protection of PHI. The entire health-care delivery team of clinicians and administrative personnel must be involved to maximize the utility of new and innovative medical and mobile devices while protecting the consumer's privacy and ensuring the security and integrity of health-care data.

Facility policies and procedures must incorporate current and emerging mobile and medical devices into the organization's overall information security plan. Robust security protocols, including encryption at all data points and multifactor authentication programs, are needed to reduce the risk of breaches of protected health information. Organizations that permit BYOD—bring your own device—to work must first do a comprehensive risk analysis assessment. Next, organizations would need to develop a comprehensive policy to assure security. Such a policy would include as a minimum an itemized list of security protocols that would be communicable to all members of the organization along with an explanation of the reasons for each protocol to assure that employees have full understanding of their obligations. In addition, the policy should spell out consequences for breaches of these protocols including termination, suspensions, and financial penalties. There also must be a mechanism for continuous monitoring and enforcement of all devices that are brought to work. A key element will be training to ensure that appropriate risk protection practices are routinely followed. Finally, the organization's risk manager must oversee development of all policies and assure that policies and protocols are routinely updated. BYOD carries substantial risks and also potential benefits for the organization. However, efforts must be dedicated to mitigate risk if benefits are to be realized.

Organizations that adopt cloud computing as part (or the entirety) of their information resource strategy must exercise due diligence in selecting a CSP, particularly with regard to the CSP's risk assessment and risk mitigation approaches. In addition to ascertaining the technological capabilities of the CSP, the administrative business practices related to access control, security infrastructure, and risk management must be explored, understood, and approved. Large fines for noncompliance with regulatory requirements and the concomitant financial losses when security breaches occur provide more than adequate motivation for ensuring that security practices are robust.

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Chapter 4
mHealth Products, Markets, and Trends

Introduction and Overview

Much has been and is being written about the perceived value of mHealth in terms of its potential to revolutionize the health-care industry by transforming service delivery as well as patient and provider relationships. Numerous revenue predictions tout growth and opportunity as the world around us becomes increasingly digitized.

The prevailing sentiment is that well-designed health apps will help consumers make better decisions, about their health behaviors or health-care options. One of the most popular health apps *iTriage* has more than 8 million downloads to date. Consumers use this app to research symptoms, find providers, and make appointments for diagnostic and treatment services. The app is touted as helping connect health-care providers and patients through powerful personal technology and ultimately supporting informed decisions (Wofford 2013). However, not all apps are equivalent: consumers, providers, and payers continue to search for high-quality apps in a market that has yet found a way to "vet" apps with objective criteria. In fact, adoption rates remain the most used measure of a "good" app, and we cannot be sure that adoption rates measure anything other than purchases or downloads. Measuring actual app usage beyond an initial trial may be elusive.

The market for mHealth app services is predicted to reach US$ 26 billion worldwide by 2017, according to a March 2013 report by research2guidance, a Berlin-based consulting company. The report, "Global Mobile Health Market Report 2013–2017," suggests that mobile application developers have begun to enable the mHealth industry to successfully monetize their services and enter the commercialization phase. In addition, most of the overall industry revenue is predicted to come from related services and products, such as monitoring devices and sensors, with less than 10% of sales attributed to application downloads (Jahns 2013).

Despite such optimistic future predictions, the reality is that health app adoption remained consistently flat between 2010 and the end of 2012. Despite significant growth in the number of health apps available, there appears to be no obvious rush by consumers in the wide-scale adoption of multiple apps. According to the Pew Internet and American Life Project (Fox and Duggan 2012), only about 10% of US adults with mobile phones have had some kind of app on their phone that helps them

D. Malvey, D. J. Slovensky, *mHealth,* DOI 10.1007/978-1-4899-7457-0_4,

track or manage their health. And this figure has remained constant, only ticking up or down a percentage point. What is holding consumers back? Will increased smartphone adoption by consumers lead consumers to also adopt health apps as some suggest (Dolan 2012)?

The answers to those types of questions remain purely speculative, especially for insurers who are betting on health apps to increase system efficiency and productivity, reduce costs, and improve health outcomes overall. App developers and investors are increasing their stake in the market, and newcomers such as Nike may be the signal that something really big is about to happen. But right now, apps have yet to enter the mainstream of health care. Five apps account for 15% of all downloads in the health-care category and more than 50% of widely available apps achieve less than 500 downloads (IMS Report 2013). Meanwhile, little is known about what makes a good mHealth app and what consumers want and are willing to pay for. Many questions are debated—Which products are successful and why? Are commercial apps better than apps created by individuals? How do consumers, providers, and payers choose apps?—but few questions have been answered definitively.

Challenges to widespread adoption of apps are numerous. The most critical obstacles include addressing the absence of objective research to evaluate outcomes, resolving uncertainty about how to pay for apps, as well as encouraging the use of cost-effective apps. Furthermore, the need for a regulatory framework that standardizes development to ensure performance is unquestionable. If this framework is created and adopted, some experts believe that apps may indeed serve as a catalyst in transforming health care (Silow-Carroll and Smith 2013).

At this time, there is little reliable guidance to assist consumers in selecting health apps. Most apps are not reviewed by experts; although there are a number of online sites that claim to do so. Thus, consumers typically encounter online self-promotional appeals from companies producing the apps and issuing untested claims about their products. In addition, consumers often are unaware of the few reputable guides available, such as those produced by the American Health Information Management Association (AHIMA) and other organizations that offer objective reviews.

The Food and Drug Administration (FDA) has limited its oversight to what it calls *mobile medical apps* and subsequently will only regulate a small subset of apps that will present significant risk to patients if they do not work properly. In fact, the FDA reports that many mHealth apps are not within their authority because either the apps do not meet the agency's definition of a medical device or they pose very low risk to patients. Examples include apps that provide medical and patient education reference materials, apps that organize and help patients track their personal health information, and apps that automate a variety of data functions (Lowes 2013). Such guidance is critical for furnishing reliable information to guide decision-making—whether a consumer is downloading an app for personal use, an individual or company is investing in development or sales of an app, or a physician is recommending an app to aid a patient in self-care.

Apps

Generally speaking, apps are Web-enabled application programs. A mobile application or mobile app is a software application designed to operate on mobile technology such as smartphones, tablet computers, and other mobile devices. They typically are available through application distribution platforms operated by the owner of the mobile operating system such as the Apple App Store, Google Play (Android), Windows Phone Store, and BlackBerry App World (IMS Report 2013). Once downloaded from the host site, the app may operate solely on the mobile device, or it may work in concert with a sponsored website, or communicate with a third party's network, such as a health-care provider.

Consumers routinely search the Web for an assortment of apps to meet their interests and needs, including health apps. It is estimated that more than 40,000 mHealth apps are currently in use (Silow-Carroll and Smith 2013). A variety of mobile apps are available to patients, insurers, and providers; some are simple, such as those involving text messaging. Other apps are more complex and are moving closer to offering diagnosis and treatment services (Schwartz 2013). However, most app development available to consumers to date has occurred in the area of health maintenance and wellness. Diet and exercise apps account for the majority of available health apps.

A comprehensive study of health apps by the IMS Institute for Healthcare Informatics (2013), found that the majority of health apps tend to be limited to simple functionality, often furnishing information and little else. In fact, two thirds of all consumer-targeted health apps (10,840) provide information; many fewer apps have other functionalities such as providing instruction (5823) or capturing data entered by the user (5095). About 10 % (1622) showed none of these capabilities at all, and includes baby monitors and apps that assist with sleep and relaxation, i.e., sound recordings.

App functionality can be conceptualized in terms of a continuum, or range of provider services, as shown in Fig. 4.1. At one end of the continuum are single-function clinical management or niche apps. For example, dermatology diagnostic apps that allow the consumer to take a photo of a suspicious mole and send to their physician to determine if it is malignant or benign. At the other end are comprehensive apps offered by health systems and insurers. These apps offer their members access to a wide array of comprehensive medical management services, ranging from scheduling appointments to communication tools to management of chronic illnesses, typically through a single portal (Silow-Carroll and Smith 2013).

Apps and mobile devices that connect with apps represent a major change for consumers and physicians alike and probably represent the next wave of app development. Diagnostic tools that were once held only in the hands of doctors are now mobile and affordable, and consequently are accessible by consumers. These devices include heart and blood pressure monitors. In making medical care more accessible to consumers, mobile technology is also simultaneously empowering and engaging them; that is, putting the consumer in charge of aspects of their health care previously withheld from them. However, many of these devices must undergo FDA review and approval, thus prolonging the time it takes to get them to the market and adds to development costs (Edney 2013b).

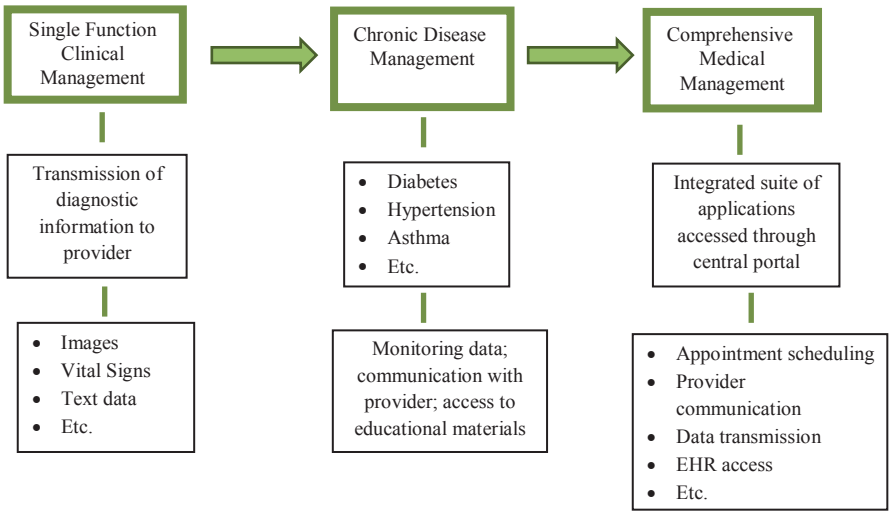

Fig. 4.1 Continuum of provider apps used by consumers. (Source: Derived/Adapted from Silow-Carroll and Smith 2013)

Consumers have easy access to wellness apps to monitor their diets, exercise, and weight, or to assist in changing health behaviors, such as quitting smoking or losing weight. These wellness apps make up most of the 97,000 health-related mobile apps available. Apps that fall into the wellness category are not subject to FDA scrutiny because they pose no risk to consumers should they fail or function poorly (Edney 2013b). Thus, wellness apps can be developed and brought forward for distribution at a much more rapid pace than apps aimed at health diagnostics and treatment.

In 2012, ModernHealthcare.com inaugurated a *Most Important Mobile Healthcare Apps competition,* based on a survey of its readers and input from professional and technology organizations. Apps receiving the highest ratings were not necessarily new; in fact, many had been in use for years—thus possibly illustrating the importance of trust and confidence contributing to longevity of the app. The competition identified Epocrates, a decade-old drug reference tool as top choice, followed by UpToDate, a 20-year-old clinical decision-support reference tool. Medscape, another clinical decision-support tool, and Lexicomp, another drug reference app, came in third and fourth. The top five categories of most commonly cited apps (Conn 2012) are shown in Box 4.1.

Box 4.1. Most commonly cited mHealth apps—2012 *Modern Healthcare* competition. (Source: Conn 2012)

1. Drug reference
2. Clinical decision support

3. Communication
4. Electronic health record access
5. Medical Education

Are there business models for app development? Apps that are available to the general public are created by a variety of different types of developers, ranging from individuals with a unique idea, to large organizations that have a strategy for commercializing the app. And, there is also a diversity of types of financing, which naturally produces a wide range of scale, investment, and expected return on investment (ROI). Consequently, there probably are not academic curricula or scholarly books that provide instruction for designing a winning health app business case. App developers' business acumen likely is based on experience in other fields or achieved via a muddling through approach. So how are apps priced? How does the app developer determine which apps will be free and for which there will be a fee for downloading? Which apps will have paid content or require subscriptions? Which apps will permit advertising? For these questions and others, the current answer is "it depends." Right now, there is little transparency or guidance in how app developers price out their apps and that is likely because developers and distributors are designing their business models in real time.

Medical Care and Clinical Management Apps

Often, the genesis for app development and deployment is attributed to physicians, but nurses, especially advanced practice nurses, are big users of mobile reference apps, especially drug reference tools such as Epocrates (Conn 2012). And, consumers repeatedly report interest in using medical care apps, although as noted previously, usage rates have been rather flat over time. One type of app technology that holds promise for enabling patients and providers to work together, especially to manage chronic conditions that are responsible for most health-care spending, is clinical management apps. These apps tend to be adopted by health plans and large health-care organizations that want to improve health outcomes while concurrently reducing costs (Silow-Carroll and Smith 2013). Most of the clinical care apps are single-function or niche apps; that is, they specialize in areas such as pharmacy, cardiology, or laboratory readings. Some examples of niche apps are addressed in the following sections.

Blood Testing

University of Rhode Island researchers have developed "lab-on-a-chip technology," which requires only a drop of blood for analysis. The blood is placed on a disposable

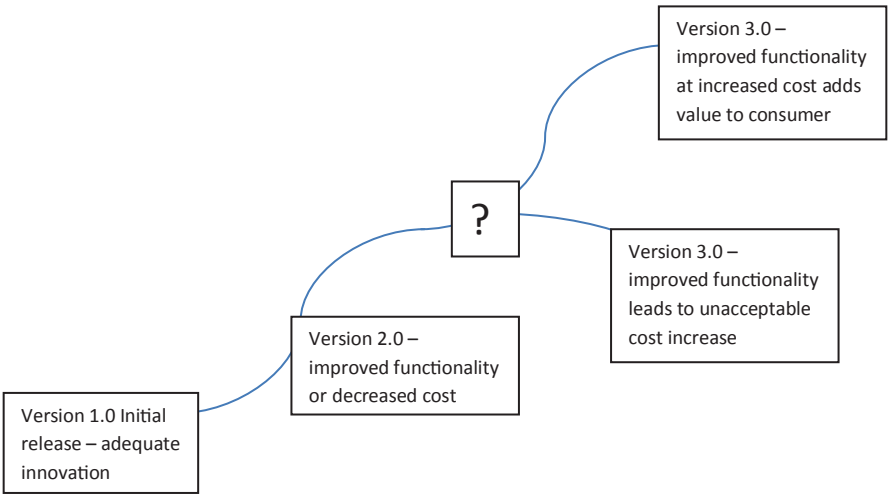

Fig. 4.2 mHealth product life cycle

credit card-sized plastic polymer cartridge that is inserted into a handheld biosensor. The smartphone app engages the system, evaluates the assay, and sends the results securely back to the patient's phone or to the appropriate doctor, all in about 20 minutes, according to the lead project researcher Mohammad Faghri. The first generation of this biosensor cost about US$ 3200. The second generation reduced the cost to US$ 10. Meanwhile, British researchers report working on a mini blood-testing laboratory, a device developed by Southampton University and the Japanese electronics maker Sharp Corporation, which is adding device programmability (Bird 2012b). If diagnostic capability is enhanced in this third-generation product, that product attribute likely will move the cost back up. Such an evolution of product development exemplifies an important question in the mHealth industry—are there alternative futures for app life cycles, as suggested in Fig. 4.2? More importantly, how do we learn business models that lead to the preferred outcome of a product that will evolve with consumer needs and interests while maintaining an acceptable cost balance? Experience to date has shown that apps come and go, often very rapidly. Consider mobile startup Cognovant's PocketHealth, intended to help patients engage in self-care and better manage their health. The app never achieved adequate user adoption or revenue required to sustain it beyond 2 months (Schreiber 2013).

Urine Analysis

Smartphone apps that permit consumers to self-diagnose a variety of medical conditions at home by testing their urine may be more challenging for app developers than originally expected. Biosense Technologies based in Thane, India, introduced

uChek in February 2013, an app that lets consumers use their phone cameras to read subtle color differences on test strips designed to show unhealthy levels of proteins and other substances in their urine. The analysis is quick, inexpensive, and can save the consumer a trip to a doctor's office or laboratory (Paddock 2013) if the results are negative or minor elevations.

However, because the app requires FDA approval to be sold in the USA, Biosense was notified to obtain FDA approval. Subsequently, Biosense stopped selling uChek in US markets and applied for approval. After initiating the approval process, the company pursued an online crowdfunding strategy, in which the company invited online customers to preorder uChek and thereby help the company raise funds to meet basic regulatory requirements. This strategy not only enables consumers to have a voice in bringing a product to market but also indicates whether it is worth time and money for a company to seek out regulatory approval. FDA approval can cost tens of thousands of dollars and take several months or even years to obtain a decision (Edney 2013a).

Pregnancy Testing App

A mobile app for a pregnancy test marketed by HVM Solutions, Inc., also uses a phone-based camera to evaluate the test results. Women use the home pregnancy test as they would any such test they purchase. The camera on their smartphone or iPod is used to take a picture of the test results and the app then uses different filters to clarify the outcome (Crodo 2013). Since simple home pregnancy test kits have a high reliability for accurate results, the added value of using the phone app is not readily evident. However, downloading the app may provide consumer information to the developer that leads to improved marketing of other products or services. This approach illustrates a key business principle met through free or low-cost apps—providing an easy point of entry to attract new consumers to a company's products and services.

Diabetes Management Apps

Diabetes is emerging as a chronic disease of consequence in the USA, especially as the disease is appearing increasingly in children. The financial burden, medical resources used, and lost worker productivity associated with the disease continues to challenge the US health-care system. According to the American Diabetes Association (ADA), the total costs of diagnosed diabetes rose to US$ 245 billion in 2012 from US$ 174 billion in 2007, representing a 41% increase over a 5-year period (American Diabetes Association 2013).

The number of prediabetics, estimated at 79 million Americans and growing, is complemented by commercial investment in diabetes management apps. One example is the stock market's positive response to the initial public offering of mobile

developer Tandem Diabetes Care, Inc. (Schwartz 2013). Ginger.io, the behavior analytics spin-off of Massachusetts Institute of Technology's (MIT's) Media Lab, also perceives market opportunity in diabetes apps, as evidenced by their efforts to engage type II diabetics in their massive data collection effort to strengthen their behavioral-based management app. The app uses sensors already contained in most smartphones to assess a diabetic's ongoing health status in terms of predictable movement patterns; that is, whether the patient is sedentary or moving—how far and how fast. In doing so, a disruption in the pattern triggers a call from a care provider to assess the situation. Novant Health, a large health-care provider based in Winston-Salem, North Carolina is conducting a yearlong trial to assess Ginger.io (Schwartz 2013).

A less intrusive example is MyAgileLife, a text messaging application from Agile Health. The application prompts and reminds diabetics concerning aspects of illness self-management. The University of Southern California (USC) has conducted studies to assess the effectiveness of the app. The company is now getting ready to launch a mini-trial with USC to measure the efficacy of expanding MyAgileLife to include social support by caregivers selected by the patient populations. Highlights of the study, published in the *Annals of Internal Medicines* showed:

- A slight statistical improvement in HbA1c hemoglobin levels, a 1.5 reduction in HbA1c for the test group, and a 0.65 HbA1c reduction in the control group.
- In a 6-month follow-up, emergency room visits were reduced significantly—35.9% of the group that received text messages returned to an emergency room versus 51.6% of the control group.
- Clinicians also saw an improvement in the patients' health habits, such as a 30% improvement in eating fruits and vegetables, as well as patients reporting that they exercised more and performed more foot checks following the text messages.
- The technology appears to represent highly scalable, low-cost, and widely accessible solutions for safety-net ED (Arora et al. 2013; Schwartz 2013).

Meanwhile, iHealth has gained widespread attention with its Wireless Smart Gluco-Monitoring System that measures glucose levels and transmits them directly to its smartphone or tablet application in the cloud. This product is sold directly to patients nationwide through Best Buy (Schwartz 2013).

Apps for Hearing

Can apps replace hearing aids? If so, what is the impact? Approximately 38 million people in the USA and 360 million globally suffer some form of hearing loss; and most (90%) can be treated with technology such as hearing aids, amplification devices typically inserted in the ear canal. The retail market for hearing aids generates US$ 5 billion in the USA and US$ 12–15 billion globally, growing 3–6% per year. The emergence of what has been labeled "smart hearing apps" essentially

leverages the smartphone's microphone and processor to enhance sound quality and regulate the environmental noise levels, ultimately emulating a hearing aid via software. These apps demonstrate potential to augment or even replace established hearing aid technology. An expanding list of such apps is available in the iOS app store; most are free or priced at less than US$ 3.99 (Teo 2013). As many highly functional—and cosmetically attractive—hearing aids cost upwards of US$ 5000, this app alternative may be especially desirable to elderly, fixed-income individuals.

Locator Apps

In 2010, The Detroit Medical Center and Henry Ford Health System made news when it began directing patients to the nearest emergency room or urgent care via free smartphone apps. The app offered addresses and phone numbers, and gave the consumer an opportunity to store important data such as emergency contacts, known medical conditions, allergies, medication, and insurance details to expedite emergency treatment and processing of insurance claims (Carmenico 2010). Today, consumers have to access more information than locations. They can preregister for service, and receive notice of waiting times for emergency departments and urgent care facilities using free smartphone apps provided by hospitals, urgent care centers, and other facilities. These facilities provide consumers information on wait times, their location in the treatment queue, and also include text or voice mail reminders of time remaining in the queue. These apps contribute to satisfaction rates as well as assist in building market share for these facilities.

Pharma/Drug Chain Apps

Pharmacy giant chains such Walgreens and CVS have embraced mobile apps and are using them to personalize services and extend convenience for consumers. CVS Caremark added a smartphone app for consumers to manage their medications. Consumers can use the app to look up medication information as well as check on prescription history and order refills. Customers who download the CVS apps also have access to a variety of other services at the chain, including making appointments at MinuteClinics, CVS' on-site retail clinics (www.myCVS.com).

Walgreens offers similar mobile app downloads and emphasizes that consumers can access the pharmacy from their mobile phone anywhere at any time (www.Walgreens.com). Walgreens also has experimented with what they call "real time solutions," using health guides, which are employees who roam the store aisles with iPads looking for customers to assist. Walgreens' health guides use the iPads to access information that ranges from checking government databases, to physician ratings, to so-called blue button medical records available only to US military personnel and government employees and retirees. The Chicago-based company

mHealthCoach won a competition against 24 other companies nationwide to develop the apps for Walgreens' health guide initiative (Guy 2011).

Emerging Apps: Portable Clinical Attachments

While many apps consist solely of software to be operated on a portable device such as a phone or tablet, as the mHealth field becomes more sophisticated, developers recognize that app functionality can be enhanced if accessory devices are added to the software/hardware equation. These devices are designed to work with the mobile device hosting the app, and may be used simply for data or bio-sample collection, or they may also have a processing function. Example devices include blood pressure cuffs and image viewers. In general, these portable attachments or accessory devices will fall into the FDA-regulated category and many have already been approved by the FDA. Several categories of devices have entered the market, with some showing promise for achieving the mHealth goal of lowering health-care costs.

Cancer Screening and Diagnosis

With current-generation iPhones and a few add-on components, physicians can diagnose some forms of cancer in just about an hour, and diagnose it with greater accuracy than standard diagnostic tests. Researchers at Massachusetts General Hospital have built a US$ 200 portable device that connects to a smartphone and analyzes a tiny amount of tissue to determine in an hour whether a patient's cancer is malignant and likely to spread. The portable device, known as diagnostic magnetic resonance or DMR, is about the size of a coffee mug, and thus has been labeled the world's smallest cancer diagnostic system. The device can display its findings using the monitors on mobile phones. In clinical trials, the data generated have been reported to be more accurate than standard diagnostic procedures (Hannaford 2011; Johnson 2011).

Dermatology Diagnostics

FotoFinder Systems, a German-based company, has created a portable device that turns an iPhone into a dermatoscope, which physicians can use to distinguish cancerous and noncancerous moles. More importantly, the physicians can take pictures of the skin and store them to review them later on a larger screen of a PC or other monitor (Murph 2011).

> The Handyscope features a case into which an iPhone 3G, 3GS and 4 slides, so that the iPhone's camera aligns with the Handyscope's lens system. The device is then placed flush

against the patient's skin, which is illuminated by polarized light from the built-in LEDs. The device features a standardized zoom and auto-focus with images captured with a single tap using the iPhone app. The images can be immediately viewed full screen with a magnification of up to 20x and saved with another tap. The shooting date and time is automatically recorded and saved with the images, while patient data and other comments can also be added manually. The data is all encrypted and can be password protected so there's no doctor/patient privilege privacy concerns. (Quick 2011)

Radiology/Medical Imaging

Mobile apps and devices are becoming ubiquitous in radiology despite the challenges that remain. Although radiologists are not expected to abandon traditional workstations just yet, according to a report by Novation, an Irving, Texas-based hospital and health-care supply chain company, the industry is definitely moving in that direction. The report describes improvements in technology (such as the Apple iPad 3) that improve the quality of images on mobile devices, an achievement contributing to their increased use as diagnostic tools. Remaining challenges include screen size—iPad and iPhone screens are smaller than traditional workstation monitors, and report preparation options—currently users can neither dictate reports nor look at comparison films side by side. In addition, the report finds that there is a need for developing health-care mobile apps to be used with portable tablets and smartphones (Novation News Release 2013).

Despite the growing need for mobile radiology apps and devices, many are in the queue awaiting approval from the FDA and European oversight. One of the approved is aycan mobile, a teleradiology app developed by Rochester, N.Y.-based aycan Medical Systems, a recognized worldwide leader in medical imaging. The app received FDA 510(k) approval as well as clearance from European CE Marking. The app enables radiographers to transfer DICOM images from hospitals and imaging centers to on-call and consultant radiologists for reading. The app also allows for remote review and diagnosis of radiological images and teleconsulting with colleagues (aycan Announcement 2012).

Ultrasound

Mobisante, a startup company in Redmond, Washington, created a device the size of a hairbrush that converts into a pocket-size ultrasound machine. Physicians and other first responders can carry these portable devices in their pockets to screen patients in emergency sites such as in the aftermath of a natural or man-made disaster or on the battlefield. Mobisante's ultrasound attachment costs about US$ 7500 compared with the high-end ultrasound machine cost of US$ 100,000. Even though the images produced by the portable attachment are not the highest quality, they appear to be adequate during an emergency situation. And, the portables are gaining the attention of large purchasers such as the Army (Kharif 2011).

Cardiology

Heart disease continues to be epidemic in the USA, and is currently the leading cause of death. The Centers for Disease Control and Prevention (CDC) estimates that approximately 600,000 people die each year from heart disease (Kochanek et al. 2011). Consequently, it is to be expected that mobile apps and portable device developers would recognize this potentially lucrative market. Furthermore, mobile health apps are not confined solely to physicians but also extend to consumer use as well. The Cardiac Designs' ECG Check app reads a heart rhythm when paired with an iPhone. Patients can send physicians data from this app that analyzes heart rhythms, thereby allowing physicians to make real-time recommendations such as increasing medication dosage or directing the patient to an emergency department if the patient is in jeopardy (Edney 2013b).

The Cardio Buddy app, developed by Azumio, a consumer health company helps consumers to measure and track their heart health. The app uses a smartphone camera to assist in detecting the user's heart rate in real-time based on changes in facial coloration as well as using bio-signal analysis from the video stream to calculate pulse rate. When a heart beats, what is not outwardly visible to the human eye is that more blood is pumped into a person's face thereby causing a color change reflected from the facial region. The Cardio Buddy app uses the bio-signal analysis from the video stream to detect heartbeat and calculate pulse rate. In addition, the app stores the readings to provide a history (McCann 2012).

A study funded by the University of Virginia's Wireless Internet Center for Advanced Technology and reported on by the American Heart Association revealed that an inexpensive iPhone app transmitted electrocardiogram images (ECGs) faster and more reliably than a previously used approach of e-mailing photo images. The advancement in speed and image quality enable the app to save lives threatened by the deadliest type of heart attack, one in which a clot blocks blood flow to the heart (American Heart Association 2013).

Another new cardiology product found to provide better data than the traditional device is the ZIO patch by iRhythm (Comstock 2014). The ZIO patch collects the same type of data as a Holter monitor, i.e., heart arrhythmias, but requires no connectivity via lead wires. Readings are stored in the device itself, which is a wireless adhesive patch that is placed on the chest wall. Although the Holter monitor captures data over a 24-hour period and the ZIO patch requires 2 weeks for data capture, both patients and physicians in a study of 146 patients preferred the ZIO patch.

Microscope Substitute

Aydogan Ozcan, UCLA professor of electrical and bioengineering, and his team created a portable smartphone attachment that can be used to perform sophisticated field-testing to detect viruses and bacteria without the need for costly microscopes and laboratory equipment. The device weighs less than half a pound. A single virus

and bits of material less than one thousandth of the width of a human hair can be viewed with this smartphone attachment. Professor Ozcan's other recent inventions include a cell phone camera-enabled sensor for detecting allergens in food products and a smart phone attachment that can conduct routine kidney tests (University of California—Los Angeles 2013).

Cholesterol

A group of Cornell University engineers developed the Smartphone Cholesterol Application for Rapid Diagnostics, or "smartCARD." SmartCARD uses a smartphone camera to read cholesterol levels. It optically detects biomarkers in a drop of blood, sweat, or saliva. When a user puts a drop of blood on the cholesterol test strip, it processes the blood through separation steps and chemical reactions. The strip is then ready for colorimetric analysis by the smartphone application. The smartCARD accessory, similar in appearance to a smartphone credit card reader, clamps over the phone's camera. Its built-in flash provides uniform, diffused light to illuminate the test strip that fits into the smartCARD reader. The application calibrates the test strip image's color values against the cholesterol hue saturation stored in the program, and the results appear on the phone's screen (Cornell University 2013).

Health and Wellness Apps

Health and wellness apps are rated by most sources as the largest consumer market for app development. Some of the more popular apps focus on consumer empowerment; putting the consumer in charge and enabling a more active role in managing their personal health. These apps engage in such activities as counting calories, monitoring daily exercise, and providing information about nutritional supplements. These apps reflect a targeted and personalized approach to help consumers monitor their progress toward fitness and health goals and ultimately to make more informed decisions about their health and lifestyles. According to Nick Martin, vice president of Innovation, Research and Development at UnitedHealth Group, the largest US health insurer, the company views apps as a way to connect with consumers and support them in pursuing healthy behaviors in ways that are convenient as well as educational, effective, and fun. For example, the company developed OptumizeMe, one of the first health challenge apps on the market. The app enables consumers to use their smartphones to challenge others to achieve health and fitness goals and post results on Facebook (Martin 2012).

Fooducate is regarded as one of the more successful apps in this category. It eliminates the need to spend time reading food labels. Moreover, it is a free download with paid upgrades available. The app shows consumers whether food products they are putting in their shopping carts are healthy. This is accomplished by swiping

Table 4.1 Examples of mobile apps that personalize advice and solve health problems. (Source: Tilenius 2013)

Product	Functionality
HealthTap	Mobile "triage" system; consumers ask doctors for advice about specific issues and get recommendations for next steps
BlueStar by Welldoc	Doctor-prescribed app for diabetes management coaching
Asthmapolis	Biosensor that logs data via Bluetooth LE to give personalized feedback and education for asthma control
Glow	Menstrual cycle tracking and alerts for optimal time to achieve pregnancy
Kaiser Permanente EHR app	Store health records, make appointments, e-mail communication with doctors, view test results, and fill prescriptions
MyFitnessPal	Track nutritional intake for weight loss and health maintenance

the product's barcode using a smartphone reader. The app rates the product with a grade of A through D, with the rating based on nutrients, ingredients, and processing. Fooducate was chosen by Apple as the best new health app of the year after its introduction in 2011 and it took first place in the US Surgeon General's healthy app contest last year (Edney 2013b).

There are thousands of apps available for download and one size clearly does not fit all. The following two tables illustrate the diversity of choices and basis for selection. Ultimately, consumers are on their own when it comes to finding high-quality worthwhile apps. At this point, it is mostly trial and error, and recommendations from friends and family. Because the majority of health apps are either free or cost a couple of dollars, there is not much financial investment in downloading them (Butler 2012). Consumers can try many apps and discard them if they do not perform as touted, or if they just do not find them useful. Examples of mobile apps that personalize advice and provide solutions for health problems are shown in Table 4.1.

Are there standout apps, and who would be a reliable source for evaluating them? Brian Dolan, cofounder and managing editor of *MobiHealthNews,* was asked by a contributor to *The Washington Post* to compile a list of such apps. Examples of mobile apps recognized as standouts by Brian Dolan are shown in Table 4.2.

