Exploring Legal Challenges to Fulfilling the Potential of mHealth in a Safe and Responsible Environment

Workshop Report 1: Regulation

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Preface

This report is based on the first of three workshops on “Exploring Legal Challenges to Fulfilling the Potential of mHealth in a Safe and Responsible Environment,” sponsored by the American Association for the Advancement of Science (AAAS), with the support of the Robert Wood Johnson Foundation, held on June 16-17, 2014 at AAAS headquarters in Washington DC. This workshop focused on regulation; the next two will focus on privacy/security and liability. The workshop was attended by attorneys, regulators, policy makers, patient advocates, health care providers, industry, and IT experts. Four papers were commissioned for the workshop and are available on the AAAS website. Although discussions among workshop participants, as well as the papers, form the basis for this report, it is not intended to be a complete account of opinions expressed at the workshop or a consensus document. Rather, it is a AAAS report and is meant to reflect the views of the authors only. Since the June 2014 workshop, the FDA issued new guidance in February 2015. Although the 2015 document was not discussed at the workshop, its contents are incorporated in this report.

Background

mHealth refers to the use of wireless devices or sensors to record and possibly transmit health information and, thereby, to promote and improve health outcomes/wellness, health care services, and research. The applications (or apps) can range from “wellness” aids, such as calorie counters or sensors that track times and distance for exercisers, to such sophisticated uses as implantable medical devices that record and transmit measures of heart function and other physiological variables. In the future, implanted mHealth devices may receive signals that change the heart’s rhythm or release a medication. mHealth devices might be worn as clothing, carried as smart phones, installed on the walls of one’s home, or even, as mentioned, implanted in a patient’s body. Whatever the mode of measurement and display or of transmission, they enable continuous monitoring of patients/consumers as they go about their daily lives instead of “snap shots” taken during occasional visits to a health care provider. These new technologies raise hopes of improved individual and public health, with better diagnostics and real-time changes in treatment, as well as enabling healthier life styles, and perhaps reduced health care costs.

The number of smart phone health apps is growing rapidly, with current estimates at 97,000, most of which are exercise or diet related. Consumers have downloaded mHealth apps 247

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1 This report benefited from the assistance of AAAS staff Rebecca Carlson, Joshua Ettinger and the Project Advisory Committee.
2 A list of attendees is included as an appendix.
million times. The market is estimated to be $1.3 billion, growing to $20 billion by 2018. Businesses involved include technology startups, as well as established hardware, software, and telecommunications companies. A regulatory and oversight framework should have a broad enough scope to cover the range of applications and the variety of mobile health companies entering the field. The regulations and other modes of oversight should be rigorous enough to protect the public’s health and privacy, while at the same time flexible and transparent enough to allow, and even promote, innovation. Regulations should enable technology, not create barriers to innovation.

Current and future technology applications

Data collected on sensors -- whether worn on the body, implanted in the body or embedded in the surrounding infrastructure – send information to a mobile phone for local processing or transmit it to the cloud, where the data can be read in near real time. Further, once received, a “decision” can be made and returned to the patient via a signal that might change a physiological function. mHealth devices are expected to play an increasing part in the following categories:

- Diagnostics: mHealth offers new ways of assessing health. For example, glucose monitoring is available, sending readings to a smart phone, where they can be transmitted to a health care provider. More advanced testing on the horizon includes implanted chip-based technology that can measure a variety of biomarkers and the presence of bacteria or viruses, including the presence of HIV, an especially useful function in developing countries. In diagnosing the causes of allergies, the GPS capabilities of smart phones can be helpful in identifying environments where allergic reactions are triggered. Even behaviors can be detected, measured, and interpreted. A smart watch can record arm movements that might reveal smoking behavior or an accelerometer can measure speed and frequency of walking.

While the possibilities for diagnosing and monitoring illnesses and states of health are exciting, it is not clear how all these data points can be managed. Although it may be useful for health care providers to learn what patients’ blood pressure or heart rhythm is as they go about their daily lives, how are providers going to manage the deluge of data from devices that feature continuous monitoring? No physician wants to review biomarkers like blood pressure taken every five minutes. Methods need to be developed to extract meaningful data from continuously recorded and stored information. Further, what are the standards for reliability and validity in a mobile environment? For example, can an EKG measured while the patient is active and outside of a medical center be compared to a stationary EKG taken at a clinic, to assess the reliability of the information? To date, we lack the evidenced-based research and experience needed for interpretation for many of the physiological and biological markers in other than a clinical setting; in short, we lack gold standards.

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4 State-of-the-Science in Mobile Health for Diagnostic, Treatment, Public Health, and Research” by Santosh Kumar and Wendy Nilsen
Context can also be important here. For example, while a heart rate of 200 might be alarming, it may be normal if the individual is exercising vigorously or climbing a steep hill. Further, it’s yet to be determined if mobile health will lead to more false positive diagnoses or more false alarms, for example, triggering an intervention every time the heart speeds up. In short, analytics and decision-making software need to be accurate and reliable for the promises of mobile measurements to come to fruition.

