

The Role of MHealth and Wearables for Anticipation in Medicine

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Abstract As the market for health-tracking wearable devices continues to expand, there is an emerging niche for healthcare applications, and data acquisition and usage. Within this area exists a wealth of clinically relevant data already collected from wearers, including physiological and lifestyle data. This information allows us to not only optimize current medical treatments and health planning, but also to expand preventive medicine by applying *anticipation* to medicine. We propose that much of the data collected through these wearable devices can be used to inform both patient and clinician of long-term physiological trends, and to anticipate potential onset of illnesses with a view to stemming their progression, or even mitigating their occurrence altogether. This paper highlights important issues within the health-wearable paradigm and presents upcoming applications of wearable technologies in medicine.

Keywords Mhealth · Tracking · Wearables · Technology · Anticipation · Prevention

1 Introduction

Health-tracking wearable devices have seen a tremendous rise over the last several years. Previously, the majority of “wearables” have been focused on the realms of activity and exercise-tracking through step-counting and heart rate measurement.

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We are now seeing a new wave of devices that capture physiological data, including more sensitive biochemical measurements such as blood glucose testing and urine analysis [1]. For example, “Smart Bands” for the Apple Watch, intended for release in 2016 will include specialized sensors that may collect this and other similarly sensitive data. New data collection devices compatible with existing smartphones and other electronics will also help drive a shift toward enabling the recording of consumer physiological data through adjunct technologies.

Mobile apps will soon begin to share the spotlight with clinical medicine in health monitoring. In June 2013, WellDoc, a Baltimore-based healthcare technology company, received FDA approval to sell the first prescription-only smartphone app [2]. WellDoc persuaded insurance companies to offer reimbursements for their app, which is designed specifically for type 2 diabetes management. The billion-dollar question is whether this development has opened the floodgates for physicians prescribing apps in addition to, or in lieu of pills.

2 Anticipation in Medicine

2.1 *Mobile Health (MHealth) Advantages for Patient and Clinician*

There is significant, untapped potential of these devices and apps to inform clinical monitoring and planning. Patients with both acute and chronic conditions may benefit. The acutely ill patient may be able to detect a fever using a smartphone-enabled thermometer, and even perform a urinalysis to help diagnose a urinary tract infection. In this way, acutely ill persons may be able to easily and reliably self-diagnose simple conditions [3].

A patient with a chronic medical condition may also benefit from enhanced, regular monitoring. In the currently diagnostic model, decisions regarding patient care are often made based on incomplete information. For example, when a patient visits her family physician, management is often guided by her presentation at that specific point in time. While the physician may have a complete medical history, he or she is being provided with a snapshot of the patient’s health at any given consult. With health-tracking wearables, longer-term physiological pictures can be painted, thus better positioning patients and doctors toward more appropriate management options, which may improve outcomes [4].

Wearables also open the door for a type of ‘shared care’ between doctor and patient [3]. For example, if a diabetic patient regularly checks his blood glucose using smartphone attachments and an app, he might also permit his family doctor or primary care physician to view his glucose trends. Instead of diabetic wellness check-ups every three months, a clinician might request to see the patient earlier or later based on his personal blood glucose tracking, with an objective of minimizing

the destructive complications of diabetes. This is an example of how healthcare may become more proactive as opposed to reactive.

Similarly, consider the patient who regularly checks her blood pressure. A rising trend in BP levels over weeks or months might inform the patient and their doctor approximately how long from any given time point a diagnosis of hypertension can be projected to occur without lifestyle modification or medical intervention. A new layer is therefore added to the model of disease prevention, or at the least, the lead-time for diagnosis can be increased.

2.2 How Valuable Is Anticipation? Can It Improve Medical Care?

The ability to collect a wealth of physiological and lifestyle data introduces the concept of ‘anticipation’ in medicine. Anticipation is not unlike prediction, but is slightly nuanced—it is the strong prediction of an outcome, however it is made with the backing of clinical evidence collected over time [5]. Medical data is already collected through widespread use of wearables and apps. We suggest that this data be used to inform patient and clinician of long-term physiological trends, and perhaps more importantly, to *anticipate* potential onset of illness with the ultimate goal of prevention. We highlight in this paper a number of important issues with this paradigm and upcoming applications of technologies in medicine.

One way to determine the benefit of any intervention is to look at a relevant endpoint [6]. Wearables can be thought of as interventions if they are used for anticipatory care. For example, the presumed purpose of continually monitored blood glucose is to reduce the development of impaired glucose tolerance and diabetes. If use of a medical wearable reduces patient progression to any adverse endpoint, then that suggests that there is value in that wearable device.