Trends to Monitor

The mHealth landscape is nothing if not dynamic. And, the dynamism seems clearly oriented toward growth, as app usage is only projected to increase. According to Research and Markets reports, by 2017 half of the 3.4 billion smartphone or tablet users worldwide will use mobile health apps, and at least 30% of Americans will regularly wear a device to passively track sleep, food, exercise, heart rate, blood pressure, or other bio-readings. And, the global market for wearables—bio-sensing

Table 4.2 Ten standout health apps for mobile phones. (Source: Recommendations from Brian Dolan of *MobiHealthNews* as reported on in Butler 2012)

App	Cost	Function
iTriage	Free	Helps evaluate symptoms and suggests best, nearest health-care facilities; reports wait times at some emergency departments
Good Rx	Free	Compares prescription drug prices at US pharmacies; provides coupons and cost-saving tips
Zoc Doc	Free	Helps local nearby doctors who accept specific insurance plans; books appointments, even last minute
RunKeeper	Free	Tracks pace, distance, time, heart rate during runs and other fitness activities; enables sharing with friends
LoseIt!	Free	Permits dieters to set and log daily caloric intake by scanning food product bar codes
Withings WiFi Scale	US$ 159 for scale; app is free	App monitors weight, BMI, body fat percentage and health data when used with the wireless scale
iBGStar Diabetes Manager	US$ 75 for meter; app is free	Tracks blood glucose levels and insulin usage; permits sharing information and trends with health-care providers
iHealth Blood Pressure Dock	US$ 99 for cuff; app is free	iPhone-enabled blood pressure cuff measures systolic and diastolic pressure, heart rate, and other vital signs; app creates interactive graphs and track data
Beam Brush	US$ 50	Bluetooth-enabled toothbrush and app tracks how long and often teeth are brushed; serves as a timer to ensure adequate brushing in each quadrant; can program a favorite song to brush to
Zeo Mobile	US$ 149 for headband; app is free	Sensor-embedded headband monitors sleep patterns, including REM and deep sleep; app offers advice on improving sleep habits

devices incorporated into clothing and accessories—in health and fitness alone could reach 170 million devices (Tilenius 2013). Some emerging trends that can shape the immediate future of mHealth include cloud technology, gateway apps, gaming and social media, and other technologies and delivery mechanisms to improve the utility and value of future apps.

Apps Using Cloud Technology

PulsePoint uses cloud technology to help save lives of those who experience a sudden cardiac arrest, a crisis event accounting for approximately 325,000 deaths in the

USA each year. At least 75,000 CPR-trained Americans have PulsePoint on their phones. The app pushes an alert tone to the user's phone when a cardiac arrest has been called in to emergency services in their geographic area. The app sends a map showing the victim's location for quick travel by the trained responder (Frangoul 2013).

The cloud computing market for medical imaging (radiology) is predicted to grow at a compounded annual rate of 27% through 2018. Cloud computing has a number of advantages, ranging from the ability to share images across providers to mitigating maintenance costs and improving collaboration. Even though there are concerns about data security and regulatory compliance, increasingly more providers are seeing the benefits of using the cloud (Novation News Release 2013). Issues associated with cloud computing are discussed in more detail in Chap. 3 mHealth Regulation, Legislation, and Cybersecurity.

Gateway Apps

As the public experiences an increasing overload of health apps and information, and desirable functions are dispersed across many apps, finding the right app and managing the information generated by the app becomes increasingly challenging. A gateway app is designed to function as a mobile portal to direct consumers to the right app among a variety of options. Gateway apps may ultimately help consumers avoid app overload; that is, having to search through too many single apps on the same topic to find the right app to meet their needs. Examples include First Aid, which was developed by the American Red Cross. This app offers consumers instant access to information on how to handle numerous everyday emergencies. Thus, rather than searching through multiple apps when there is a first aid need, the consumer can use this app to quickly access information (http://www.redcross.org/mobile-apps/first-aid-app). First Aid functions as a portal or gateway to a variety of information on first aid needs. For health professionals, Epocrates is reportedly already making progress toward a status as a gateway app. Epocrates offer a variety of drug information and resources, including access to journal articles, updates on drug interactions, as well as current medical news and also announcements (VanVelsen et al. 2013).

mHealth Gaming

Despite some hype about adapting game technologies for health care, it appears that we are not quite on the verge of integrating health and wellness tools into popular video or online games. At the 2013 HIMSS Media mHealth Summit, mHealth gaming was described as being "in its infancy." Developers, insurers, and providers are working to figure out how gaming technology might address health-care challenges. Game developers know to create a game, but they lack knowledge about

the health-care industry, specifically about how to connect the games with clinical outcomes. Meanwhile, the health-care industry needs to see the connection to justify investment. Nevertheless, the challenge applications that engage two or more individuals in achieving a fitness goal or behavioral change, such as United Healthcare's OptumizeMe may achieve widespread use and push development in this area more quickly than is expected.

Smartphones Combining with Twitter Accounts

More than 160 stroke patients have been treated remotely using smartphone diagnostic technology and Twitter accounts. Twitter, a microblogging service, claims more than 230 million active users. Importantly, the service supports more than 35 languages (www.about.twitter.com); a characteristic that offers exceptional value for health-care applications. The i-Stroke system transfers hospital-generated data, including computed tomography (CT) scans, MRIs, and CT angiograms to the physician's smartphone, which has been preloaded with the appropriate diagnostic tools for interpreting the data. The provider–patient consultation is conducted through Twitter direct messages, which can only be read by the message recipient (Bird 2012a).

Substitutable Medical Apps, Reusable Technologies

Substitutability is the capability of a system to replace one application with another of similar functionality. HealthIT.Gov defines substitutability as follows:

> Substitutability requires that the purchaser of an application can replace one application with another without being technically expert, requiring re-engineering of other applications they are using, or having to seek assistance from any of the vendors of previously or currently installed applications.

Consequently, substitutability capability enables developers to rapidly create a large marketplace of apps for consumers to choose from. Substitutable apps will be constructed around core components, thus driving down costs, supporting evolution of industry standards, and accelerating innovation. With the potential of decreased costs, a physician or a patient would be empowered to discard an underperforming app and replace it with one of higher quality or more utility (Substitutable Medical Apps 2013).

Usability with Electronic Health Records

Physicians overwhelmingly indicate a strong preference for electronic health record *usability* with their mobile devices. Can we expect that app developers will focus

on delivering apps that connect records with mobile phones and tablets? In most cases, seamless interfaces between app platforms and providers' existing health IT systems do not exist (Norton 2013). There are few examples of data from mHealth apps that automatically download into provider-based electronic health records. What actually occurs most often is that data from apps are fed into separate portals and then manually transferred to electronic health records. In many cases, it is unclear where data end up once transmitted from an individual's app (Silow-Carroll and Smith 2013).

Apps that Offer Instant Diagnosis

For many conditions, a diagnosis is based on visual examination and gross analysis of body sounds. For example, health-care workers are trained to diagnose and differentiate between pneumonia and the common cold by listening to breathing and coughing sounds. An app that transmits the needed visual or auditory data to the diagnostician using a camera or microphone could prevent a trip to a doctor's office for diagnosis and medication prescriptions if the condition does not warrant further diagnostic study or treatment intervention beyond medication. Such an app would be particularly attractive for caregivers of children and elderly adults. The convenience of diagnosis from home is complemented by the avoidance of exposure to other pathogens, an unfortunate by-product of visiting physicians' office and other ambulatory care settings. One example of this type of app is software developed by American and Australian scientists at STAR Analytical Services that allows patients to cough into their iPhone's microphone and get an "instant diagnosis" of cold, flu, pneumonia, or other respiratory disease. The cough sound is compared against a database of cough sounds associated with various respiratory disorders. The research behind this app is funded by a Bill and Melinda Gates Foundation grant. This app, and others like it, could prove exceedingly useful in developing countries where pneumonia is the leading cause of death among children (Chivers 2009; Gould 2010).

Avatar Apps

As the app market becomes increasingly crowded, virtual health apps and avatars are expected to gain a foothold. In 2010, Aetna began offering consumers round-the-clock help with the registration process, using an intelligent virtual assistant conversational software program developed by Next IT, a privately held Spokane, Washington-based company. Aetna named the virtual assistant Ann, and reports that Ann answers about 50,000 questions per day and nearly 1.5 million questions per month. Aetna claims to have reduced operating expenses without having an impact on the quality of service to its members (Tremoglie 2013). Meanwhile, in 2013, Samsung launched a health app designed for its Android-based Galaxy S4

smartphone that features an avatar that grows thinner or fatter along with the user in accordance with what the user eats and how much the user exercises. The app is a free download on the Google Play Store, available in Samsung's home market of Korea (Lee 2013).

Sensors and Wearables

There is increasing competition in the wearables market for wrist products, with Apple and Samsung both entering the market. Apple Insider estimates that the Apple iWatch will sell 63 million units in the first year. If Apple includes health and fitness sensors, this product will accelerate market growth for these mobile technology innovations (Tilenius 2013).

The mobile health sensor market is projected to grow approximately 70% annually over the next 5 years (Pogoreic 2013b). While the sensor market has been the purview of small technology companies, retail giants like Samsung and Nike recognize the market potential of pairing health sensors with consumer apps This pairing of products is expected to create a health product market that will reach US$ 5.6 billion by 2017. The consumer interest in this market is attributed to the developers' ability to make the medical products look more like fashion accessories than medical devices. Examples of wearable products include wristbands, helmets, socks, and patches. The sensors in these products can transmit data about falls, head injuries, skin ulcers, and many other situations that require medical intervention to providers who monitor the data.

There are a growing number of wearable devices on the market, including products such as Fitbit, Jawbone UP, Nike Fuel, and Misfit Shine, all of which use a three-axis accelerometer to track physical activity and calorie burn, and analyze sleep patterns. Estimates suggest sales exceeded 8 million devices in 2013. One example of a wearable device is a T-shirt embedded with wireless sensors that monitor respiration. This wearable device is particularly useful in diagnosing sleep apnea patients while they sleep comfortably at home, allowing patients to avoid an overnight stay at a hospital or sleep center. The respiration T-shirt is a product developed by a Boston-based start-up, Rest Devices, Inc., founded by three MIT graduates (Needleman 2012). Many analysts predict continuing strong growth in the future, especially as the wearables attain greater levels of accuracy with heart rate and other biometrics (Tilenius 2013).

Google Glass in Health Care

Google Glass, a wearable computer with an optical head-mounted display currently in beta testing, has the potential to innovate transmission and display of key data in virtually every facet of health-care delivery. A surgeon in the operating room can use Google Glass to review a checklist or images from patient scans or share the

view with another surgeon. An anesthesiologist could use Google Glass to access vital signs that otherwise would be on monitors, while maintaining his focus on the patient. And, physicians and nurses checking on patients could use the device to have the patient's chart appear without leaving the patient's bedside. Possible applications for the glasses appear to be gaining excitement and momentum, especially because of the potential to layer in different modalities. For example, the physician could examine a patient's arm and overlay the CT scan data or examine a patient's rash while comparing it to a database of cataloged rash images to determine a diagnosis.

A surgical team at the University of Alabama at Birmingham (UAB) performed one of the first telemedicine surgeries in the world in September 2013 using a combination of Google Glass and virtual augmented reality technology (Shepard 2013). A UAB orthopedic surgeon performed a shoulder replacement surgery in Birmingham, Alabama, while a surgeon in Atlanta, Georgia, interacted in the surgical field through the virtual reality application. His interaction was based on images transmitted via the Google Glass device worn by the UAB surgeon. The combination of these two technologies enabled a real-time engagement between two surgeons, allowing for interactive consultation and recommendations to be pursued immediately.

Smartphone-Enabled Devices

A growing number of medical devices are helping people bypass or reduce the need for medical professionals to manage "low-end" issues associated with chronic health conditions. For example, amputees can make fitting adjustments to their prosthetic devices using a smartphone app. This app contributes to physical comfort and patient empowerment, as well as less hassle for the wearer due to fewer trips to the prosthetist's office, where travel and wait time may exceed the actual intervention time. The app-adjustable prosthesis was developed by Orthocare Innovations LLC, a start-up company in Oklahoma City (Needleman 2012).

Think global, too. Spanish telecom operator Telefonica worked with Barcelona's Hospital de la Esperanza on a knee brace embedded with motion sensors that allow physicians to remotely monitor patients' rehabilitation after they have been discharged from inpatient therapy programs. Physicians watch avatars simulating the patient's movements and can monitor patients from their PC or mobile phone (Capell and Scott 2010).

Crowdfunding

This capitalization strategy offers consumers a chance to preorder products pending regulatory approval while giving potential investors an idea of the viability of the product once it gets FDA clearance. According to Rock Health's *Digital*

Health Funding in Review (2013), crowdfunding for digital health start-ups is on the increase. In 2013, Rock Health tracked 120 crowdfunding campaigns that raised US$ 9.2 million, 85 % of those on Indiegogo, referred to as the "go-to digital health crowdfunding platform" (Gold 2014).

Student Innovators

Students preparing for careers in health-care technology show promise as a source of future app developers. For example, students from the University of Pennsylvania won a health IT innovation award at Startup Weekend Health 2.0 in Philadelphia in February 2013. Graduate nursing student David Bendell won first place for his my In Case of Emergency (mICE) app. The app furnishes essential personal health information including blood type and allergies for people experiencing a health emergency. Third place was captured by a nursing student also for the KnowMe app, which creates profiles of nursing home residents that can be used by families and providers (Gold 2013).

Mobile Threats

Things change rapidly in the world of mHealth apps and consequently continuous monitoring is required. An example that gained media attention was the iPharmacy Drug Guide and Pill ID app. As reported on by *PC Magazine,* this is an Android app that earned a top developer award from Google Play; but according to Appthority was also one of the top offenders when it comes to risky privacy behaviors for apps in the health or medical category. iPharmacy claims that it encrypts personal information, but consumer drug searches are sent over the host network along with user-specific data. In addition, the app's privacy claims were not upheld (Eddy 2013). Appthority describes itself as an app risk management service that employs static, dynamic, and behavioral analysis to uncover the hidden actions of apps and empower organizations to apply custom policies to prevent unwanted app behaviors (https://www.appthority.com).

Privacy

Privacy Rights Clearinghouse, a California nonprofit corporation dedicated to helping consumers protect their privacy rights, published a study that evaluated the privacy risks for 43 of the most popular mobile health and fitness apps, including both free and paid apps (Privacy Rights Clearinghouse Study 2013). The study found that:

- there is considerable privacy risk for app users—72 % of the apps evaluated presented medium (32 %) to high (40 %) risk regarding personal privacy
- Privacy policies for apps studied did not describe the risks involved
- Many apps connect to several third-party sites without user knowledge
- Apps showing the lowest privacy risk were the paid apps

Integration and Interoperability

Lack of integration and interoperability exists throughout the health-care system, and is no different in the mHealth world. For example, blood pressure monitoring apps are available for consumers to use with their smartphones, but the ability to transmit the captured information to physicians, hospitals, or health plans is not assured. Providers and health plans must have health IT systems that are configured to accept information transmitted from a smartphone or tablet. Providing consumer access to an enterprise's network not only can pose great risk to internal data and patient privacy but also require significant financial investment to establish secure connectivity. And, that investment may not be a strategic priority for all organizations. As an anecdotal example, the head of the Indiana University-Purdue University Center for Biomedical Informatics learned this lesson first-hand. While his wife was able to record and organize her blood pressure readings on a smartphone app, her smartphone "couldn't talk" to their health care system's portal. Her "low-tech" solution to the problem was to take her smartphone with her to her doctor's visit (Norton 2013). However, the only way to get the data recorded in her clinic health record would be to manually transcribe the data onto a paper form and either scan the document or use a keyboard for entry into an electronic record.

Conclusions

The market for health-care technology products is big business and mHealth is emerging as a key player. However, not all health-care apps are widely available to the general public in their mobile platform stores. For example, some advanced medical apps already approved by the FDA are not aimed at the general public. Some apps are designed especially for health professionals; others are developed for patient use, but require a prescription. Still other apps target only a small subset of the populations, and remain outside the general app stores such US Apple iTunes app store (IMS Report 2013).

Innovation and investment in health apps may be on the rise, but according to health tech experts the vast majority of apps have failed to engage consumers or win over physicians. There are thousands of health apps available for download, many of them at no cost or minimal cost. But some of them are not of high quality and if downloaded will be dropped immediately. Other apps will be used a few times,

but once the novelty wears off and the interest wanes, consumers will quickly drop those apps and move on to something else (Heussner 2012). Foh (2012) identified five key drivers pushing the mHealth market, shown Box 4.2.

Box 4.2. Key drivers pushing the mHealth market. (Source: Foh 2012).

1. Consumer adoption of the product
2. Clinical adoption of the product
3. Evidence of effectiveness
4. Cost
5. Regulatory Climate

While these key drivers individually influence the mHealth market, each driver also has the potential to influence other drivers. For example, evidence of effectiveness and cost will likely affect adoption of an app by both the clinician and the consumer. In addition, evidence and cost will also likely be influenced by and in turn influence the regulatory climate (Koh 2012).

Is each of these key drivers being addressed? Are there some drivers that need more attention than others? The answers to both questions would be *yes* and *not yet*. The mHealth app market has not yet reached maturity. There are a large number and variety of apps to be found in the market, but few apps have demonstrated sustainability in terms of usage or funding. The apps tend to emerge without adequate testing or evaluation. There is no proof of concept demonstrated and cost savings are not visible. Furthermore, there is no measure of productivity offered. For example, an oncologist may now use an app on an iPhone instead of a specialty slide rule to assess tumor mass, but there is no evidence that doing so improves physician productivity.

Mobile technology used by physicians is clearly on the rise, and physicians are becoming accustomed to routinely engaging in online tasks and interactions, personally and professionally. Nearly all US physicians are on some form of social media, such as LinkedIn or Facebook (Dolan 2011). And, many physicians are taking to Twitter as well. About 1300 doctors signed up for TwitterDoctors.net, a site that describes itself as a directory of the most influential doctors on Twitter. That number may be indicative of a new generation of physicians using social media to comment on health and medical issues. A group of doctors analyzed the Twitter habits of 260 self-identified physicians who all had at least 500 followers. Half of the tweets were related to health or medicine and 12 % were self-promotional in nature. Around 3 % were flagged as "unprofessional," meaning they contained either profanity or discriminatory statements or represented a violation of a patient's privacy. These findings were published in a letter in *JAMA* (Pearson 2011; Letters 2011).

According to Manhattan Research's annual survey (*Taking the Pulse*), even though physicians increasingly are becoming open to the idea of reviewing data that patients have tracked themselves, most patients write their data on paper or share a printout from their home computer rather than transmitting data electronically. This

finding is consistent with data from the Pew Internet and American Life Project's annual survey, which has shown flat adoption of mobile health apps at around 10% (Pogoreic 2013a). What will it take to get consumers and physicians in the same health space?

The good news is that interest in mHealth seems to be growing among consumers, as evidenced by survey results that continue to reflect this trend. A Harris Interactive nationwide online survey conducted in May 2013 reported that more than one third of consumers are interested or very interested in using smartphones or tablets to ask their doctors questions, and to obtain appointments or medical test results. In addition, similar numbers reported being eager to use mobile phones and tablets for diagnostic and tracking health-care services such as monitoring blood pressure or blood sugar. The less good news is that demand may be outpacing the technology to deliver it; most of these apps are just being launched or are not yet available on the market. What type of services will eventually be offered to consumers and when is unclear (Norton 2013). And keep in mind even though mHealth tools such as requesting prescription refills, receiving e-mail reminders, and booking appointments have been available for more than a decade, many physician practices still do not offer these tools to patients (Terry 2012).

Moreover, the demographic skew of smartphones toward younger users makes it that much harder for the most expensive health-care users, the elderly, and those suffering multiple chronic conditions, to be targeted and for the health-care system overall to rein in costs. Current apps do not address this problem. Furthermore, because consumers are often confused and lack guidance to figure out which app best meets their needs, they often download and discard inappropriate apps, thereby creating a download skew to whatever has been downloaded by the masses, not those with the most utility. In doing so, the most downloaded apps continue to receive prominent attention as a result of high installation numbers. Physicians are confronted by a similar challenge when they venture to recommend an app to a patient (IMS Report 2013).

There is also a continuing need for a business case for health apps. Challenges arise in bringing apps to scale and are evident with the case of clinical management. Clinical management apps are mostly found in integrated health systems or through large employers. Apps that enable patients to interact with a physician's office are not yet in general use among either smaller provider groups or hospitals. This finding reflects the reimbursement, regulatory, technical, personal, and financial challenges associated with scaling apps. Integrated health systems may have the capacity to experiment with apps that help manage patient's conditions and show promise of reducing costs, but providers working in fee-for-service environments are looking to be paid for time spent on managing care through apps as well as for the equipment costs and software involved in doing so. Meanwhile, insurers as well as employers are awaiting documentation of app effectiveness before committing to reimbursing such costs (Silow-Carroll and Smith 2013). However, establishing efficacy is not a challenge that is easily met.

New York-based mobile health-care provider Happtique spent considerable effort in an attempt to verify the effectiveness of apps. In March 2013, the com-

pany published its final standards for its mHealth application certification program. The certification was viewed as the penultimate seal of approval, thereby offering providers and consumers the maximum confidence in the apps they downloaded. Happtique's Health App Certification Program (HACP) was developed with the assistance of the Association of American Medical Colleges (AAMC), CGFNS International, and Intertek. The certification program was developed to evaluate and certify apps using standards that are grouped into four major categories—privacy, security, content, and operability. In December 2013, Happtique announced it had certified 19 health and medical apps. However, less than 2 weeks after the announcement, Happtique suspended the certification program after a software developer revealed security vulnerabilities. This example only serves to underscore the sizable obstacles facing the future of mHealth in general and app development in particular (Baum 2013).

Others wonder whether advancements in mHealth will ultimately create the phenomenon of "do-it-yourself" (DIY) "physicians." Some observers believe this is possible, especially when we are witness to apps that can diagnose respiratory conditions after coughing into a smartphone (Gould 2010). This DIY perspective would fit with other aspects of consumer culture that directs us to go online and download information to accomplish what we once asked others to do for us. Whether it involves resolving payment disputes or finalizing travel arrangements, or ordering dinner—consumers have gotten used to going it alone with their phone or tablet. In addition, others suggest that we are becoming the CEOs of our own health, with a big assist from technology, and that consumers are driving health-care transformation in the USA (Tilenius 2013). Regardless of whether consumers are labeled CEOs of their own health or DIY physicians, the outcome is similar; technology is putting the consumer in charge.

Whether the consumer wants to be in charge is still undetermined. Some analysts suggest that despite increasing adoption of smartphones and availability of apps, consumer demand for health apps is ephemeral. Why? Because, in many cases, they are boring, time consuming, and the value returned is not worth the effort. Apps might make it easier to measure calories and track exercise activity, but can they lead consumers to lose weight? Unless apps provide willpower, too, the outcome often ends up with consumers returning to earlier behaviors. Anecdotally, consumers report that the constant reminders sent to their phone come to resemble nagging. And who likes to be nagged? In addition, too many apps require too much work for consumers (inputting information) and are boring. Eventually, consumers might find it hard to stay motivated to use the app, especially the growing contingent of couch potatoes who will likely prefer to reach for the aspirin bottle versus recording and inputting data (Richman 2010). Thus, app developers will also be charged with figuring out how to sustain consumer engagement. Bottom line: Getting consumers to download a health app may turn out to be the easy part—incentivizing them to continually use the app effectively probably will be the larger challenge.

The mHealth Conundrum

Do patients really prefer online visits with their care team? Or are consultants, health plans, and app developers hyping virtual visits to the extent that consumers are led to believe they should prefer online consults with physicians?

mHealth is expected to improve medical diagnosis and treatment as well as health outcomes. mHealth is also viewed as transforming how doctors, nurses, and patients think about health care. mHealth tools enable physicians and nurses to monitor vital signs, note changes in activity levels, and verify that medications have been consumed—all without ever seeing the patient face to face. So there will be fewer office visits and hospitalizations. The tradeoff for decreased face time with providers will be that consumers will have unprecedented access to data that will help them take charge of their own health care.

Is this remote relationship a good thing for patients? A global survey by Cisco reported that 74% of consumers were open to virtual doctor visits and were comfortable with the use of technology for the clinician interaction. The study's findings challenged existing assumptions that face-to-face interaction is always the preferred health-care experience (Cisco Press Release 2013). Is virtual good for physicians, too?

Dr. Alexander Friedman (2010) wrote a guest column in the *Wall Street Journal,* talking about how electronic medical records had shifted physician attention away from the patient and toward a computer where physicians spend time checking boxes and inserting codes. He wrote:

> I often stood turned away, typing on the computer mounted against the wall, occasionally turning my head over my shoulder to make eye contact. I used a pre-emptive apology—"I'm sorry. I apologize for having my back to you"—but knew the excuses didn't make up for the rudeness. A patient in pain or worried about her pregnancy deserves attention.

Perhaps both consumers and physicians are becoming less enamored with face-to-face visits because both are becoming increasingly distracted by technology during the office visit. The physician may be doing as Dr. Friedman described, checking boxes for electronic health records. Perhaps the patient is also online searching for medical information. Or maybe both are just checking other e-mails. Who knows? Regardless, neither is occupying the same mobile space and so it may be that virtual visits are gaining on actual face-to-face visits.

A 2012 Accenture consumer survey reported that 90% of respondents wanted to have online access to their medical information and 75% of respondents wanted to be able to have e-mail consultations with physicians. However, 80% said they still wanted to have face-to-face interactions with their doctors when needed (Terry 2012). And we are back to the conundrum.

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Chapter 5
mHealth Stakeholders: Follow the Money

Introduction and Overview

The health-care industry generally is highly complex and the mHealth segment considered separately is no less so, although some of the factors driving the complexity differ between the macro and micro levels. At both levels, the number and influence of various stakeholders are important factors organizations and individuals must address to achieve viability and success in their endeavors. A stakeholder is an individual, group, or organization with the ability to affect the operations and success of an organization, or conversely to be affected by the organization's decisions and actions. Typically, relationships are reciprocal rather than unidirectional, and often the various stakeholders will have independent relationships among themselves. These stakeholders, acting independently or as cabals, can influence an organization's strategy, either to constrain options that can be pursued or to inhibit the achievement of established goals (Freeman 1984).

Knowing who their stakeholders are, what they want or need from the firm, their relative strength and importance, and other factors that facilitate managing the relationships may be pivotal to the success of an organization, particularly for start-ups and players in a volatile environment. The mHealth field not only qualifies for these dual concerns of volatility and new market entry but also faces issues such as emerging regulation, lack of proven business plan models, and other challenges that are attributable to dependence on stakeholders. Developers, investors, and sales firms alike should formalize their assessment of stakeholders, both those that are industry level and those that are firm level, and acknowledge sources of power, self-interest, support, and threat. Management strategies can then be developed to ensure that stakeholder relationships are optimized.

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Identifying and Classifying Stakeholders

The stakeholder concept entered the strategic management literature in the 1970s, but was not used in health services management research until the late 1980s, and then primarily with regard to hospitals, the central and controlling point of care delivery during that time. Initially, stakeholders were classified as cooperative or threatening with regard to their inclination to support or not support the hospital's initiatives. However, as the delivery system and payment mechanisms changed, managers and researchers began to consider which stakeholder groups had the potential—and the interest—to affect a hospital's financial resources. This analysis led to the development of techniques for identifying and managing stakeholders determined to be key to the organization's success (Blair and Whitehead 1988).

One of the first steps to understanding stakeholders is to categorize them by descriptive labels. The simplest classification is to distinguish those within the organization's boundaries from those outside. *Internal* stakeholders operate almost entirely within the boundaries of the organization, affecting organizational processes. *External* stakeholders may provide inputs to the organization (suppliers of goods and services) or use the organization's output (customers or downstream producers). External stakeholders may also be competitors that offer similar products or services. *Boundary spanners* operate both inside and outside the firm's structure, such as a consultant hired for unique knowledge or skill that may also provide similar services to competitors or related companies (Freeman 1984; Blair and Fottler 1990).

Among these broad groups will be stakeholders designated as "key," those who have the greatest stake in the firm, and are most likely to be aggressive in exerting influence. Key stakeholders may be either cooperative or threatening. The degree of consensus about issues or shared concerns among stakeholders is an important assessment as well. It is true there is "power in numbers," and larger interest groups require more management, particularly if they are not supportive of the firm's strategic goals. Stakeholders achieve power in various ways; some typical sources of power are shown in Box 5.1. The pivotal questions are whether the stakeholder(s) will use their power to help or to hinder the organization, and how likely they are to exert their power (Freeman 1984; Blair and Whitehead 1988).

Box 5.1 Sources of Stakeholder Power

- Have control over needed resources
- Possess skills critical to design or operations
- Provide necessary services
- Exert political power or influence
- Have veto power
- Are high-dollar investors or large-volume purchasers

Who are the key stakeholders for app development companies and investors in the field of mHealth and what are their primary interests? Because the Affordable Care Act (ACA) promoted patients' engagement in their own health care, consumers are the starting point, followed by providers—health systems and physicians, insurers/payers/private sector investors, app developers and start-up companies, big pharma and biotech companies, followed by the military. The government, due to its regulatory and technology deployment roles, is a key stakeholder, but because it is discussed throughout this book, the focus here is on the emerging role of the military in developing mobile health applications.

Consumers/Patients

According to extensive survey data, patients report that they want health apps to connect them with their doctors and nurses. What they do not want are apps designed to complicate their lives—make self-care more work for them and essentially "nag" them with continuous reminders (Gruman 2013; Silow-Carroll and Smith 2013). Nevertheless, consumers are confronted with an overwhelming number of apps with little if any help available to guide them in choosing the best ones. The Internet has placed an astounding amount of health-care information within easy access by consumers, which has created expectations for similar benefits from the mHealth industry. Increasingly, consumers will demand more utility from technology to enable their participation in the health-care decision-making process along with their providers. In short, consumer expectations will expand, not shrink, and app developers must meet the demands of the consumer markets to survive and thrive (IMS Report 2013). Consumers often complain that app designers are inattentive to what they really want and online blogs and social media illustrate this belief. Some finger pointing is done at the high-tech (and young) Silicon Valley developers who think about app development from the perspective of the young and healthy consumer, whom they likely expect to be more tech savvy, versus the consumer who is older and/or has multiple chronic health conditions that contribute to rising health costs. This second group of consumers may have the greater need for disease management apps, and a greater need for them to be easy to use and reasonably priced.

Providers/Health Systems

Prominent integrated health systems, including Geisinger Health System, Kaiser Permanente, and Group Health Cooperative (Puget Sound, Washington), appear to have embraced the mHealth trend fairly early on. For example, in 2011, Geisinger Health System launched a patient portal mobile app, called MyChart, which offers patients access to their health records as well as the ability to communicate directly

with members of their care team, including text messaging involving appointment and medication reminders. In 2013, Geisinger began testing a Cardiac Rehab app that enables patients to track physical activity, receive educational materials along with medication reminders, and transmit concerns to their care team. The app is intended to decrease patient visits to the hospital or ambulatory clinics. One of Geisinger's emerging mHealth projects involves the electronic capture of patient-reported data, using a third-party tool to gather information from their asthma patients about how effectively they are managing their condition (Dorfman 2013; Silow-Carroll and Smith 2013).

Integrated health system Kaiser Permanente, one of the largest nonprofit health plans in the USA, is launching an open application programming interface (API) called Interchange that will enable developers to use publicly available information from Kaiser Permanente in their own apps. Initially, Kaiser Permanente will share data about the location, hours of operation, and specialty information for the organization's 37 hospitals and more than 600 medical offices. This development is expected to facilitate innovation as well as decrease app production time and bring apps to market more quickly (Comstock 2013b).

The prominent Cleveland Clinic has created an incubator to foster internal app development in the belief that its physicians, IT staff, and others have some great ideas for apps and other mobile products. They formed a mobile "governance committee" of physicians, marketers, administrators, registered nurses, and IT representatives to encourage all Clinic staff to submit their ideas—even if they do not know how to make the ideas actionable. The committee resembles private incubator companies such as Rock Health because it also intends to find the funding for approved products and guides the creator through the development process. The Clinic already has a suite of apps in development, including a consumer-oriented health news app for iPad with videos, a physician app that will deliver the Clinic's clinical content to doctors around the USA, and a sleep app from the Clinic's Wellness Institute (Jackson 2011). Overall, app developers should be attuned to an essential provider "need"—the ability of commercially developed apps to transmit their stored data to the proprietary apps in a secure fashion. Furthermore, patients should be expected to retain control over the data transfer, sending it only to whom and when they choose.

Physicians

Physicians have long been the patient's advocate, as well as gatekeepers to health information and treatment options. But when it comes to recommending a health app, they have been unable to provide much assistance to patients depending on them for guidance. While physicians may perceive potential benefits of health apps, many remain skeptical about their utility for widespread adoption largely because they have not yet seen evidence of value or clear professional guidelines regarding app use in practice (IMS Report 2013).

