

Mobile Health: Revolutionizing Healthcare Through Trans- disciplinary Research

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Mobile health (mHealth) seeks to improve individuals' health and well-being by continuously monitoring their status, rapidly diagnosing medical conditions, recognizing behaviors, and delivering just-in-time interventions, all in the user's natural mobile environment.

Recent advances in mobile technology have opened up enormous opportunities to improve patients' health and well-being. mHealth technologies offer real-time monitoring and detection of changes in health status, support the adoption and maintenance of a healthy lifestyle, provide rapid diagnosis of health conditions, and facilitate the implementation of interventions ranging from promoting patient self-care to providing remote healthcare services.

Although mHealth is a new area of scientific development, researchers have been laying the groundwork over the past four decades. Medical practice and healthcare originated as a system to treat infectious diseases (such as smallpox) and traumatic injuries. As life expectancy increased, by the mid-1900s attention had shifted to managing chronic illnesses such as diabetes and heart disease. By definition, chronic illnesses are not expected to be resolved through treatment.

This transition from acute to chronic treatment, paired with an extended life span, resulted in a healthcare system that is growing with unsustainable levels of cost (percentage of GDP). While this problem is evident in the US, it is also becoming an issue in developing countries.¹

In tandem with these changes, high-quality, user-friendly wireless consumer devices, such as mobile phones, have emerged that accompany users most of the time. These devices provide not only mobile communication, but also sensing, analytic, and visual capabilities, as well as access to the cloud. Sensors embedded in a mobile phone, complemented by sensors on and in a body, can provide an unprecedented view of the person's health status and behavior patterns.

mHealth builds upon earlier work in telehealth, mobile computing, and persuasive technology in healthcare settings.² It has the potential to turn mobile devices into personal labs that continuously assess a person's physiology, behavior, social context, and environmental exposure. For example, a personal therapist application on a mobile device could mine the Internet for information about the latest health research and apply it while continuously collecting personal health data to make inferences about the user's health, and then share these results with caregivers so they can provide appropriate treatments. Persuasive user interfaces on the mobile device could facilitate compliance with the prescribed treatment protocol by applying just-in-time intervention. In addition to directly improving healthcare, mHealth could also accelerate health research and inform the formulation of public health policies.