Decreasing progression to undesired health endpoints could have further positive implications other than better patient outcomes. Insurance providers may opt to cover the cost of a wearable for risky patient-groups in order to lower the combined risk of a patient developing an expensive illness. John Hancock Insurance has already begun providing complimentary Fitbits, and offering reduced cost insurance plans for Fitbit wearers [7].

Beyond benefiting patients and insurance companies, wearables offer unique opportunities for medical researchers. First, participants would have options to allow or deny collection of individual metrics as they see fit. Second, provided that the relevant data is accurately measured by the device being used, or is at least reliable enough for correlations to be made, the continuous stream of data could benefit clinical trials. The FDA would have more clinical data with which to consider relevant regulatory decisions, and the increase in clinical applications of new technology will inform the improvement and use of even more technologies to improve evidence-based medicine [8].

3 Users of MHealth Technology

Two broad groups of users benefit most from wearables. The first general group includes young, healthy, tech-savvy persons who primarily use these devices for activity and exercise tracking. Companies such as Under Armour and Adidas have acquired mobile application companies such as MyFitnessPal and RunKeeper to program and provide a more complete digital fitness/data collection platform. As another example, researchers have used data from Apple's HealthKit package to obtain helpful de-identified data that can be used to study a disease, condition, device, or sensor [9, 10]. Thus, while the most apt (and likely) to use these digital fitness applications, for the most part this younger cohort has less use for metrics associated with possible pathology—glucose, cholesterol, blood pressure, etc. This group primarily benefits from wearables through activity-tracking, and the resulting lower risk of disease conferred by their healthier lifestyles.

The second broad group consists of more elderly and chronically ill patients. This population is more likely to be diabetic, arrhythmic, and/or rife with cardiovascular problems, such as those arising from high cholesterol or long-term smoking. Ironically, this group could stand to benefit from health-monitoring wearables the most, but there is often a hesitancy to adopt new tech in this group for reasons including high financial costs, privacy concerns, and misconceptions around ease of use [11, 12]. This group primarily benefits from wearables by anticipatory means—predicting adverse outcomes with a view to mitigation. For example, loss of balance upon rising from bed or a chair is due to failing anticipation in the body's ability to prepare for the change in position.¹ By tracking the effects of aging and recording them on an individual's *Anticipatory Profile*TM the intention is to develop means for maintaining anticipation in the aging.

Usage and de-identified physiological data collected from different age groups and subpopulations will provide useful stratified data that not only allows for better applications of the technologies, but also allows for better marketing to target consumer groups.

4 FDA Regulation of Medical Devices, Wearables, and Applications

The Food and Drug Administration (FDA), which has regulatory control over medical devices, categorizes medical devices into three classes [13]. A medical device is defined by the FDA as any product or equipment used to diagnose a

¹By tracking the effects of aging and recording them on an individual's *Anticipatory Profile*TM the intention is to develop means for maintaining anticipation in the aging. See: The anticipatory profile. An attempt to describe anticipation as process, <http://www.tandfonline.com/doi/abs/10.1080/03081079.2011.622093>.

disease or other conditions, to cure, to treat or to prevent disease. Class I devices are simple in design and have no potential risk. Examples include tongue depressors and Band-aids. These devices must be registered, exhibit proper branding and labeling, and be produced using proper manufacturing techniques. Class II devices are more complicated in design but have minimal risk. Examples are X-ray machines, powered wheelchairs, and surgical or acupuncture needles. Class III devices are intricate in design and have the strictest guidelines because they pose the greatest risk. Examples include implanted pacemakers and prosthetic or artificial heart valves. However, in general, the FDA does not regulate most health-related wearable devices as long as they are low-risk for consumers to use.

4.1 FDA Guidelines

To provide oversight and clarity to the development of mobile health (mHealth) applications, the FDA recently released their guidelines on regulations involving mobile medical apps (February 2015). By some definitions, a mobile app can itself be considered a medical device, leading to stricter regulations. This can be the case when a mobile app transforms a mobile platform into a regulated device with the addition of a sensor that is used in the diagnosis of disease or other conditions. An ECG sensor attached to a mobile phone would transform the mobile app into a device since the readouts become useable patient data. These rules are nevertheless malleable and will vary depending on application. The FDA will not regulate but will “exercise enforcement discretion” over apps that help users self-manage, track, or monitor their disease or conditions without providing medical advice or suggestions. Fitness wearables and mobile sensors and trackers for diet, exercise, sleep and mood that bring control to the user are examples, and therefore are not under regulation. Additionally, aiding patient communication with physicians via video-conferencing or telemedicine portals is not strictly regulated.