Most medical students receive tablets, iPods, and other mobile devices along with their standard dissection kits. The expectation of mHealth adoption for the next generation of physicians is quite high. Studies show that physician smartphone adoption rate is increasing and was projected to reach 81% in 2012 (Rajecki 2009). However, more recent studies reveal where and to what extent physicians use smartphones and laptops. The 2013 Kantar Media Sources and Interactions Study of more than 3000 physicians representing 21 specialties revealed that 74% of physicians are using their smartphones at work for work-related tasks. Of particular significance is the finding that of all tasks performed on smartphones and tracked in the study, not one showed a decrease year over year. This finding illustrates how deeply entrenched smartphone usage is becoming in the medical workplace. Other study highlights included:

- Forty-three percent of all physicians surveyed reported that they look up reference drug data on their smartphones. This is a 13% increase over last year's survey results.
- Thirty-nine percent of all physicians surveyed said they use their smartphones to find and perform clinical calculations. This is a 4% increase over last year.
- Thirty-one percent of all physicians said they made prescribing decisions from their smartphones, up from about 21% last year (Alvarez 2013; Dolan 2013).

Manhattan Research's *Taking the Pulse,* the annual survey of trends in physician technology adoption, showed that about 72% of US physicians now use tablet devices. This finding reflects an increase of about 30% over physicians who were using tablets in 2011. Whereas the smartphone appears to be the "quick hit device" for looking up information, the laptop appears to be more oriented towards content consumption and accessing electronic health records. The survey was conducted online with 2950 physicians participating (Comstock 2013a).

A survey of medical residents indicated positive usage with iPads and other tablets. However, because of their reported high initial expectations for these mobile devices, it was believed that such expectations might ultimately be obscuring overall satisfaction results (Slabodkin 2013a). It is also possible that the survey results are only affirming what we anticipate intuitively, that younger physicians may be overly optimistic concerning the use of these devices.

A nationwide study from Black Book Rankings, a Florida-based market and opinion research company, showed that primary care and internal medicine physicians indicate a strong preference for electronic health record *usability* with their mobile devices. That is, these physicians want access to patient data anywhere, anytime, and on any type of mobile device. Yet surgeons, especially orthopedic, ophthalmologic, and ear, nose, and throat surgeons, revealed low interest in using mobile devices generally—less than 14% on average (Black Book Rankings 2013; Slabodkin 2013b). A study by eClinicalWorks found that 93% of doctors interviewed perceived value in linking mHealth apps with electronic health records. The same survey found that 93% of physician respondents believe that mobile health apps can improve a patient's health outcome (eClinicalWorks 2013; Slabodkin 2013b).

Physicians are also being influenced by government incentives to foster patient engagement online. Consumers are increasingly connecting to a variety of businesses using online communication tools, including such services as appointment reminders and solicitations from service companies ranging from hairdressers to banks. However, the online relationship with physicians has not been encouraged, although it is expected to start growing in 2014 because of financial incentives offered through government insurance programs run by the Centers for Medicare and Medicaid Services (CMS). Physicians will be rewarded if they make electronic health records available to patients online, communicate with patients online, and assure 5 % or more of their patients use the technology (Consumer Reports 2014).

An app known as "Medical Information Anytime Anywhere" (MIAA), developed by Palomar Pomerado Health in San Diego, CA, was highly touted in February 2011 at the HIMSS meeting in Orlando. The app purportedly gives physicians access to records regardless of software systems used. Cisco was a major funder for the prototype development (Bowman 2011; Millard 2011). Whether the app has found success is not yet documented in the press or on its Facebook pages.

Payers: Insurers and Employers

Currently, payers have the most influence over health-care treatments and patterns as well as the evaluation of health outcomes results. Accordingly, they are moving to embrace mobile apps as a means to achieving goals of improving health and productivity while reducing costs. However, payers also require clear evidence of value and benefit before they will reimburse or promote the use of apps. The mHealth industry must begin to generate credible evidence of benefit from the use of apps to show payers the potential magnitude for improving health outcomes and behavioral changes (IMS Report 2013).

UnitedHealth Group is ranked as the #1 insurance company in America by *U.S. News and World Report* (2013). UnitedHealthcare, its health benefits company, uses an online virtual health-care website (www.healthcarelane.com) to engage its members and offer access to a variety of information sources, on topics ranging from preventive care, to health-care reform, to how to access pharmacy benefits. The website uses short videos, all of which can be accessed on mobile devices. In January 2012, UnitedHealth Group announced that it had partnered with three mobile health information technology companies, CareSpeak Communications, Lose It!, and Fitbit. These IT companies all offer health-related mobile applications or devices aimed at achieving health and wellness goals (Lewis 2012).

Another health insurance giant, Cigna, has partnered with Samsung to codevelop health and wellness features to be built into Samsung's "S" Health platform. This is believed to be a new service model of innovation that links a mobile industry giant, Samsung, with the health-care industry. Initial development is aimed at delivering health-related tips and articles through the Samsung "S" with an ultimate goal of connecting individuals with caregivers, doctors, and hospitals to improve health and

wellness globally (Mondy 2013). The app received Food and Drug Administration (FDA) clearance for use as a cardiology signal transmitter in early 2014, paving the way for the app to connect with other medical devices (Comstock 2014).

Private Sector Investors

Most mHealth apps do not require FDA approval, and the FDA has no plans to regulate smartphones or tablets in their roles as platforms for these apps. According to Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, this type of clarity is essential for attracting investors and also for accelerating app innovations (Lowes 2013). Furthermore, mobile technology has created a seemingly open playing field for investment, app development, and innovation compared with past technology opportunities that often required the commitment of huge sums of capital and other resources to bring the product to market. Even though the FDA represents a significant obstacle in the mHealth market, the cost and time to get mobile health apps cleared is expected to decrease with improvements in guidelines (Kharif 2011; Lowes 2013).

Many believe that investment funding and venture capital groups have the potential to be significant players in the health-care app space. For example, in August 2013, the Calorie Counter app by MyFitnessPal, the most popular free calorie counter and fitness tracker on Google Play in the USA, and coming in second on the Apple Store in the USA, was the recipient of a venture capital infusion of US$ 18 million. The app and its affiliated website reportedly had more than 40 million users, with the majority coming from desktop use (not mobiles), and had achieved profitability through product advertising revenues. The venture capital firms underwriting this investment, Kleiner Perkins Caufield & Byers and Accel Partners, believe that consumers are ready to take more control over monitoring their health (IMS Report 2013; Ziobro 2013).

Venture capitalists (VC) are said to "love" mobile health devices and apps. According to a research report by Rutberg & Company, a self-described research-centric investment company, 50 companies in the mobile health segment attracted a combined US$ 310 million in VC funding during the period January–August 2013 compared with US$ 229 million raised by 42 firms during the same period in 2012. In the mobile health app space, Healthtap, MyFitnessPal, and Medivo led the funding race overall. The top three recipients of VC funding during the first 8 months of 2013 were Proteus Digital, a smart-pill maker, and Fitbit and Withings, makers of fitness measurement bands.

Proteus's product, a tiny silicon chip embedded in a pill activated by stomach acids, communicates with a smartphone. Because it is ingested by the patient as a medical product, the smart pill is a regulated device, requiring FDA approval. The Fitbit and Withings bands are consumer devices that do not offer any risk of harm to the consumer and therefore do not require FDA approval (Jha 2013).

Mercom Capital Group (2013) announced that VC funding continued its rapid growth in the second quarter of 2013, raising US$ 623 million. There were 168 funding deals negotiated during this quarter compared to 104 the previous quarter, and a total of 163 in all of 2012. According to CEO Raj Prabhu, "VC funding in Healthcare IT is now on pace to exceed US$ 2 billion in 2013. The government's initiative to open up health-care data has been a contributor to the surge in activity and investments in consumer-focused companies as they turn available data into usable applications and services."

App Developers and Start-ups

Apps that are available to the general public are created by a variety of developers, ranging from individuals with a unique idea they want to pursue to large organizations that have a strategy for commercializing apps for revenue. Because of this diversity, there will be a wide range of scale as well as investment and capitalization and return on investment (ROI) assumptions to be found in business models for consumer health apps. Meanwhile, the potential pool of app developers shown in the box is likely growing because of the expanding market for mobile health apps.

Box 5.2 App Developer Categories

- Individuals, including physicians/clinicians
- Integrated health systems
- Facilities such as clinics
- Academic organizations and research groups
- Patient advocacy groups
- Corporate investors and venture capitalists
- Hedge funds
- Pharma and biotech companies
- Weight loss and fitness companies
- Retail pharmacy chains
- Health insurers, public and private
- Health IT companies
- Mobile device companies
- Mobile telecom operators

According to mobile health IT experts, mobile app developers must move beyond innovation to achieving integration. If mobile apps are not integrated with clinical workflow and associated with payment incentives, they are dead-ended (Conn 2012). One of the challenges for app developers is combining health-care industry knowledge and experience with health IT. A company that sets out to address such

challenges is Rock Health (www.rockhealth.com), a full-service funding company and incubator platform for mHealth. Read the case "The Genesis of Rock Health, The mHealth Start-up Platform and Health 2.0 Incubator" to learn how this start-up platform company has progressed and also about its prestigious partnerships with investors and providers such as the Mayo Clinic.

Case: The Genesis of Rock Health, The mHealth Start-up Platform, and Health 2.0 Incubator (Source: Dolan, B. (March 10, 2011). Harvard Students to launch mHealth, Health 2.0 Incubator Rock Health. *MobiHealthNews,* and the company website http://rockhealth.com/) Four Harvard Business School students launched a San Francisco-based mobile health and Health 2.0 incubator Rock Health that has evolved into a full-service start-up funding group for mHealth entrepreneurs. Rock Health looks to provide health-care expertise, development resources, and eventually funding to winning ideas. The core team at Rock Health includes Medical Director Nate Gross (who is also involved with the soon-to-launch Doximity), Interim CFO Dan Monahan, Creative Director Leslie Ziegler, and Managing Director Halle Tecco.

According to Rock Health's website, the incubator's investor partners include Accel Partners, Mohr Davidow Ventures, Aberdare Ventures, California HealthCare Foundation, and others. More importantly, the team is also working closely with the Mayo Clinic (consistently ranked one of the top hospitals in the world). The incubator's FAQ reads

> No experience in the health space? That's great. We've built a program to give you resources and connections in the sector.

And it emphasizes that their "friends" at the Mayo Clinic are excited to help out.

In a recent interview with MobiHealthNews, Rock Health's Halle Tecco explained that the incubator intends to bring new talent to health care: "We are trying to focus on the technology itself and are looking to find technologists," she said. "We are trying to bring in really great developers and programmers and encourage experimentation and out-of-the-box thinking about health care."

Similar to other incubators, Rock Health plans to host pitch days that provide their start-ups with an audience to its venture capital partners and down the road other VCs as well, "We are putting together a panel of judges including our advisors as well as our other partners," Tecco said. "This is typical for any incubator, it's not person making the decision, it's a team of people. We are going to look at this from a number of lenses," including from the health-care provider's perspective and the investor's.

Rock Health's website lists an impressive group of advisors from Twitter, 23andMe, HealthTap, Mayo Clinic, and more. Mentors include the founder and CEO of Sermo, Dr. Dan Palestrant.

In 2012, tech companies invested a total of US$ 1.4 billion into digital health companies, an increase of 45% over 2011
There was a 56% increase in investment deals in 2012 for digital health compared with the previous year
Compared to the declining investment in traditional health care, software and digital health funding is increasing
A total of 134 digital health companies each raised US$ 2 million in 2012
A total of 179 organizations invested in digital health companies, with most only committed to a single deal
Eight investors, including Qualcomm Ventures, Aberdare Ventures, and Merck Global Health Innovation Fund, invested in three or more digital health companies
Notable digital wellness start-ups such as PingMd, Wello, BreakThrough, and BeyondLucid individually raised as much as US$ 1.3 million to fund their programs
The market for embedded health devices is on an accelerated pace and is predicted to reach 170 million devices by 2017
The digital health market's rapid expansion is good for the job market; hundreds of positions opened across the country in digital health start-ups (Gold 2013; Digital Health Funding in Review 2012)

Table 5.1 Highlights of Rock Health's Digital Health Funding in Review (2012). (Source: Digital Health Funding In Review (2012) and Gold (January 08, 2013). Digital Health Funding up 45% in 2012. *FierceHealthIT.* Retrieved online at http://www.fiercehealthit.com/story/digital-health-funding-45-2012/2013-01-08)

Digital Health Funding in Review (2012), a report prepared by Rock Health, offered a comprehensive analysis of the investment and overall funding markets for mHealth for the year. Highlights from the report show that in 2012, tech companies invested a total of US$ 1.4 billion into digital health companies, an increase of 45% over 2011. In addition, compared to the declining investment in traditional health care, software and digital health funding is on its way up. The digital health market's rapid expansion is good for the job market too, with hundreds of positions open across the country in digital health start-ups (Gold 2013; Digital Health Funding in Review 2012). Table 5.1 provides more details.

The most recent version of Rock Health's *Digital Health Funding in Review* (2013) reported that total digital health funding in 2013 reached US$ 1.92 billion. This represents 35% growth since 2012 and more than 100% growth since 2011. Overall, 195 digital health deals above US$ 2 million took place in 2013, according to the report. In addition, the report also indicates that 27 separate investors made three or more digital health investments in 2013, compared with only 8 investors in 2012. Finally, the six themes shown in the box emerged in 2013, representing nearly 50% of last year's funding.

Box 5.3 Funding Themes for Digital Health Investments (Source: Gold (2013))

- EHR/Clinical Workflow
- Analytics/Big Data
- Digital Medical Devices
- Wearables/Biosensors
- Population Health Management
- Healthcare Consumer Engagement

Big Pharma and Biotech

The 2013 class of big pharma and biotech apps is projected to be a bellwether. Previously, biopharma companies introduced apps on Apple devices first and on Google's Android later. But 2013 has seen the emergence of simultaneous launches so that Apple has fewer exclusive arrangements, and app developers can pursue Android opportunities, too. Growth in the numbers of Apple and Android devices also has extended the potential reach of biopharma apps, and companies have responded by diversifying their output beyond typical adherence, diary, and text-based education apps. Examples of these apps include:

- *AstraZeneca's Grace 2.0*: AstraZeneca supported the creation of an app based on the Global Registry of Acute Coronary Events (GRACE). Health-care providers can use GRACE 2.0 to identify high-risk heart patients. AstraZeneca also lent its support to the UK's National Health Service's My Medication Passport, which allows patients to track the names, doses, and timings of their drugs. Both apps arrived on Apple and Android devices almost simultaneously.
- *Bayer's My iPill*: Forgetting to take a contraceptive has far-reaching consequences. In December, Bayer made My iPill available on iPhones to help women remember to take their daily contraceptive pills. The app sends personalized reminders at the same, user-defined time every day and works with both 21- and 28-day packs of pills.
- *Janssen's Care4Today*: In August 2013, Johnson & Johnson subsidiary Janssen released version 2.0 of its health management app, Care4Today. The app can now send alerts to family members when someone does not take their medication and produce charts showing adherence to treatment regimens. Janssen donates 5 cents to charity for each day the user is fully adherent to their medications (Taylor 2013).

The Military

The government's digital strategy has created several partnerships to develop mobile health technologies relevant to government-sponsored groups such as military personnel and government insurance beneficiaries. Of particular interest is the military's

involvement in adopting mHealth tools to advance its health-care programs. Throughout history, wars have contributed to rapid technological advances in health care. The immediacy of battlefield issues such as wounds and illnesses historically has led to rapid technology advancements and scientific discoveries. Whether it was antibiotics, mobile surgical units, or new surgical procedures and protocols, or prosthetic devices to replace missing limbs, the pace of technology accelerates to meet the demands of treating patients on site and in their return to postwar life. With the emergence of mobile technologies, the military is aggressively seeking apps to help soldiers on today's battlefields and afterward when they return to civilian lives.

Among the plethora of health mobile apps for self-monitoring and medical diagnosis, a number of them are aimed at veterans' health issues. For example, the Department of Defense (DOD) has released a biofeedback app to help soldiers deal with stress. The mobile app, BioZen, is reportedly the first portable, low-cost method to enable patients to use biofeedback in and outside of clinic treatment (American Forces Press Service News Release 2013). Examples of other mobile health apps for veterans include:

- PE (prolonged exposure) Coach helps patients process memories, records therapy sessions for playback between sessions, and offers breathing exercises.
- Mobilyze uses phone sensors to capture data for comparison to a mood diary and applies a predictive model to recommend that the patient engage with another person.
- T2 Mood Tracker records a range of emotions for transmission to the patient's therapist. An updated version allows storage on a home computer as well (Hall 2013).

Additionally, the US Army is funding researchers at the Worcester Polytechnic Institute and the University of Massachusetts Medical School for a 3-year, US$ 1.9 million project to develop a small wireless sensor that will be able to detect blood loss. Similar sensors are planned to be developed for smartphones. Thus, Army medics and other first responders in the field will be able to use their smartphones as a diagnostic tool to triage trauma patients with blunt-force injury for which there are no visible signs of bleeding (Bowman 2012).

Managing Key Stakeholders

Once the key stakeholders are identified, and their needs and concerns are assessed, management tactics can be established to optimize a stakeholder's contribution to the organization or to restrict their potential for harm (Malvey et al. 2002). As described previously, stakeholders can be classified logically as supportive or threatening. Supportive stakeholders generally are allies, with goals that are congruent with those of the company. The term non-supportive may also be used to describe a stakeholder who has a high potential for threat and little potential to cooperate or contribute positively. A third category, "mixed blessing," provides more precise labeling and, thus, better formulation of management tactics.

While the terms supportive and threatening are self-explanatory and engagement or defense tactics are relatively intuitive, mixed-blessing stakeholders require more analysis and formulation of responses. A mixed-blessing stakeholder can be either supportive or threatening, depending on the particular issue under consideration. That is, they are on the fence depending on what they perceive as potentially beneficial or harmful to them, and multiple management tactics may be needed if they cannot be moved to a completely supportive role. Table 5.2 offers an analysis of key mHealth stakeholders and evaluates them in terms of their likelihood of support and their potential to migrate from being a mixed-blessing stakeholder to becoming supportive.

Stakeholders who pose a threat to the company or product require a straightforward approach of defense. A defensive strategy can be time-consuming and expensive to pursue, but threats to the organization must be controlled. For stakeholders with little potential for threat or cooperation, those on the margin, very little attention is required unless a new initiative is likely to bring them into the game. A simplistic monitoring approach may be sufficient to recognize when the stakeholder is taking an interest in a new product or market development.

Supportive stakeholders are the ideal. Management tactics should be focused on involvement and engagement, increasing your connection to them and theirs to you. This approach requires managing communications and creating forums for participation and input, particularly into new product development. In a field such as mHealth apps, strong customer service programs are extremely important to maintain continuing support and willingness to explore new offerings.

From many perspectives, the most challenging group of stakeholders to manage is the mixed-blessing group, because of their volatility. They can move from passive to aggressive to marginal depending on the current situation or a particular strategy under consideration. One management approach is not sufficient for these stakeholders, because of their propensity to withdraw their support or actively challenge a company's direction. Effective management approaches include collaboration to the extent possible—the more a stakeholder engages and commits support over time, the more difficult it is to switch positions over a single future issue. Defensive strategies, when required, should not be so aggressive that future collaborative efforts are stymied.

Summary and Conclusions

No business or service organization exists without stakeholders, and savvy executives, investors, and entrepreneurs recognize the need to manage those considered to be key to the success of the organization. Whether a stakeholder is supportive or non-supportive, their power, and the likelihood of using that power, must be assessed, along with understanding what they need and want from the organization. Relationships among the stakeholders must be considered as well, because size is

Table 5.2 mHealth stakeholder analysis

mHealth stakeholder	Stakeholder category	Assessment
Patients	Supportive	Surveys repeatedly show that patients want to engage with their care team and have access to health information and options
Patient advocacy groups	Supportive	These groups want to facilitate the positive benefits of mobile technology for patients
Physicians	Mixed blessing Could be moved to supportive category if the evidence emerges to help them recommend and use apps with assurance Could be moved to threat category if evidence is not there or if they feel technology is interfering instead of enhancing the patient–physician relationship	Physician surveys and studies demonstrate that physicians are getting more comfortable online, but they want more evidence of value and clear professional guidelines to feel confident recommending apps to patients
Nurses	Supportive	Nurses especially like the health information tools, the potential for patient education, and enhancements
Institutions where care is provided (hospitals, clinics, physicians' offices, and others)	Large integrated health systems are supportive Smaller facilities are probably mixed blessing	In general, providers want mHealth apps to reduce costs. Larger facilities can afford to experiment with mHealth and develop mHealth tools with multiple uses, ranging from patient management to clinical treatments. Smaller facilities, including physician practices are unable to afford much experimentation and subsequent adoption
Payers (government/public, private, and employers)	Supportive	All of these stakeholders are looking to mHealth to rein in costs, create efficiencies, and improve health outcomes
The US military	Supportive	mHealth assists the military in providing medical care on the battlefield and when the veteran returns home. Partnerships with universities and tech companies reflect the military's financial commitment to furthering the development of these apps

Table 5.2 (continued)

mHealth stakeholder	Stakeholder category	Assessment
Biopharma companies	Supportive	Growth in the numbers of Apple and Android devices has extended the potential reach of biopharma apps, and companies have responded by diversifying their output beyond typical adherence, diary, and text-based education apps. The 2013 class of big pharma and biotech apps is suggested to be a bellwether
Technology companies (devices, applications, software, infrastructure, data analytics, and others)	Supportive	mHealth has opened up new opportunities and markets for these companies, especially start-ups. Rock Health reported tech company investment of US$ 1.4 billion into digital health companies in 2012, an increase of 45% over 2011. Total digital health funding in 2013 reached US$ 1.92 billion
Telecommunication services providers	Supportive	These providers have saturated the mobile phone markets. Health care offers a growing opportunity to partner with providers in developing app technology

one source of strength and stakeholders with shared interests can be a boon or a challenge.

mHealth stakeholders can be identified at the organization level and at the industry level, and include those who can promote app adoption, such as physicians and advocacy groups, and those who can be pivotal to bringing a product to market, such as investors and regulators. All categories should be identified and attention given to those with the greatest potential for support or threat, and those most likely to use their power. The group requiring the most attention is the mixed-blessing category due to the volatility of their engagement—supportive on some issues, non-supportive on others.

The ACA's focus on patient engagement in their own health-care places them at the forefront of the stakeholder assessment. Survey and app usage data suggest that consumers *want* technology-based contact with their health-care providers, but the data also suggest that the apps must be convenient, easy to use, and provide the desired functionality. Otherwise, the app is discarded and replaced by another one. The no-cost/low-cost feature of most apps makes this approach a very attractive

Table 5.3 Potential app developer categories

Individuals
Integrated health systems
Physician offices
Diagnostic facilities
Urgent care facilities and retail clinics
Academic organizations and research groups
Organizations dedicated to patient needs
Corporate investors
Venture capitalists
Hedge funds
Pharma and biotech companies
Weight loss and fitness companies
Pharmacy retail chains (such as CVS, Walgreens, and Rite-Aid drugstores)
Health insurers, private
Health insurers, public (US, state government, and local governments)
Health IT companies
IT companies looking to expand into health-care markets
Mobile device companies
Mobile telecom operators

option. In some cases, the app's data capture and processing functions are adequate, but the app cannot transmit stored data to providers' information systems. Thus, the consumer's efforts to participate in the complete patient experience are challenged.

Providers and health plans are highly motivated to employ mHealth apps to achieve efficiencies and cost savings as well as improved health outcomes. To that end, many have developed proprietary apps to engage patients with their enterprise clinical and administrative information systems. Patients can schedule appointments, communicate with providers, access clinical reports, and perform other important actions. Again, however, a commercial app used by the patient usually will not interface with the proprietary systems.

Several categories of app developers exist. Table 5.3 identifies the wide range of possible app developers, ranging from individuals to sizable health systems and insurers, most with a goal of commercializing a product. Even though technology makes app development possible and affordable even for individuals and start-ups, creating apps that can be commercialized and sustainable is another challenge. The lack of business models remains a formidable barrier for app developers, too. However, as investors expand their contributions to app development, ROI will likely follow. If there is no ROI, investors will look elsewhere.

It is not always the app that generates the revenue, although many free apps generate advertising revenue. Increasingly, the app is a free good, designed to promote or operate a device or product sold with the app. Examples include weight management apps that work with a digital scale or a biosensor that monitors blood pressure. Because proven business models have not been established, commercialization efforts fail probably more often than they succeed—at this point. However, the

mHealth field is in its infancy, and the ratio of successes to failures should reflect evolution of commercialization.

Of note, the US military is emerging as a key player in the development and implementation of mHealth apps and associated devices. While developed primarily for enlisted personnel, particularly those in combat and those returning with service-related injuries, many military apps may be useful for civilian health care once they have been proven to have sustained usability and value. And, military partnerships with academic researchers and technology companies assure robust design and testing.

The explosive growth in numbers of mobile devices and the sophistication of their operating systems has created a marketplace for apps that is seemingly without limits. The ACA and other industry-level regulations are driving health care toward mobile and other wireless technologies for patient–provider engagement and cost reduction. And, technology companies and telecommunications providers are seeking partners for entry into new markets, including health care. These factors and others create a predominantly supportive environment for the development and deployment of mHealth apps and biosensing products.

Ultimately, the success of mHealth will depend on sustainability, which can be defined in terms of acceptance and use by the consumer and also in terms of reducing health-care costs and achieving improved health outcomes. But, the price of success is also a preeminent consideration. The money will not follow chronic failure; it will look elsewhere as it always does. Will financing of mHealth be sustained and even increase in support of mobile technologies? Will key stakeholders partner, joint venture, and engage in strategic tactics to enhance the potential growth and eventual revenue generation of mHealth products? Will government regulation help or hinder innovation? Will commercial apps integrate with proprietary systems? The evolution of the mHealth industry and its future configuration will largely depend on the answers to these questions.

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Chapter 6
Putting mHealth in Public Health

Introduction and Overview

This chapter explores the impact of mHealth on the US public health system and whether the explosive growth of mobile phones across the nation can be leveraged to change public health access, delivery, and health outcomes at both the individual and aggregate population level. Can mobile technologies be used to more effectively and efficiently protect against public health threats while simultaneously promoting prevention and wellness? mHealth proponents believe it can do what no other technology has done to date; that is, provide access and information whenever and wherever needed. Consequently, mHealth can help the nation's citizens and health workers alike make more informed decisions on a wide variety of public health issues ranging from attaining healthier lifestyles and behavior changes to guarding against outbreaks of disease and providing humanitarian assistance during times of crisis such as the aftermath of tornados, floods, and earthquakes. If designed and implemented effectively, mHealth has the potential to help assure that everyone in the USA has access to some range of health-care services. As Harvard School of Public Health Dean Julio Frenk noted:

> The use of cellular phones for health care and public health is one of the most promising developments in the quest to achieve universal health care coverage worldwide because mobile phones are rapidly becoming the communication technology of choice—and increasingly so among the poor. (HSPH News 2012)

However, the potential and promise of mHealth are not guaranteed. Many challenges exist that obstruct or distract from achieving goals and objectives. In order to successfully leverage mobile phones for public health, significant obstacles of scale, lack of standards to assure interoperability, and training people to use mobile technologies must be addressed and resolved. The culture of innovation reportedly has not kept up with the mHealth field. Consequently, the trend is to continue with small-scale pilot projects instead of learning what works and what does not, and moving on to deploy workable products on a larger scale. The status quo must be overcome so that public health funding and efforts are not continually spent in doing the same thing over and over without any real gain (Martin 2013).

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There are also entrenched legacy systems—technological, political, and social—in terms of public health infrastructure, health policy, and public health culture that must be addressed as well. Bureaucratic disarray must be overcome, and research, especially longitudinal studies that collect behavioral and health data over time, must become a serious priority. Such data can help to identify specific factors that ultimately may detect public health threats or health status improvements (HSPH 2012).

The US Public Health System

The USA has a public health system that largely resembles its health-care system: fragmented, disorganized, with unstable funding and no discernible mechanisms for accountability of its mission. Unlike the health-care system, which includes both private and public sector components and stakeholders, public health remains primarily a governmental operation. However, the US Public Health Service (USPHS) is not a cabinet-level agency. It is located within the Department of Health and Human Services (HHS), and is led by a Surgeon General organizationally located within the Office of the Assistant Secretary for Health in the Office of the HHS Secretary.

The USPHS is not a visible entity on the current HHS Organizational Chart although a variety of other HHS offices and agencies have asterisks identifying them as a component of the USPHS, including the Office of the Assistant Secretary for Preparedness and Response, Indian Health Services, and the Center for Disease Control and Prevention (CDC). Thus, despite having a consequential mission of assuring the health and safety of the nation, the USPHS does not have the visibility or political status of other cabinet level agencies such as the US Department of Veterans Affairs (VA) that represents only a fraction, albeit an important one, of the nation's citizens.

A search for the USPHS on the HHS website redirects to the Office of the Surgeon General and the USPHS Commissioned Corps. Most Americans have little knowledge of the Surgeon General, or his/her role with respect to the USPHS, although some may recall Dr. C. Everett Koop, who served as the Surgeon General from 1981 to 1989. Dr. Koop is often considered to have been the most influential Surgeon General in American history due in large part to his very visible advocacy role and success with an antismoking campaign that helped change attitudes toward smoking. He also played an important role in educating the public about AIDS (Noble 2013). Despite his quasi-celebrity status, Dr. Koop was well aware of the challenges to public health in the USA. As he wrote before the advent of the twenty-first century:

> Public health has never received the recognition it deserves. The late nineteenth and the twentieth century have been referred to as the "Age of Modern Medical Miracles," yet it was not these miracles of high technology that brought this nation to the health status it

> now it enjoys. Instead, it was public health advances that accomplished that: clean water, proper housing, immunization, eradication of smallpox, increased life expectancy, and the understanding of preventive medicine as exemplified by health lifestyle choices. (C. Everett Koop, 1998)

What may be ironic about Dr. Koop's observation is that technology, in this case mHealth, may become the pivotal tool to drive public health forward in the twenty-first century, improving the health status of the nation and enhancing the role of the USPHS and its operating units, especially local health departments, in achieving improvements in population health outcomes. Moreover, mHealth may enable public health agencies to play a more important role in health-care delivery. Despite the many achievements of public health administrators and workers mentioned by Dr. Koop, public health has occupied a supportive rather than a leadership role in health care. In Paul Starr's Pulitzer Prize winning book, *The Social Transformation of American Medicine* (1982), the author details public health's accomplishments and also its struggles to remain in the mainstream of health care. Eventually public health ended up on the periphery as physicians came to dominate the US health-care system, due in large part to the focus on hospital-based acute care.

Will the implementation of health reform efforts, notably the Affordable Care Act (ACA), enable public health to move from its historical place on the periphery into the mainstream of health care? The ACA's focus on preventative care and adoption of healthy behaviors to improve population health and also reduce health-care costs seems well aligned with public health goals. If Americans eat healthy foods, exercise, and pursue overall healthier lifestyles, it is expected that they will require less expensive health-care services. Furthermore, mHealth could serve to catalyze the leadership role of public health as state health departments move to adopt mHealth technologies, including apps to promote healthy lifestyles, deliver health education, and support illness prevention. Whether public health in the USA will succeed in assuming a larger role for the health of Americans is unknown, as the agencies must overcome formidable obstacles, including entrenched legacy systems and inadequate funding.

In 1988, the Institute of Medicine (IOM) issued what was considered a landmark report on the future of public health. The report revealed that the nation's public health system was in disarray, inadequately funded, and subsequently unable to deliver what was expected of it—to create and assure a nation in which people could be healthy (Tilson 1998). The IOM has issued subsequent reports and briefs over the years. A recent report of the IOM (IOM Report Brief 2012) pointed, again, to unsustainable funding, but also suggested that the ACA may create opportunities for public health departments to focus on delivering population-based services. The implementation of the ACA is expected "to trigger a concerted effort to shift clinical care out of health departments" (p. 3). Again, this is speculative, but the implications of such shifts would impact the role of mHealth in public health as mHealth could also be used to collect and track population data.