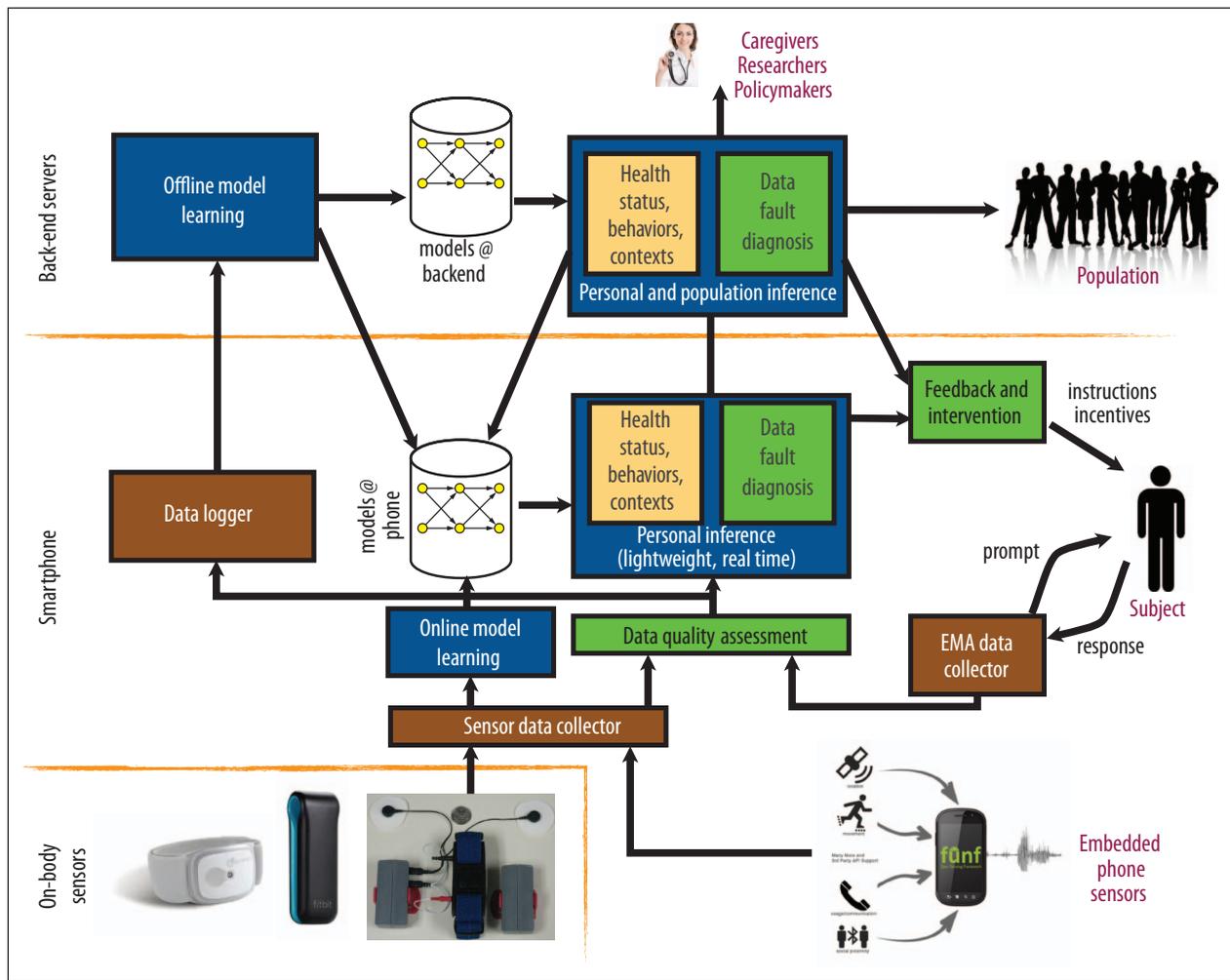


Figure 1. An overview of mobile health systems. Sensors at the lowest layer collect raw data that is processed to make inferences about individuals. These inferences can then be used to inform the design or delivery of just-in-time interventions and to make health inferences at the population level to inform health research, practice, delivery, and policy formulation.

This vision of mHealth can be realized by building on recent advances in mobile technology, but the success of mHealth will require considerable innovation in fundamental science and engineering, as well as integration of the technology with healthcare systems.

MOBILE HEALTH SYSTEMS RESEARCH

As Figure 1 shows, mobile technology can simultaneously acquire information, process the data, make inferences, mediate a range of interventions, and provide communications with other devices and systems.

Sensing in mHealth

To reach its potential, mHealth technology must be able to capture diverse personal and environmental signals relevant to the health of both individuals and communities. Researchers are repurposing a variety of sensors already included in mobile phones, such as accelerometers and GPS technology, via sophisticated algorithms for

use in mHealth applications, resulting in many innovative health-, wellness-, and fitness-related applications. However, the measured signals from these sensors often lack clinical relevance and fall short of the specificity needed to allow definitive diagnosis and treatment of complex health conditions.

As interest in mHealth grows, we anticipate the increasing availability of sensors that are specifically targeted at and optimized for mHealth. In the short term, factors such as cost, market size, mass, volume, and placement constraints might necessitate using external sensors that are wirelessly connected to a smartphone. Over the long term, however, the need for a better user experience is likely to require integrating such sensing into smartphones or other emergent cellular-connected wearable devices such as eyeglasses.

The core challenge lies in developing new sensors that are compatible with incorporation in a smartphone from a cost and size perspective, can be used for continuous real-time sensing without much burden on the user, and



enable various tests that can only be done in a clinical setting today. Biomolecular sensing, imaging, and bioelectric sensing are particularly important.