The line is drawn at the point where apps help transform a mobile device into a medical device, for example as a blood pressure cuff, otoscope, sphygmomanometer, pulse oximeter, spirometer, or ophthalmoscope. The argument is that the non-digital version of these medical devices are already FDA-regulated and if they were used incorrectly or malfunctioned, they may pose a risk to patients. By the FDA’s definition, a ‘mobile medical app’ is a mobile app intended to either (1) be used as an accessory to a regulated medical device, or (2) transform a mobile platform into a regulated medical device. What is a regulated medical device? The FDA guidance states:

When the intended use of a mobile app 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 of man [or woman], the mobile app is a device.

4.2 Data Security

On the patient or consumer's side, one of the first concerns regarding a mobile application is the security of their personal data. Many devices allow for background monitoring of activity, such as a heart rate-sensing mirror or a car seat that measures weight. Notably, many mobile phones are also able to log keystrokes or GPS location data in addition to number of steps taken. Furthermore, commercial wet labs such as Therasys, 23andMe, and Cleveland Heart Lab that are offering their services to the public are making genetics, proteomics, and epigenetics increasingly available. Used laboratory equipment can also be easily purchased at auctions or on websites such as eBay. Easy access to equipment and in-depth personal data makes it possible for consumers to bring the lab into their homes and personal health analyses to themselves without having to go to an institution, company, or outside location. There is a perhaps unintended consequence of these devices and technologies whereby they are providing health care capabilities to the consumer/patient. As the average person lacks a medical education with which to put collected data into context, it is important that clinicians help to provide the platform, knowledge, and experience for these shifts to take place. Undoubtedly, data security will become a critical component to consider, as it could be disastrous for certain devices, for example, a cardiac pacemaker, to become "hackable" and controlled by an unauthorized third-party.

4.3 Electronic Medical Records

Physicians often dictate patient charts on their mobile devices or computers, take images on their mobile phones, and check medical records remotely. The major healthcare corporations in the United States have already begun multi-million dollar shifts from paper to electronic records to allow healthcare professionals to have structured methods of keeping patient data. On the other end, patient portals are beginning to be built into these systems whereby patients are slowly being given the option of checking their own health data remotely. This gives patients a chance to read their diagnoses and check their medications list. There is public health potential here, where through Internet resources, patients can monitor side effects of drugs, or monitor their symptoms even more closely using new devices and technology.

A potential danger is that patients risk becoming afflicted with "cyberchondria," a state where patients become hyper-aware of symptoms, and believe they may have diseases and syndromes that they do not actually have. There are likely to be many false positives in certain diagnostic devices and false diagnoses in general as these technologies are developed.

5 Current Devices, Mobile Applications, and Commercial Companies

Mainstream fitness wearable devices from companies such as Fitbit, Jawbone, Garmin, Misfit, Moov, and Apple currently provide users with personal fitness data that includes heart rate, steps taken, stairs climbed, calories consumed, body mass index (BMI), and sleep activity. The appearance of these devices has created a psychological shift in the mindset of users, toward being more proactive with their lifestyle and health. Studies have demonstrated that just being aware of the number of steps taken per day and wearing a device that measures these steps can be powerful enough to motivate the wearer to walk the longer route to a destination, although more extensive studies involving behavior change techniques implemented in technologies need to be performed [14]. Moreover, the ability to analyze health trends and data on an individualized basis can encourage the user to be more self-conscious about health and fitness.

5.1 Gamification and Interactivity

“Gamification” of fitness milestones has become one method of encouraging users to link their peers to their accounts and make their data viewable. In this way they can compete with each other in tasks such as walking 20,000 steps a day, or climbing the most number of stairs in a week. Similarly on the mobile app software end, push notifications are another way to remind or encourage the user to interact with the app interface more often and frequently. The Fogg behavior model describes 3 main elements that must converge in order for there to be a change in behavior: motivation, ability, and trigger [15]. In the case of a fitness wearable device, the motivation is often a desire for better health, and a trigger to act may be facilitated by friends who also own the same wearable. Ability is defined by simplicity factors that include time, money, and physical effort, where the idea is to make a behavior simpler to accomplish.