Even though mobile technologies are expected to reduce health-care costs for adopted services, adequate funding to support and sustain mHealth in public health

Table 6.1 Key economic indicators of US health expenditures. (Source: Key Industry Facts 2013)

Key economic indicator	Year	Dollars or percentages
Total US health expenditures	1990	US$ 724.3 billion
	2000	US$ 1372.2 billion
	2011	US$ 2700.7 billion
Health expenditures as a percentage of GDP	1990	12.5 %
	2000	13.8 %
	2011	17.9 %
Amount per capita	1990	US$ 2854
	2000	US$ 4878
	2011	US$ 8680

is essential to success. Rapidly rising national health expenditures over the past two decades, with national health-care expenditures almost 18 % of gross domestic product (GDP) in 2011, have gained public and political attention (Key Industry Facts 2013). Despite the amount spent on health care in total, less than 3 % is spent on governmental public health. When arguing for health reform in the USA, the claim is made that the health-care system is focused on people who are ill. Rather than spending money and efforts on preventive care, health promotion, and other efforts aimed at keeping people healthy, dollars are spent when people get sick. Table 6.1 reports on some of the key indicators for health expenditures.

The role of public health in America is ill defined, unclear, and underdeveloped. There is no universally accepted definition for public health, nor is there a standard definition for what constitutes public health activities. Public health services also have not been subject to standardization. To compensate for the absence of standardized services, public health agencies claim to be moving in the direction of a voluntary national accreditation program. But voluntary accreditation will not resolve the problems that arise when there are no universally accepted standards. Consequently, it is likely that public health approaches to mHealth will also be variable given the lack of standards and uniformity.

For this book, the following definition was chosen because it is succinct yet comprehensive in summarizing what constitutes public health.

> Public health is the practice of preventing disease, injury, and disability; protecting people from disease outbreaks and public health threats; and promoting policies, practices, and conditions that support good health. With a primary focus on wellness and prevention, public health is a cost-effective means of addressing health at a population level, often well before individual problems become acute. (CADH Website 2013)

Public health continues to experience added responsibilities to its historical work. Following the September 11, 2001 attacks on the USA, bioterrorism emerged as a public health threat and became another challenge for public health organizations. In 2005, the impact of the worst hurricane ever to hit the USA, Katrina, highlighted the need for public health services to include enhanced disaster and emergency preparedness planning and response. Consequently, the workload for public health organizations continues to grow without commensurate funding as new public health threats unfold.

Public Health Infrastructure

The public health infrastructure, the foundation for planning, delivering, and evaluating public health services, is composed of multiple levels, ranging from federal, state, and tribal (i.e., Indian Public Health Services) to local health agencies and organizations (Healthypeople2020.gov). At the federal level, HHS is primarily responsible for the health and welfare of the nation, including funding of many public health initiatives. Within HHS, there is an Office of the Surgeon General that is organizationally located in the Office of the Assistant Secretary for Health in the Office of the HHS Secretary.

The Surgeon General is described on the website as serving as "America's Doctor," and is the primary spokesperson and leader for public health at the federal level. The Surgeon General is appointed by the President and oversees the USPHS's Commissioned Corps of approximately 6500 officers in meeting the needs of the nation's public health. The Corps is one of the seven uniformed services of the USA with a mission to protect, promote, and advance the health and safety of the nation by achieving specific mission goals of:

- Rapid and effective response to public health needs
- Leadership and excellence in public health practices
- Advancement of public health science (www.usphs.gov)

The federal government is not involved in the day-to-day running of state and local health departments even though federal funding of public health at the state level requires states to meet federal mandates. Efforts overall tend to be more collaborative than prescribed. For example, USPHS Corps officers are often dispatched during public health disasters and emergencies, and many work closely with both state and federal agencies. And, the Surgeon General's health prevention strategies are often used as state guidelines. Ultimately, however, responsibility for operating state and local health departments resides with individual states.

State health departments were created to meet the unique and different needs and preferences of people in each state. As such, state health departments vary in organizational structure, per capita spending, staffing, and responsibility for local public health services. At the state level, there is usually a state health officer, appointed by the governor and who is charged with leading the state's health department and public health efforts. Meanwhile, the state's health department typically is composed of local health departments, often at the county level, and other local public health organizations. However, there are some states in which there is no operational relationship with state and local health departments. In addition, federal funding may bypass state government and distribute funds directly to local health departments (Dandoy 1998).

State and local health departments derive their authority and responsibility from both state and local laws that govern them. Thus, there is no unifying structure that organizes or coordinates public health efforts nationwide. The National Association of City and County Health Officials (NACCHO), a membership organization that provides news, networking, and advocacy for local health departments, recom-

Table 6.2 Ten essential public health functions. (Source: *10 Essential Public Health Services*. http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=35)

Essential public health services
1. Monitor health status to identify and solve community health problems
2. Diagnose and investigate health problems and health hazards in the community
3. Inform, educate, and empower people about health issues
4. Mobilize community partnerships and action to identify and solve health problems
5. Develop policies and plans that support individual and community health efforts
6. Enforce laws and regulations that protect health and ensure safety
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable
8. Ensure competent public and personal health-care workforces
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services
10. Research for new insights and innovative solutions to health problems

mends standards for directing local health department operations (NACCHO website), but lacks the authority to require compliance. Consequently, there is a great deal of flexibility and variability in how the local departments operate. In addition, funding for public health derives from a variety of sources including federal, state, and local authorities. The bottom line for health departments is that they often go their own way and rely on voluntary oversight and associations to guide them. Thus, we can expect adoption of mHealth technologies to be highly differentiated across states and local health departments.

A strong public health infrastructure is considered essential for the implementation of public health services at all levels, including responding to the nation's acute needs such as emergency preparedness and disaster planning and ongoing needs such as health education (HealthyPeople2020.gov). Yet evidence of a strong infrastructure is absent. Instead, at the local level we find loosely organized health departments across the USA pursuing voluntary standards and engaged in a wide variety of public health endeavors. At the national level, public health activities are spread across a variety of federal departments and agencies.

What appears inevitable is that public health will be influenced by the rapid growth of mHealth, especially because of its ease of use and affordability in fulfilling prescribed public health functions. For example, HealthyPeople2020.gov identifies ten essential public health functions that are considered an integral component of public health practice and represent possibilities and opportunities for mHealth applications (2013). Table 6.2 lists these functions. Progress has been achieved for many of these functions. For example, functions 9 and 10, functions associated with research, effectiveness, and outcomes, have been addressed in part with *mHealth Evidence,* an online reference tool developed by researchers at Johns Hopkins to

advance mHealth research and strengthen the overall quality of research methods (Versel 2013).

In addition, in 2011 the Office of the US Surgeon General demonstrated national interest in mobile health applications when it conducted a "Healthy Apps Challenge." The competition called for submission of apps to enhance key aspects of the Surgeon General's prevention agenda for the nation, including promoting health behaviors related to fitness and physical activity, nutrition, and healthy eating, and/or physical, mental, and emotional well-being. The challenge was conducted in collaboration with the Office of the National Coordinator for Health IT (ONC). Winners were recognized in a ceremony and their apps were featured on the HHS website. Examples of winners include Lose It!, an app focused on weight loss, and Fooducate-eat a bit better, an app concerned with helping the consumer establish healthier eating habits (Healthy Apps Challenge 2012).

Other National Agendas for mHealth

Because the USPHS is a governmental entity where funding and programming is greatly influenced by political agendas, it is helpful to consider the support for mHealth evidenced by other governmental units, nongovernmental organizations, and by public–private partnerships. In particular, it is important to consider proponents that could advance the widespread adoption of mHealth to achieve public health objectives.

The Executive Level (White House)

> I want us to ask ourselves every day, how we are using technology to make a real difference in people's lives. (President Barack Obama 2012)

This statement was included in introductory remarks prepared by the President for inclusion in *Digital Government: Building a 21st Century Platform to Better Serve the American People* (Digital Government 2012). This directive signals the significant and impactful role intended for technology in reshaping how government functions, communicates, and interacts with key stakeholders, especially the public. Digital Government recognizes and offers both a strategy and an open data policy for creating a customer-centric government using digital technology. The focus is on customers' needs and assurances that citizens and government employees alike can access government information and services wherever they are, whenever they need it, and on any type of communication device. The potential of mobile phones is highlighted because of their widespread use. Furthermore, the strategy's goals call for consumer transactions with government information and services that are competitive with the private sector, especially in terms of efficiency and customer satisfaction. Thus, expectations for mHealth at the executive level of government are high.

Digital Government (2012) establishes goals and objectives for federal agencies and departments. The HHS mobile strategy is intended to meet the many goals and objectives outlined in the document. The HHS strategy undergoes regular evaluation and review (Digital Strategy at One Year 2013) that is posted online and updated as required. In addition, there is also a HHS Mobile Technology Strategy (2012) that concentrates on business drivers as indicated below:

> The purpose of the U.S. Department of Health and Human Services (HHS) Mobile Technology Strategy is to describe business drivers for use of mobile technologies within the HHS enterprise, identify the security requirements to adequately protect these devices and the information that they transmit and store, and offer recommendations for selection and implementation of mobile technologies which meet or exceed these requirements. (p. 1)

The HHS Mobile Technology Strategy (2012) includes the following health-care business drivers:

- Electronic communications that include forwarding prescriptions to pharmacies
- Storing reference materials such as the *Physician's Desk Reference,* medical journals, and interactive media
- Recording diagnostic and scheduling information
- Giving patients access to information on their mobile devices as they wait for a physician visit

However, nowhere in the strategy document is there mention of using mobile technology specifically for public health purposes. An exploration of mHealth at the federal level reveals that even though many of the HHS mobile apps may be used in conjunction with public health initiatives, there is no attempt at organizing them within a designated public health context.

HHS has created a variety of mobile apps in response to the White House's Digital Government (2012) strategic vision. Approximately, 33 HHS-sponsored apps aimed at health education and health tracking are available for iPhones, Androids, iPod Touches, iPad, Blackberries, Blackberry tablets, Android tablets, Palm OS/webOS, and Windows Mobile. The apps can be accessed at Explore HHS's Mobile Apps online at http://www.hhs.gov/digitalstrategy/mobile/mobile-apps.html.

The Federal Level

The federal government appears committed to playing a prominent role in mHealth, especially as it relates to planning and delivering public health. Numerous government agencies, departments, and other entities are involved. Table 6.3 offers some examples of these federal entities and their responsibilities with regard to mHealth. Because mHealth involves consumer health data, security and privacy are primary challenges across all agencies and offices of the federal government. In addition, a listing of federal mHealth projects is available with program description, agency affiliation, and links to program websites. http://www.hrsa.gov/healthit/mhealthfedpro.html#T4B

Table 6.3 The federal role in mHealth. (Source: This table is derived from information contained in *Mobile Devices Roundtable: Overview of Federal Role in Mobile Health,* http://www.healthit.gov/policy-researchers-implementers/overview-federal-role-mobile-health)

Federal entity	Examples of areas of performance of authority and responsibility
Federal Communications Commission (FCC)	Authorizes carriers whose networks are used by mobile devices such as smartphones to access, store, or transmit health information
Food and Drug Administration (FDA)	Public health responsibility to oversee the safety and effectiveness of medical apps that pose potential risks to patients Provides guidelines for development of mobile medical applications
Federal Trade Commission (FTC)	Ensures consumer privacy and security when it comes to electronic health information and mobile applications
National Institute of Standards and Technology (U.S. Department of Commerce)	Its computer security division develops standards, guidelines, tests, and metrics that are used as a resource for enhancing information security in the private sector
U.S. Department of Health and Human Services (DHHS), Office of Civil Rights	Implementing and enforcing the privacy and security rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Of course, HHS is the major federal player when it comes to public health. According to HHS Secretary, Kathleen Sebelius, the federal government can play a critical role in catalyzing mHealth innovations. The core of HHS's mobile strategy is building websites that consumers can access when and wherever they need information—on a computer, tablet, or smartphone (Sebelius 2011).

For the past 5 years, HHS has been actively engaged in mHealth, both promoting and supporting mHealth initiatives that would offer health information and resources to consumers via their mobile phones. HHS formed the Text4Health Task Force, comprised of public health experts across HHS to identify and make recommendations to HHS Secretary about text messaging and other mHealth projects (Mobile Devices Roundtable 2013). For more detail on this important task force, see Text4Health Task Force below.

Text4Health Task Force In November 2010, HHS established the Text4Health Task Force as part of the agency's commitment to promoting innovation at HHS. The task force, comprised of public health experts across HHS, was charged with providing recommendations for the HHS role in encouraging and developing health text messaging initiatives which would deliver health information and resources to individuals via their mobile phones. The report recommends that: (1) HHS develop and host evidence-based health text message libraries that leverage the department's rich and

scientifically based information, (2) HHS develop further evidence on the effectiveness of health text messaging programs, and (3) HHS explore and develop partnerships to create, implement and disseminate health text messaging and mHealth programs.Source: http://www.hrsa.gov/healthit/mhealth.html

Text messaging is an integral component of HHS efforts to promote public health via mobile phones. Consequently, text messaging is especially highlighted in HHS Text4Health projects that hope to take advantage of the rapid growth of mobile technology and platforms. HHS is also concerned with using text messaging because the key demographic groups include teens, African Americans, and Latinos, all of whom are groups that are more likely to use health apps compared with other groups (Lewis 2011).

An example of a Text4Health project is Text4Baby (http://www.text4baby.org), which was also was the winner of the HHS Innovates award. This program is a public–private partnership that provides pregnant women and new mothers with free health text messages. HHS serves as a monitor to ensure that the messages sent are both evidence-based and noncommercial, and also evaluates the overall program (HHS Text4health Projects 2013). HHS reportedly has invested US$ 5 million since January 2010 to develop its eHealth/mHealth smoking cessation resources targeting teens, young adults, and adults (Merrill 2013). HHS also has launched a number of mHealth initiatives guided by the Text4Health Task Force:

- Text4Tots is a public text messaging library that offers health information for parents, providers, and caregivers of children aged 1–5 years. The messages about nutrition and physical activity, available in both English and Spanish, were created by the American Academy of Pediatrics.
- SmokeFreeTXT, accessed at http://smokefree.gov/smokefreetxt, is a text messaging program to discourage smoking among teens and young adults across the USA. This program is an extension of the smoking cessation website, www.smokefree.gov.
- The Apps Against Abuse developers challenge was launched with the White House and represents a national competition to engage developers to create apps aimed at reducing abuse or violence among young adults (mHealth Initiatives 2013).

In addition, HHS offers a number of innovative HHS public health programs that utilize mobile technologies. HHS blogs report that several agencies have created mobile phone versions of their websites. Two examples are mobile AIDS.gov and the National Library of Medicine's Mobile Medline Plus. The National Heart, Lung, and Blood Institute created a mobile app version of its web-based BMI calculator, and the Substance Abuse and Mental Health Services Administration developed a Treatment Locator mobile app. However, the lack of interoperability among smart-

phone operating systems often requires different versions of health programs, including programs for those who do not own a smartphone (Atienza 2011).

The CDC uses webcasts to educate public health practitioners on how to use social media, gaming, and mHealth tools for communication and maximum public health outreach. Read more about this below in What's Trending: AIDS, Social Media, and Public Health.

What's Trending: AIDS, Social Media, and Public Health The CDC is using mobile technologies to engage public health practitioners in learning about how to use gaming and mHealth for maximum public health impact. The following announcement illustrates how webcasts are being used as an educational tool for advancing education, communication and outreach to the practice community.

> As part of its live webcast series, the CDC National Prevention Information Network (NPIN) is pleased to announce, "In the Know: Gaming and Mobile for Public Health" on Tuesday, April 2 at 2 P.M. (ET). The webcast will feature slide presentations, Q & A, and public health success stories from social media experts on how best to utilize gaming and mobile for greatest public health impact. NPIN is excited to have staff from Games for Health joining this session. This is also a great opportunity to ask questions and learn from fellow public health practitioners. The webcast will explore social media best practices and advancing public health outreach and communication. While viewing the webcast, you can follow along and ask questions on Twitter using the hashtag #SM4PH or submit questions to info@cdcnpin.org.

Source: http://blog.aids.gov/2013/03/in-the-know-social-media-for-public-health-gaming-mobile.html

Meanwhile, the National Library of Medicine has developed a "gallery" of mobile apps and mobile-optimized websites that offer health information to the public. Consumers can also access health information using mobile devices through the CDC website (http://m.cdc.gov and sign up for daily text messaging health alerts; Atienza 2012). The downloadable HHS apps tend to be free and available through iTunes. Sample resources for mHealth are detailed below.

Sample HHS Resources for mHealth

- The ePSS is an application designed to help primary care clinicians identify clinical preventive services that are appropriate for their patients. Use the tool to search and browse U.S. Preventive Services Task Force (USPSTF) recommendations on the web or on your PDA or mobile device. To search from your mobile device select from the following devices (http://epss.ahrq.gov/PDA/index.jsp).

- The Centers for Disease Control and Prevention (CDC) has a number of mobile apps available on a variety of platforms: iOS, Android, and Microsoft Windows 8. All apps are free downloads through the iTunes. The CDC mobile app allows access to health articles, Disease of the Week, popular journals, prevention tips, and updates timed with important health concerns and events throughout the year. It also provides easy access to social media for sharing stories, links, podcasts, and videos (http://www.cdc.gov/mobile/).
- The US National Library of Medicine has a Gallery of Mobile Apps and Sites. The apps are available for downloading at iTunes. Examples of the diversity of apps include Health Hotlines, which offers a directory of organizations with toll-free telephone numbers. MyMedList (MML) allows users to electronically manage their medication list(s). Medication lists can be e-mailed or printed, can serve as a reminder for taking medications, or be shown as reference information in doctor's offices or hospitals. *Reunite* is an app for medical aid and relief workers that are assisting in family reunification efforts after a disaster, but also can be used by the general public to report missing and/or found people to the site (http://www.nlm.nih.gov/mobile/).

Source: Information compiled for HHS website sources, including hhs.gov/open/discussion/mhealth_publichealth.html

In addition, HHS is using mHealth and online training to combat HIV/AIDS. HHS is partnering with the MAC AIDS Fund, launching a pilot mobile texting program called UCARE4LIFE. The program assists patients in receiving important information about their disease as well as reminders of appointments and for taking medications as prescribed. In addition, the Centers for Medicare and Medicaid Services (CMS) is working with Medscape, a provider of online continuing education for clinicians to create new updated training programs to help clinicians better meet the needs of their HIV patients. Also, HHS has partnered with Walgreens to develop medication therapy management programs and creation of easy-to-use forms for HIV patients to use when enrolling in patient assistance programs (HHS Using mHealth 2012).

HHS also uses challenges or competitions to elicit suggestions for many of their mHealth and online projects. For example, one competition from the HHS Office of the Assistant Secretary for Preparedness and Response, called "Now Trending-#Health in My Community," challenged developers to design web-based applications that use Twitter to track health trends in real time. The aim of such applications is to gain knowledge for identifying emerging health problems and warning communities about public health emergencies (HHS Contest 2012).

HHS also created a challenge targeting women of color with cancer. The "Reducing Cancer Among Women of Color" App Challenge invited developers to create an application for mobile devices that can help improve the prevention and treat-

ment of breast, cervical, uterine, and ovarian cancer. Read more about this event in What's Trending at HHS: HHS Goes Mobile to Reduce Racial Disparities in Cancer.

What's Trending at HHS: HHS Goes Mobile to Reduce Racial Disparities in Cancer Because minorities represent a disproportionate number of the 300,000 women diagnosed with breast, cervical, uterine, and ovarian cancer annually due to lack of education and access to care, HHS has launched a challenge to help reduce racial disparities among women of color. "Reducing Cancer Among Women of Color" App Challenge invited developers to create an application (app) for mobile devices that can help improve the prevention and treatment of breast, cervical, uterine, and ovarian cancer. Up to US$ 100,000 was awarded for apps that promise to provide high-quality health information to women and community health workers, interface securely with patient health records, and strengthen communication across provider care teams.

The first place winner, Everhealthier Women, is a mobile web app that works on all mobile devices, including iPhone, Android phones, and Windows phones. It helps women track cancer prevention tasks for themselves and others in their "healthy circle" through the web and SMS text messaging. The tasks which users can track for themselves and their loved ones promote the screenings and prevention recommendations that match their age and profile according to national guidelines. Everhealthier Women is currently available in English and Spanish.

Source: Bernstein, C. (May 30, 2013). Winners of the 'Reducing Cancer Among Women of Color' Challenge Announced. Retrieved online at http://www.hhs.gov/digitalstrategy/blog/2013/05/reducing-cancer-among-women-app-challenge-winner.html

Public–Private Partnerships

The goal of making data available to private sector entrepreneurs and app developers through HHS data initiatives continues to both reflect and support the goals of the Digital Government (2012) strategy to interact with the private sector. HHS has embarked on a plan to expand its reach and advance public–private sector partnerships in order to offer app developers access to huge amounts of health-care data, some of which were not previously made available to the public, in usable formats so that they could create new applications. It is anticipated that new applications will enable more efficient and effective efforts toward disease prevention, health promotion, and quality improvement.

On June 02, 2010, the Community Health Data Initiative (CDI) was formed following a meeting hosted by IOM and HHS with a group of leaders from federal agencies, academic public health communities, major businesses, and health-care delivery systems. Eventually, types of available health data expanded beyond community data to include data on coverage, access, cost, quality, products and recalls, benefits, and more. The HHS CDI was rebranded as Health Data Initiative (HDI). By 2012, The Health Datapalooza, a national annual conference organized by the Health Data Consortium, was originally launched as part of the HDI. Health Datapalooza held its first forum in June 5–6, 2012 in Washington, D.C., which brought together more than 1500 app developers, entrepreneurs, data experts, policy makers, health system leaders, and community advocates—all to support development of innovative applications of health and health-care data. Its 2013 forum drew an even larger crowd (History of Health Datapalooza 2013; Health Data Initiative 2011; Community Data Initiative 2010).

Irrespective of rebranding and setting up annual conferences, the goal of making data available to private sector entrepreneurs and app developers through HHS data initiatives continues to both reflect and support the goals of the Digital Government (2012) strategy to interact with the private sector. With respect to HHS and public health goals, CDI plans revealed that community health data obtained across HHS was to be made easily accessible, standardized, structured, and downloadable. Types of data included determinants of health performance at the national, state, and county levels, as well as by demographics such as age, gender, race and ethnicity, and income—if available in communities (HHS Community Health Data Initiative 2010).

For public health purposes, the data set will likely include health status indicators, county health rankings, obesity rates, smoking rates, and other relevant information, some of which has never been previously published. This would include CMS data on prevalence of disease, quality, cost, and utilization. The Community Health Data Set is expected to be downloadable from a webpage. Meanwhile, HHS is also looking to deploy a new HHS Health Indicators Warehouse and web portal developed by the National Center for Health Statistics. HHS expects that innovators from business, academia, technology, health care, and public health will be able to utilize the data to turn it into applications for public benefit. Examples of ways developers use the data for public health include:

- Developing dashboards that can used by mayors and civic leaders to track and publicize the performance of their local communities
- Social networking applications that foster health improvement
- Online games that provide health education for local communities (HHS Community Health Data Initiative 2010)

Despite all the meetings, forums, and conferences, there is little evidence of success attributed to the HDI. That is, the HHS website does not point to accomplishments of endeavoring to advance public–private partnerships through open government and data sharing. Whether the data is yet available in downloadable easy-to-use

formats is unknown as is whether the private sector has been able to access the data and translate the data into creative, innovative, and user-friendly apps.

Office of Global Affairs

On October 11, 2011, HHS Secretary Kathleen Sebelius announced the creation of HHS's first global strategy and the HHS Office of Global Affairs. The Office of Global Affairs is listed on the HHS organization chart showing linkages with USPHS (HHS Organizational Chart 2013). HHS Global Health Strategy (2011) showcases a strategy that emphasizes the role of global public health for positively impacting US public health. The strategy puts forward goals that are focused on protecting and promoting the health and welfare of all Americans through global actions. Thus, HHS will not only work to prevent disease and health crises domestically, but also abroad, in order to fulfill its health and welfare mission. In expanding HHS's reach, it is anticipated that the USA will gain opportunities to learn from other nations' successes in achieving sustainable health systems. In addition, the strategy's vision specifically addresses public health services. The following statement comes from the HHS' Global Vision, a component of the strategy:

> HHS is committed to acting to create a healthier, safer world. This reflects our recognition that public health, healthcare services, and health equity are best addressed across national boundaries and through collaborative international efforts. (HHS Global Strategy 2011, p. 9)

What is missing in the HHS Global Strategy is any mention of mobile technologies or mHealth. Thus, while HHS expresses commitment to its digital strategy and the White House's Digital Government (2012) focus on mobile technologies, it appears as if the department has not yet integrated mobile or mHealth into its vision and/or strategic plan for globalhealthcare.gov.

State and Local Levels

State and local health programs receive little to no guidance or direction in undertaking digital initiatives, yet they are making progress digitally and with planned online outreach. According to Jay Bernhardt, Professor of Health Education and Behavior at the University of Florida and director of the Center for Digital Health and Wellness, digital health technologies will be transformative for public health. As keynote speaker for the 2013 National Public Health Information Coalition Symposium, Bernhardt detailed his optimism. The majority of state health departments are active online. The local health departments, with access to fewer resources, are reportedly slower to adopt new technologies. However, many health departments are making use of social media, including Facebook, and YouTube. Over time, mobile technologies, especially text messaging, are expected to be the game changers

because of ease of access and the fact that approximately 95% of people read text messages within 3 min of receipt (Fouse 2013).

Local and state health departments are beginning to gain attention from the launching of mobile apps for health and wellness. The Alabama Department of Public Health reportedly was the first state to launch a mobile app for its residents. The app offers what can be found at the state's website. That is, the app combines social media streams with health news alerts, along with information on local health and wellness events. For example, on August 19, 2013, when the shellfish waters in certain Alabama counties were closed because of possible bacterial contamination, the public was alerted through the app (Shute 2013; Sifferlin 2013). Thus, people are engaged with their state health department by pushing a button on their phones.

Denver's Public Department (Denver Public Health) won an award from NACCHO for creating the Hand-held Automated Notification for Drugs and Immunizations (HANDI) system for collecting immunization data via mobile apps. During the H1N1 flu outbreak, Denver Public Health had to manually digitize paper records. With HANDI, technology eliminates the manual labor. The three-step system processes vaccination records by using mobile device scanners to register people, record their immunizations, and then uploads the data to a server that can be shared later on with others (Brino 2013).

New York City has embarked on an ambitious agenda for fulfilling the city's mission of becoming the world's leading digital city (nyc.gov/ digital). However, the city's health department website (nyc.gov/health) reflects little digitization even though reportedly the city's health department introduced four mobile apps within the past 2 years. These apps reportedly were all built in-house by the health department's technical staff. The apps targeted unique user cohorts such as the obese, healthy eaters, and teens or young adults.

- *CalCutter* provides nutrition tips for healthy cooking for restaurant chefs and people cooking at home. It converts recipes to estimated calorie counts and allows for conversion of the recipe to lower calorie versions.
- *ABCEats* furnishes city inspection reports and restaurant grades for 24,000 city restaurants.
- *Find Condoms NYC* gives information to find free condoms in the city. The app scans the Health Department's list of 3000 sites that distribute free condoms and then uses a smartphone's GPS to map the five distribution locations nearest to the consumer's current location.
- NYC Protection+ app searches for clinics that provide sexual health services for the teenaged cohort. The app includes a database of health-care providers that offer teens free and confidential help to prevent pregnancy and STDs.

Apps created by the state and local health departments are small in number, but often make a lot of health data available to the person downloading it. Furthermore, even though the number of downloads is small (i.e., 33,500 for NYC Condom), given the large NYC population of 8.2 million, city health officials are confident that the apps are working to reach special groups (Shute 2013; Sifferlin 2013; Health Departments Launch Apps 2013). Clearly, more evidence needs to be collected to demonstrate app effectiveness and usage rates.

Nongovernmental Contributors to Public Health Initiatives

Many private organizations and other nongovernmental entities profess missions that contribute to or support achieving public health agendas. Some have pursued notable mHealth strategies that are potentially transferrable to other public health providers.

Online mHealth Certificate Course

Two nonprofits, TechChange, which creates interactive online courses, and mHealth Alliance, developed a 4-week online mHealth certificate course "mHealth: Mobile Phones for Public Health." The course was planned to overlap with the 2012 mHealth Summit in Washington, D.C. area. The course will explore how mobile technologies are revolutionizing service delivery, diagnostics, health education, health worker training, and data collection. Topics include interactive voice recognition (IVR), text messaging communication programs, smartphone applications, and health information systems for data collection and management (mHealth: Mobile Phones for Public Health 2013).

The Aetna Foundation

Aetna, one of the nation's largest health-care insurers, established the Aetna Foundation in 1972. Since 1980, Aetna and the Aetna Foundation have contributed more than US$ 427 million in grants and sponsorships. The website documents how these efforts have helped to strengthen public health at the community level, including disease prevention programs (www.aetna-foundation.org). The Aetna Foundation acknowledges the potential of mHealth to transform the field of public health. The foundation is aiming to fund projects that implement and evaluate innovative mobile apps that promote healthful choices at the community level, specifically within underserved communities (Aetna Foundation Request for Proposals 2013).

The Center for Innovation and Technology in Public Health

According to their website (www.citph.org), Center for Innovation and Technology in Public Health (CITPH) is a research group that:

- Promotes quality improvement, cost reductions, and access in public health through highlighting the role of innovation and technology
- Is engaged in public policy development, public health practices, and the direct provision of services related to enabling technologies

- Employs staff members to systematically study, evaluate, and disseminate assessments of technology-enabled innovations that deliver improvements in population health, represent cost-effective solutions in low-income settings, and can be deployed on a large scale to drive real systems change

Because few sources provide oversight of effectiveness and/or efficiency of public health apps, CITPH could play a critical role in documenting utility and outcomes. For example, CITPH and Mathematica Policy Research jointly conducted a national evaluation of the implementation and effects of the Text4baby text messaging program. The assessment was sponsored by HHS's Health Resources Services Administration (Text4BabyEvaluation 2010).

The Public Health Institute

The Public Health Institute's (PHI) mission is similar to that of CITPH, encompassing research and leadership, and advancing partnerships that are aimed at building capacity for strong public health policy, programs, systems, and practices. Among its core principles is fostering evidence-based public health. As with CITPH, PHI partners with foundations, federal and state agencies, and other nonprofit organizations in support of projects and public health interventions in California, the USA, and worldwide (www.phi.org/focus).

Two important examples of PHI mHealth programs include:

- Patient-centered mHealth: New Horizons in Diabetes Care in Community Health Centers. This program involves the Center for Technology and Aging. This study evaluates the effectiveness of an interactive mobile health information service, Care4Life, in supporting patient self-management of diabetes by facilitating patient education, behavior change, and improved adherence with standard care practices. It is part of the McKesson Foundation's Mobilizing for Health initiative to improve the health of underserved populations with chronic diseases through the use of mobile phone technology.
- Safety Net Transformation Through Engagement of mHealth. This program involves CITPH and will conduct a landscape analysis through key informant interviews and a survey of US safety net providers on the current state of mobile health practice to address the needs of vulnerable populations, specifically mobile solutions that engage patients in their own care. The analysis will identify opportunities to advance mHealth solutions at a scale to reduce health disparities.

American Public Health Association

The American Public Health Association (APHA), the national association for public health professionals, also serves as a source for policy and advocacy for public health. The APHA, founded in 1872, was recently rebranded, including launching

a new website to promote its current initiatives. The new brand was announced on November 3, 2013, at APHA's 141st annual meeting in Boston. Important aspects of rebranding include a clear mission to "improve the health of the public and achieve equity in health status," and a vision of "a healthy global society."

The revised APHA website contains public health links to Twitter, Facebook, Pinterest, and other social media. Notably absent from the redesigned website is any evidence of engagement in mHealth programs, projects, or activities. However, National Public Health Week, for which the APHA serves as lead organizer, showcased mobile technology as a theme for 2013—"Public Health is ROI: Save Lives, Save Money." APHA used the event to promote the importance of health IT and digital/mobile health technologies for disease prevention, health promotion, and overall improvement of public health systems (McShane 2013).

Robert Wood Johnson Foundation

The Robert Wood Johnson Foundation (RWJF) has stepped in to create a transparent digital meeting place, NewPublicHealth.org, to promote, connect, and advance an online community to meet public health challenges. The expectation is that visitors to the online community will engage in conversations with a variety of key public health stakeholders and encourage expansion to include businesses and others. The goal is to bring about innovation and change to assure that public health can meet demands of doing more with less.

The online community found at NewPublicHealth.org offers conversation starters, access to Facebook, Twitter, Pinterest, and other social media. The website also contains a variety of postings of public health up-to-date news and videos that highlight public health events and other matters of interest. But as yet, the website shows few comments posted or tweeted from the community it seeks to engage. Even the section on County Health Rankings does not report significant postings or tweets for most of its information except for the actual displayed rankings. For this item, there are more than 102 tweets, but still no posted comments.