Biomolecular sensing. With their high selectivity, ultra sensitivity, and energy efficiency, solid-state sensors can turn a common smartphone into a powerful and easy-to-use diagnostic tool.

Assessing biomarkers and pathogens in body fluids and human breath to detect diseases, their progression, and therapy effectiveness is essential in healthcare. Such sensing typically relies on sample preparation and laboratory analysis, which are not usually available in a mobile setting. Advancements in nanotechnology, microfluidics, and solid-state sensors, however, offer the promise of miniature, low-cost, chip-sized sensors that can provide “lab-on-chip” capabilities.

For imaging to scale in mHealth, it must move beyond the current human-in-the-loop approach for interpreting images to perform computational triage.

Examples include

- Nanowire sensors, which are fabricated at low cost in high-yield semiconductor foundries and packaged into disposable electronic strips.³ These embedded sensors can detect the presence of specific molecules such as cardiac troponins in a mobile setting to facilitate the diagnosis, monitoring, and risk stratification of suspected acute myocardial infarction in cardiovascular patients.
- All-electronic digital microfluidic devices operated by electrowetting-on-dielectric actuators, which can stimulate highly precise, programmable microreactions to allow performing a wide range of assays in a mobile setting.
- DNA microarrays, which can capture the epigenetic information necessary to understand the protein-DNA interactions that underlie many biological processes and disease states.
- Low-power solid-state chemical sensors, which use inorganic materials for potentiometric and resistive sensing of trace gases in human breath in real time and at low parts per billion (ppb) concentrations. Research has associated the presence of trace gases with various diseases, such as nitric oxide for asthma, acetone for diabetes, and hydrogen for gastroenteric ailments.

Imaging. Passive and active imaging methods such as ultrasound, x-rays, MRI, and CT scans are mainstays of modern healthcare. However, factors such as optical

pathway impose size constraints and the need to generate powerful or even dangerous signals (such as x-rays) or fields (such as MRI) make it impossible to embed them in a smartphone. Indeed, cameras are the only imaging devices widely available in a mobile environment. Using computer vision methods, researchers have incorporated smartphone cameras in mHealth applications to perform tasks such as detecting the heart rate from microblushes and estimating refractive errors in the eye. For imaging to scale in mHealth, it must move beyond the current human-in-the-loop approach for interpreting images to perform computational triage. Two solutions are emerging that provide complementary capabilities.

The first one is lens-free computational microscopy and tomography⁴ running on a smartphone that can algorithmically overcome optical constraints to provide high-resolution 3D imaging of biological samples with a wide field of view and a large depth of field. These methods have been shown to assay blood samples for malaria.

The second solution is radio frequency (RF) imaging, which is an attractive option for smartphones as they already have several built-in radio transmitters and receivers—for example, cellular, Wi-Fi, and Bluetooth—that researchers can potentially repurpose. Wideband signals from an RF transmitter can penetrate and illuminate the interior of the human body, and the mobile device can analyze the interferogram image resulting from the reflected signal waveforms to infer a variety of internal variables, such as heart motion, blood flow, respiration, and fluid accumulation. Because RF imaging is inherently contactless—that is, it does not require coupling transducers to the body via gels or fixed electrodes—it allows unobtrusive, real-time physiological sensing.

Bioelectric sensing. The measurement and analysis of surface biopotentials is a powerful, and often the only, sensing modality for diagnosing and monitoring many disorders. Examples include electrocardiography (ECG) for the heart, electroencephalography (EEG) for the brain, and electromyography (EMG) for muscles.

Although devices for measuring surface bioelectric signals in mobile environments have been available for many years (Holter monitors, for example), they are too cumbersome for long-term monitoring, which requires affixing multiple electrodes to the body. With ongoing developments in low-power electronics, smarter and compressive sampling, and energy harvesting, batteryless wireless patches could offer a less obtrusive bioelectric sensing approach that eliminates the tangle of wires and electrodes.⁵ For sporadic monitoring, emerging contactless bioelectric sensors that use through-the-clothing capacitive coupling could allow building the entire sensor into a smartphone.