Although much of the discussion of mHealth diagnostics and monitoring envisions the important role of smart phones, this may not always be the preferred mode of transmission. Not everyone owns – or wants to own – a smartphone or the phone may be left at home when a person goes about his or her daily activities. Smart watches may be a better choice for some people. Then again, some people may prefer visiting a nurse weekly to have their blood pressure taken instead of relying upon a mobile device. In short, mHealth may reduce some people’s access to needed social contacts.

- Treatment: Mobile health devices are mainly used today by people who don’t consider themselves patients, but rather define themselves as health care consumers. This is due in part to the fact that most current mobile health applications are actually wellness applications, allowing individuals to count both their footsteps and their calories. While these good living habits may prevent increased health costs in the future, they are not money savers now, and it may be that the people wearing a Fitbit would have exercised even without high tech helpers. However, mobile health applications that measure movement can also be used by therapists to monitor progress in physical rehabilitation. The ability to measure physiological functions remotely also raises the possibility of pairing these measurements with physiological or biological interventions. Patients may be able to receive precise doses of medication via implants responding to signals of biological functions sent wirelessly to a source that, in turn, sends wireless signals back to the patient’s body.

Many observers think that chronic health conditions are the most fruitful area for successful mHealth treatments, and chronic health problems are particularly present in the elderly population. Importantly, allowing a rapidly increasing cohort of aging individuals to stay in their homes – satisfying their wishes and saving the high expenses of nursing homes – may rely on devices embedded in the walls of a house, letting family and health care providers know quickly if a fall occurs or activity seems to slow from its usual level. Measuring arm movements – say, with a smart watch – may allow providers to be aware of the eating habits of those elderly individuals remaining on their own.

It remains to be seen whether the elderly will want or be able to use mobile health apps; there may well be people who don’t want to be continuously monitored, perceiving it as an infringement of their autonomy. Further, care must be taken to make adjustments in the use of mHealth appropriate to elderly patients’ health state, for example, providing a mouse for a keyboard as a communication system for patients
with certain movement disorders. Mobile health apps are particularly welcomed by this
demographic group when they are paired with social networks.

This population is particularly dependent on family caregivers, whose assistance can
eliminate or postpone the necessity of costly residential care, so the needs and input
from the caregivers should be considered when developing mHealth solutions for the
elderly. (Of course, many caregivers are helping non-elderly individuals with cognitive or
physical impairments.) The valuable service that family caregivers provide could be
leveraged if they can enter data from a mobile device that interacted with a patient’s
EHR (Electronic Health Record), allowing their observations to be an important factor in
the overall medical care.

One of the most vexing issues in medical treatment, in both developed and developing
countries, is compliance. The ability to monitor in real time through internal sensors
whether patients are taking prescribed medication and to send the patients signals
reminding them to take their drugs may be the most effective way to reduce poor
outcomes caused by non-compliant patients.

Diagnosis and treatment are closely related functions of a mobile health future that will depend
on clear and appropriately tailored regulation. It is not technology that is regulated, but rather
the risks associated with that technology. The benefits and risks raised by diagnosis and
treatment from a distance are somewhat similar. No technology works all the time, no software
is 100% reliable. The harms that may accompany mobile health can be much more serious than
under- or over-counting calories. The analytic and decision-making software needs to be highly
reliable and the signals need to be authenticated, so that inferences derived from wireless
signals are accurate and the messages back to the body are appropriate. Mobile health needs
to prove that it is not just “cool” but also that it has advantages over today’s methods of
delivering health care by, for example, improving outcomes and/or reducing costs. As of today,
mHealth has yet to meet these benchmarks.

- Public (or population) health: Not only individual health, but also public health, is likely
to benefit from mHealth applications. Most adult Americans have cell phones, with
about half of them being smart phones. In fact, mobile phone usage of all kinds is used
by individuals across socioeconomic and demographic classes. Some public health uses
may be simply informational, for example, education about the importance of
mammograms and reminders to make an appointment at a health center. Health
information for pregnant women is a means of possibly improving a population’s health,
and is being used both in developed and developing countries. mHealth is a promising
candidate for improving health outcomes for underserved populations, including rural
populations that have no nearby and convenient health care providers.

Further, as use of mobile health spreads to the developing world, the technology may
be particularly important in tracking health trends and the appearance of diseases.
These data from the field can be used to pinpoint geographical areas that need special
attention, a situation that might be key to detecting the next outbreak of Ebola or other infectious diseases. Tracking disease trends is also of use in developed countries, of course. Data sent to the cloud from large numbers of people spread throughout the country may allow public health officials to detect influenza outbreaks or food-borne illnesses. It is even possible that data from social media, such as Facebook or Twitter, may be aggregated and analyzed to spot disease incidence that could otherwise go undetected for days or weeks.

- Health research: mHealth poses new opportunities and challenges for medical research. First, studies need to be designed and conducted to determine if mHealth applications are superior to current diagnostic and treatment modalities in outcomes, cost, and/or usability. However, many of the developers of mobile devices are newcomers to the world of medical research and know little about the conduct of evidence-based research for analysis. Randomized clinical trials often take a long time and are costly, and mobile health technology is changing so rapidly that testing the efficacy of today’s mobile applications may be outdated even before a study is completed. Adjustments are, therefore, necessary in clinical trials assessing mobile technology to speed them up. Information collected from devices that collect data continuously can be merged with patients’ electronic medical records (EMRs), genomic databases, and biomarkers. In this way, scientists may gain new insights by studying, for example, gene/environment interactions. It also may make studies of populations in developing countries or hard-to-reach areas feasible.