As for mHealth, a search of the website reveals fewer than ten mHealth postings dating from December 05, 2011 through February 22, 2012. There are no postings for the remainder of 2012 or 2013. The posted items include interviews, mHealth Summit meeting news, and the winners of the Surgeon General's Healthy Apps Challenge. Of the few items posted, most have no comments or only one comment. Thus, for mHealth at least, it does not seem as if the online community is engaging on the topic to the extent that meaningful communication ensues.

Grassroots Change

Is mobile technology associated with public health initiatives found only at various levels of the government or is it found also at the grassroots level? Grassroots Change, a project supported by the RWJF, declared a mission to empower grass-

roots leaders to build and sustain effective public health movements at the local, state, and national levels. In addition to its web presence (www.grassroots.change.net/) and Twitter activity (#Grassroots Change@GCpublic), Grassroots Change has hosted workshops aimed at helping to make other websites more engaging and more effective communication mediums. They have sponsored the Mobile Technology in Public Health**:** Workshop (June 12, 2013) at the California Endowment. The workshop's learning outcomes included:

- Understand how open source mobile tools and applications can be used to strategically support advocacy efforts as well as health promotion and education goals.
- Understand the value of user-centered design and testing with the community.
- Identify tips for successful implementation and also how to measure impact.
- Explore examples of how organizations across health/public health sectors are using mobile technologies effectively.
- Learn how to integrate mobile technology with other social media tools (Mobile Technology Workshop 2013).

Public Health Solutions

Public Health Solutions is a New York City-based nonprofit organization that has provided safety-net services to a low-income population for more than 50 years. The October 2012 issue of their monthly newsletter featured "Developments in Public Health Technology," and reported on mHealth tools for the public health community. The newsletter showcased Google Flu Trends, which began using search data in 2008 to produce flu estimates worldwide. This information could be used to apprise health officials of possible flu outbreaks. HHS uses a similar approach with MappyHealth, an app that monitors tweets to track health trends globally. MappyHealth was developed in response to the NowTrending2012 application challenge sponsored by HHS (www.mappyhealth.com).

Conclusions: Using mHealth for Public health

Advances in mobile technologies have the potential to transform public health today and more importantly, for the future. mHealth opportunities are growing in both public health practice and research, creating tools that can be used to promote healthy behavioral change and also to change relationships among patients, their physicians, and caregivers (Kellogg 2012). Mobile phones are the perhaps the perfect delivery mechanism to support behavioral change, which is an important component of public health programs, because the phones can furnish support anywhere and at any time—24/7. Furthermore, this help can be individualized to enhance the impact of positive reinforcement for consumers. This is especially important

in terms of motivational goals to support behavioral change in smoking cessation programs where participants often quit several times before they finally stop smoking altogether. Programs delivered by phone do not require participants to even sit at a computer or open a web page; the only requirement is to push a button. These programs also offer anonymity, which may make it easier for those who have difficulty talking face to face with health professionals about highly personal issues (Whittaker and Smith 2008).

However, technology is the easy part of mHealth. Anyone can build an app quickly and often at no cost (e.g., http://ibuildapp.com/). Similarly, anyone can construct a website with a mobile application, again, at no cost (e.g., wix.com). Furthermore, research indicates that at least with respect to weight-loss apps, the paid-for apps were not any better than the free ones. The hard part, as it happens, is building an app that engages and provides value to the end user. Has public health met this challenge?

HHS is viewed by many as having pushed mobile technologies forward in recent years. Moreover, HHS claims that mHealth initiatives offer the promise of creating a healthier and more secure nation because of improved access to a wide variety of health resources (Rooney 2012). The National Institutes of Health (NIH) funds a good amount of mobile research and envisions being able to change the actual quality of public health, especially enabling better disease management. NIH experts have speculated that mHealth apps "can make a significant difference in public health and health care delivery" (Pros and Cons of Mobile Technology 2013).

For example, there are a number of apps to help diabetics monitor their blood sugar. But the Diabetes Management Initiative with ADA, CDC, HRSA, Beacon Communities and Voxiva (a mobile technology company named one of *Fast Company's* "World's 50 Most Innovative Companies") goes well beyond monitoring efforts. The mobile app actually connects individuals to a wealth of existing wellness and diabetes care resources available today in order to help them manage their diabetes more effectively (New Mobile App Will Use Texting for Diabetes Management 2011).

Meanwhile, it is estimated that approximately 50 million people in the USA live with some type of chronic respiratory disease. Asthma is a US$ 50 billion problem: Uncontrolled asthma results in two million emergency department visits and 500,000 hospitalizations annually. Asthmapolis, now Propellor Health, developed an FDA-approved asthma app that uses a smartphone and snap on sensors (Bluetooth) to track when and how patients use their inhaled medications. In addition to the tracking function, the company collects data and offers patients tools to improve health outcomes. The recent name change reflects a broadening of the vision of the company to become the leading mobile platform for respiratory management (Gallagher 2013; Grant 2013).

An examination of various public websites within HHS, including CDC, shows that there are a variety of mHealth and related apps. Most of the apps are made available through the popular iTunes Store. But some of the websites have not been updated in some time. The videos and apps also do not appear to receive much updating, improvement, or refinement. Some of the efforts appear questionable, such

as the CDC's Health-e-Cards that allow, according to the website, the public to send electronic greeting cards to friends, family, and coworkers (Health-e-Cards n.d.).

Similarly, reviewing different state and local websites, along with nongovernmental websites such as NewPublicHealth.org, reveals little activity beyond a downloadable app, a single tweet, or a posting. Clearly, there is a need to engage expert app developers and others with mobile technology expertise. For public health to move into mHealth, there must be leadership to move beyond a "checklist" mentality to one that actually embraces the potential and promise of mHealth. Failing to do so may lead to public health online debacles similar to Healthcare.gov, the government website that was the portal to affordable care under ACA.

Public health in the USA clearly requires concerted effort, which is difficult given the organizational structure for public health activities. Despite the fact that public health needs improvements in its organizational structure, HHS may further complicate matters by its move to include globalizing public health actions. It is likely that public health in the USA will continue to be a disaggregated effort trying to achieve digital strategy goals prescribed at federal, executive, state, and local levels. Digital Government (2012) calls for more interaction with the private sector. Perhaps such linkages will be helpful, or they may contribute further to the disarray. At this point, it is obvious that President Obama and his administration want to move the government into the digital world. But, getting there turns out to be more of a challenge than anyone expected. Similarly, moving public health into the digital world requires more than creating an app, posting a video, or including links to Facebook and Twitter. It requires focusing on the end user and figuring out what the end user needs and wants and how to provide for these mobile goals.

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Other HHS resources on mHealth:

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AHRQ: http://epss.ahrq.gov/PDA/index.jsp.
CDC: http://www.cdc.gov/mobile/.
FDA: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ucm255978.htm.
HRSA: http://www.hrsa.gov/healthit/mhealth.html.
NIH National Library of Medicine: http://www.nlm.nih.gov/mobile/.
NIH National Institute of Biomedical Imaging and Bioengineering: http://www.nibib.nih.gov/HealthEdu/Discovery/DigitalDoctors.
NIH Office of Behavioral and Social Science Research: http://obssr.od.nih.gov/scientific_areas/methodology/mhealth/index.aspx.
SAMHSA: http://www.samhsa.gov/mobile/treatmentlocator.aspx.

Chapter 7
Mobile Means Global

Introduction/Overview

As a phenomenon, mHealth is rapidly expanding globally in terms of the number and type of initiatives emerging, and is projected to become a multibillion dollar industry by 2017 (Levy 2012). According to a report prepared by Pricewaterhouse Coopers (PwC 2010), the powerhouse international consulting and service enterprise, annual mHealth industry revenues are projected to reach US$ 23 billion worldwide, with Europe, Asia, and North America achieving similar revenue volumes by that time. Figure 7.1 illustrates the five largest projected growth areas.

The pivotal enabling technology to advance mHealth globally is arguably the mobile telephone, which can be used to quickly and directly reach people wherever they are (Adler 2009). While it is not a necessarily intuitive fact, mobile phones are believed to be used throughout the developing world more than any other modern technology (Sutherland 2006). Moreover, the penetration of mobile phone networks in many low- and middle-income countries surpasses other social infrastructure such as paved roads and electricity (World Health Organization (WHO) 2011).

It is estimated that as much as 90% of the world's population has wireless coverage with approximately 65% of total cellular subscribers located in the developing nations (Hampton 2012). Data from the International Telecommunications Union (ITU 2012) reveal the following facts:

- Total mobile-cellular subscriptions worldwide reached almost 6 billion by year-end 2011, which corresponds to a global penetration of 86%.
- Most of the growth was driven by developing countries, which accounted for more than 80% of the 660 million new mobile-cellular subscriptions added in 2011.
- By year-end 2011, there were 105 countries with more mobile-cellular subscriptions than inhabitants, including African countries such as Botswana, Gabon, Namibia, Seychelles, and South Africa.

Because of these increasing user numbers, there are high expectations for mHealth globally. Market penetration and the increasing sophistication of these mobile networks, i.e., greater speeds of data transmission combined with cheaper and more

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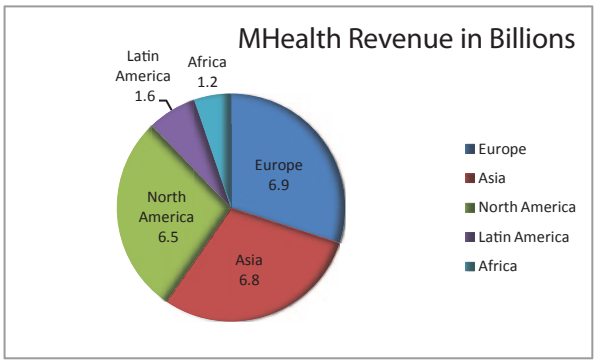

Fig. 7.1 Global mHealth revenue—2017 projections. (Source: Levy 2012 using PwC report data)

powerful handsets, are transforming the way health services and information are accessed, delivered, and managed (WHO 2011).

In addition to this cellular use explosion, the percentage of individuals using the Internet continues to grow worldwide and by year-end 2011, 2.3 billion people were online. Even with a doubling of Internet users in developing countries between 2007 and 2011, the total number of users grew only to 25% of the population. In comparison, 70% of the total households in developed countries had Internet access by year-end 2011 (ITU 2012).

Examples of mobile phone-based mHealth globally abound, including programs for information access, health monitoring, and alerts to potential disease outbreaks. Mobile phone technology is bringing greater health-care access to the masses in India through remote triage, medical advice, and health monitoring. Millions of poorer rural inhabitants in India are able to access health-care services from urban tertiary care centers that previously were not within their reach. In Mexico, Medicall Home has 5 million subscribers who can access medical advice via their phones (Levy 2012). In Cambodia, monitoring disease outbreaks is enhanced by using short message service (SMS) or text messaging for early detection or communication of abnormal events via mobile phones. Similarly in Bangladesh, mobile phones have been used to broadcast text messages to mobilize citizens for National Immunization Day. The messages especially encourage families to bring their children to get vaccinated (WHO 2011). Across the globe, mobile phones are used to reach out to those suffering with HIV/AIDs or those in search of information on disease prevention. Mobile phones are also offering pregnant women and mothers of newborns just-in-time information and access to care. Mobile phones—and the apps that run on them—have definitely gone global.

Clearly, the need for mHealth is growing, especially in developing countries that have high rates of communicable diseases, but are also now experiencing a steady growth of chronic diseases similar to those found in developed countries such as the USA. These diseases include hypertension, obesity, heart disease, and diabetes. The combination of communicable and chronic diseases is referred to as a "dual burden" (Boutayeb 2006). The dual burden presents unprecedented challenges for health delivery systems that are underdeveloped, as evidenced by limited infrastructure,

insufficient and inaccessible hospital resources, and shortages of health-care workers. However, proponents of mHealth suggest it has the potential to overcome many barriers to care and service delivery in order to meet the public health and clinical care needs of both types of diseases (Kahn et al. 2010).

Exploring the topic of global mHealth is complicated by a lack of standard terminology for identifying the economic and social status of countries. For example, when considering mHealth's global impact, it is important to recognize that countries are often categorized as developing/emerging or developed, and some sources use the term newly industrialized. Other classification systems use income as a differentiator, such as low income compared with high income. In some cases, such as with the World Trade Organization (WTO), member countries self-identify their status (WTO n.d.). We found no universally accepted criteria or definitions that distinguish a developing country from one that is developed or otherwise. Consequently, for this book we will use the various designations applied by researchers, analysts, and others investigating global mHealth in citing their findings.

The challenge for those attempting to quantify the impact of mHealth globally with regard to its effect on population health status is to separate fact from hype and speculation. Most of what is publicized about mHealth touts the successes of specific applications in a local setting. Yet, existing research reports that the quality of mHealth interventions and measurement of effect is poor. In fact, most mHealth research trials have been performed in the developed world with its impressive technology infrastructure and not in developing nations where the health needs are greatest and the technology is less robust.

However, we must acknowledge that technology is a means to an end, not the end point. One of the premier challenges of assessing global mHealth is that there is insufficient attention given to identifying and measuring global health outcomes generally. According to Bill Gates, founder and former CEO of Microsoft and also founder of the Bill & Melinda Gates Foundation, the largest transparently operated private foundation in the world, measurement is critically important—especially in light of global resource scarcity:

> Given how tight budgets are around the world, governments are rightfully demanding effectiveness in the programs they pay for. To address these demands, we need better measurement tools to determine which approaches work and which do not. (Gates 2013)

According to a recent white paper published by the Center for Technology Innovation of the Brookings Institution, more research is required to link mobile technology to health outcomes. The paper (West 2012) examined how mobile devices were transforming health care. Even though the research showed that there are considerable data demonstrating positive results for user satisfaction, reductions in wait time, improving attendance at medical appointments, and significant cost savings, the report also identified the need for more information demonstrating the connection to health outcomes, specifically outcomes such as declines in infant mortality, reductions in the spread of infectious diseases, and positive treatment of chronic illnesses.

In developing countries, mHealth innovations have not gone beyond pilot studies and have been funded primarily by private philanthropies and charitable donors. With the absence of formal evaluation processes, there is little documented evidence to encourage governments and businesses to invest in mHealth (Hampton 2012). Although mHealth innovation is coming from developing countries such as Africa and Asia, the funding is mostly provided by and through organizations and partners in the developed world (Curioso and Mechael 2010).

In emerging countries, mHealth trailblazers appear to be experiencing different levels of focus and engagement across the globe. Some countries are incubators of mHealth innovation and are engaged in a wide range of substantial mHealth activities and projects while other countries appear to be less focused and engaged. In 2011, 142 million mobile-cellular subscriptions were added in India, twice as many as in the whole of Africa, and more than in the Arab states, the Commonwealth of Independent States (CIS), and Europe together (ITU 2012). According to a 2012 New York-based Transparency Market Research Report, India is emerging as one of the incubators for launching mHealth innovations.

India, considered an emerging nation, has severe doctor shortages (0.6 doctors per 1000 people) and access to care is a major challenge. In this environment, telemedicine is thriving. The Apollo Telemedicine Network has more than 70 telemedicine centers serving rural areas, where most of the population resides. Plus, the government also has announced plans to create national telemedicine networks that include disease surveillance and oncology. On the other hand, the UK, a developed nation, has shown uneven progress in mHealth activity, including terminating a 10-year attempt to create a nationwide electronic health record program and reducing budgets for telemedicine efforts. Some experts suggest that there is a leapfrog phenomenon occurring in which developing countries can expedite adoption of mHealth because they face less entrenched opposition and barriers such as legacy health systems. This could help explain why studies have shown less engagement in mHealth activities among developed nations such as the UK: Approximately 48% of British respondents did not engage in any mHealth-related activity compared with 12% of Indian respondents (Levy 2012). The bottom line is that emerging countries are, and will continue to be, sources of considerable innovation that can be shared with developed nations (Levy 2012; NHS Press Release 2011).

Measurement Challenges

Annually, Bill Gates writes a letter on behalf of the Bill & Melinda Gates Foundation. In these annual letters, Gates documents the foundation's accomplishments and challenges, especially in regard to the health and education. In his 2013 Annual Letter, Gates focused on the impact of measurement and how mobile technology is facilitating more accurate measurement.

> In Nigeria, I've seen how the digital revolution allows us to improve the use of measurement in the campaign to eradicate polio. Thanks to cell phones, satellites, and cheap sensors, we can gather and organize data with increasing speed and accuracy. (Gates 2013)

But, after the data are collected and organized, they must be analyzed. Outcomes must be evaluated. As yet, no standard methods and definitions of evaluation exist to do so. There is no way to uniformly measure health outcomes for mHealth interventions. This statement is intuitively reasonable for global mHealth. The sheer size of the global mHealth market makes measurement a challenge, especially combined with the number of countries that are not communicating with one another because of political constraints, wars, and other hostilities. Also, there is no entity in charge of collecting data or authorized to conduct assessments. Accordingly, much of the data are derived from private sector research, including consultancy firms.

The estimates of mHealth initiatives and revenue also vary considerably because of lack of standard reporting and forecasting methods. Market research and consultancy firms produce varying estimates about the global mHealth market because they rely on their unique forecasting tools. An excellent example is various estimates of the financial impact of mHealth:

- Transparency Market Research (Albany, New York) reported that the global mHealth market will reach US$ 10.2 billion by 2018, up from US$ 1.3 billion in 2012, with North America representing the largest share of mHealth market revenue, followed by Europe and the Asia Pacific region (Mobile Health Market 2013; Slabodkin 2013a).
- Markets and Markets Research reported a forecast that the global mHealth market would reach US$ 20.7 billion by 2018, up from current estimate of US$ 6.6 billion (Slabodkin 2013b).
- SNS Research projected global mHealth revenue to reach US$ 9 billion by the end of 2014 (Slabodkin 2013c).

Measurement is crucial to move forward with global mHealth. But as Bill Gates observed, it is not easy to do and even more difficult to do well. It requires accuracy in measuring, but it also requires an open environment where problems can be raised and discussed to figure out what is working and what is not. Setting targets for immunization and other interventions can motivate government health workers, but it can also encourage overreporting to avoid problems with supervisors (Gates 2013).

The challenges to measuring global mHealth progress can be seen in the following *Case of Africa.* Africa reflects the heterogeneity of demographics, health needs, resources, and geography that make it difficult to assess mHealth globally. However, as the case demonstrates, changing economics as well as important patterns of mobile phone sharing among poor women in rural areas are emerging. These developments are expected to influence the diffusion and projected progress of mHealth in the second most populous continent in the world, with numbers exceeded only by Asia.

The Case of Africa

Fifty-five countries/states are internationally recognized and members of either the African Union or the UN or both (Becker 2012). By 2009, the population of Africa had exceeded 1 billion for the first time, thereby making Africa the second most populous continent, behind Asia (World Population Review 2013). Africa's population has rapidly increased over the past 40 years, and consequently, it is a relatively young population. In some African states, half or more of the population is under 25 years of age. A growing number of countries in Africa are moving into "middle-income" status countries. Currently, 22 states (with a combined population of 400 million people) have officially achieved middle-income status. Key demographics driving the future for Africa will be urbanization, an expanding labor force, and the rise of the African middle-class consumer. In 1980, just 28 % of Africans lived in cities. Today, 40 % of the Africa's one-billion-plus people live in cities (Africa Overview 2013, Population of Africa 2013).

Africa has reported rapid adoption of mobile phone technologies with over 400 million mobile phone subscribers. However, a 2009 study of phone ownership and usage across Kenya revealed the existence of distinct regional, gender, and socioeconomic variations among rural communities and the poor. Furthermore, ownership of mobile phones was reported as low in rural communities and among the poor. In particular, poor rural women are the least likely to own phones. Consequently, evolving patterns of phone-sharing, which appear to be extremely common in rural areas, may have significant future implications for mHealth diffusion in Africa (Wesolowski et al. 2012).

The Status of Global mHealth: What is Known and Unknown?

Research in the global mHealth field is expanding and includes some of the most prestigious and well-known global nongovernmental organizations (NGOs), including the WHO, the Center for Technology Innovation at Brookings, and the mHealth Alliance (mHA) that works to generate public and private partnerships in support of mHealth innovation. Private sector research by PwC, who commissioned the Economic Intelligence Unit (EIU) to conduct two comprehensive global surveys, also offers a comprehensive examination of the challenges and opportunities, especially for entrepreneurs and companies seeking significant and increasing roles in mHealth. In addition, universities and other academic enterprises continue to investigate and report their findings. These research efforts reveal some striking differences between mHealth in emerging and developed countries as well as formidable barriers and opportunities for achieving the promise of mHealth globally.

The differences are significant between developed and developing nations when it comes to adopting mHealth initiatives (West 2012). In addition, variation exists

within the category of developing nations, as not all developing nations are similar in terms of their capacity, motivations, or incentives for adopting mHealth. Some developing nations such as India are experiencing rising income levels and a trend toward growth of more urbanized populations. Others are not, including some example countries in sub-Saharan Africa.

Take as an example maternal and infant mortality, which is a serious global problem. The UN has targeted reducing these deaths in their Millennium Development Goals. Mobile phone interventions appear to be a viable tactic in achieving UN objectives. However, a study by Lund et al. (2012) shows that the special needs of rural women are not being addressed when considering the implementation of mHealth solutions in the developing world. Their study in sub-Saharan Africa showed that mobile phones may contribute to saving the lives of newborns and mothers, because the phones offer increasing communication linkages with primary care providers and enable more opportunities for skilled assistance during difficult labor and delivery. Yet, the mobile intervention strategies failed to reach rural women who are the poorest and most vulnerable to obstetric emergencies.

The results of the study by Lund et al. (2012), along with prior research (Koblinsky et al 2006; Kowalewski et al. 2000; Cole-Lewis and Kershaw 2010), suggest formidable access barriers exist. Specifically, geographical distances, poverty, quality of care, and sociocultural factors have the potential to impact implementation of mobile phone interventions. Furthermore, in rural populations, limited access to mobile phones, electricity to charge them, and inability to read text messages because of illiteracy presents challenges that are not easily resolved.

The study by the WHO (2011) is a major effort and represents their first attempt to determine the status of mHealth among its member countries. Completed by 114 countries, the survey documented four aspects of mHealth: adoption of initiatives, types of initiatives, status of evaluation, and barriers to implementation. A total of 14 categories of mHealth services were surveyed. Table 7.1 illustrates the most-reported categories and initiatives.

The four most frequently reported mHealth initiatives were health call centers (59%), emergency toll-free telephone services (55%), managing emergencies and disasters (54%), and mobile telemedicine (49%). Approximately two thirds of mHealth programs are in the pilot or informal stages of implementation, except for the health call centers, emergency toll-free telephone services, and managing emergencies and disasters.

Consistent with other eHealth trends, higher-income countries tend to report more mHealth activity than do lower-income countries. Countries in Europe were identified as the most actively engaged in mHealth activities. Meanwhile, countries in the African region demonstrated the lowest level of engagement. The most commonly seen service involves voice communication through phones, which would probably explain the prevalence of health call centers and emergency telephone services. The least frequently seen applications are the use of mHealth in surveillance, raising public awareness, and decision support systems. These require enhanced capabilities and infrastructure to implement, and consequently may not be a health

Table 7.1 Leading categories of mHealth in WHO 2011 survey. (Source: World Health Organization 2011)

Categories	Examples of health initiatives
Communication between individuals and health services	Health call centers
	Emergency toll-free telephone services
Communication between health services and individuals	Appointment reminders
	Treatment compliance
	Raising health awareness
	Community mobilization and health promotion
Consultation between health care professionals	Mobile telemedicine
Intersectoral communications in emergencies	Managing emergencies and disasters
Health monitoring and surveillance	Patient monitoring
	Surveillance
	Mobile health surveys and data collection
Access to health information for health professionals at point of care	Mobile patient records
	Information access
	Decision support systems

priority in countries with financial constraints. Many countries reported up to six mHealth programs in use (WHO 2011).

A UN Blog identified the availability of two reports from the mHA offering additional evidence to support mHealth efforts (Sugrue 2013). The first report, *mHealth and MNCH: State of the Evidence, mHealth Alliance,* presents findings of a needs assessment and a gaps analysis using mHealth for maternal, newborn, and child health (MNCH) as a case study, with the goal of ultimately encouraging further evidence-based research. One of the key findings of this research was that mHealth and MNCH research tends to be focused more often on maternal health interventions, such as reminders for appointments, than on newborn and child health interventions. The literature review also showed more studies using health outcome indicators as primary or secondary measurement units as well as using more rigorous methodologies (Philbrick 2013).

The second report of the mHA is *Baseline Evaluation of the mHealth Ecosystem* (2012), which provides information about the current level of adoption, implementation, funding, and impact of mHealth in low- and middle-income countries. It also measures the impact of the mHA on promoting mHealth in the global health ecosystem. The report had several significant findings at the impact level:

- Sub-Saharan Africa has the highest number of identified mHealth projects compared with Asia and Latin America regions.

- Nearly 50% of projects were focused on UN Millennium Development Goal #6: Combat HIV/AIDS, malaria, and other communicable diseases.
- Limited funding is available for mHealth initiatives. Only 22% of the leading 50 global health donors were funding mHealth activities.

Findings at the outcome level were important as well:

- A review of studies and published journal articles revealed a dearth in the quantity and rigor of evidence for mHealth.
- Adoption of technology standards was very low.
- The alliance has been successful in providing support to facilitate technical working groups.
- 100% of the Every Woman Every Child Innovation Working Group catalytic grantees surveyed had made a plan for sustainable financing of their project when their grant funding ends.

Emerging mHealth: Paths for Growth (Levy 2012) is a PwC report based in large part on extensive survey research by the EIU. The purpose of the report was to examine the current and potential state of mHealth, including challenges and opportunities. This work is especially noteworthy because it looks at mHealth from a variety of perspectives, including payers, providers, and patients. Key findings include the following:

- Patients and physicians living in emerging markets are much more likely to use mHealth than those in developed countries.
- Eight out of ten doctors practicing in emerging markets recommend mHealth services.
- Fifty-nine percent of patients surveyed already use some form of mHealth.
- Remote monitoring, a component of telemedicine, is expected to comprise about two thirds of this global market as doctors and patients use these devices to manage chronic illnesses.

The finding that patients in emerging markets are much more likely to use mHealth applications or services than those in developed countries is particularly intriguing. Patients in emerging markets reported higher awareness of and expectations for mHealth, on average, when compared with patients in developed countries. Patients in emerging markets are more aware of mHealth (61 vs. 37%). They are also reportedly more optimistic about the contributions of mHealth for their overall health care as noted in patient expectations for improvements in affordability (reduced costs), quality, and access (convenience). Table 7.2 describes the comparisons and key findings among them.

Furthermore, emerging market patients are already using mHealth, as 59% said that they are using at least one mHealth application or service. This number of users is compared with 35% of patients in developed countries. In many instances, mHealth is the only method to deliver health-care services. mHealth in the developing world may not be an alternative or luxury as it is in developed countries that have well-established health systems.

Table 7.2 Comparison of patient expectations in developed and emerging markets. (Source: Derived from Economic Intelligence Unit 2012 as reported in Levy 2012)

Patient expectations	Key differences among markets
% of patients who are familiar with the terms "mobile health" or "mHealth"	Patients in emerging markets are more aware of mHealth compared with patients in developed markets
61 % emerging markets	
37 % developed markets	
% of patients who report that in the next 3 years mHealth will change how they seek information on health issues	Patients in emerging markets have higher expectations of mHealth with regard to obtaining health information
64 % emerging markets	
53 % developed markets	
% of patients who report that in the next 3 years mHealth will change how they manage their chronic conditions	Patients in emerging markets have higher expectations of mHealth with regard to managing chronic conditions
54 % emerging markets	
42 % developed markets	
% of patients who expect that mHealth applications/services will substantially cut their overall health-care costs in the next 3 years	Patients in emerging markets believe that mHealth will substantially reduce health-care costs
53 % emerging markets	
40 % developed markets	
% of patients who expect that mHealth applications/services will make health care substantially more convenient in the next 3 years	Patients in emerging markets believe that mHealth will make their health care more convenient
57 % emerging markets	
48 % developed markets	
% of patients who expect that mHealth applications/services will improve the quality of their health care in the next 3 years.	Patients in emerging markets believe that mHealth will improve the quality of their health care
54 % emerging markets	
42 % developed markets	

Levy's findings (2012) also revealed that more emerging-market physicians offer mHealth services than colleagues in developed countries, and more payers cover the cost of mHealth services. Specifically, 43 % of telephone-based consultations and 37 % of text-based consultations were identified as covered by emerging markets payers compared with 29 and 23 % of consultations, respectively, covered by developed country payers. This finding is especially meaningful because it reinforces claims that reimbursement is a major impediment to mHealth implementation in the USA.

Meanwhile, mHealth research has drawn increasing scrutiny and news attention because of the lack of solid evidence and rigor in studies. UN Blog postings referenced the works of Free et al. (2010), Tatalovic (2013), and others documenting gaps in the literature and evidence challenges (Sugrue 2013).

Evaluation has been identified by researchers and analysts as an underdeveloped component of mHealth. Because mHealth is a relatively new field of study, it is expected that increased scrutiny and calls for improvements in this area will lead to more useful assessments of mobile health technology's impact. However, evaluation is challenging in a real-world setting, especially as smartphone applications and technology are updated and evolve on a continuous basis. It can be anticipated that some aspects of mHealth intervention may be outdated by the time of implementation; such is the nature of the rapidly changing market (Whittaker et al. 2012), all of which begs the question—are we becoming too hung up on using conventional assessment mechanisms for unconventional technologies?

The September 2013 launch of an online reference database to help overcome gaps in the literature and offer researchers a tool for locating evidence-based literature was announced by The Center for Communication Programs at Johns Hopkins University's (JHU) Bloomberg School of Public Health. The Case of Knowledge for Health (K4Health) provides more details on the project efforts.

The Case of Knowledge for Health (K4Health)

The Center for Communication Programs at JHU Bloomberg School of Public Health launched an online reference database in September 2013. The project, Knowledge for Health (K4Health), was federally funded by US Agency for International Development (USAID). The database was specifically designed to help researchers overcome gaps in the literature with evidence-based knowledge. The database can quickly locate relevant literature demonstrating the feasibility, usability, and efficacy of mobile technologies in health care. The database is designed to serve as a global resource for the worldwide mobile health-care community. Project goals included efforts to catalog, categorize, and grade all of the known peer-reviewed literature on mHealth in high-, middle-, and low-income countries. In addition, USAID recently awarded the JHU Center for Communication Programs a 5-year, US$ 40 million grant to improve knowledge and information sharing in global health programs, particularly for family planning and reproductive health (Versel 2013).

The Real World of Global mHealth: Beta Testing Environment

There seems to be little testing beyond the pilot or introductory stages of mHealth implementation. The predominant form of mHealth today is characterized by small-scale pilot projects that address single issues such as information sharing and access.

Large-scale, more complex mHealth implementations, mostly supported by public–private partnership, are reported to be limited. Even though it is anticipated that larger programs will become more common as the field of mHealth matures, strategies and policies that integrate eHealth and mHealth interoperability into health service delivery are needed (WHO 2011; Hampton 2012). Moreover, few of the mHealth applications and services have been tested scientifically or validated with respect to their long-term impact. Randomized control trials and traditional methods of scientific evaluation take too long and the technology might become obsolete before the end of the trial. Equally important is whether mHealth applications can be scaled up (Hampton 2012).

A study by Gurman et al. (2012) identified the lack of long-term evaluation and suggested that it could be the result of an emerging field that has yet to address this aspect of research or because of inadequate funding for program evaluation. In addition, the mHealth focus has been on interventions for chronic conditions, which is consistent with the rising incidence of chronic diseases. However, there is also a need to explore mHealth applications for acute care as well. Mobile phones enable real-time, continuous, interactive communication from just about anywhere, all of which would be useful in meeting the needs of patients with acute conditions such as chest pain or moderate-to-severe trauma. In addition, often smartphone apps that are tested are not available to the public; instead, they are created just for testing purposes (Fiordelli et al. 2013). Using real-world smartphone apps in testing should be encouraged.

Despite the demonstrated potential of mobile phone technology to improve health service delivery, there is little guidance about scaled implementation. Success in a pilot study does not necessarily mean the technology can be adapted for more wide-scale use. Limited implementation capacity can be the result of a variety of factors, including securing privacy of information, ensuring interoperability, integration with other systems, or lack of sustainable funding (Leon et al. 2012).

Global mHealth: Challenges and Recommendations

There is no “one size fits all” solution for implementing mHealth globally, in part because challenges are different in different parts of the world. Even though mobile phone penetration is skyrocketing, there are still countries where geography, lack of electricity (to recharge phone batteries), poverty, and functional illiteracy mitigate the benefits of the potential of mHealth. In some countries, there are problems of funding, competing interests, sustainability, legal issues, and lack of a supporting political and technical infrastructure. Perhaps the greatest challenge of global mHealth is diffusing mobile health technologies across such varying political, economic, technical, and social environments.