Mobile computing for mHealth

An effective mHealth computing platform must be able to efficiently make semantically rich and medically trusted inferences about physical, physiological, psychological, cognitive, and behavioral states from sensor information, and correlate these inferences with environmental, social, and other factors.

Current mobile operating systems offer sophisticated network communications capabilities and provide applications with rich abstractions of communication patterns such as Web services. Rich networking stacks and frameworks free individual applications from handling low-level data types such as bits, bytes, and packets or managing low-level protocols for media access, routing, and transport. However, these systems provide rather primitive software support for sensory applications. mHealth applications are developed as ad hoc stovepipes handling all the system layers, from raw transducer signals to semantically rich inferences to actionable information. The lack of a standard approach is largely due to the failure to provide reusable and semantically rich abstractions of sensory information for mobile operating systems.

We envision the emergence of a “sensing stack” analogous to the networking stack. The sensing stack might similarly be organized as a layered set of modules that systematically transforms sensor measurements into rich inferences that applications subscribe to. The sensing stack would have layers reflecting the needs of typical sensing applications:

- a bottom layer that samples front-end signal processing to extract feature vectors,
- an inference layer that maps classifiers and recognizers such as support vector machines (SVM) into semantic labels, and
- a top layer that extracts complex events from the time series of inference labels.

Applications would access the stack via a suitable API. For example, an application might ask to be notified when the user is engaged in a particular activity or is in a particular behavioral state—for example, “running,” “stressed,” or “talking to Bob.” However, unlike networking stacks, which deal with relatively few network interface types, the sensing stack would need to deal with many diverse sensors and corresponding processing.

Energy is another challenge. The realistic lifetime of current mobile phones when engaged in continuous sensing is woefully short. As smartphones begin to use sensors for continuous inferencing, they will need sensing subsystems for efficient sampling and duty cycling. In addition, the supporting architecture will need to be both efficient and high performance, providing dedicated sensor processors that applications can configure and program.

Addressing the current shortcomings will require revisiting assumptions underlying the hardware and software organization of mobile devices, which are optimized for sporadic interactive computing and communication. For example, designers will need to optimize the analog-sampling-computation-communication chain using advances in adaptive and sub-Nyquist sampling,⁶ tiered processing architectures, in situ measurement of system performance to cope with environmental and platform variability affecting power performance, and emerging ultra-low-power wireless technologies.

mHealth analytics

As the variety and availability of sensing and mobile computing technologies for mHealth increase, the data collected from the mobile environment will grow exponentially; multiple sensors will continuously collect data at high frequency for the user's lifetime. A major challenge is extracting actionable information and knowledge from

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this data deluge to provide accurate health information for users and professionals and help researchers and policymakers reach optimal conclusions.

For the data to be useful in making health decisions, they must represent their provenance, quality, and validity. mHealth applications can use well-characterized data to make inferences using models of the relationship between the acquired data and the phenomena of interest. For example, if the applications can estimate the uncertainties associated with the placement of the device relative to the user's body, they can use the data obtained from a mobile device's accelerometer to estimate an individual's actions and activities.

Data quality. Data collection in mHealth sensing introduces various data-quality challenges. Sensors such as ECG electrodes might be placed incorrectly on the body, or, even if initially placed at the correct location, could subsequently slip or become detached. Sensor measurements might be noisy not only because of placement and attachment errors, but also because of the variability inherent in a patient's daily activities and the mobile environment. Wearable wireless communication devices are convenient, but can be another source of signal distortion. Finally, a device might intentionally degrade data quality to conserve battery life. These issues call for new research in data quality.



We need metrics to characterize the distortions and uncertainties associated with collecting the data and the resulting inaccuracy because decisions are based on that data. The specification of such metrics is an open question. For example, can the metric indicate the inaccuracy expected in computing heart rate from a poor-quality ECG signal? Having the same or similar metrics for different sensors will make interpreting and processing the data much easier. But is a universal data-quality metric feasible for a single sensor, let alone for different sensors? In an ECG, for example, can the same metric measure inaccuracy in computing both heart rate and heart rate variability? Metrics should preserve information quality even when the data quality varies.