Importantly, health recordings collected from a device worn on the person in a day-to-day manner undoubtedly will provide researchers with a data-rich context for traditional studies of new treatments or comparing current standard-of-care methods. Testing a drug meant to lower blood pressure is more ambiguous when study participants come to a research center once a week than if the measurements can be made in a continuous manner. This may lower the drop-out rate of study participants and, as noted, allows studies to include participants who are geographically distant from clinics, for example, in rural areas, which are currently underrepresented in clinical research.

Using mobile devices as a source of data collection during medical research raises similar challenges to those that arise when those devices are used for diagnosis or treatment. Data need to be authenticated, and software is not always reliable. Additionally, in the process of collecting large amounts of data, some unanticipated or incidental findings may be revealed. Although unexpected findings can occur in the course of traditional diagnostic and research methods, both health care providers and

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5 The ONC defines an EHR as an electronic record that is more inclusive than an EMR (electronic medical record), because it encompasses the totality of information that relates to health, not just the information in a typical paper medical record. Because medical records are in a state of flux, this report uses the terms interchangeably.
researchers should think this situation through as they begin to use mobile data in their practices and studies. Because research involving a mobile device is relatively new and raises issues not present in traditional clinical studies, informed consent and confidentiality also will need careful attention from participants and researchers. With mHealth, patients, subjects, and consumers may need to be given concrete scenarios of what might happen in the event of a data breach, for example, how would you feel if your bank knew you had cancer?

In addition to the risks mobile health applications might pose to patient safety, including the possibility of lower reliability than traditional medical diagnostics and treatment, one of the biggest challenges to wide adoption of mobile health is privacy. Although privacy has always been a concern with paper records, mHealth is able to capture much more information about a person, including behavioral and locational data, and is capable of disseminating it to a larger group of people. Mobile health developers and manufacturers are not treated as covered entities under HIPAA and thus the protections of the Privacy Rule and Security Rule do not apply. Additionally, there are no prohibitions on mHealth developers and manufacturers mining such data for its own purposes or to sell to other vendors. mHealth information, whether stored in a device or in transmission, must be secure for diagnostics, treatment, public health applications, and clinical research to move forward as anticipated. The issue is unique to mobile devices simply because they are mobile, and GPS technology can reveal where a patient or research subject has been. Privacy and security will be the subjects of a subsequent AAAS report.

Current regulatory and policy environment

FDA: The FDA has long had responsibility for regulating medical devices, which in the past decade has come increasingly to encompass converged mobile medical devices. When the U.S. Congress gave the agency the mandate to regulate devices, it defined the term broadly, leaving it to FDA to winnow down the types and numbers of devices subject to review through regulation, guidance, and enforcement discretion. While this broad authority may be practical, as mobile health continues to develop more specific authority may be needed. The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), which “expands the FDA’s authorities and strengthens the agency’s ability to safeguard and advance public health” by, among other things “promoting innovation to speed patient access to safe and effective products,” including mobile health products. FDASIA also directed FDA to consult with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC) to develop a report with recommendations on a regulatory framework for health information technology, not limited to but including mobile health.

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6Food and Drug Administration Safety and Innovation Act (FDASIA)
technologies. That report,\textsuperscript{7} issued in 2014, outlines a risk-based framework for health IT regulation.

The FDA is the linchpin in the mHealth regulatory space, with mobile health applications, including software, being regulated as medical devices so long as they meet the definition of a device. Many mHealth applications are devices that have long been regulated when they were stationary in a medical care environment, but are now being carried around with a patient. For example, a mobile EKG has the same intended utility as an EKG in a medical clinic, but the agency has to consider the risk in implementing the device to be used in novel environments.

There are players in the mHealth arena that never considered themselves medical device manufacturers, such as some software developers or telecommunications companies, which are facing new challenges as they interact with the FDA. Further, the mobile health area is attracting hundreds of start-ups with few employees, who may not be familiar with the FDA regulatory process. The fact that there is such rapid innovation in mobile health technologies is itself a problem for the FDA and other regulatory agencies, because while technology acts according to Moore’s law, regulation operates on laws that are slower to advance. In short, technology outpaces regulation.

To address the confusion in parts of the industry, the FDA issued draft guidance in July 2011\textsuperscript{8} and final guidance in September 2013,\textsuperscript{9} (which was further updated in February 2015\textsuperscript{10}) setting forth the agency’s position on what level of scrutiny different types of devices should receive. These guidance documents were a step forward, helping to clarify the subset of mobile apps to which the FDA intends to apply its authority. The guidances distinguish, with examples, three tiers of devices, each of which will be treated differently by the FDA:\textsuperscript{11}

- Apps that are considered “mobile medical apps” and will be subject to regulatory oversight include (1) apps that are an extension of one or more medical devices;\textsuperscript{12} (2) apps that transform a mobile platform into a regulated device through the use of sensors, display screens or attachments; and (3) mobile apps that perform patient-specific analysis, diagnosis or treatment recommendations.