For many fitness technology companies, much of the success of their devices is owed to the user experience and interface (UX/UI) of their mHealth app and fitness tracker, as well as the culture that has developed around fitness wearables. Ease-of-use, portability, convenience, and devices that require very little time to use are favored by consumers. Additional appeal comes from functions beyond passive data tracking, which includes nudges for time-sensitive events or activities, reminders, or options for personalized programmable prompts.

5.2 Usability

Devices that require the least amount of work to maintain and that allow for the maximum interpretable data collected are therefore ideal, e.g., long battery life or wireless syncing. A major design flaw would be the requirement of a device to be physically connected to a computer in order to sync data, and its marketability would be significantly affected even if the physical design was aesthetically desirable. Devices must excel on both the hardware and software levels. The hardware must be attractive and streamlined, such that the consumer feels good about wearing and using a device in public, and the software must be intuitive and easy to use and follow, offering simple-to-understand analytical data outputs. Admittedly, a portion of user attraction to a product is often due to creative marketing strategies and intelligent branding.

6 New Commercial Opportunities

Bridging into the more specialized mHealth app arena are health trackers such as iRhythm for the detection of cardiac arrhythmias, Neumitra for measuring the autonomic nervous system, or BodyMedia armbands that can additionally measure skin temperature and heat flux. These health trackers can potentially offer clinicians data that can be integrated into more advanced levels of healthcare. An example use case would be using skin temperature and heat flux to predict onset of a hot-and-cold flash during menopause, or to predict the onset of heat stroke. Interpretation and utilization of these collected data offers a unique challenge in the years to come, as our increasingly advanced sensors and technology will allow us to identify and monitor parameters we have not previously considered.

Technology giants such as Google X, Google's semi-secretive facility dedicated to major technological advancements, have continued to research and release various health-related products. For example, Google Glass was created in this facility and has been used by physicians to help with their daily clinical work in ways that include telemedicine, accessing patient records and charts, and during surgery to aid in recognizing anatomical structures. Other interesting innovations include a contact lens capable of detecting glucose levels in tear fluid for diabetic patients, and a project known as Baseline Study. Baseline Study analyzes medical information and uses genomics to define what a healthy human body actually is, or rather, gives a 'baseline' such that deviations from that genomic "norm" will allow a change to be detected that may suggest predisposition to a certain disease state. This data is determined through an aggregate of data from a population of anonymized individuals. The clinician would have the ability to more easily predict the onset of a major disease or condition and provide prophylactic options.

In an effort to combine many of the new mHealth apps and technology, the Smartphone Physical was curated and implemented in 2012 [16, 17]. The

Smartphone Physical includes the use of nine devices total, categorized into 3 broad groups each aimed at a unique demographic. The first group of devices, intended for everyday use by consumers, includes a scale for weight, a blood pressure cuff, and an oxygen saturation monitor. The second group, intended to reach specific patient-groups, includes an ECG, spirometer, and otoscope for ear examination. The third group, for medical providers, includes more advanced devices requiring professional training to interpret, and includes the stethoscope, ophthalmoscope, and ultrasound.

7 Data Management, Analysis, Application

Utility of collected data from a medically approved wearable will be maximized if the output can be easily reviewed and interpreted by the patient's family physician or other clinicians. Application data scientists will be key in properly parsing out large data sets such that usable conclusions, or at least strong correlations can be made between trends and diagnoses. While some sensors are able to offer relatively objective data, e.g. a glucose meter, other sensors that record spirometry, skin tone coloring for stages of bruising, or blood flow may offer more subjective correlations, and large data sets would likely have to be analyzed for statistical significance.

Preventice, as a standout example of how to do things in an informed manner, has created a remotely monitored arrhythmia tracker [18]. Physicians are given access to a 'dashboard' of data on which displays their patient's heart rhythm and other key biometric data. This type of connectivity represents a seamless adaptation of wearable-collected data into clinical decision-making. This type of data usage, however, does not involve more complex embedded algorithms that have thresholds set to help interpret the data. Instead, it continues to require the clinician's expertise to make decisions and diagnoses.

Algorithms that perform more complex analyses of collected data will become more prevalent over the next few years. Clinician input will be most critical when setting the relevant thresholds and clinical significance of individual patient data. AliveCor's FDA-approved atrial fibrillation diagnosis algorithm is a good example of point-of-collection algorithms that are used at the time of device usage to provide ECG data about the heart's current state [19, 20]. Collected information can then be shared with a healthcare professional if any unusual heart rhythms are recorded.