Economic, organizational, and technology disparities across nations represent a significant impediment to developing mHealth. According to research by Patricia Mechael and colleagues at the Columbia University Center for Global Health and

Economic Development (2010), countries that have made progress in developing mHealth should transmit their best practices to other countries to enable them to move forward and overcome such obstacles (West 2012).

In addition, implementation of mHealth is complicated because many organizations have unclear goals and focus when they originally decide to use mobile applications. They may initially concentrate on mobile data collection, but rapidly switch to using mobile devices to support the workflow once the data are collected. Meanwhile, the mobile technologies used for data collections may not be appropriate for follow-up work (Derenzi et al. 2011).

Some of the challenges appear to be shared worldwide. For example, "competing health system priorities" was consistently rated as the number one barrier to mHealth adoption by countries participating in the WHO survey (2011). The survey also found that the need for further knowledge and information specifically assessing impact and cost-effectiveness of mHealth applications ranked at the top of the list. The WHO survey also discovered that health systems worldwide are under increasing pressure to perform with multiple health challenges, chronic workforce shortages, and limited budgets. In order to be considered among other priorities, mHealth programs require evaluation; that is, evidence showing the effort will yield desired long-term effects and be worth the expense. Decision makers require reliable evidence, but the study showed that results-based evaluation of mHealth initiatives is not routinely conducted, with only 12% of countries responding that they conducted evaluations.

Documenting Effectiveness

mHealth assessments tend to focus on feasibility studies rather than on measuring impact, including long-term outcomes, as well as cost-effectiveness. This approach produces limited information, thereby making it difficult to determine whether the investment is worth the effort and funding, especially long term.

Positive examples of the benefits of mHealth interventions exist, but there is little reliable information regarding clinical or economic performance, both of which are important for the future of mHealth. Furthermore, in order for mHealth to remain competitive with other types of interventions, it must be measurable in terms of cost per disability-adjusted life year (DALY) averted, which is becoming an accepted measure of health intervention performance (Jamison 2006).

A framework for economic evaluation of mHealth should include the following five foci, according to Kahn et al. (2010):

- Description of the mHealth intervention
- Computed costs of the intervention
- Expected clinical outcomes, i.e., changes in health status, mortality, etc.
- Potential drawbacks and adverse effects of using this intervention versus another or none
- Awareness of practical/real-world issues such as sustainability of the product, costs, and outcomes

An example of sustainability challenges can be seen with regard to the mHealth project, Cam e-Warn, in Cambodia. Following an outbreak of severe acute respiratory syndrome (SARS) in Cambodia in 2003, Cam e-Warn, a text messaging system, was implemented to detect and monitor disease outbreaks. Thus far, Cam e-Warn has increased the accuracy of reporting and improved the ability to control the spread of diseases compared with earlier telephone hotline surveillance systems. The project initially cost US$ 100,000 and was financed with funds from the WHO, the Asian Development Bank, and other donors, and supplemented with Cambodian budget resources. Because most of the funding for this mHealth effort is supplied by external sources, there is concern about long-term sustainability, and the government is aware of the need to develop long-term funding strategies (WHO 2011).

Security/Privacy Concerns Mobile applications may introduce or affect security and privacy concerns, with the greater risks occurring during transmission and storage of data. And, patient data may be made available on multiple handsets and phone software platforms making it difficult to protect access beyond basic passwords. Linking different mHealth tools and then connecting them to existing databases can be challenging as well. mHealth programs often operate with different data systems developed at different times or perhaps from different funding sources, which can mean separate platforms run by different sources, such as the government or private sector or a grant-funding agency. While open standards have been proposed to address such problems, they are still a work in progress (Derenzi et al. 2011).

Scaling Up Researchers in South Africa (Leon et al. 2012) found that a developmental approach was preferred over large-scale implementation in their examination of mHealth in community-based services in South Africa. Even though South Africa represents a positive environment for mHealth implementation, scaling up of programs creates challenges to organizational capacities and culture that can compromise possibilities for sustaining larger, more mainstream mHealth service delivery.

Lack of Global Standards The need for mHealth to adopt globally accepted standards and interoperable technologies, ideally using open architecture, is widely recognized. The use of standardized information and communication technologies would enhance efficiency and reduce cost. This will necessitate collaboration across countries for developing global best practices so that data can move more effectively between systems and applications (WHO 2011).

Major barriers identified by the WHO (2011) analysis include:

- Lack of knowledge about mHealth applications and public health outcomes
- High operating costs for mobile communications
- Undeveloped infrastructure, such as unreliable mobile networks
- Lack of supportive policies at the country or regional level

System fragmentation is often a problem for developed nations. The medical infrastructure is enormous, conservative, and resistant to change. In the USA, fragmentation is often identified as a major cause of access, cost, and quality problems.

However, in the UK, a highly centralized, top-down approach failed in establishing a nationwide health information network with subsequent calls for more localized health IT approaches (NHS Press Release 2011; Rowe 2011).

Reliable electricity is a major barrier to mHealth adoption in developing countries. If there is no way to charge a cellphone, mHealth will not work. The private sector has recognized the need to find sustainable sources of power for their overseas markets such as Africa. For example, Motorola has been involved in testing wind- and solar-powered base stations in Namibia, which could bring down the cost of connecting remote areas to cellular networks (Corbett 2008). If alternate energy sources are found to work, an important barrier will be marginalized for the developing world. However, reliable electricity and battery life are less pertinent considerations for developed nations.

Battery life is also an impediment for community health-care workers in low-income countries. These workers are out in the field, usually covering large geographic areas, and poor connectivity as well as difficulty keeping batteries charged impinges on their ability to see patients and/or conduct surveys. In addition, these workers often face theft or loss of their mobile phone and have to devise ways to work around such events (Derenzi et al. 2011).

Global mHealth Opportunities

The potential inherent in mHealth is recognized by the UN and the WHO. The UN included mHealth as a key innovation to achieve the goals outlined in the new Global Strategy for Women's and Children's Health launched in New York on September 22, 2010. The WHO has conducted focused research on the topic of mHealth worldwide. Growing attention and interest has culminated in a series of mHealth deployments that are providing early evidence of the potential for mHealth globally. mHealth is being used and tested in several key areas, including:

- Maternal and child health
- Programs reducing the burden of diseases linked with poverty, including HIV/AIDS, malaria, and tuberculosis
- Improving timely access to emergency and general health services and information
- Managing patient care
- Reducing drug shortages at health clinics
- Enhancing clinical diagnosis and treatment adherence (WHO 2011)

An example of opportunities for innovations is the development and implementation of telementoring, developed at the University of Pittsburgh Medical Center (UPMC) and its Center for Crania Base Surgery. Telementoring uses virtual technologies to train and educate physicians worldwide. The Case of Telementoring provides more details.

The Case of Telementoring

The standard model of surgeons traveling around the world to perform complex surgeries or teach others how to do them is an extremely limited model, especially in view of today's resource shortages. The impact of treating one person at a time is neither efficient nor cost-effective. Telementoring, combining telemedicine with surgical education, however, can broaden the impact and reduce the costs. The UPMC and its Center for Cranial Base Surgery offers telementoring for international physicians who have completed their onsite courses. They do so because after they return home, physicians may encounter difficulty implementing new and highly complicated surgical procedures. Using virtual technology, a surgical team of specialists continues training by providing live support and mentoring for their colleagues from other countries. Telementoring began at UPMC in 2005 and since that time over 500 surgeons from 30 countries have trained in cranial base procedures. Telementored surgeries were introduced in 2011 and have been done twice thus far. Everything is done over the Internet, using existing connections and standard telemedicine capabilities with different types of cameras (Hagland 2012).

mHealth can offer solutions at different organizational levels in developing countries, large geographic areas, local communities, and individual patients and providers. For example, social networking, including text messaging, can be helpful in averting and mitigating disasters in large geographical areas. These mHealth tools can also be used in large-scale health promotion campaigns that encourage people to get tested for HIV/AIDS or eat healthier. At the community level, social networking can connect people to available services in the community. At the individual level, text messaging and phone reminders can improve appointment attendance and medication adherence (Kahn et al. 2010).

Partnerships and Collaborations

The majority of mHealth interventions considered successful in both low- and middle-income countries are based in NGOs and are not part of the mainstream of the country's public health (Mechael et al. 2010). Therefore, the need for partnerships and other collaborative efforts among private and public sectors is underscored.

The mHA has as its mission to serve as a global catalyst for advancing the use of mobile technologies to improve health care globally, especially in developing countries. Membership is free and open to institutions across all sectors that are actively engaged or interested in mHealth. As of October 31, 2012, the Alliance reported 1387 member organizations. Nearly 40% of members are based in Asia, Africa, or Latin America. Most members (44%) are from the private sector with

39% representing nonprofit organizations. Representation also includes academic, foundation, and government institutions.

The National Institutes of Health (NIH) in partnership with the mHA conducts a variety of summer institutes that connect technology leaders, behavioral science researchers, federal health officials, providers, and others to discuss research, advance collaboration, and facilitate partnerships. The mHA also hosts Health UnBound (HUB), a global online community for resource sharing and collaborative solution generation. The mHA is hosted by the UN foundation and funded by the UN, Rockefeller, and Vodafone foundations.

In many countries, private and public sector organizations are collaborating to encourage healthy behaviors, help people monitor their care, provide disease surveillance, improve diagnostic care and treatment, and train health-care workers to support mHealth service delivery (Curioso and Mechael 2010). As a result, mHealth tools are being created to meet the specific needs and resources of local communities, including remote and isolated ones.

Health eVillages, a nonprofit organization based in Marlborough, Massachusetts, is a collaborative effort to bring mHealth tools and services to primary care providers in remote and underserved areas globally, including Haiti, Uganda, Kenya, China, and some of the more remote islands in the Pacific. Launched about 2 years ago by Physicians Interactive and the Robert F. Kennedy Center for Justice & Human Rights, Health eVillages furnishes iPods, iPads, and other mobile devices equipped with health-care information and clinical decision support tools (Wicklund 2013).

mHealth efforts do not have to be complicated. They can be simple in design and implementation, such as the Mobile Alliance for Maternal Action, a public–private partnership inaugurated in 2011. This alliance furnishes health information through mobile phone services such as text messages and voice mail alerts for new and expectant mothers in Bangladesh, India, and South Africa, countries with high maternal and infant mortality (Hampton 2012). Many of the new mHealth innovations are originating from Africa, Asia, and Latin America.

Key Drivers of mHealth

Drivers are different in different countries. However, even though the mHealth market has witnessed widespread growth in emerging economies, the highest per capita expenditure on mHealth applications is expected to continue from developed countries such as the USA and Canada that experience increases in chronic diseases and higher disposable incomes (Slabodkin 2012). Among the most often cited mHealth applications are:

- Widespread availability of mobile phones. The low levels of literacy required to use them is an added benefit.
- Familiarity with texting. Short message service (SMS or texting) has been used by doctors for patient communication since the 1980s.

- Scarcity of health-care resources. mHealth offers a means for extending medical care to underserved geographic areas or disadvantaged populations.
- Growing need for medical care, especially with the rising incidence of chronic diseases.

Availability Mobile technology is often the only way to reach people in emerging countries such as Africa—where the cellphone is the only way to access health care for the majority of those living there. This is also true for much of Asia. Bangladesh is a country with less than one doctor per 4000 people. But by establishing Healthlink, a telephone service that allows people to talk with a doctor at any time, day or night, medical care is available to those who otherwise would not have it (Levy 2012).

Overwhelming Need Overwhelming need for basic medical care might help explain the rapid adoption of mHealth in emerging countries where health-care challenges are more practical and immediate. For example, physicians worldwide tend to concentrate in urban areas. In the USA, such distribution has led to access problems, especially for those living in rural and remote areas. However, the impact is especially dramatic in countries such as India, China, and South Africa, where physicians are scarce and much of the population resides in rural areas (Levy 2012).

Need Versus Want In emerging markets, mHealth is perceived as driven more by need than by want, that is, getting medical care for a sick child when there are no available doctors or health-care workers. In developed countries, mHealth is often viewed as a luxury or fad such as downloading a diet or fitness app.

Value A study published by the World Resources Institute entitled *The Next 4 Billion: Market Size and Business Strategy at the Base of the Pyramid* revealed that the poor and very poor families in developing countries spend a substantial portion of their income on telecommunications, specifically on cellphones and airtime, usually in the form of prepaid cards. Furthermore, as a family's income increases—from US$ 1 per day to US$ 4, for example—their spending on telecommunications increases faster than spending in any other category, including health, education, and housing. Such spending patterns demonstrate that the perceived value of mobile communication supersedes basic needs for even the very poor (Corbett 2008). A study of mobile phone usage and ownership in Kenya (Wesolowski et al. 2012) found that the poor in this country spent a disproportionate amount of their income on phone airtime, providing additional documentation of the significance of mobile phones in their lives, too.

mHealth Drivers of Cost, Quality, and Access

The EIU surveys commissioned by PwC (Levy 2012) reported that 54% of patients in emerging markets identified cost of health care as a driver for increased use of mHealth compared with 34% of patients in developed nations. In emerging

Table 7.3 Comparison of cost, access, and quality drivers for mHealth usage. (Source: Derived from Economic Intelligence Unit 2012 Survey Data reported in Levy 2012)

Motivator	India (emerging country)	UK (developed country)	Comment
Cost	Indians cover ~75% of their medical expenses out of their own pocket	UK's National Health Service (NHS) provides free care at point of need, thereby removing any economic burden of care	Medical care is beyond the financial reach of many in India. In the UK, the care is mostly free
Access to care	0.6 doctors per 1000 people, with most doctors, including specialists, located in urban areas where less than 30% of India's population (1.2 billion) reside. Rural residents receive much of their care from certified social health activists versus trained medical personnel	2.15 doctors per 1000; Long waiting lists and inconvenience inhibit access to care	Because doctors tend to locate in urban areas, their services will be inaccessible to the majority of Indians (1.2 billion) In the UK, patients wait for months to get access to specialists and high-tech services such as CT scans and MRIs
Quality	Ability to obtain information otherwise unavailable was rated as important by 40% of India's respondents	Greater control over their own health was rated as important by 43% of UK respondents	Both of these items suggest adoption of mHealth technologies that will enable quality efforts

markets, such as India, health care is indeed expensive, with Indians themselves covering about 75% their medical care expense. In developed countries, such as the UK, health care is free at the point of care, and therefore not a financial burden. Indian respondents prioritized reasons for using mHealth as follows:

- Fifty-eight percent cited cost reduction as the number one reason for using mHealth.
- Fifty-five percent cited convenience of access.
- Forty percent cited the ability to obtain information otherwise unobtainable.

Meanwhile, respondents from the UK ranked cost reduction farther down on their list; however, convenience of access, which was second on the Indian listing, was at the top of the UK list:

- Forty-nine percent cited convenience of access.
- Forty-three percent cited the desire to take greater control over their health care.
- Twenty-five percent cited cost reduction (Levy 2012).

Table 7.3 further describes and differentiates the mHealth drivers between India, an emerging nation, and the UK, a developed nation.

Success Meets Global mHealth

DataDyne.org initiated a project known as *Coded in Country* that promotes using local software developers to create programming solutions that address local information technology challenges. *Coded in Country* was developed in conjunction with D-Tree International, a nonprofit organization, and Dimagi, a health-care technology company. The company encourages funding sources or operators to allocate more than 50% of their program monies toward local coders. The idea is that using locals will (1) develop more effective solutions because they are closer to the problems and (2) build information and communication technology capacity that will not disappear, as happens when outside software developers leave (Curioso and Mechael 2010). Other researchers agree with the need for developing local technical capacity in order to implement mHealth as well as promoting local microenterprise that will generate more economic opportunities (Kahn et al. 2010) and perhaps lead to sustainable mHealth interventions.

The OpenROSA consortium is a group of developers working to create open-source, nonproprietary, standards-based tools for mobile data collection that meets a common need. Open source development increases opportunities to work on larger-scale development efforts that include different countries and systems. Members include small companies, giants such as Google, and universities, including the University of Washington and the University of Bergen. The group has active developers working in a variety of developing countries such as India, Bangladesh, Kenya, Pakistan, Tanzania, and Uganda. OpenROSA successes include devising ways to capture or record data transferred via mobile devices (mobile data capture). Current initiatives of OpenROSA include JavaROSA, an open-source platform for mobile data collection. Uses are wide ranged and include disease surveillance and collecting data for electronic medical records. Projects that use the JavaROSA platform can be run on most Java-enabled phones. Even though these phones can usually be found in low-income areas, Java compatibility is not universal or inexpensive (Curioso and Mechael 2010).

Extending Rural Access Access to specialty medical care for rural residents is especially challenging in developing and low-income countries. Digital technology and mobile applications are viewed as helping people in rural areas overcome geographical barriers to care. In China, mobile devices often allow for remote consultations with specialists in urban areas. In India, videoconferencing enables some rural residents to access care. A mobile health app called Health Buddy has been used in Singapore to provide access to health information from specialists. In Bangladesh, where 90% of births in rural areas occur outside of hospitals or clinics, a mobile notification system is used to alert health clinics of the need for midwife services (West 2012).

Counterfeit drugs kill at least 100,000 people a year, mostly in the poor world. The UN estimates that about half of the antimalarial drugs sold in Africa, which are valued at close to US$ 438 million a year are fakes. Expensive radio frequency identification (RFID) technology and database software are being used to detect fakes, but mobile phones offer a less expensive alternative for developing countries

to screen drugs. For example, a Ghanaian start-up firm mPedigree has developed a way to use mobile phones to authenticate drugs. Participating drug companies emboss a special code onto packages, which customers find by scratching off a coating. By sending a free text with that code, customers can find out instantly if the drugs are fakes (Poison Pills 2010). A US-based company is beta testing an app that visually compares a patient's pills against a database of images to aid clinicians in managing a patient's total pharmaceutical profile. The app is particularly useful in interviewing elderly patients who cannot self-report their drug regimens.

The expanded functionality of cell phones offers a solution to another problem identified in a polio immunization program funded by the Bill & Melinda Gates Foundation. Program administrators found that some teams were simply not going to the geographical regions they were assigned. To resolve this issue, the program is piloting the use of phones equipped with a Global Positioning System (GPS) application for the vaccinators to carry. Tracks are downloaded from the phone to a laptop at the end of the day so managers can see the route the vaccinators followed and compare it to the route they were assigned. This helps ensure that geographical areas that were missed can be reassigned to vaccinators, ensuring that children are not left unprotected from polio (Gates 2013).

Because developing countries have fewer infrastructure barriers to innovation, they are often the incubators of innovation. As such, developed countries can learn from them. For example, Text4Baby, which is a free service that sends information to pregnant mothers, drew on the design of Mexico's VidaNet service (for patients with HIV/AIDS) and Kenya's MobileforGood Health Tips (Levy 2012). The potential for technology transfers from emerging countries to advance the deployment of mHealth is one of the most advantageous entrepreneurial assets in the industry.

mHealth phone tools also help train, supervise, and monitor community health workers in low-income countries. Supervising large numbers of workers who are distributed over large geographic areas is one of the most costly and difficult components of multinational companies. Mobile data collection can reduce costs, save time, and assure accuracy of data compared with traditional paper methods. Despite the considerable number of ICT projects for community health workers, little published research exists describing what works and what does not. Table 7.4 explains some of the possible benefits of these tools. If a community health program is not working well, adding mHealth to the mix is unlikely to resolve fundamental underlying programs as these tools cannot remedy more serious problems of politics, infrastructure, or funding (Derenzi et al. 2011). However, mHealth tools can support and/or strengthen a program, such as enhancing remote guidance and supervision of health workers.

Conclusions and the Future of Global mHealth

We began this chapter by asking what is known about the impact of mHealth globally and its future. As it happens, we know a great deal about how mHealth is changing the nature and extent of health service delivery worldwide. For example, text messaging turns out to be a particularly cost-effective way to connect with people

Table 7.4 Benefits of mobile phone applications by health system function. (Source: Derived from Derenzi et al. 2011)

Health system function	Description and example	Benefits
Facilitate communication with health-care workers	Transmit images to physicians for remote diagnosis. Pilot telemedicine projects in Botswana in dermatology, radiology, cervical cancer, and oral medicine	Enables patients in remote and rural areas access to specialists; improves quality of medical care
Data collection	Global positioning systems (GPS) technology in a mobile phone can track health workers and identify location of patient homes in the absence of accurate maps	Improves accuracy, efficiency, and costs of data collection Enhances surveillance activities
Training and access to information for health-care workers	Continuous training for health-care workers in community health centers in remote areas of Uganda. Sharing new clinical information and procedures via satellite in Uganda, AED-SATELLIFE	Make training/retraining more efficient, less expensive, more effective
Supervision of health workers	Mobile phone applications can enable real-time monitoring of health-care workers remotely. Remote guidance can also include automatic message reminders and/or motivation from supervisors	Offers supervisors the ability to stay in contact with field workers and quickly react to changes and provide corrections or positive feedback
Promoting population health, healthy behaviors	Chronic disease management tools have been deployed for health prevention and promotion. Text messaging to improve compliance with treatment regimens, including weekly and customized messages, games that can be downloaded to phones for incentivizing and encouraging healthy behaviors	Relatively easy and inexpensive way to reach large populations, especially those who live in rural and remote areas
Providing job aids and decision support	Mobile applications designed to help clinicians adhere to clinical guidelines and procedures by guiding clinicians through a series of protocols by offering one question at a time, with a question automatically determined by the answer to the preceding question	Improved adherence to clinical guidelines can improve treatments and reduce mortality rates

privately and across great distances. Public health workers in South Africa now send text messages to tuberculosis patients with reminders to take their medication. In Kenya, people can use SMS to ask anonymous questions about culturally taboo

subjects such as AIDS, breast cancer, and sexually transmitted diseases, receiving prompt answers from health experts for no charge (Corbett 2008).

Overall, mobile data traffic is expected to increase 18 times over between 2011 and 2016, when it is projected that there will be 10 billion mobile devices in use around the world (Cisco Virtual Networking Index 2012; West 2012). However, mobile phone ownership and usage is not uniform across populations. Heterogeneities of ownership may distort estimates of population dynamics and social networks, especially in countries such as Africa where few people in rural areas have phones and phone-sharing practices are extensive. In the meantime, penetration of mobile phones is expected to increase and subsequently reduce, if not eliminate, many of the problems associated with predicting the growth and impact of mHealth (Wesolowski et al. 2012).

In terms of mHealth's transformative potential, we learned that among developing countries there are extraordinary opportunities to strengthen existing weak or underdeveloped health systems and to take on serious health challenges ranging from chronic to infectious diseases. Cell phones and the Internet are rapidly penetrating the world and allowing remote and underserved communities to gain access to health information and services—often in real time (Curioso and Mechael 2010). Thus, access to care when and where you want it is becoming a reality for much of the world.

In developing countries, because the need for health care is overwhelming, money is scarce, and the infrastructure is less developed and entrenched, mHealth likely has a cleaner path to adoption of mobile technology. In developing countries, cellphones are perceived to be a lifeline to health care for many who live there and have had limited to no access to health care previously. Cellphones appear to extend the reach of health-care providers to underserved, disadvantaged, and vulnerable populations wherever they may be (Whittaker et al. 2012). Meanwhile, in the developed world, cellphones are more often seen as intriguing gadgets for entertainment and personal convenience, with thousands lining up to buy the latest upgrade of an iPhone.

Most of what is communicated about mHealth touts the successes; yet, existing research reports that the quality of mHealth interventions is poor. In fact, most of the mHealth trials have been performed in the developed world and not in the developing nations where the need is greatest. While mHealth is often publicized as having the potential to improve health care in developing countries, there is little supporting hard evidence to validate the hype. Furthermore, much of the testing has not gone beyond the pilot or introductory stages. In the future, there is a need for formative research and documenting outcomes, including lasting effects, of mHealth interventions (Curioso and Mechael 2010).

Because the field of mHealth research is new, there is a need to adequately investigate and corroborate findings to assure that findings are reliable and valid (Gurman et al. 2012). Beyond this, the lack of studies attempting to measure cost-effectiveness or health outcomes (Free et al. 2010; Tatalovic 2013) is a serious concern. Without this type of research, there is no way to know what works and what does not, particularly with regard to large-scale deployment. There is little to no evidence

to show governments, foundations, entrepreneurs, and businesses that mHealth is worthy of investment. Consequently, stronger evidence is necessary to distinguish reality from hype and to encourage investor and entrepreneur participation.

Measuring the impact of mHealth is challenging in a large part because of a lack of standardization in many important dimensions. There are no standards for evaluating mHealth and no universally accepted definition of terms such as mHealth, telemedicine, or telehealth. Thus, the numbers often do not add up nor do they paint a conclusive mHealth landscape. However, the field of mHealth is young, and researchers have called for more scrutiny and use of rigorous methodologies. The online reference database launched by JHU Bloomberg school of Public Health and the K4Health project should help improve the quality of mHealth research globally.

An important question is whether mHealth can be scaled and sustained for the foreseeable future. To be scalable and sustainable, mHealth requires more cost analysis research and further development and analysis of business models. Because of the significant role evaluation and assessment plays in demonstrating cost-effectiveness, the WHO and its partners are working to develop a framework to assist in evaluating mHealth programs, especially with regard to including meaningful and measurable indicators of robust outcomes. A global database of selected evaluation research findings will be built for mHealth with a particular emphasis on mHealth initiatives in developing countries. And, member states will gain access to the database to assist in planning projects and preparing project proposals (WHO 2011).

Because mobile phones and other mobile technologies require less investment and infrastructure than other health system transformative efforts, scaling up and widespread deployment of mHealth appears very achievable in developing countries. However, patient financial support has not yet been determined. Survey research shows that patients overall express a reluctance to pay out of pocket for mHealth. More patients in emerging markets reported that they were willing to pay for mHealth compared with patients in developed countries. However, some reluctance to pay for mHealth was evident even in developing countries (Levy 2012).

The possible future for mHealth is that it will continue to foster increased access to care in emerging countries while transforming the developed nations' large and costly health systems into affordable, prevention-based, and patient-focused delivery systems. Physicians and payers alike believe that widespread adoption of mHealth is inevitable. Furthermore, physicians predict the impact of mHealth on patient relationships will be as significant as the Internet has been in creating opportunities for individuals to engage in actions to influence their own health and well-being. Research has shown that patients have high hopes for the future of mHealth, including improvements in convenience, quality, and affordability. In the meantime, experts appear to remain more cautious about the future of mHealth—awaiting the intersection of health care and business models (Levy 2012). Thus, the development of business models remains a challenge for the future of mHealth globally.

Global mHealth is addressing many of the challenges of health-care access, cost, and quality issues worldwide, but impediments do exist. Developing countries often do not face the health-care infrastructure and bureaucracies that ultimately impede the diffusion of mHealth. Without these legacy systems, innovation has fewer

barriers to overcome. But many developing nations have formidable problems such as illiteracy and poverty. Even though the price of cellphones continues to decrease, they still remain unaffordable to someone earning less than US$ 5 per day. In addition, voicemail and video transmissions may ultimately address many of the needs of those who cannot read or text. Challenges to mHealth adoption will persist and require continuing attention.

mHealth services and applications will continue to be developed and used everywhere, regardless of country of origin, the patient, provider, or payer's location. But implementation will depend largely on what motivates the end users, the patients, and providers, and in many cases, the payers who can encourage adoption of mHealth with financial incentives for use. Technology is not the complicated piece of the global mHealth puzzle. How technology is used is what matters most and demands focus and attention (Derenzi et al. 2011). Barriers exist, but they are not insurmountable in most cases. Businesses are investing in development of solar, wind, and other technologies to resolve challenges of battery life and electricity in developing countries (Corbett 2008). And, governments are seeking partnerships to help build their global mHealth infrastructure.

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Chapter 8
Research Evidence and Other Information Sources

Introduction/Overview

Much of the aggregated information about the efficacy and impact of mHealth is published in "grey literature," defined among the information sciences as documents "produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers" (Grey Literature Report 2014). Practically speaking, grey literature includes conference proceedings, theses and dissertations, government and industry reports, white papers, and many other documents of limited circulation. Although the information is credible, one notable challenge with regard to using grey literature as source documents for research and scholarly papers has been accessibility limitations, as these documents are not indexed in standard scholarly and business publication indexes. While the Internet has mitigated the direct access problem for much of the work, issues remain regarding identification of authors and referenced data, publication dates, and even the publishing source. With the largest proportion of the body of literature related to mHealth found in grey literature and trade publications, it is fairly easy to conclude that rigorous, theory-based research to support policy and regulation is significantly lacking. In fact, many experts as well as the general public believe that there is a gap between app development and evaluation.

Nevertheless, a rather large body of credible and useful information does exist, and much of it provides actionable guidance for the purpose for which it was generated. As illustrated in Fig. 8.1, the research topics investigated differ by publishing category. This is intuitive as grey and trade literature tend to address time-sensitive topics, while academic researchers tend to pursue "fundable" investigations that require robust methods to accrue the expected levels of validity and reliability. Most identified gaps could be classified as generating the type of information needed to inform policy, that is, needing rigorous, controlled studies, and well-documented research designs. Unfortunately, such research is also time- and resource intensive, and often incurs a significant lag before results are made public through presentations, scholarly journals, and other media. Entrepreneurs and investors are more interested in quick, actionable data to inform a business decision, that is, the types of research reports that appear in trade and grey literature, frequently as digital

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Fig. 8.1 Identified mHealth research gaps

media. Thus, it is essential to acknowledge that both types of research serve important purposes, and both should be pursued with a focus on pairing the appropriate investigative and analysis methods with the research aim.

Beginning with a conclusion that "the exponential growth of the technology has outpaced the science" of mobile health, the National Institutes of Health (NIH) sponsored two focused initiatives in 2011—the mHealth Evidence Workshop and the mHealth Training Institute (Nilsen et al. 2012). The Evidence Workshop was intended to accelerate medical innovation and move research findings into practice more quickly through expert advice in three key research areas: study design, statistical strategies, and infrastructure. These areas and the foundational Workshop conclusions are shown in Fig. 8.2. A later comprehensive report of the Workshop proceedings (Kumar et al. 2013) reinforced the need to employ research designs that accommodate the dynamic nature of mHealth interventions, The Training Institutes aimed to build research capacity by providing cross-disciplinary training to early career investigators interested in mHealth research. The identified need for "solid, interdisciplinary scientific approach[es] that pair the need for rapid change associated for technological progress with rigorous evaluation method[s]" remains a current driver toward a science of mHealth.

What is most needed at this stage of the mHealth evolution is focused research in areas pivotal to adoption of mHealth technologies at the scope needed to achieve system-level benefits. These areas include:

- Consumer preferences and satisfaction with health apps for personal use
- Provider goals when recommending health apps to foster patient engagement in self-care as well as primary treatment options
- Developers' and distributors' expectations when deciding which apps and products to push to market

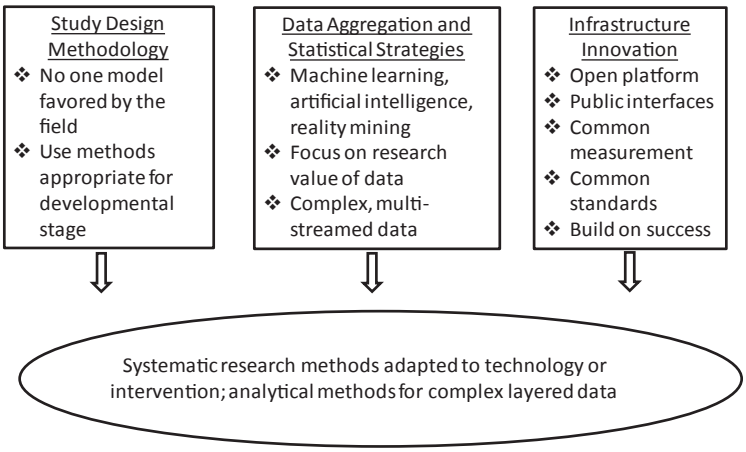

Fig. 8.2 mHealth evidence workshop findings

- Investors' and payers' expectations when deciding which apps to underwrite financially
- Cost–benefit analyses related to clinical outcomes, and
- Safety and efficacy studies to advance FDA approvals

Table 8.1 shows primary stakeholders' information drivers for mHealth research, their current information sources, and the types of research needed to inform decisions for the effective use of mHealth apps and devices at all system levels. While much of the research is of necessity long term, immediate needs include evaluation rubrics and assessment criteria to guide consumer and provider choices among current and emerging consumer apps.