- Apps for which the FDA will exercise enforcement discretion include (1) apps that supplement clinical care by coaching or prompting people to engage in certain activities; (2) apps that allow patients to organize and track health information; (3) apps that provide access to information related to a patient’s health condition or treatment; (4)


\textsuperscript{8} http://www.genomicslawreport.com/wp-content/uploads/2013/03/FDA-mHealth-Draft-Guidance.pdf

\textsuperscript{9} http://www.regulations.gov/#documentDetail;D=FDA-2011-D-0530-0108

\textsuperscript{10} http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

\textsuperscript{11} These definitions and examples are derived from the 2015 guidance document.

\textsuperscript{12} According to the FDA, a device becomes a “medical device” when the intended use (demonstrated by, for example, claims or advertising materials) is for “the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body....”
apps that help patients document or communicate potential medical conditions to
providers; (5) apps that perform simple calculations used in clinical practice, such as
Body Mass Index or delivery date estimator; (6) apps that enable an individual to
interact with an EHR; and (7) apps that meet the definition of a Medical Device Data
System.

- Mobile apps that are not medical devices and face no regulatory requirements include
  (1) apps that are designed to provide access to electronic versions (for example, e-
  books) of medical textbooks or other generic documents; (2) apps that are intended as
  educational or training aids for health care providers; (3) apps that are intended for
general education for patients; (4) apps that automate general medical office
administration; and (5) apps that are generic aids or general purpose products, such as
magnifying glasses or directions to medical facilities.

Deciding where to draw the line between those apps that will require pre-market notification
or approval and those that will not is important because if a device requires such approval,
development will be slowed. The FDA is required to regulate devices or drugs that prevent, cure
or treat disease, not those that address wellness. So it’s clear that a device that counts
footsteps or otherwise tracks motion for exercisers is not a medical device. Or is it? That largely
depends on the intended use of the health information. Where does the line for
disease/wellness lie? Is a certain exercise a treatment for obesity or for monitoring the
progress of a patient with a new hip by tracking footsteps? Further, FDA is supposed to
regulate accessories — those devices that connect or plug into a medical device -- in the same
way it regulates the device itself. However, that may not work very well in an era when
everything is connected to everything else and at different risk levels.

In February 2015, the FDA issued a guidance13 “to inform manufacturers, distributors, and
other entities that the Agency does not intend to enforce compliance with the regulatory
controls that apply to MDDS (Medical Device Data Systems), medical image storage devices,
and medical image communications devices” because they pose a low risk to patients and
because of their “important” role in the progress being made in digital health. The Agency
defines a MDDS as either hardware or software that “transfers, stores, convert formats, and
displays medical device data.” A MDDS does not modify the information nor does it control the
functions of any connected medical device. Importantly for mobile health, a MDDS does not
include devices intended for “active patient monitoring,” which are defined as devices in a
context requiring a prompt response (such as, in-hospital patient monitoring) or rapid
identification of a disease or condition (such as, a monitor that is intended to detect life-
threatening arrhythmias).

Recognizing that the development cycle is rapid in mHealth devices and software, the agency
attempts to answer questions it receives regarding whether a potential application will be
regulated or not in real time (or “almost real time”), and it updates its website frequently with

examples of applications and the regulatory decisions they engendered. While the agency has an obligation to protect patients and other consumers from harm, a lengthy FDA approval process increases costs at a time when there is a national focus on reducing health care costs, and places a barrier in the way of the adoption of innovative health solutions. If the review process is not timely, a small company may have expended its limited capital resources and gone out of business by the time the agency rules on its application. The regulatory process also has the reputation of being unnecessarily cumbersome, especially for start-ups with little regulatory experience. Often, developers must look in many places and piece together regulatory requirements as they apply to their products.

There may be facets of mHealth that don’t fit well into the usual FDA framework, including some of the rigorous aspects of quality systems regulations. Indeed, FDA has yet to resolve issues related to how software may be regulated to a medical device.

FCC: In its 2012 report, the “mHealth Task Force” recommended that “[t]he FCC should appoint a Healthcare Director responsible for supporting the regulatory needs of the healthcare technology sector and working toward the goal of improving healthcare delivery.” The FCC has the following primary responsibilities:

- The FCC allocates spectrum in the private sector, allowing mHealth transmissions to avoid harmful interference from, say, wireless microphones or microwave ovens. The United States was the first country to allocate spectrum for wireless body networks.

- The FCC authorizes equipment that transmits radio frequency, including health care-related equipment like cell phones or baby monitors.

- The agency subsidizes broadband in order to encourage wider use of broadband-dependent technologies to meet community needs. In this sense, the FCC is an advocate as well as a regulator. In fact, one of the Commission’s responsibilities is to ensure equality of access to broadband for all segments of the population, including persons with disabilities. It will be important as mHealth becomes widely used to determine whether this mandate is being met.

In addition to these main responsibilities, the agency serves as a convener, bringing together other federal agencies, as well as representatives from the private sector. In fact, the Taskforce cited above also recommended that “[t]he Healthcare Director should serve as an important liaison with other federal agencies ....” Hosting discussions about roadblocks and opportunities in health care technologies with a broad segment of the affected audience is an important role with a fast-moving technology. FCC also issues experimental licensing in order to facilitate innovation in the wireless space. Health care and some research institutions need only apply for such licenses once and can avoid having to submit additional requests.