Mobile devices offer a powerful platform for delivering just-in-time adaptive intervention.

We also need methods to restore data quality. These methods will need to not only detect data quality deterioration, but also identify the deterioration source—for example, poor attachment or component malfunction—and use this diagnosis to engage the sensor user in taking appropriate action to restore the data quality.

Model-based inference. For mHealth data to be usable in making health-related decisions—for example, to initiate a just-in-time intervention, alert a caregiver, or even to solicit more information via self-reporting, mHealth tools will need higher-level inferences regarding health status, behavior, and context. Such inferences require new computational models that relate the observable variables to the quantities of interest.

Researchers are making progress in inferring physical state (such as posture and activity using accelerometers⁷), psychological state (such as stress using sensory measurements⁸), social context (such as conversation based on respiratory patterns⁹), and environment (such as place and commuting status using GPS). Significant work, however, is required to make these models and inferences reliable enough to use in the real world with a diverse sample of participants, so they can provide the basis for real-time inferences, decisions, and actions. A key concern is the potential for high false-alarm rates that can render the entire system annoying and ineffective.

Under limited circumstances, researchers can derive the computational models from principles such as biomechanics.¹⁰ In most cases, however, they develop these models by combining principled approaches with machine learning and statistical pattern-recognition techniques. With this approach, however, the difficulty in obtaining

representative labeled data limits the development of reliable and validated models.

Although data collected in the lab might have valid labels, it might not represent the natural environment in which mHealth systems ultimately need to work.¹¹ Labels collected in a mobile environment represent the natural environment, but they can be noisy, uncertain, biased, missing, or spurious. For example, researchers could use self-reported times of smoking to develop a model for automated detection of smoking, but these labels might not accurately represent the actual start and end times of the smoking episodes. Subjects might forget to report an episode or might even falsely report it to earn compensation. The models for inferring health states must also account for between-subject differences and changes in context without requiring subject-specific training with the model parameters.

Inference models should also adapt to changes in resource and data quality and be able to separate out the effects of various confounds. For example, having both ECG and respiration measurements available would improve the models' ability to infer psychosocial stress, but the models should work even if only one measurement is available. Further, activity, smoking, speaking, and so on, affect physiology. The model should therefore be able to demultiplex the effects of these and other confounding events to reliably infer the stress level.

A model based on engineering, physical sciences, and health and behavioral sciences principles will have a better chance of addressing these issues and generalizing across subjects, contexts, and environments.

Design of mHealth interventions

Because mobile devices are usually continuously with an individual and have the sensing and computational capacity needed to collect and analyze health-related data in real time to infer health and behavior, they offer a powerful platform for delivering just-in-time adaptive intervention.

A mobile device that is aware of an individual's health status and environment can adjust an intervention's content and timing accordingly. For example, if it can recognize vulnerable moments for a newly abstinent smoker, the device can deliver interventions to help resist the urge to smoke and prevent a relapse.

Mobile devices could also adapt the intervention's content to the vulnerability type (stress, alcohol, tobacco, and so on) as well as personalize the intervention to both the individual and the context (for example, "at work" versus "at home"). They could then apply their sensing capabilities to evaluate adherence and response to an intervention and use this information to adapt the interventions.

In general, an intervention can be viewed as analogous to closing a loop in an automatic control system. In classic control system theory, the system derives the input control signal by comparing the desired output to the actual

system behavior. Modern automatic control systems compute the optimal control signal from the desired outcome and a learned computational model of the target system.

Thus, achieving an optimal outcome for an intervention would require characterizing the human user's behaviors in terms of a predictive computational model, which is an open transdisciplinary research problem. Capturing the complexities, nonlinearities, and uncertainties associated with human response to interventions requires developing new predictive computational models for the controlled systems.