7.1 Processing Big Data

There will be no shortage of data collected by current and future devices, but there will be a lag phase wherein our processing of this large set of data will need to catch up to hardware development. Scientists and clinicians will need to determine how

to interpret and utilize vast amounts of collected information. Going forward, for algorithm purposes, monitoring for each disease or health condition will require the creation of ‘thresholds’ to distinguish between good and ill health. Subsequent clinical trials may need to be conducted to test the thresholds that are set. Given the complexity of the human body, co-morbidities on top of lifestyle choices will make this task of parsing out data even more complex. Machine learning in the form of using patient data to train an electronic ecosystem on what is significant will become widespread practice in mHealth app development. Hypothetically, machine learning could be used to identify the group of healthy individuals that have increasing blood pressures over 4.5 years with a given slope, and determine that this trend may result in a diagnosis of hypertension at the 5-year mark. Similar analyses could be performed for other health conditions.

Within a generation we will witness an effort to replace the need for a live, real-time clinician with a virtual “artificial intelligence” clinician for a general checkup. The ability to perform experiments such as mobile polymerase chain reaction (PCR) will give individuals the ability to self-diagnose, given that the correct primers for a disease biomarker or gene are provided. Advanced technologies could allow for complex microarrays or multivalent ligand targeting to be performed remotely and on a mobile device—potentially useful in diagnosing genetic conditions or infectious diseases. Biopsies of tumors could potentially be performed in the future, where advanced imaging technologies are able to reconcile pathological states and offer a tentative or definitive diagnosis immediately (e.g. suspected squamous or basal cell carcinoma). However, while we are making fast progress from science fiction to reality, a trained pathologist’s eye will still be the preferred method of diagnosis for the coming years.

8 Conclusions

Health-tracking wearables have become far more sophisticated over the past few years. Previously only able to measure rudimentary data such as heart rate and steps taken, they are now able to directly measure and/or estimate metrics such as blood glucose, heart rhythm, and brain activity [1].

8.1 Anticipation

Anticipation as a concept within medicine refers to prediction of a health outcome that is informed by collected physiological data. If disease or complication-onset can be anticipated, clinician and patient alike are empowered to redouble their effort to delay or prevent morbidity [5]. There may be an increased dependence by insurance companies on collecting personalized health information that may begin to drive medicine towards a world involving ‘genetic discrimination’ (not unlike in

the science fiction film *Gattaca*) [21]. It will be critical that clinicians understand that prediction does not always result in onset, just as a healthy lifestyle and behavior do not guarantee a disease-free state. We will want to stray away from examining humans as machines using machines, but instead use these technologies in ways that best augment current healthcare. Since human beings are each unique biological systems, we need to consider each individual as a unique case and not as only part of an aggregate population. We also need to be careful not to further discriminate in healthcare against those who have a predisposition for certain congenital or familial conditions, and to appreciate what makes us organic and distinctive as humans. Part of the human condition involves illnesses and diseases, and new technologies should first aim to alleviate these health conditions before considering the potential creation of super-humans or cyborgs.

8.2 Anticipating New Challenges

Despite the benefits that medical wearables have, there are still major challenges to overcome. Given the diverse depth of collected information, where will wearables fit in FDA guidelines? How will data be resolved and interpreted? How will we determine patient-specific thresholds for various diagnoses and conditions, and can they be generalized to the population? How can we ensure we reach the demographic who will benefit the most from wearable technology? Finally, devices will need to remain portable and simple to use in order to drive widespread market adoption.

Regardless of the challenges on the horizon, medical wearables and mHealth applications objectively provide unique, long-term insight into a patient's health, and will undoubtedly continue to improve patient outcomes as they become more and more sophisticated. The key lies in balancing the use of newer technologies between modern and traditional healthcare. It is important to recognize that the use of technologies will fall at different ends of the spectrum according to their applications and utilization in different medical fields. Some technologies will only be used to further verify a diagnosis or aid in creating one, while other technologies may provide the gold standard for diagnosis or treatment. Certain clinical occupations may be eventually replaced by advanced computer programs and devices—but there is a balance there still. Consider medical imaging diagnostics: someday a machine may be better able to discern minor differences on imaging than a human clinician, but a physician's skill in parsing subtle clues from a patient's history with findings on imaging to weave a diagnosis cannot easily be replaced. Nevertheless, new technologies can augment and improve the lives of patients and general consumers, and have the potential to allow for better, cheaper, and more accurate diagnoses.

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