14 http://transition.fcc.gov/cgb/mhealth/mHealthRecommendations.pdf
ONC: The Office of the National Coordinator for Health Information Technology (ONC) works closely with the Centers for Medicare and Medicaid Services (CMS) on its program to provide incentives to hospitals and other health care providers to adopt electronic health records. It sets the standards and criteria for health IT, including certified EHR technology. This responsibility involves a challenging balancing act of pushing for standardization while promoting innovation. It also implements a certification program that enables developers to have products certified to these criteria.

ONC also works with CMS to develop measures that providers will have to achieve in order to meet the requirements of “meaningful use.”\(^{15}\) As ONC proceeds with the next stage of defining certification criteria and working with CMS in defining requirements for meaningful use, it is considering how to support the incorporation of patient-generated health data, including from mobile devices, into patients’ EHRs, thus making health information bi-directional instead of the traditional health provider-centric record system.

Finally, in those areas where the FDA is instituting a light touch regulatory approach, ONC is looking for ways to take a step forward. ONC has taken a leadership position in the recent FDASIA.

FTC: With its mandate to protect consumers, the Federal Trade Commission has been looking closely at new health technologies. It fulfills its mission through three mechanisms: enforcement, policy initiatives, and outreach. In the case of these new technologies, it is highly interested in issues related to privacy and security.

The FTC may bring an enforcement action pursuant to Section 5 of the FTC Act when a company makes a deceptive claim regarding its protection of consumer information. The agency may also use its Section 5 enforcement authority against “unfair” acts or practices, i.e., those that cause or are likely to cause substantial harm to consumers that is neither reasonably avoidable by consumers nor outweighed by countervailing benefits. Section 5’s proscription against unfair or deceptive acts or practices is a flexible one that allows the agency a great amount of discretion.

On the policy front, the agency held a workshop\(^{16}\) on “The Internet of Things” that included a session on connected health and fitness devices and a seminar on consumer generated and controlled health data.\(^{17}\) One take-away from both events for the agency was that consumers need to be confident that their health devices and apps are secure and protect their privacy in order for the health benefits of the technologies to be realized.

\(^{15}\) The Medicare and Medicaid Incentive Programs provide financial incentives for the “meaningful use” of certified EHR technology. To receive their incentive payment, providers have to demonstrate that they are meeting certain measurement thresholds.


Another core activity of the FTC is outreach to both businesses and consumers. Its website has guidance documents that companies can use in developing new health products, instructing them to build security into their products and services from the beginning. For example, one such document gives developers of apps suggestions on best practices, such as being truthful when describing the app’s capabilities and disclosing key app information clearly and conspicuously.

State regulation: The FDA and FCC regulate mobile medical devices, but the states regulate health care providers. Physicians are required to meet a “standard of care” set in the state where they are licensed to practice, but standard of care is an ambiguous term and constantly evolving. Just as FDA has had to examine its approval process for devices that are now mobile, so the states are having to look at certain rules when a patient is being “seen” in a setting distant from a medical care provider.

For example, the location of a patient during a medical encounter may determine which state’s regulations govern. Yet physicians must abide by national standards of care as set forth by the specialty societies in their area of practice. In this case, the geospatial locator on a mobile device, pinpointing where the patient is, may provide useful information that helps a physician be compliant. Rules regarding adequate supervision of medical personnel – for example, a physician supervising a nurse who might be just down the hall – are well-established for situations where care is provided locally in a medical facility, but need to be clarified in a mobile context. And many states require a patient and a physician to have established a hands-on professional relationship before care may be given electronically.

In an attempt to help states as they face challenges in regulating medical practice based on mobile platforms, the Federation of State Medical Boards (FSMB) established a FSMB Appropriate Regulation of Telemedicine (SMART) Workgroup, comprised of members of state medical boards, payers, representatives from industry, and health care providers. In April 2014, this group produced a (non-binding) model policy for regulators and health care providers to consider as they increasingly make use of all kinds of telemedicine, including mobile devices. The policy addresses issues such as the importance of a doctor-patient relationship and continuity of care and offers guidance on how standard of care might be defined and implemented in a mobile environment. The guidance recommends that standard of care for diagnosis and treatment be the same for mobile health as for traditional health care practice. The guidelines also state that a diagnosis may be made from a distance, but the technology must allow physicians to gather the same information as is possible when a patient is standing in front of them. Importantly, although the American Medical Association (AMA) has long been opposed to telemedicine, which would include mobile medical devices, it has recently taken

18 http://www.ftc.gov/tips-advice/business-center
19 There are exceptions to this rule for consulting physicians. For example, a radiologist is a consulting physician to the treating doctor.
steps to further the practice. Finally, medical device developers, although knowing that the states regulate the practice of medicine and not devices, should be aware that the devices they produce are an integral part of a medical practice, so they need to keep abreast of the state rules.