In addition to developing an appropriate theoretical framework for control, researchers need simulation tools that leverage technological advances to create models that account for the many factors that determine health. They can then use both the theoretical model and simulation tools to analyze the safety and efficacy of mHealth interventions prior to conducting human user studies.

mHEALTH SAFETY, EFFICACY, PRIVACY, AND SECURITY

Unlike other human-cyber-physical systems, where the human is just an operator, a sensor, or an actuator (such as in avionics or cars), in mHealth systems, humans are the “plant” whose health and well-being is to be affected and controlled. The life-and-death implications and the associated economic and legal burdens place a high degree of responsibility on mHealth system designers. Moreover, the human body is complex, highly variable, and not well understood. Thus, traditional computing verification and validation approaches are not particularly effective.

Designing trustworthy mHealth systems requires extensive collaboration between engineering and health professionals to create and evaluate effective mechanisms. The overall goal of ensuring that mHealth systems are trustworthy comprises several dimensions.

mHealth safety

When assessing health products, the first question evaluators ask is whether the device, medication, or treatment is safe. Likewise, researchers must ask whether an overall mHealth system is safe from both a health and an engineering perspective.

From a health perspective, safety means the mHealth system produces information that is valid and of adequate quality for critical decision making. For example, given the rapid onset of a heart failure event and the potentially catastrophic impact of a missed detection, an mHealth system that predicts heart failure in patients with congestive heart disease must maintain high-quality information continuously over an extended time period. For more advanced mHealth systems that might also trigger autonomous physiological and behavioral interventions, safety from a health perspective means that the interventions are medically safe and appropriate.

From an engineering perspective, safety means that devices, such as sensors, used in mHealth systems will not cause their users unanticipated harm or discomfort because of design or manufacturing errors. For example, a wearable sensor with poor circuit and thermal design could lead to excessive heating or a battery fire. Engineering safety is not just a hardware matter—errors in the embedded software are also a source of concern about safety. For example, faulty firmware in a defibrillator can cause unintended shocking, and an ill-designed user interface might confuse the user and elicit incorrect responses. Even when a device is functioning as engineered, the human body's variability combined with ambient conditions can result in safety issues in unexpected contexts, such as in extreme environmental conditions. For a device to be safe, designers must address all of these factors.

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mHealth efficacy

Efficacy—the evaluation of whether a device does what it claims, as well as for whom and in what context—is crucial for devices used in health applications. Health researchers ask whether the device is valid, that is, it measures what it claims, and reliable, that is, it generates reproducible measurements. Although these are common healthcare issues, defining and assessing such metrics is difficult in a mobile environment. For example, what's the best way to test the reliability of a device that is designed to assess temporal variability or address a concept's validity for which there is no ground truth (stress, for example)? These issues call for new research and specific metrics.

The evaluation of health interventions usually occurs in multiple phases. Early in development, carefully designed studies with individual patients (*n-of-1* design) or small groups (pretest, post-test, or time-series designs) are useful. Researchers can use these studies to assess safety, feasibility, and usability and determine the interventions' potential effect.

Later in development, when an intervention is mature, the use of randomized clinical trials (RCTs) is common. To minimize biases, RCTs involve randomly assigning a large number (perhaps thousands) of potential participants to a treatment group and a control group, in which some participants receive a placebo. The RCT lets researchers estimate the treatment effects' statistical significance and size. Although statistically sound, RCTs are generally expensive, inefficient, and lengthy. Other designs, such as regression-discontinuity and stepped-wedge, have similar



methodological rigor and might be suitable alternatives for mHealth.