Navigating the mHealth App Maze

Choosing the "right" app from among those available is increasingly difficult for consumers, providers, insurers, investors, and others as the online environment proliferates daily with apps, many promising far more benefit than can possibly be realized. And for consumers, the ease with which an app can be accessed and deleted, often at no direct user cost, encourages a try-and-discard approach rather than thoughtful assessment and deliberate choice. Those who want to make considered choices may be unsure about trusted information sources or even what information is needed to support decisions. In reality, appropriate decision criteria and available information resources differ among the various stakeholders. The industry would benefit from standardization to facilitate app innovation and development as well as encourage use of apps. However, to date there have been few attempts by public or private entities to evaluate and certify health apps and those few have met with

Table 8.1 Summary of stakeholder research needs

	Evaluation bases	Current information sources	Type of research information needed
Consumer Personal use	Need or want Cost effective Ease of use	Product descriptions User reviews No-risk trial Provider recommendations	Practical, applied Assessment criteria User reviews Social media
Consumers Medically supervised use	Efficacy of app or device Cost–benefit Insurance coverage	Provider prescription	Empirical (efficacy and safety) Product/treatment comparisons
Developers	Consumer interest Expected revenue Product life cycle	Trade/grey publications Survey data Market analyses	Consumer preferences App functionality requirements
Distributors/vendors	Consumer interest Expected revenue Product life cycle	Business proposals Revenue projections	Market analyses Optimal deployment strategies
Insurers/payers	Efficacy of app or device Safety/risk Cost–benefit	Empirical research Patient satisfaction	Theoretical, empirical Cost analyses Patient satisfaction
Investors	Sales/ROI potential	Business proposals Revenue projections	App functionality Risk assessment/ evaluation Financial analyses
Policy-makers/ regulators	Safety and efficacy Cost–benefit User acceptance	Empirical (limited) Cost analyses Patient satisfaction	Theoretical, empirical Cost analyses Patient satisfaction
Providers Consumer recommendations	Safety and efficacy Cost–benefit Ability to link with EHR	Vendor marketing Trade/grey publications	Empirical (Efficacy and safety) User reviews (usability)
Providers Primary & adjunct therapeutic use	Efficacy of app or device Cost–benefit Insurance coverage Ability to link with EHR	Trade/grey publications Vendor marketing Empirical research	Empirical (efficacy) User reviews (usability)

limited success. In fact, Happtique's much-heralded Health App Certification Program was suspended less than 2 weeks after announcing it had certified 19 health and medical apps. The suspension followed a software developer's identification of security vulnerabilities. This suspension was a major setback to Happtique's efforts to create a certification program that would offer physicians confidence in prescribing apps for patients (Baum 2013).

Consumers

Consumers frequently learn about available and emerging apps through word-of-mouth, advertising, web searches, and by scanning for products in the app stores. They clearly are disadvantaged in their searches by the dearth of comprehensive, organized directories of mHealth apps, and there is little to no incentive for groups or organizations to develop them. Compiling and maintaining a directory is quite challenging for several reasons, including the sheer volume of apps and the rapidity with which new ones enter the market and unsuccessful ones depart. In large part, the app marketplace is undocumented and without established review processes. That is, there is no certification process or registration required—with the exception of apps subject to FDA review. Additionally, the rapid pace of app development seemingly has outpaced government review and regulation, and the government is often viewed as struggling to keep up with clinical apps. The few online directories and consumer guides available are recent market entrants; a key question will be the sustainability and accuracy of the sites in light of the dynamic nature of the app market.

Mobile Health Marketplace (www.mobilehealthmarketplace.com), self-promoted as "the leading directory of mobile health apps and devices," launched in September 2013 (Allen 2013), listing more than 40,000 apps for smart phones and tables sorted into 33 categories. The directory is intended for use by consumers and medical professionals, and includes both prescription-based apps and apps for self-selection or recommendation by providers. Directory entries list the app name, a brief description, pricing and purchase venues, and several other evaluative categories, including the ability to interface with other software platforms (New Mobile Health App Directory 2013). As expected in this early stage, not all information is available for all apps, but the scope of information for which the directory is designed is quite comprehensive. The directory is supplemented by a blog. The directory can be searched without membership, but a free subscription option is available to access additional resources.

The Department of Health and Human Services (HHS) offers a directory of 34 HHS-sponsored mobile apps (HHS 2013). While little information beyond a basic description is provided in the directory, consumers can presume credibility of content based on government sponsorship. The apps are aimed at a broad range of users—from children to adults to researchers. Some apps are basic, such as MyMedList and My Dietary Supplements, which are used to document current medications and supplements, but can also remind users to take their medications or purchase refills. Others are designed for specific user groups, such as the NIH Fellows and Young Investigators App, which offers resources for training and professional development.

In 2013, Partner's HealthCare's Center for Connected Health in Boston announced the launch of their online guide, Wellocracy (www.wellocracy.com) whose goal is to "empower consumers to self-manage their health, create and maintain individual wellness goals and achieve a greater quality of life." A Harris Interactive

survey on behalf of Wellocracy reported that the majority of adults surveyed (56%) had never used any type of health tracking device, app, or website. Wellocracy is described as a "clinically-based source of impartial, easy to understand information on new personal 'self-health' technologies such as health and fitness trackers and mobile apps" (Slabodkin 2013b). The Wellocracy site also has a membership option that includes a personal survey of demographic information and use of health trackers. The site includes surveys and daily health tips and is connected to several social media forums. The number of apps reviewed on the site is not stated, but the number of categories—activity trackers, sleep trackers, and mobile apps for running and pedometers—is much less extensive than Mobile Health Marketplace, and the information provided is less robust.

HealthTap gained attention in the mobile world with its online mobile information network, HealthTap Express. The free membership service provides a forum for consumers to ask medical questions online to be answered by practicing physicians. Subsequently, HealthTap launched AppRX, a service to help consumers locate the right app. What distinguishes this effort is that the company is using its network of 40,000 physicians to review and recommend the best apps. There are 30 different health and wellness categories of apps. The company believes that AppRX would serve as a quasi-seal of approval, thereby giving consumers more confidence that the apps deliver what is promised (HealthTap Blog 2013).

Interestingly, one directory identified is a downloadable PDF document, the *European Directory of Health Apps 2012–2013* (PatientView 2012). This alphabetical compendium of 200 apps reviewed by patient groups and consumers is indexed by app name, clinical specialty, and language. Information provided for each app is limited to a few categories, but reviews are provided by credible consumer groups and health professional organizations.

There are also lists of the "top" apps created by various groups, such as the iMedialApps listings (www.iMedicalApps.com). The selection criteria for these lists are not consistent, and they may be based on personal reviews, download volume, free availability, or other criteria. And of course, consumers can browse the iTunes and Google Play stores catalogs or search for consumer-provided information via social networks. Table 8.2 provides a comparison of information available in the app directories described here with the exception of HealthTap's AppRX, which requires registration to view.

One useful resource offering advice to consumers choosing specific apps for personal use is the American Health Information Management Association's (AHIMA) best practice guide, *Mobile Health Apps 101: A Primer for Consumers* (AHIMA n.d.), available as a free online file download. Because the AHIMA has credibility and status in the industry, this guide is well-regarded, especially because it advises consumers about information security issues, such as the recommendation to review the app's privacy policy. The guide presents consumers with specific questions to consider when selecting a health app, especially with regard to privacy, security, and management of their personal health information.

Table 8.2 Summary of available app directory information (Source: http://www.mobilehealthmarketplace.com; http://www.wellocracy.com; http://www.PV_AppDirectory_Final_Web_300812.pdf; http://www.hhs.gov/digitalstrategy/mobile/mobile-apps.html; http://www.imedicalapps.com/top-10/)

	Mobile Health Marketplace	Wellocracy	European Directory	iMedicalApps Top 10	HHS Mobile Apps
Certifications	X				
Comparison with similar products		X			
Consumer reviews	X	X	X	X	
Consumer support	X				
Countries of use			X		
Credibility assessment	X				
Description	X	X	X	X	X
Developer	X		X		X
Distributor(s)	X				
Interface/device capabilities	X	X	X		
Languages			X		
Links to related sites	X	X	X		
Manufacturer		X			
Platforms					X
Price	X		X	X	
Privacy policy	X				
Purchase link				X	
Security policy	X				
Suggested product improvements		X			

Providers

Access to mHealth apps and devices used therapeutically as a primary treatment modality or in a supportive capacity is controlled by the treating physician. Essentially the physician "prescribes" the device or app, which likely has undergone rigorous testing for efficacy and safety to receive FDA approval. Under this circumstance, the physician has access to appropriate evaluative data and approval documentation. Also, the use of the devices has been incorporated in payment plans by insurers well in advance of the time a bill must be presented for payment. The IMS Institute Report (IMS 2013) suggests a "formulary" of apps approved for physician prescription after approval by the health care organization's (HCO) legal team. Managing this listing of endorsed apps would be the responsibility of the HCO chief medical information officer or other designated clinical official.

The more challenging circumstance for many physicians lies in recommending non-FDA approved devices and apps for direct personal use by their patients as a tool for self-care or health maintenance. Here, as for consumers themselves, they have little authoritative guidance. Many resort to identifying one or two apps in the categories most requested and recommending those consistently. Their recommendations may be based on a personal use, discussions with patients or other physicians, website reviews, or some combination of approaches and assessment criteria. If a physician is seeking authoritative information about an app or wants to make comparisons among several, the most comprehensive online source at this time is the Mobile Health Marketplace directory, as shown by the information previously summarized in Table 8.2. Notably, this directory is the only one to include security and privacy information to the extent it is available at this time.

Without scientific evidence that apps work and without reproducible results, physician skepticism about apps is unremarkable. Physicians rely on and trust peer-reviewed research appearing in their journals. When medical research reports on the effects of clinical apps is perceived as valid and reliable, the physician community will pay attention. Critics who complain that physicians are techno-challenged would do well to remember that it is the physician who advocates for the patients and performs fiduciary functions on their behalf. Until the research is validated, physicians will continue to question new apps that have yet to demonstrate ROI with regard to time and outcomes (IMS 2013).

Sorting Through the Research

There is a lot of "breaking news" published about apps and a limited amount of empirical research has been reported, but much of the available information has not been validated or examined with adequate rigor and a great deal of variability exists among the quantitative data reported. For example, estimates about the numbers of health care apps available and their usage rates vary widely. This is likely attributable to some degree to the lack of a universally accepted method of classification of health care apps. As a result, health, beauty, fitness, diet, and clinical apps are included or excluded from the various tabulations or reports, often without a specified reason or explanation for inclusion or exclusion. Despite this generalization about the lack of rigorous evaluation, there are some excellent and reliable sources of information about health apps and mHealth available. The following sections summarize key contributions to mHealth knowledge made by some recent research reported.

As discussed throughout this book, much of the research reported is of limited scope intended to provide answers to some very specific, market-oriented questions without using a robust, controlled research design. Such questions include:

- National and global growth in the use of mobile devices, especially smart phones
- Extent of use of personal mobile devices in the workplace

- Preferred mobile device and platform
- mHealth market expenditures and projections
- Most frequently downloaded apps
- Consumer app trends

While these are important questions and the data can inform app development and marketing decisions, research of this type does not provide the scope of information or the assurance of data integrity required to inform clinical and policy decisions. The body of empirical research grows slowly and builds toward accumulated evidence over time. Additionally, research may be focused on a single dimension or characteristic of a phenomenon, a single application, or a single context, either geographic or organizational. These and other delimitations (researcher-defined constraints) are accompanied by study design limitations—circumstances outside the researcher's control that may affect the outcomes. Both must be considered in evaluating research reports and conclusions drawn from data analysis.

IMS Report

Possibly the most recent consequential and comprehensive report was published in October 2013 by the Institute for Healthcare Informatics (IMS), which issued findings from a review of more than 43,000 apps available through the iTunes store in June 2013. After excluding approximately 20,000 apps that were not truly health related and another 7400 intended for use by health care professionals, a total of 16,275 consumer-oriented health apps were submitted to full-functionality analysis (IMS 2013). This final number is more consistent with published app availability totals from other reputable sources, although online publications suggest that tens of thousands of medical apps exist.

The 65-page study report offered some sobering findings about apps, including the finding that more than half the available apps are not downloaded frequently (i.e., fewer than 500 times total), few apps address areas of greatest need (i.e., chronic conditions), and many physicians lack the confidence and trust to recommend the apps because of the lack of supporting evidence. Additionally, the vast majority of health apps available to the general public have limited functionality beyond displaying information. Less than half of the apps offered any instruction, and only about 20% had the capacity to accept patient-entered data.

Five of the apps studied accounted for 15% of all downloads, which indicates limited "traction" among users to the point of abandonment. Even though the report illustrated areas for potential gains involving attainment of healthy lifestyles through diet and fitness apps, systematic evaluation is needed to provide patients, physicians, and payers with evidence of value achieved from app use.

The report suggested that few apps were designed to meet the needs of the largest group using health care services, seniors aged 65 and older, which represents a significant market opportunity for future development. This finding is consistent with the Accenture Health Survey and the Pew Internet and American Life Project

Table 8.3 Unique attributes of mHealth. (Source: Adapted from Akter et al. 2013)

Attribute	Key concept
Accessibility	"Any-time, anywhere solutions"
Immediacy	"Right-time, relevant, targeted"
Interactivity	"Value co-creation"
Location-based information	"Use of GPS and COO[a] technology"
Mobility	"Temporal, spatial, contextual mobility"
Personalized solutions	"Needs of specific person"

[a] Global positioning system and cell of origin

reports, which target seniors, especially aging baby boomers, as interested in self-management of their health and the fastest-growing population group moving to online technology use.

Service Quality

A good example of robust research findings where generalizability may be constrained by the study limitation of geographic context comes from the Universities of Wollongong and New South Wales in Australia. Researchers conceptualized and validated a multi-dimensional scale to measure service quality in mHealth (Akter et al. 2013). Development and validation of measurement instruments is crucial to reliable comparison of alternatives in any scientific discipline, and this study, a first for mHealth, makes several important contributions. First, a comprehensive review of mHealth literature spanning 2000 to 2011 informed the conceptual framework of the service quality scale tested. Second, the literature was categorized to establish the "unique" attributes of mHealth shown in Table 8.3. Identification of these attributes is important because the measurement scale must be both inclusive and appropriately delimited.

Third, the study builds on existing research and knowledge about health care service quality generally, and distinguishes the mHealth dimensions from general dimensions. Thus, this instrument potentially contributes to a larger body of knowledge. While the conceptual framework of the study is quite robust and the research design is well documented, the qualitative component of the study comprised of focus groups and interviews was limited to consumers of a specific telemedicine application in Bangladesh. Thus, conclusions drawn from this segment of the study data may not be generalizable to a population of individuals whose collective health care experiences occurred under a different medical delivery model.

Despite this caveat, isolating the dimensions of service quality specific to mHealth is a very important contribution. The three dimensions and the associated sub-dimensions, shown in Fig. 8.3 collectively produce an assessment of quality,

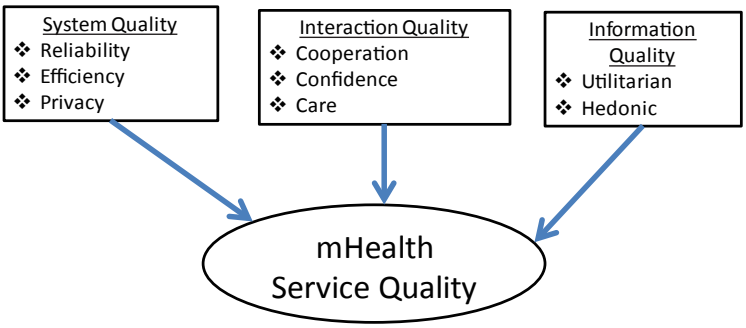

Fig. 8.3 Dimensions of mHealth service quality. (Source: Adapted from Akter et al. 2013)

which is hypothesized to lead to consumer satisfaction and a willingness to continue utilizing an mHealth service or product. The ability to predict satisfaction and long-term utilization is pivotal to decisions about product development, distribution, and investment, as well as clinician referrals, insurance coverage, and certification processes.

Technology Adoption

The adoption of health technology by consumers has been a productive research stream, contributing to the knowledge bases of information and behavioral sciences as well as health care, albeit using a variety of theoretical perspectives and contextual models. Adoption of mobile health technology has been a somewhat recent addition to the contexts studied and much of that work has not been theoretically grounded. Sun et al. (2013) attempt to unify the leading technology acceptance and health behavior theoretical perspectives to create a technology adoption model with more predictive power than previous models and importantly, to do so in the context of mobile health technology. Statistical testing showed that the integrative model was indeed more powerful than any of the models considered separately. A key point of the integration model is the acknowledgement that an individual's health behavior must be considered along with their technology acceptance behavior when assessing propensity to adopt mHealth technologies as a component of their health and wellness lifestyle.

As with the service quality study (Akter et al. 2013), the research setting (China) must be considered a limitation to generalizability considering differences in national medical models and cultural health behaviors. However, this study's sample of elderly consumers of home health care services is important in light of claims that the elderly could benefit greatly from mHealth products and services, but are rarely considered during the design phase. Additionally, the focus on consumers' acceptance behavior is a welcome supplement to studies of health professionals' acceptance behavior, which have been more common previously. Important findings

include the effect of social influences on individual decision and the effect that perceived effort of use has on technology adoption. Practical recommendations include employing user-centric service design, marketing surveys to establish acceptable pricing rates, and a strong focus on ensuring service quality.

Other Research Recommendations

As noted, theoretical and empirical research of necessity entails a significant time lag to public release of findings and recommendations. While relatively few studies of this type were identified through current literature searches, it is likely that many more are currently in progress and will emerge in the near future. As a case in point, the National Institutes of Health (NIH) awarded 150 grants for mobile phone-related research in 2010 (Collins 2011). We can expect the reports of these projects to begin entering the public literature as early as 2014, although those with longitudinal designs may not appear for 2–3 years more. This will be an important stream of research to validate assumptions about the extent of mobile phone usage for health care access, app trends and user behaviors, long-term effectiveness of mobile phone-based health services, safety and efficacy of mobile devices, and many others. Additionally, with funding from NIH, the credibility of the findings will have been prior established through expert assessment of design proposals and study objectives.

Key findings and recommendations of other literature reviewed are summarized in Table 8.4. This listing is not intended to be comprehensive; reports were selected for specific contributions to an actionable information base for mHealth stakeholders.

Information for Investors

The mHealth environment has been characterized by rapid change, especially rapid turnover of technology. In this type of environment, investment decision making is complicated by high levels of uncertainty, with concerns focused on several key questions.

- Will the product work as intended?
- What is the probability of long-term adoption?
- Can the product be developed and implemented at a market-competitive price?
- Will the product be easy to replicate or supplant by competitors?
- Will continuing product revisions be required?
- Will the product confront unanticipated legal or regulatory challenges?

Investors will most likely need to think differently and look beyond conventional business models for help in developing risk assessment matrices. For example, investors may look to the biotech industry for insight on investment strategies. Biotechnology is a rapidly evolving industry that deals with health and consumer

Table 8.4 Key research findings and future direction implications

Date	Research sponsor (author)	Findings	Implications
2012	(Whittaker 2012)	Little systematic research of impact of mobile technologies on health outcomes	Driver for theoretical and empirical research Need funding for research
2012	HIMSS	IT professionals do not rate the mobile environment as "mature" Mobile data rarely integrated into EHR	Product and network interface development Implementation models
2012	KLAS Research (Slabodkin 2012)	Apple is the number one personal mobile device choice for health care providers	HCO policies re: use personal devices at work Device/EHR interfaces Enhanced security practices
2013	(Fiorelli et al. 2013)	Basic services such as text have been studied, but little research on impact of mobile phone apps	Market for new phone-based apps Product and service opportunities
2013	(Solano-Lorente et al. 2013)	Patient satisfaction is a determinant of loyalty to online/eHealth services	Need investment in the service delivery component Need user-centric app design Developers should focus on ease of use and perceived usefulness
2013	(Tomlinson et al. 2013)	Many mHealth pilot projects do not include programmatic implementation and evaluation strategies	Efficacy and effectiveness trials needed Open mHealth architecture is needed
2013	Cisco	Prediction for increased government funding for tele-health	Likelihood of expanded deployment by providers if Medicare funding Likelihood of increase in funded empirical research
2013	Cisco	Consumers and providers differ in views on privacy and security and preferences for mobile services	Research needed to clarify differences and promote consensus
2013	Medullan IT Consulting (Medullan 2012)	IT professionals identify no clear organizational driver for mHealth and no clear strategy or objective	HCOs need to articulate the role of mHealth in clinical strategy
2013	mHealth Alliance (Philbrick 2013)	Evidence base for interventions is nascent	More rigorous research using health and cost-effectiveness indicators and more robust designs

Table 8.4 (continued)

Date	Research sponsor (author)	Findings	Implications
2013	Transparency Market Research (2013) report	Remote patient monitoring is projected as the most impactful trend in mHealth	Product development FDA regulation Efficacy research
n.d.	Intel Corporation (n.d.) report	Little information about impact of mobile technology on bottom line (ROI) or required investment in hardware, software, policy development, security, and implementation	More cost–benefit and other financial analyses Business planning models

technologies facing similar challenges of uncertainty and also the need to concurrently development business plans along with exit strategies. In both biotech and mHealth, increasingly small start-up companies are subject to acquisition by larger firms that can easily capitalize and expand product development.

Ultimately, investors need evidence upon which to make decisions. Because rigorous studies require extensive time, investors will look elsewhere for needed information and recognize that short-to-medium term randomized trials (vs. long-term studies) may furnish adequate data for risk assessments. In addition, investors may also look to cohort studies that focus on specific groups as a starting point and include observational studies to furnish needed information. Observational studies are not considered to be the "gold standard" of evidence-based research. However, these studies provide real-world data about actual use and practice to support conjectures and predictions about effectiveness, efficacy, and safety. Thus, observational studies may be useful for comparing effectiveness of mobile apps within specific classifications such as diet or fitness. As one report stated succinctly, "All research, so long as there is transparent disclosure of limitations and results, adds to the evidence base" (Philbrick 2013). Ultimately, patient-reported outcomes may serve as an acceptable measurement basis (IMS 2013). This makes sense as health care moves towards empowering consumers and embracing the concepts of self-care and self-management.

Investors are used to taking risks and understand that rewards are not guaranteed, but they do not want to pour money into projects whose implications are neither fully explained nor discernible. Thus, app developers must provide sufficient detail about product adoption and sustainability, including details on app functionality, potential product liability as well as emerging issues of data privacy and security. Market analyses, including segmentation identifying specific intended user cohorts will also provide investors with real-world market potential for implementation. Such transparency will go a long way in obtaining buy-in from investors.

In the mHealth markets, investors will focus on financials, including medium-to-long-term financial returns as the user base grows and also as the revenue model

evolves toward sustainability. Also essential are the financial assumptions that associate capital with predictive future technological and regulatory developments. For example, will national telemedicine legislation guarantee payment models that compensate virtual visits? Will cloud computing advance mHealth adoption? It is up to app developers to make their case for the future of their product, and make it robustly, if they want to secure investor commitment to underwrite development.

Investors will also look for valuations that are sustainable. App developers will need to furnish valuations that transcend hype and establish their products as legitimate market entries with staying power in a dynamic environment. For example, physicians want reliable evidence before prescribing an app. Even though an app formulary has not yet been compiled, app developers might project how their product would fit within the context of possible formulary requirements. In addition, physicians want to know that their institutions (e.g., the hospitals in which they work) will endorse the apps and that their patients will have the ability to pay for apps themselves or have insurance reimburse the cost (IMS 2013).

Summary and Conclusions

A key take-away from this chapter is accepting that all research, whether theoretical, empirical, anecdotal, or conjectural, adds to the evidence base underlying the mHealth phenomenon. The correlating caveat is that research designs, study limitations, analytical methods used, and other evaluative information must be present to allow consumers of the information to determine its fitness for a specific use. And, a correlating recommendation is that research results and aggregated information should be available through an easily accessible knowledge platform, using appropriate quality screens to permit inclusion (Philbrick 2013). Accepting the intrinsic value of transparent information allows users to select personally relevant guidance from among various information sources, including government and industry reports and grey and trade literature, as well as scholarly manuscripts.

Many of the research topics indicated as “gaps” in the currently available literature include those requiring rigorous, controlled studies needed to inform policy, funding, and regulatory decisions. This is intuitive, as the time lag for such reports to enter the mainstream is long relative to the less rigorous and more time-sensitive information needs experienced by consumers and developers. Unfortunately, a very real challenge is ease of access to the type of data needed and the ability to evaluate whether the data meets user needs.

Directories of apps and comparative information across available apps are almost nonexistent, although the Mobile Health Marketplace directory shows promise once all information fields have been completed for the products included. And, standardization and certification programs to guide consumer and provider choices have not emerged to date. Thus, much work remains to be done.

The overwhelming majority of mHealth analyses and promotions tout its system transformative capability and the potential to humanize care through access to

health care anywhere, anytime, anyplace. Conversely, most also say that mHealth has not reached its potential, and is not likely do so without scholarly and scientific research validating the positive clinical outcomes and system efficiencies and cost savings to be gained through widespread deployment of mHealth. It is expected that advances in these areas will be supported by the NIH initiatives to accelerate innovation and move findings into practice more quickly.

However, the body of empirical research builds on, and often emerges from, smaller-scale investigations and focused organization and industry analyses. In the end, one type of investigation informs the other and both are necessary for the improved and successful future of the mHealth industry.

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Chapter 9
The Possible Future of mHealth: Likely Trends and Speculation

Introduction

More than 20 years ago, Dr. Robert Istepanian, a data communications professor at Kingston University in London, coined and defined the term mHealth (Kingston University SEC Research News 2013). While we cannot say that this is a new concept, the question of where mHealth is going and how long it will take to get there remains speculative. What will the next 20 years of mHealth's history bring?

mHealth has been characterized as a disruptive innovation, displacing prior ways of doing things at much lower costs. There have been, and continue to be, high expectations for ways in which mHealth can transform health care, but only few have yet proved functional and sustainable. As it happens, the technology is the easy part of mHealth, and the technology is only as good as the system it is connected to (Rosenberg 2013). The US health care system is seriously flawed, fragmented, disconnected, and subject to market forces. Hitching the mHealth wagon to the US health care system is not a recipe for success. Systemic changes will be required to benefit from mHealth. Eric Dishman, M.D., a founding member of the Digital Health Group, has called for a culture of innovation, not just technology innovation. This would mean reinventing the health care system to include customizing care, care networking, and changing to assure mainstreaming and scalability (Comstock 2013). Will mHealth be a key driver of this full-system innovation, or merely one of the many supportive technologies?

Which directions will mHealth likely take? Patients say they want apps and virtual visits, but will they really use the technology to the extent that utility merits cost? Do providers and patients agree or disagree on what they want the future products to be? Will investors continue to capitalize investment when there is limited evidence of a business case and the emergence of a long-term commitment for profitability? What happens if payers do not reimburse for mHealth? What impact will rapid turnover of technology have on implementation; will it make it that much more difficult to gain buy-in from physicians and other health professionals? Will failure to resolve growing security and privacy threats impede mHealth implementation?

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Ultimately, the future of mHealth can be viewed as fluid, tenuous, and dependent on many factors. However, the mHealth trends play out over time; the attendant mobility provides opportunity to redress health care disparities, especially among minorities and underserved populations. Evidence suggests that minorities and Hispanic and Black people tend to use their mobile phones for health reasons more than white people, including searching for health information as well as using mobile apps to monitor biometrics. This information is especially useful for future public health initiatives to target population groups that are underserved or at risk (Sarasohn-Kahn 2010; Fox 2010). There are also impacts of global trends, including the rise of self-care, as shown by the summary of research data presented in Box 9.1.

Box 9.1: Impact of What is Trending Globally (Source: Fischer (2013))

If we can expect that what is trending globally influences the future of health care in the USA, we can look forward to:

- Rise of self-care
- Less need for hospitals and also health professionals to perform medical tests
- Increased willingness to share personal health data could lead to deregulation and also to increased security costs for data storage and exchange

This expectation is based on growing global research assessing the impact of mobile health care technologies. For example, an Intel survey of global health care revealed that 80% of respondents are optimistic about using mobile health care. In addition, respondents show confidence in their capacity to perform their own medical tests. Thus, there is an expectation that consumers can reasonably be expected to prove more self-care, including using ingestible monitoring systems.

But the global survey results also indicate that those living outside the USA do not perceive hospital utilization being necessary, especially in remote areas. In fact, 57% of respondents reported that they believe that traditional hospitals will be obsolete in the future. Meanwhile, the Intel survey revealed that the majority of respondents (84%) would be willing to share their personal health information to advance and lower costs in the health care system.

Highlights of the global Intel survey include:

- More than 70% of people are receptive to using toilet sensors, prescription bottle sensors, and swallowed health monitors.
- Seventy-two percent of those surveyed would be willing to see a doctor via video conference for nonurgent appointments.
- Sixty-six percent of people say they would prefer a care regimen that is designed specifically for them based on their genetic profile or biology.
- More than half of people (53%) would trust a test they personally administered as much or more than if that same test was performed by a doctor.
- About 30% of people would trust themselves to perform their own ultrasound.

Among the more interesting unintended consequences of the mHealth explosion are the emerging executive positions needed to better integrate and manage technology in delivering health care services (Honaman 2013). Many health facilities are adding new positions to the C-suite to meet specific challenges created in large part by rapid advances in technologies. Suggested new positions include a chief innovation officer who would identify leading-edge processes and technology to help the organization adapt to future needs. Also recommended is a chief integration officer/transformation executive. This position would lead the digital side of the clinical and medical operations infrastructure. These executives could be called on to figure out how to best merge the wireless needs and devices of patients, staff, physicians, and community to maximize the health care delivery system.

Measures of mHealth Success

However, as the mHealth future unfolds, several factors are essential to assure its success as a system change agent, including the following:

- Establishing and assuring both privacy and security of data transmission. There is no compromise on this point for either consumers or providers of health care. Even though consumers are increasingly using mobile technology for daily activities, including paying bills and performing banking chores via their phones, doing so increases access opportunities for data theft. As the media continues to report on hacking and data breaches, consumer awareness of the need to ensure secure data is growing.
- Creating a mHealth certification program that works is a priority. The suspension of Happtique's widely publicized Health App Certification Program after only a week and a half is unsettling. How could massive security holes go unnoticed in the program development? Could the rush to fill a void, the need to vet mHealth apps, have led to such serious development breaches?
- Eliminating regulatory uncertainty is requisite for mHealth to progress. Technology is rapidly developing, and the Food and Drug Administration (FDA)'s attempts at regulation have been criticized for not keeping up. Some experts perceive that too much regulatory uncertainty still exists, despite recent FDA rulings differentiating the use of mobile devices for disease and those for wellness. The uncertainty arises from the need for a precise definition of an accessory to a medical device and the use of apps that support medical decision making (Nundy et al. 2014).
- Producing rigorous evidence showing that mHealth has an impact on health, access to care, cost, quality, and patient satisfaction is essential. Up until now, everyone, including investors, providers, consumers, and governmental entities, has taken the benefits of mHealth on faith; that is, they assumed that mHealth was having a positive impact. To move forward, these stakeholders require confirmation that mHealth is achieving its intended goals.

- Establishing payment or reimbursement models for mHealth is essential. Even though there is speculation that the Affordable Care Act (ACA) and Accountable Care Organizations (ACOs) will create an environment conducive to financial models for sustaining mHealth, reimbursement for mHealth remains uncertain. Existing fee-for-service payment models do not reimburse virtual visits and other activities that take place outside of the physical location of a hospital or physician's office. Without adequate financing, mHealth will not be sustainable, and it is likely that innovation will also slow down.
- Focusing on the workflows rather than the gadgets is imperative, because the goal is to improve clinical and nonclinical workflows through mobile technologies. The key is to identify and understand workflows up front before attempting to configure the use of technology around those workflows. Even though the technology is enticing, organizations should focus on developing systems that meet both provider and consumer needs. Organizations should also aim for a collaborative process with IT services, especially when it comes to clinicians, because their buy-in is essential for successful implementation. Inova, a five-hospital health care system in Northern Virginia, reports that early on they focused on getting a general wireless system up and running across the enterprise, but during the past 3 years, shifted focus to enhancing service line capabilities one specialty at a time (Rowe 2013).
- Developing apps that focus on the end user is critical and is necessary to assure a promising future for adoption. Apps that are difficult to use can lead to nonuse. A report from Research2Guidance, a German firm, disclosed that even though over 1,100 diabetes-related apps are on the market, there are few users of the majority of these apps. Reasons for nonuse include the fact that many of the apps still require manual inputting of data; have problems integrating with existing blood-glucose meters; or simply fail to measure blood sugar, activity, and food intake adequately (Wicklund 2014). Thus, app development must focus on the needs of the end user and ease of use.
- Achieving sustainability, financial stability, and diffusion of technology requires establishing actionable goals for developers, entrepreneurs, and innovators, as well as payers, policymakers and others who view mHealth as essential to revolutionize health delivery systems.