National Institutes of Health: The NIH is not a regulatory body, it’s “all about the science.” Nonetheless, NIH’s traditional role of funding research to ensure safe and effective medical treatments is the foundation of progress in all modes of delivering care, including mHealth applications. mHealth is posing new challenges to NIH’s gold standard of evaluation, the random clinical trial (RCT). Although RCTs are a tried and (mostly) true means of judging new treatments or evaluating competing treatments, they are not as well suited to a rapidly changing medical technology, in this case mHealth. The typical lifetime of a rigorous mHealth RCT is overtaken by new technological developments, so that the clinical trial ends up being a test of applications that are outdated, and thus is not useful. While NIH is not abolishing RCTs, it is adapting by not requiring “hard ends” in a clinical trial, such as a heart attack. Rather, there is a trend toward continuous testing, for example, of markers of future heart attacks. Demonstrating the superiority, or even equality, of mHealth apps over traditional – and old-fashioned – methods of treatment is vital in order for these new technologies to be more than a passing fad.

**Stakeholder Perspectives**

Health Care Provider: What will the doctor-patient relationship look like in the 21st century? We will be re-defining “doctor” as patients relate to a whole team – doctors, physician assistants, nurses, pharmacists, case managers, social workers, educators, and community health workers. Mobile health applications add a lot of health information about a patient, but is anyone paying attention? The health care team must “connect” with each other in order for this added information to be useful in caring for a patient, and sometimes real communication is needed, not just virtual communication, in order to have an effect on patient behavior.

Some vulnerable populations probably need the most assistance in managing their chronic diseases. Yet, many of their problems are ancillary to medicine itself – do they have transportation to the doctor? Where is their pharmacy located and can they reach it? Are there unmet food and housing needs? Do they know when their next appointment is? All of these factors are important in the health of these populations, and yet mobile health may not be capable of providing solutions. Simply providing these patients with feedback on their blood sugar levels or blood pressure may fall short. Community health workers need to be educated not only on aspects of the chronic illness, but also on how to make the best use of mobile health data. They need to assess the large amount of data, integrate relevant clinical data into the EHR and communicate effectively with both the patient and the health care team.

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Some health care applications need to be increased or decreased, as appropriate. For example, given that patient compliance is one of the largest medical problems and the first month after receiving a new prescription is the most important time to encourage a patient to be compliant, it is during this period that reminders to fill a prescription or to take the drug should be frequent. If, after a month or so, the patient is doing well, the reminders can be discontinued. Further, when patients are introduced to a new health care app, they must be fully informed of any privacy concerns. If they are texting to their provider team, is that communication encrypted and secure? In this example, patients may be so pleased they are receiving more frequent attention that security issues may not be a concern to them.

An additional problem is that the mobile device does not interact with an EMR, creating an additional task for the medical team, which now has to manually enter data received via an app into the digital record. The more interoperability there is between the “field” and the health center, the more valuable mobile apps will become. Overall, increased interoperability among mobile devices is imperative, so that data can be combined and multiple measures of health can be easily aggregated.

Industry: The mobile health industry is populated by several big companies and a large number of small companies. Start-up companies are fortunate that health IT is not a particularly capital-intensive industry, so there are opportunities for very small companies to innovate and develop products. The down side is that many of these small companies have little or no capital at all, and survival can be a week-to-week matter. Although start-up companies may be the “soul” of the mobile health industry, they face special challenges and have special “asks” from the regulators. In its 2015 guidelines, the FDA clarified what will and what won’t be regulated, which is particularly important for start-ups, because when they approach venture capitalists, they need business plans that account for the time it takes to obtain regulatory clearance. That said, some ambiguity is desirable. If a regulation is at a broad level, setting out goals but not prescriptive, it allows developers the freedom to arrive at innovative solutions to meet those goals. Just to complicate the issue, ambiguity can also be “bad” if the scope of what will and what won’t be regulated isn’t clear.

In going from broad to specific – Congressional action, regulation, guidance – there are advantages and disadvantages at each level. A strength of Congressional statutes is that they are not “written in sand,” but rather require another act of Congress to change them. This, of course, is also a weakness in a fast developing technology, such as mobile health, particularly when the authors of the laws (members of Congress) are not experts in this highly technical field. Guidance is drafted by experts and might have the flexibility required for mobile health technologies, but also can be more easily changed with new leadership at the regulatory agency, thus providing less certainty for developers. Regulations have the force of law, and are more stable than guidance, but can also be rigid.

In a fast-growing technology field with many competitors, a company with a new product that appears to require regulation will be at a competitive disadvantage if a similar product is going on the market without approval. Given a choice, investors would clearly prefer to invest in a
product that does not require approval, because it can reach the market faster. This could lead to a situation where bad products drive good products from the market. The FDA should ensure that any new app that must be approved follows the FDA pathway. There often is not adequate FDA staff to monitor new products coming to market and ensure that they have met the proper level of regulation and approval. Sometimes, tips from competitors can alert regulators to companies trying to skirt regulations. On the other hand, start-ups are likely to be wary when contemplating filing a complaint against a large company competitor, as they may be hoping that someday their small firm will be acquired by that company. Overall, investors seek developers whose products will not encounter excessive impediments before returning a profit, including the medical device tax, passed as part of the Affordable Care Act, which will, therefore, hit start-ups the hardest, as it targets sales, not profits. This obviously is out of the hands of regulators and is a policy decision for Congress.