Because technology evolves rapidly in this area, freezing an intervention during evaluation, which usually lasts for years, is not feasible. Therefore, further work is needed to develop research designs suitable for evaluating mHealth interventions.¹²

mHealth privacy and security

Patient information privacy has long been an area of concern in healthcare. Health information is managed under the 1996 Health Insurance Portability and Accountability Act (HIPAA), which aims to ensure that the information remains private (by regulating the use and disclosure of data to various parties) and secure (by mandating administrative, physical, and technical safeguards against intrusion by unauthorized parties). Created in an era when health information had just begun to be digitized, HIPAA could not have anticipated the many ways in which health information is now collected, exchanged, and processed.

mHealth systems pose enormous challenges for HIPAA. One challenge comes from the openness of mHealth systems. Sensors, computers, and networks that collect, transmit, process, and act upon healthcare information are owned and operated by multiple parties with complex trust relationships and technical competence. Ensuring privacy and security in such a setting, while well understood from a theoretical perspective, is difficult in practice where concerns of usability, cost, legacy, and conflicting interests intrude.

mHealth systems pose an even bigger privacy challenge because the data they collect from wearable sensors and personal mobile devices presents fundamentally new risks and vulnerabilities.¹³ Embedded in this data, which users share willingly and often not anonymously with others, are many privacy-revealing behaviors such as addictive behaviors and movement patterns. Smart algorithms can fuse these behaviors with digital footprints—that is, information from other sensors and publicly available information—to construct a near-real-time virtual biography of previously private behaviors and lifestyle patterns.

Although certain architectural principles, such as giving individuals more control over the data that sensors collect about them, have begun to emerge, designing mHealth systems that are sensitive to the needs of both producers and consumers of information remains an open challenge. Privacy-preserving mHealth systems would need to go beyond the traditional focus on data and identity privacy to providing behavior privacy.

In addition, because mHealth systems are continuously connected to the network, they are more vulnerable to tampering and jamming of sensing and communication functions by third parties, resulting in denial of service

and incorrect operation that could cause medical harm and threaten users' well-being.¹⁴

mHEALTH REGULATION

In the US, mHealth devices come under the regulatory authority of the Food and Drug Administration (FDA). In mHealth, as in other healthcare areas, the FDA regulates products that are intended for medical use. Products can include software, hardware, and devices that combine them.

The intent of the person or vendor who develops or sells a product gives it a medical-use quality. Some items, such as artificial heart valves, clearly have an intended medical use. But, when there is less than 100 percent clarity about intended use, the FDA considers a vendor's words, actions, and recommendations to customers to determine intended use. For example, if a vendor promotes an mHealth product such as a sensor or a mobile app as a sleep aid, the FDA can label it as a wellness device rather than as a product for medical use. If the same technology is marketed as a treatment for a sleep disorder, it will likely have a medical-use quality. In this case, the device will be subject to regulation and must be tested and evaluated using the FDA's scientific standards and processes. While using a product beyond its approved uses is not illegal, promoting it for something beyond what it is approved for is. The FDA is allowed some regulatory discretion; it can choose not to regulate something or can classify it for a specific type or level of regulation.

In 2011, the FDA released draft guidance for mHealth,¹⁵ and it now has congressional authority to formalize the guidelines.

Multiple US federal agencies that touch on various aspects of mobile computing also regulate and govern mHealth. This includes the Federal Communications Commission (FCC), which governs wireless operators and spectrum, and the Federal Trade Commission (FTC), which regulates interstate commerce and works for consumer protections, including mobile data security. Additionally, mHealth operates within the frameworks of other federal agencies that address mobility issues within the greater healthcare and standards systems. This includes the Office of the National Coordinator for Health IT, which provides guidance and support for the nation's health information technology infrastructure, and the Department of Health and Human Services' Office for Civil Rights, which is responsible for implementing and enforcing HIPAA. These agencies work together to regulate and guide the mHealth domain.¹⁶



Health systems herald an exciting new era in health with a shifting focus of healthcare to wellness and prevention. These devices also portend a transformed health research environment, where most

data is collected remotely and entire clinical trials might be run without the researcher and the participant ever meeting face to face. The data from these systems, in combination with the multiple fixed sensors in the environment, will also create a rich database for exploring new ways of understanding health. Thus, as mHealth systems become more prevalent and versatile, their use will not only enable myriad disruptive transformations in healthcare delivery and medical research, but will also present many scientific, engineering, and regulatory challenges. mHealth's success will, therefore, depend on transdisciplinary research collaboration among computing, engineering, and medical researchers. **C**

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