Uncertainty is Certain

It appears that uncertainty is a major characteristic of the future of mHealth. For example, as medical care becomes increasingly commoditized and widely available, price competition from providers in other parts of the country or across the globe could emerge. Consequently, competition for patients could shift into much broader markets where providers would face unexpected price competition and increased financial risk. Physicians may discover that their patients are opting to receive care *virtually* from competing physicians, including those located at large, prestigious,

distant health systems (Schwamm 2014). Expanding the market for health services will call for new organizational strategies.

The challenges and limitations with possible impacts on mHealth are numerous. From a basic perspective, what do you do when your battery dies? From a market perspective, if you build it, they will not always buy it. The rapidly expanding number of available apps is crowding the marketplace and there is a strong potential to confuse the consumer into doing nothing. Product life cycles, recycling/reinvention, and exit strategies continue to occupy attention.

The slogan "*Today Is So Yesterday*" was depicted on an Intel T-shirt worn at the 2014 *Consumer Electronics Show (CES),* an annual global consumer electronics and technology trade show that takes place every January in Las Vegas, Nevada. Herein lies a major demand for mHealth: What to do with rapid turnover of technology? In the past, technological changes were sustainable over decades; now most occur in a little over a year. This is a relatively new phenomenon: rapid technology changes that lead to compressed or what seems like premature obsolescence, and in some cases forced obsolescence, such as with Apple and their continuous production of new iPhones that compel user upgrades.

Yet, just as rapid advances in technology can result in outmodedness, they can also fuel innovation. Take the case of advances in prosthetic development. An article in the *Smithsonian* (Brumfiel 2013) showcased the revolution in personal electronics and its impact on bionic limbs and organs. Some experts believe that new technologies will help to largely eliminate the physical limitations of disabilities by the end of the twenty-first century. And, mobile apps appear to play a role in this achievement. An example is the advanced prosthetic development of a hand featuring fingers, each powered by a 0.4-inch motor that senses when sufficient pressure is being applied. It calls for an iPhone app to provide prosthetics users access to a menu of 24 different grips to direct movement.

mHealth Trending

The trend toward do-it-yourself (DIY) became popular at the turn of the twentieth century when corporations began to give customers the tools to design and demand exactly what they want. Consumers were invited to become collaborators in product design and also redesign (Coy 2000). With the advent of mobile technology, the DIY trend has moved into health care. mHealth and the ACA are intersecting with common goals of consumer engagement and responsibility and shared outcomes of self-managing care or self-care, that is, the consumer becomes involved in the digital production of health services such as monitoring medications or tracking health behaviors. In addition, both mHealth and the ACA aim to reduce costs, improve quality, and assure patient satisfaction. Because the ACA is designed to shift the focus from volume (numbers of visits and procedures performed) to value (keeping patients healthy), the shift is perceived to be consistent with and conducive to mHealth's diffusion.

mHealth's presence in health care is intensifying. Unfortunately, in most cases, mHealth is seen as advancing without any purposeful system-wide design. In health care organizations, mHealth promises intrinsic organizational value, that is, it can be a market differentiator (Martinez 2012). But simply putting new technologies in place does not automatically translate to cost reductions or added value. If mHealth is to succeed, the organization and its delivery systems must change to accommodate it.

Some view health innovation as the primary mechanism for reducing costs, but the power of innovation goes beyond achieving operational efficiencies. mHealth has the potential to revise the boundaries of health care in terms of time, space, and care provider. As a result, visits to physician offices may become a thing of the past, and care traditionally provided in a hospital may take place outside of the brick-and-mortar building. What emerges is health care that is continuous and asynchronous; delivered anywhere and at any time. Health care is no longer viewed as "local." Instead, boundaries are disappearing as providers and patients are no longer required to be in the same physical space. Mobile technologies promise opportunities to better understand patients' real-world needs (Shaywitz 2013). Entrepreneurs and innovators are looking for opportunities to help contribute to and create a digital health care continuum.

Where is Now Versus the Future?

We are living in a mobile world or mWorld—as some refer to it. There are five billion mobile phones, about one phone for every person over the age of 15 years (Rosenberg 2013). Wireless connectivity allows us access to the Internet as well as the ability to gain information and to communicate anywhere and anytime. The portability and affordability of wireless technology is a game changer. And we are right smack in the path of tremendous hyperchange. Quite frankly, we really do not know where the end point of this change is. And perhaps there is no *fixed* end point!

Or maybe we are at the midpoint? Perhaps the mobile evolution in health care has only reached its halfway mark, and the biological imperative of punctuated equilibrium could be a more appropriate way of viewing mHealth. The concept of prolonged periods of status quo interrupted by bursts of significant change may be the best way to illustrate what is occurring with digital health products. For example, wearables such as Fitbit, a wrist-worn device often used to track workouts by step counting, are now migrating to clinical applications. The Mayo Clinic recently completed a study using Fitbit to monitor recovery in cardiac surgery patients by adding new sensors to monitor heart rate and blood pressure (Nosta 2013).

Technology has always driven change in the delivery of health care services. In the early twentieth century, automobiles allowed physicians to see more patients because of reduced travel time. Hospitals became the venues for complex surgery and diagnostics instead of the doctor's office or patient's home due to innovations such as X-rays and anesthesia. Physicians gained control over medicine in part because of technology, and the rise of the modern hospital was built on growth of medical technology.

But when it comes to health information technologies (HIT), health care has never been an early adopter. Computers were first used in hospitals in the finance or billing departments and have pretty much remained in administrative departments over the years. Explanations for late adoption of computers include regulatory and payment or reimbursement barriers as well as too few incentives encouraging technology adoption. Similarly, the US health care system has also been slow to adopt Internet, mobile, and video technologies as service media, all of which can lead to patient engagement and improved quality of care, while reducing costs. Reasons for the delay are often attributed to two factors: the fee-for-service payment model that does not reimburse for virtual visits and the considerable expense required for implementation (Pearl 2014).

But while technology is underlying rapid change in the industry, implementing available technology is not necessarily the outcome. In health care, the expected end results include:

- Improved health outcomes
- Healthier lifestyles and behaviors
- Patient engagement—consumers assuming responsibility for their care (self-care)
- Reduced costs
- More efficient delivery of health services
- Care that is of high quality

Who Wants What?

For some stakeholders, mHealth represents high-tech toys and gadgets that can improve workflow and attract new clients. For others, it symbolizes investment opportunities. Regardless, the promise of mHealth depends largely on the context and intended use. It is helpful to consider pivotal "wants" and "don't wants" of individual stakeholders.

Consumers

Consumers want mHealth to lead to better health and health care delivered more efficiently (resulting in lower cost), anywhere, anytime, and anyplace. Will mHealth improve the consumer's place in the health care environment by assisting physicians and researchers in understanding our long-term and real health needs? They want to be healthy, and they want more health for less money. They also desire improved convenience and more active engagement in sustaining their health. They want access to their health care records and the ability to schedule needed appointments anywhere, anytime, but they still want in-person access to their physicians. According to a 2012 Accenture Survey of 1,100 US patients, most report that they want to use technology to manage their own health care. Ninety percent indicated

a preference for web-based access to health information and education with 72% wanting to handle their appointments online. Yet, 85% want face time with their doctors when necessary (Accenture News Release 2012).

mHealth has the potential to radically change the health care environment and could benefit consumers by enabling them to easily and reliably self-diagnose their acute symptoms. mHealth could also benefit consumers via self-care by offering enhanced monitoring, tracking, and transmission of biometric information such as blood pressure and glucose levels. mHealth can also improve consumer convenience by allowing for more rapid diagnosis and treatment as well as better control of chronic diseases and eliminating unnecessary physician office and emergency department visits (Steinhubl et al. 2013).

We cannot discount the "fickle factor" as consumers are showing to be increasingly fickle as they download, try for brief periods, and discard free apps. Other examples include changing assessments of an app's desirable features. Google Glass and wearables were at first perceived as super-innovative. Then came the criticisms; consumers wanted style with their innovative devices. It was not enough for the technology to be performing feats that only a few months ago were deemed impossible, such as allowing physicians to access patient records and possibly visualize cancer cells during surgery with Google Glass or enabling the tracking and transmission of biometric health data through wearables such as a wristband. Consumers wanted the technology to also be fashionable.

As yet, the cost of mHealth to consumers has been negligible. But that could change. In Oklahoma, for example, telemedicine services for hospitals eventually led to additional fees tacked on to consumers' phone bills. Even though there is funding from both federal (Universal Service Fund) and state (Oklahoma Universal Fund) that reimburses telecom companies that offer free or discounted Internet and phone services to hospitals, the demand has not kept pace with growing telemedicine programs (Monies 2013).

And, do not forget that while apps are free or relatively inexpensive for the moment, that fact could change as well. Some free apps now come with advertising or share consumer data with advertisers. In the future, consumers could decide that this sharing is too high a price for a free app that they download and discard a few days later. Even though the sharing of personal health information and experiences has become more common with Internet access, consumers remain concerned about their privacy and future use of their medical information in ways they cannot control (Vodicka et al. 2013).

Providers

Clinicians and administrators look forward to increasing productivity and eliminating non-value-added activities. They look to mHealth to help gain efficient access to clinical information at the point of care and eliminate waiting time. They also want access to collateral data, whether from organization or public domain, which can enhance clinical decision making (Martinez 2012). In addition, providers want

access to be reliable and of high-quality bandwidth to mitigate against connectivity gaps. In other words, they want it all, too.

Physicians want more efficacy evidence and evaluation guidance before prescribing apps to their patients (Steinhubl et al. 2013). They also want to be reimbursed for using mHealth to keep patients well and reduce unnecessary visits (Levy 2012). What they do not want is to see all the data generated from mobile medical and fitness devices. Physicians report being inundated with countless pages of information that is not even helpful in caring for patients. Some have advocated for physicians to assume a leadership role in mHealth to assure that the technology is enhancing the physician–patient relationship by capturing the right information to help patients get well and stay healthy (Wicklund 2013b).

Physicians facing adoption of mHealth are looking at additional costs, both investment of capital, training, and more work, at least at the outset. In some respects, physicians appear wary of the rise of the *m-patient,* that is, being tethered to mobile devices so that a patient is only known to them online or through video. David Shaywitz, M.D., cofounder of the Boston-based Center for Assessment Technology and Continuous Health (CATCH), observed that physicians are struggling with emerging technologies and the challenge to ensure humanism in digital health (Shaywitz 2012). Will loss of personal connections be the price that patients and physicians pay to have increased efficiencies, reduced costs, and convenience? And is this loss worth the price?

On the other hand, there is speculation about how technology may actually replace physicians for some services. At the 2012 mHealth Summit, health and health care without physicians was presented by Vinod Khosla, founder and CEO of Sun Microsystems and Joseph Kvedar, M.D., who launched Partners Healthcare's Center of for Connected Health. Khosla claimed that 80% of what doctors currently do can be replaced by computer applications. Kvedar argued that because computers are better at algorithm tasks, which constitute a large share of a doctor's activities, technology will permit providers to spread their services across a larger population of patients (Rowe 2013).

Physicians also do not want mHealth to lead to increased interruptions in their work. A Norwegian study showed that mobile devices, smartphones, increased interruptions and unprofessional behavior by physicians. Physicians in the study reportedly took calls during patient procedures and interrupted clinical consultations to read or respond to messages (Solvoll et al. 2013).

Hospitals and Health Systems

Hospitals and health systems want to successfully engage their patients so that they can manage their own care (self-care), increase patients' access to providers and information, and improve the quality of care while simultaneously reducing costs. Kaiser Permanente Northern California (KPNC) implemented an inpatient and ambulatory care electronic health record system for its 3.4 million members, and also developed a suite of patient-friendly Internet, mobile, and video tools to achieve

these goals. What KPNC realized from these efforts was enhanced patient and physician satisfaction as well as indicators of quality improvement. But KPNC's experience also highlighted obstacles to continued success. These included ensuring appropriate levels of privacy and security to protect patient data and dealing with cost savings that emerged slowly because of a time lag between investment and widespread adoption of technology by patients (Pearl 2014).

Even though virtual visits were less expensive than office visits, they still occupied significant physician time and could require, in some cases, follow-up office visits. Technologies were not found to be evenly embraced by all patients. KPNC had to maintain parallel systems of paper, phone, and in-person contact for those patients not using Internet, mobile, or video services. Finally, KPNC introduced a *desktop medicine* time, additional time required by physicians to review patients' laboratory and test results, for planning and conducting outreach to patients for screening and preventive care, responding to e-mails, renewing prescriptions, and follow-up with telephone calls. To deal with this, KPNC had to schedule staff to fill in for physicians when they are away from their offices (Pearl 2014).

Insurers

Payers also want guidance. Because there is no consensus or criteria regarding payment for virtual care, payers continue to be concerned that reimbursement of virtual visits in a fee-for-service system carries the risk of actually driving up volume and cost (Pearl 2014). They want mHealth to reduce costs and help capture market share, especially the consumer market. They do not want to be left out of the move to mobile. For example, American Well, whose business focused on health plans, self-insured businesses, and providers, has moved into mobile by offering services that also connect consumers with physicians within minutes on their mobile devices (iPhone, iPad, Android smartphone, or tablet). American Well has also partnered with Online Care Group, a physician-owned primary and urgent care group that specializes in video telehealth (Wicklund 2013b).

Investors/Entrepreneurs

Investors are wary of committing funds without demonstrable evidence that mHealth has a real impact on health outcomes, especially patient care. They want to see a return on their investments. They want to see a business case emerge that shows the potential for success. They want less hype and more reality, facts, and evidence. Investors know that there are risks involved in any venture. With mHealth, too often the promise has been exaggerated. What investors and entrepreneurs do not want is a long-term commitment that results in failure because of rapid turnover of technology or inadequate financing.

All stakeholders must see reduction in costs and improvements in access, quality, and affordability. They must also see incentives in the system and opportunities

for innovation while simultaneously assuring regulation that enhances security and privacy for all participants. Whether the stakeholders are private or public sector, there must be a return on investment (ROI) to compensate for the considerable investment needed to deploy the technology. Even though some researchers suggest a business case for the use of mHealth, sustainability and diffusion depend on a supportive policy and regulatory environment. Some experts perceive that too much regulatory uncertainty still exists, despite recent FDA rulings differentiating the use of mobile devices for disease and for wellness. The uncertainty arises from the need for a precise definition of an accessory to a medical device and the use of apps that support medical decision making (Nundy et al. 2014).

Has mHealth Overpromised Transformation?

If you believe what you read or hear, mHealth is the panacea for what ails the US health care system—whether it is quality, cost, efficiency, or enhancing access—mHealth will solve all of our problems. mHealth may hold the promise for reinventing health care, but the data show that we are not there yet and we do not know when we will arrive. There is a lot of hope placed on technology, and yet, thus far the evidence does not appear to sustain the hope. There is little evidence that smartphone apps actually reduce lifestyle-associated diseases or the high costs associated with them. Much of what occurs with an app is unsupervised and relies on patients faithfully recording their activities. Yet we know that people can lie to their phones or ignore reminders (Bradley 2013).

In 2013, venture funds contributed about US$ 150 million into companies, whose mobile software programs track and analyze a variety of factors that contribute to good health, including sleep and diet. Much of the software is aimed at motivating people by making healthy lifestyles more of a contest or game. The game pits users against their family, friends, coworkers, or other online participants. The games are supposed to make healthy living fun. In 2012, mobile health apps for iPhones and devices using Google's Android operating system generated about US$ 718 million in revenue when compared with US$ 100 million revenue in 2010. A lot of people were having fun, apparently, but were they getting healthier (Bradley 2013)?

Three powerful forces are promoting mHealth as a game changer: the unsustainability of current spending, rapid growth of wireless connectivity, and the need for more precise individualized medicine (Steinhubl et al. 2013). Despite the convergence of these forces, mHealth continues to face many obstacles. According to Whittaker (2012), key challenges to mHealth implementation include privacy, data security, funding and reimbursement, the emergence of few models demonstrating the efficacy and cost-effectiveness of mHealth in practice, and the need for more high-quality research to validate claims and promote implementation. Physicians are reluctant to recommend apps that have not been formally vetted.

It is too early to tell if a killer app is on the horizon, and most experts cannot identify what a killer app would consist of or even where it will come from. Notable mobile giants at this time include Apple, who started the mobile health care

revolution with the iPad, Samsung, and Google. However, Dell and Microsoft are making entry into the mobile health market currently dominated by Apple, whose products remain the choice of clinicians (Slabodkin 2013a). The industry "shake-out" has not yet begun in earnest. In addition, Google, which launched Google Health, the electronic personal health product, is back in the health business. This time, it includes funding for Calico, a new health company focused on aging and related diseases. Few details are known, but experts look to gain more insight about this new venture through earnings reports (Farr 2013).

According to an Accenture Health Survey, America's seniors are very much interested in managing their health online and with mobile devices. However, it appears as if the seniors have not been receiving these services from their health care providers. Therefore, providers and health plans should shift attention to this prospective market, which is the fastest growing segment of the population that is moving online, according to the Pew Internet & American Life Project. Internet use tripled among seniors (65 and over) and doubled among the 50–64 age cohort during the period 2000–2012. These data represent significant gains in seniors using the Internet, especially for everyday activities such as banking, shopping, entertainment, and communicating (Zickuhur and Madden 2012; Wicklund 2013a).

The Department of Health and Human Services (HHS) is looking to citizen innovators to produce mHealth applications and conducts online contests for such innovators. Foundations, including the prestigious Robert Wood Johnson Foundation, are establishing sizeable monetary awards for innovative app work. For example, two medical students at Johns Hopkins University were awarded US$ 100,000 in 2012 for Symcat, an mHealth app that enables people to look up their systems and locate nearby hospitals and clinics (Howard 2012). Whether the future of mHealth can depend on such a disaggregated approach to innovation is uncertain.

Privacy, Security, and Other Technology Challenges

The cost of data breaches continues to climb, reaching US$ 7 billion annually. An annual study on patient privacy and data security performed by the Ponemon Institute and the Health Information Trust Alliance documented that the health care industry is playing catch-up, but that the rise in data breaches continues. More than half (54%) of organizations participating in the study reported that they had very little confidence, if any, in being able to detect breaches. One of the most troubling aspects was that even though data breaches are probably occurring every day, they are not yet a priority for executives at the C-suite level. The anticipated caution and concern for data beaches was not seen as comparable to what is shown in banking and other industries (Bowman 2012).

Security and compliance requirements are a major issue. The mobile phone's camera represents organizational risk. A cursory online search of clinicians cited for Health Insurance Portability and Accountability Act (HIPAA) violations illustrates the inappropriate use of cameras or text messages in discussing aspects of clinical cases. Mostly, such disclosures were unintentional, but occurred nevertheless.

Consequently, compliance and risk managers, along with internal auditors, and IT security staff must manage the use of mobile devices within the restrictions provided by the regulatory standards. Beyond unauthorized disclosure is the concern that the communication occurred by way of public domain channels and therefore was not encrypted. Finally, the lifespan of such communications is eternal; electronic data do not expire (Martinez 2012).

Interoperability

The Healthcare Information and Management Systems Society (HIMSS) defines "interoperability" as follows:

> Interoperability describes the extent to which systems and devices can exchange data, and interpret that shared data. For two systems to be interoperable, they must be able to exchange data and subsequently present that data such that it can be understood by a user. (www.HIMSS.org)

Operability is a major challenge for providers because patients have multiple health issues and concerns and subsequently need to interact with different providers at different access points in the system. In addition, with the growth of patient engagement tools such as Fitbit and personal health records, there is an increased need to facilitate exchange of information and avoid actually obstructing the flow of information between consumers and their providers (Bowman 2014).

Fear of Innovation

Ryan Bosch, chief medical information officer at northern Virginia-based Inova Health System, described the health care industry in general as fearful of innovation. While speaking on a patient engagement panel at the Office of the National Coordinator for Health IT's annual meeting in Washington, D.C., in January 2014, Bosch explained:

> But healthcare is very scared; we're scared to develop on our own. If you look at any other industry, they have a huge research and development technology arm. Healthcare wants to manage technology like you'd manage a couple of horses in the stable. We'll care for them and feed them, but we wouldn't dare do anything else on our own. We've got to change our mindset. (Bowman 2014)

System Challenges

mHealth may be doable from the IT perspective—but not from the perspective of a fragmented health care system that is increasingly confronted by governmental and bureaucratic obstacles. Less developed countries seem to have an easier time for implementing mobile health and it is speculated that this is the case because they

have fewer obstacles in their way. In the USA, it may be that we have too many obstacles in our way, ranging from the scrutiny of a number of federal agencies and organizations, including the Federal Communications Commission's (FCC) oversight of communication issues such as net neutrality, to the FCC's ability to regulate Internet usage. How will consumers be affected in terms of their ability to use mHealth? In addition, there is continuing FDA review of mHealth products. There is also the problem of establishing reimbursement for mHealth and mounting uncertainty about security and privacy.

Employment Implications

The most significant employment implication rests with the expanded and efficient use of expensive clinical resources, such as physicians and nurses. Doing more with less is the mantra, and mHealth can address some access issues, especially with respect to shortages of health care professionals and competition to both recruit and retain them. The economic rationale is evident when considering physicians, especially those who are paid to be on call at the hospital for anticipated emergencies such as strokes.

Evidence from a demonstration project of CareSmarts, an mHealth diabetes program at the University of Chicago Medicine, an academic medical center on Chicago's South Side, which provides automated self-management support and facilitates team-based care for patients, showed significant cost savings, US$ 323,888 over 6 months, which was an 8.8% savings over pre-period costs. Because the program is largely automated, full-time staff members are not required. Instead, part-time nurses can enroll patients and respond to alerts. While conventional care management models routinely have staffing ratios of 30–100 patients per full-time employee (FTE), CareSmarts was able to allow for 400 per FTE. In addition, because CareSmarts focused on self-management instead of clinical care, the role of the nurse could be filled by less expensive substitutes such as diabetes educators, medical assistants, or health coaches with minimal training (Nundy et al. 2014). On the other hand, mHealth can also lead to standby costs. Who covers for physicians when they are out of the office and unavailable to respond to e-mails, tweets, and other mobile inquiries?

Actual Impact on Health

Right now, there is insufficient evidence to measure whether and how mHealth has improved individual and population health. Most of the health evaluation projects only examine feasibility—does it work, will people use it? As a result, mHealth is far from achieving its health outcome goals (Rosenberg 2013). Recently, researchers at Johns Hopkins University performed rigorous assessments of health apps,

equivalent to medical trials. The findings showed that the apps were at best mediocre. In fact, most of the apps were found to be of low quality in terms of managing disease (Bradley 2013).

Despite the dearth of evidence, especially rigorous research, it is intuitively understood that mHealth will positively influence health, including the health of patients with chronic illnesses. These patients spend just a few hours a year in a health care setting; yet most health outcomes are largely determined by activities occurring during the remaining 5,000 waking hours for which there are relatively few health care resources available. Thus, mobile phones offer a promising platform to engage these patients. Through apps and text messaging, chronically ill patients can access care all year long (Nundy et al. 2014).

Smartphones are moving toward clinical applications, and research laboratories worldwide are focusing on turning smartphones into point-of-care devices. Some patents indicate that smartphones will increasingly be used as diagnostic tools. Apple has reportedly applied for patents to integrate a sensor with the iPhone that detects a user's cardiac activity and a hover, rather than the touch screen, to enable reading electrocardiograms (EKGs; Schwartz 2014).

Globally, mobile has the potential to change the way health care is delivered, especially with respect to providing telemedicine in remote geographical areas, and doing so with a cell phone signal. In one study, researchers used a mobile device in a remote area of the Bolivian Andes Mountains to conduct a complete prenatal ultrasonographic evaluation using an obstetrician in his office in Halifax Nova Scotia. This example showcases the capacity of mobile devices to enable point-of-care diagnosis. It also exemplifies existing barriers to implementation because the cost for connectivity alone was US$ 25,000, and there are also issues of possible medical liability, patient confidentiality, and reimbursement (Slabodkin 2013b).

Are We There Yet?

Not yet, according to Eric Dishman, a founding member of the Digital Health Group, Intel Fellow, and Global General Manager of Health & Life Sciences. In reference to Intel's recently released global survey of health care expectations (Fischer 2013), Dishman said the following:

> We're not quite there yet. We're not quite ready for prime time. But the public is. The public is ready to be part of the solution. More than 80% of the people in the survey were optimistic in terms of innovation and technology. (Source: Comstock 2013)

We live in a world that is rapidly migrating to a completely digital existence where consumers can communicate and access information at anytime and anywhere. No matter where you live, you can share the same space on the Internet and watch wars and uprisings and play chess with people who do not speak your language. People use their phones to go online for conversations, shopping, and even digital grieving. With mobile phones, The Internet of Things has become our new environment. But

when it comes to health care, the digital revolution has not caught up with the retail/shopping revolution. Why? What is the hold up?

Health care is a conservative industry in part because of the nature of its business—life, death, and human suffering. It is also an industry that is driven in large part by regulation, especially regulation that consistently results in major upheavals in reimbursement. Examples include Medicare and Medicaid in the 1960s and the shift to resource-based systems with DRGs (Diagnosis Related Groups) in the 1980s. Finally, people want their health care data to be secure and they want privacy assured when exchanging that data.

Facebook's CEO, Mark Zuckerberg, believes that individuals want to live their lives on Facebook and do everything from paying bills to exchanging health care information on this platform. What may be less obvious to Zuckerberg and others who share such beliefs is that some health information may be too personal to share. People may be comfortable with total transparency in their personal lives and posting just about everything on Facebook, but when it comes to their personal health care data, they appear to want some privacy and they want guarantees that their data will be secure. While consumers are opening up to sharing exercise (25%), weight (28%), and sleep information (26%) online, they remain opposed to sharing vital signs such as blood pressure or heart rate (15%), thereby demonstrating that some things may be too personal to post online after all (Halls 2013).

Some data have shown that there is a lack of consensus about the future of mHealth. In particular, physicians and patients appear to disagree about their readiness for mHealth. A PricewaterhouseCoopers report illustrated that consumers are definitely more optimistic when compared with physicians. Nearly one half of consumers said that in the next 3 years mHealth will improve convenience (46%), cost (52%), and quality (48%). Meanwhile less than one third (27%) of doctors indicated that they encourage patients to use health apps and 13% admitted to actively discouraging it (Levy 2012).

Technology is changing the way care is delivered and where it is delivered. But there is no sufficient evidence to support claims that virtual visits can substitute for face-to-face visits. Until more studies are done, providers have to be careful in making the leap to treating patients virtually. A physician in eastern Oklahoma was disciplined for practicing telemedicine using Skype. The physician treated and prescribed Xanax and powerful narcotics for his rural patients with mental health problems. The video conference platform, Skype, had not been approved for use as a telemedicine communication system by The State Medical Board of Oklahoma (Gold 2013).

Near Misses / But Back to the Drawing Board

When HealthCare.gov was rolled out in October 2013, its many failures and shortcomings quickly occupied media space. However, at around the same time, but with far less attention, the US Department of Veterans Affairs (VA) revealed that it had encountered problems with its highly anticipated Veteran Appointment Request

app. The appointment app is intended to assist veterans in making primary care and mental health appointments. Despite significant pilot testing, the app was not working with the scheduled software across the VA medical centers. Until the app was fixed, veterans were advised that it may often, but not always, be faster to call and speak with a scheduling clerk (Slabodkin 2013c).

The Not-So-Benign Side of Technology

Emerging research indicates a growth of Internet-related addictions and disorders, including documented cases of Internet-related psychosis; all of which open up for discussion on the idea that the Web may be driving us mad (Doukoupil 2012). The *iDisorder,* identified by Larry Rosen, originated from studies that showed the growing incidence of compulsion to stay online, especially among those under 50 years of age. Studies are also showing that digitized minds scan like those of drug addicts, and people are becoming anxious over such things as updating Facebook postings. Academic investigations are under way, studying technology's potential to negatively influence individuals, and the potential involvement of the Internet in psychopathology. Why is this information important for health care? Because some experts already worry that mHealth may contribute to overfocusing on one's health to the point of developing hypochondriac fixations.

Currently, technology is like an elusive giant wave that a surfer tries to catch. Entrepreneurs, investors, insurers, and providers are going with their instincts in making technology decisions. And they are often wrong. For example, 6 years after Facebook was founded, it did not recognize that the next big wave in technology was the rise of wireless—that people were abandoning their laptops for mobile phones. As a result, because Facebook had no wireless strategy, the company had to scramble to go mobile. But Facebook was able to do so, and do so successfully. But others have not been so fortunate.

When it comes to health care, mobile gadgets and toys thus far have limited motivational impact. Younger individuals add and drop mobile apps at whim. However, sick patients, especially those who suffer from chronic illnesses, embrace mobile technology because it fulfills their need for continuous monitoring of biometric health measures. For these patients, technology enables them to access information, have more contact with their providers, and gain support from a variety of others, including social networks.

Achieving Sustainability of mHealth: An Action Plan

Two factors are pivotal to achieving a long-term viable and sustainable success with mHealth—meeting stakeholder needs and employing robust financial models for business development and service delivery. Ultimately, a focus has to remain on

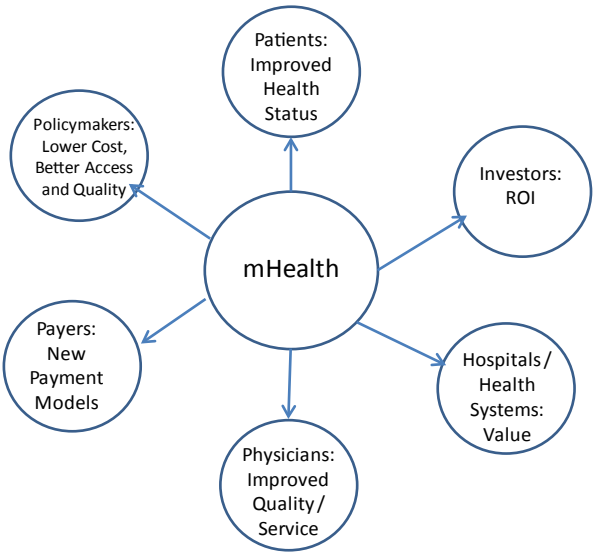

Fig. 9.1 mHealth Stakeholder Needs

the end users and their individual needs. These needs differ among stakeholders and some even compete, such as the need for a strong financial return for investors supporting product development and the consumers' need for cost-effective products. Top priority needs for primary stakeholder groups are shown in Fig. 9.1.

The growing trend toward ACOs, in which both payers and providers share responsibility and cost savings for the health of a defined patient population, is expected to significantly influence the sustainability and diffusion of mHealth programs (Nundy et al. 2014). Expectations aside, virtual visits are usually not paid for by Medicare, except under special circumstances in which patients are located in a designated health professional shortage area. Commercial insurers reimburse for virtual care delivered via phone or video connections only when they are required to do so by state law. Even if health plans want to reimburse providers for virtual care, there are no definitive criteria or reimbursement rates for a virtual visit (Pearl 2014)

Maintaining financial support is a key challenge, especially for telemedicine and telehealth networks. Ten million Americans use some sort of telemedicine and the market is growing. Forty-two percent of US hospitals have adopted telehealth platforms and are using the technology for treating patients. The CEO of the American Telemedicine Association, Jonathan Linkous, told *Healthcare IT News* that this growth can be attributed in large part to the fact that more payers are reimbursing for telemedicine services (McCann 2014).

Arkansas's e-Link network infrastructure has been underwritten primarily through grants and state support, which may provide funds for launching programs, but are finite resources and cannot offer continual support. Options to establish financial sustainability include subscription-based models and enhanced reimbursement for telemedicine consults that includes payments from private insurers that typically do not reimburse (Lowery et al. 2014).

Sustainability of any innovation requires adequate financing, and mHealth is no different. Subsequently, the obvious solution to this significant problem is removal of regulatory and reimbursement barriers, especially fee for service models that do not reimburse for virtual visits and ultimately limit growth and diffusion of mHealth. mHealth options such as virtual visits and e-mail consults can demonstrate compliance with ACA requirements for meaningful technology use and patient engagement, but these services will require payment just as an in-office encounter to motivate providers to pursue the option. Furthermore, physicians cannot be expected to respond to patient e-mails in a timely manner without additional support, also a financial requirement. Additionally, portable licensure would go a long way toward enabling nurses and physicians to practice across state lines.

Despite any altruistic interest in meeting society's need for access to affordable, high-quality health care, providers are compelled to work within existing business models to remain operational. Until mHealth services are recognized in the current fee-for-service model, or the financing model is transformed at the system level to embrace mHealth as a legitimate delivery option, potential health and financial benefits will remain unrealized.

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