Most quality system processes that health app developers apply are standard across products, with a smaller percentage being unique to that device. Because many small companies are not familiar with the device industry or the corresponding regulations, the FDA can assist them by setting forth guidance that helps these developers apply those standard processes. Early-stage developers want to observe high quality standards, but can’t afford to pay a consultant to develop the standards for them, so the FDA can help the innovation process by taking this step.

The NIH’s SBIR (Small Business Innovation Research) program helps spur innovation by funding research, but these grants go mostly to spin-offs from universities. Further, they don’t provide helpful guidance with the many steps that need to be taken to attract investors. Thinking outside of the box, tax credits would be helpful. The state of Maryland, for example, gives credits to investors in small companies in the biotechnology industry in that state. This sort of a program on a national basis would be a spur to innovation in mobile health devices.

Large companies are in an advantaged position because of their size and resources, which enables them to absorb high development costs and to hire individuals who have experience with the regulatory landscape. They can take risks and have several pilot studies in progress at one time; a failed product will not bankrupt the company. However, large companies are not always good innovators and, often, grow incrementally by purchasing smaller companies that have a niche product or expertise. This ongoing growth by acquisition permits consolidation by bringing together under one roof the many one-off products typical of start-ups, thus creating interoperable mobile health systems, which may be the future of mobile health care. Another strategy for growth in the mobile health industry occurs when several smaller companies in the same space partner with one another to go deeper, rather than broader, with their particular mobile application. An additional model for growth is followed by some small companies that start with a simple product, pilot it and, if successful, further develop the product, making it more useful.

Telecommunications companies are among the players in this area that likely never thought of themselves as part of the health industry. Because they must deal with both the FCC and the FDA, they need a consistent device approval process. Although the two agencies have an MOU,
it is still necessary for an applicant to obtain approval from each of the agencies. A one-step process would be an improvement over the existing policy.

Insurance: “Who will pay?” is often the important question with any nascent and not fully tested medical advance. A major stumbling block for the mobile industry and incorporating mHealth into medical practice is that until recently there were no reimbursement mechanisms.

The insurance industry realizes that we may be on the cusp of finally having a health system instead of a health care system, with major implications for their business sector, as well as society as a whole. The industry has a high stake in experimentation with this new medical technology; they need to know what actually works. Insurers are rational economic actors and want a “bang for their buck.” Only through research, including comparative effectiveness studies, will we know which mobile technologies are effective, and which are not. Often it will be consumers themselves who do this experimentation. Big data may help move this process forward more quickly, and insurers sit on a lot of data and thus may play an important part as the mobile industry winnows out losers and supports winners.

CMS is the biggest insurer of all, and generally sets the pace for the private sector insurers. Just because a device has met all FDA requirements, CMS will not automatically cover its use. This decision will rest more on whether the standard of care evolves to include the use of mobile devices in one or more specialty areas. CMS does not always require a physician-to-patient encounter for reimbursement. For example, radiology and pathology do not involve such an encounter. CMS does not consider radiology to be a telemedicine service and reimburse for this service, but does consider dermatological distance diagnoses by means of a mobile application as a reimbursable service. In 2014, CMS issued guidance22 on its “coverage with evidence development (CED)” policy, which provides for conditional coverage of new technologies “on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data.” This approach is promising because it indicates that CMS may be willing to cover mHealth applications for which the evidence of effectiveness is being studied. Further, beginning in 2015, CMS will reimburse for some remote monitoring, an important step in moving away from only covering face-to-face medicine.

Conclusion

This report began with some observations on the possible benefits from emerging mHealth technologies. It is, indeed, an exciting field with much potential to improve individual and public health. As with all new technologies, however, mHealth raises questions that challenge the “old way” of doing things. So concurrently with the development of mobile health devices and apps, existing legal structures need to be assessed and a determination made as to whether

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they are adequate to meet the challenges that arise with these new technologies or whether they must be adapted to provide a good fit for the new methods of delivering health care. This report and the workshop on which it is based focuses on one important aspect of the legal environment—regulation. The first workshop of three was chosen to address regulation in the belief that a major determinant of whether new innovations “catch on” is the regulatory scheme in place to guide their entry into the market place, and in this case, into 21st century health care. Weighing the promise of benefits against the risks that accompany any new technology in the health arena is never a simple and straightforward task; it is marked by rapidly-moving technology, a diverse group of stakeholders, competing claims about what constitutes useful evidence, and a sense of urgency for decisions to be made. We hope this report demonstrates the complexity just described, while also pointing to some steps that might be taken at different levels by various key actors to move mHealth forward.

Recommendations

General

1. As part of its role in promoting this growing industry, the Department of Health and Human Services (HHS), through ONC, should launch a national initiative to advance the use and implementation of mobile health. Goals of this initiative might include drafting of guidelines and devising models for expanded reimbursement for both CMS and private insurers. This initiative should include, in addition to government regulators—such as, the FCC, FDA, and FTC--policy makers, providers, industry, patient representatives, health lawyers and standard-setting organizations.

Level of government oversight – Congress

2. This is not the time for Congress to make changes to the current regulatory environment. Industry and those advising it should wait to seek Congressional action until it is essential. Specifically, as Congress considers repealing the device tax, it should not define medical software in a way that would take regulatory authority away from the FDA.

3. Congress should not pass legislation that sets forth unrealistic timetables for the FDA, an already overburdened agency.

4. Congress should not attempt to define where FDA should exercise enforcement discretion. Mobile health technology is moving at such a rapid pace that the agency should be allowed flexibility in where it sets the dividing line between those devices that merit regulatory oversight and approval and those that do not. This science-based decision should initially be left in the hands of experts.

5. As an incentive to innovation, Congress should consider a tax credit for investors in mHealth.

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Level of government oversight – FDA

6. Where the agency has said it will regulate, it should issue those regulations, and there needs to be a mechanism that ensures that apps that require approval in fact seek it, even if that mechanism involves players other than FDA.
7. The agency should have specially trained reviewers for mHealth and it should coordinate internal policies and understanding of mHealth regulations, so that misinformation is not inadvertently provided to developers, possibly leading to inconsistent agency reviews.
8. The agency should encourage innovation by creating a “roadmap” or users’ manual for developers and should pursue more outreach to first-time developers.
9. FDA needs to further develop its regulatory approach to software, for example, by creating a pathway for beta testing, a step with which the software industry is familiar. When a software module in common use is integrated into software unique to a particular mHealth app, the evaluation process should not be onerous and needs to be clear. Quality system requirements for standard software should be issued. FDA should extend its current practice of not treating a software update as a recall to mHealth software. Post-market obligations, such as adverse event reporting, need to be spelled out, making clear where the responsibility lies, for example, in a networked system.
10. FDA should establish a certification process for identifying safe and effective interactions between interoperable software and devices.
11. FDA and FCC should develop a joint method for demonstrating certain requirements under the law for purposes of FCC equipment authorization and FDA classification, thereby replacing the current need to demonstrate similar requirements before each agency that is now in place.

Level of government oversight – states

12. In order for physicians to continue to treat patients using mobile medical devices while in another state, interstate licensing of physicians, with an easier path to reciprocity, should be adopted, for example, by encouraging compacts among states.

Private sector

13. There should be a method by which low-risk products that do not require FDA clearance can be registered, for example, using the UL process as a model. This registry, used by developers and manufacturers, could develop into a “safety center,” a location where best practices are defined. Clinical input should be part of the safety center to ensure that the experiences of health care professionals are considered.

Clinical

14. Certain patient-generated data derived from mobile applications should be incorporated into an EHR, with incoming data to be timely and authenticated (i.e.,
accurate and complete). The definition of what constitutes medical or health data should be clarified, so that medical records do not become so filled with non-essential data as to be not useful to health care providers.

15. A professional body (or bodies) should review the effectiveness of mobile health applications to aid practitioners wishing to adopt this new technology. Health care providers should have resources to which they can turn, which might include best practices. The AMA and/or the specialty societies could play a role in this effort to ensure that the use of mHealth is evidence-based.

NIH

16. Methods for assessing the effectiveness of mobile applications must be aggressively developed, with a goal of defining standards of reliable and valid clinical research. To accomplish this goal, NIH should consider convening periodic consensus conferences – with clinicians, academic researchers, and developers – to develop best research practices.

Insurance

17. As a step in the right direction, CMS should make further progress in reimbursing health care providers for remote care consistent with current reimbursement models for quality health care, including mHealth, thus providing incentives for outcomes, rather than for the manner in which the provider cares for the patient.

18. CMS should continue to develop and expand its CED policy.

19. CPT (Current Procedural Terminology) codes should be assigned by the AMA, so that treatment using mobile devices is more easily reimbursable.
Appendix: Workshop Attendees

Exploring Legal Challenges to Fulfilling the Potential of mHealth in a Safe and Responsible Environment

Workshop I: Regulation
Convened and Hosted by AAAS
June 16-17, 2014

Workshop Participants

AAAS Staff:

Mark S. Frankel
Deborah Runkle
Bethany Spencer
Rebecca Carlson
Josh Ettinger

Participants:

Elisabeth Belmont  MaineHealth
Jason Brooke   Vasoptic Medical
Jodi Daniel HHS/Office of the National Health Coordinator for Health Information Technology
Kent Dicks   Alere
Alexis Gilroy    Jones Day
Melissa Goldstein   George Washington University
Sonali Gunawardhana   Wiley Rein
Cora Tung Han   Federal Trade Commission
Gail Gibson Hunt National Alliance for Caregiving
Robert Jarrin   Qualcomm Inc.
Richard Katz   George Washington University
James Kelly Food and Drug Law Institute (emeritus)
Charlie Klippel   Aetna Inc.
Santosh Kumar   University of Memphis
Insup Lee University of Pennsylvania
Carol Ley   3M
Wendy Nilsen National Institutes of Health
Frank Pasquale   University of Maryland School of Law
Bakul Patel   US Food and Drug Association
Kyle Peterson   Calgary Scientific
Matthew Quinn   Federal Communications Commission
Nithya Ramanathan UCLA/NexLeaf
Payal Shah   C-Change
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<td>Jeffrey Shapiro</td>
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<td>Kaiser</td>
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<td>Jon Thomas</td>
<td>Federation of State Medical Boards</td>
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