Mobile Health and Preventive Medicine

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KEYWORDS

• Mobile health • Preventive medicine • Prevention • Digital medicine • Sensors
• Activity trackers • Electrocardiogram monitors • Continuous glucose monitoring

KEY POINTS

- The development of wearable devices that provide health-related data (mobile health or mHealth) relevant to prevention has a long history, starting with pedometers, with roots in centuries past.
- Technological advances, accelerated by smartphones and smartwatches, have brought a wide array of mHealth, modalities to the fingertips of millions, with many more devices providing data of all types to come.
- Research on the application of mHealth to preventive medicine is most mature for devices including activity trackers, electrocardiogram monitors, and continuous glucose monitors that are highlighted in this article.
- Lessons learned include the need for continued integration of mHealth technologies, including those related to behavior change, to maximize its impact on prevention, as the concepts of digital health coaching and hospital-at-home advance.

Since the introduction of wearable devices that generate personal health data, the potential for their use in prevention has been met with great enthusiasm. From the introduction of wrist-worn devices ushered in by the Fitbit craze of the 2010s–along with the 10,000 steps mantra—to the more recent advent of the mobile electrocardiogram (ECG), continuous glucose monitors, and an ever-growing list of other devices, preventive medicine-related applications have expanded beyond personal fitness to early detection and disease management. At the same time, technology has continued to advance, creating devices that are increasingly smaller, less obtrusive and more accurate. Although the term "mobile" in mobile health (mHealth) once referred to devices that could theoretically be used at home—such as Holter monitors and ambulatory blood pressure cuffs–mHealth now affords convenient and continuous monitoring of various physiologic processes passively, requiring little effort or inconvenience to the user.

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For all the advancements and proliferation of personal wearable devices delivering health-related data, challenges remain for mHealth to have a large-scale impact on personal and population health. The availability of data flowing from these devices does not always translate into their use for guiding healthful behavior. There is also a significant lag between the often splashy market introduction of these devices and the development of a sufficient evidence base on their effectiveness and best strategies for their use in impacting health outcomes. Use of these data by health care providers has also lagged, with the literature mostly limited to feasibility studies to date.

In this review, three of the currently most widely used and studied mHealth technologies are highlighted in the major domains of preventive medicine as examples of the realized potential, the common challenges in their effective application in prevention, and the new measures of health and disease they are introducing. The many smart sensors along with the accompanying artificial intelligence (AI) that are in various stages of development are also previewed with their potential to further transform mHealth and preventive medicine to improve human health.

PRIMARY PREVENTION: ACTIVITY TRACKERS TO INCREASE PHYSICAL FITNESS FOR PEOPLE OF ALL AGES AND HEALTH STATUS

A Brief History

The personal activity tracker has one of the longest histories as a prototypic mHealth device, beginning with the pedometer, a purely mechanical device for counting steps. One of the earliest of these, designed by Leonardo da Vinci, involved a lever attached to the thigh, with later versions using a string attached to the knee. By the 1820s, Swiss watchmakers had developed mechanisms that could be included in watch-sized devices using spring-suspended lever arms to detect motion.[1] As refinements continued, the daily goal of 10,000 steps originated with the Japanese pedometer maker Yamasa in 1965; an electronic pedometer with a digital display came from the same company 1990. With the introduction of the first wrist-worn devices by companies such as Fitbit, Jawbone, and Garmin, among many others in 2009, the popularity of activity tracking (along with the 10,000 step mantra), skyrocketed and soon the technology was available in smartphones and smartwatches.

As one of the oldest examples of mHealth, these devices also have the longest track record of study, with the expected health benefits based on the simple premise that activity measured by the device translates into energy expenditure, the tracking of which can promote increased activity, leading to fitness and weight loss. Given the numerous studies that have been performed on each aspect of that premise, a clear picture of the effects of these devices is available.

Device Accuracy and Impact in Randomized Controlled Trials

Numerous studies have shown the accuracy of these devices is highest for step counts, with much more variability within and between devices in measures of distance, physical activity level, and energy expenditure.[2–5] Despite the imprecision of its translation into energy expenditure, the measure of steps, which represent a major form of daily physical activity, has been considered useful in promoting that activity. Some of the cited advantages of the step count as such a measure of physical activity are that they

- Are objective, intuitive, and easy to understand for laypeople and translatable into motivational and public health messages
- Are useful for categorizing people into less active and more active categories

Have strong associations with physical health variables[1]

In fact, multiple randomized controlled trials (RCTs) have found that they influence activity levels and some physiological measures in a positive direction in various populations of all ages and levels of health. A recent comprehensive umbrella review encompassing systematic reviews and meta-analyses representing a total of 390 RCTs including nearly 164,000 participants across all age groups summarized various outcomes.[6] These studies showed that use of wearable activity trackers significantly increased physical activity, with effect sizes ranging from 0.3 to 0.6, translating into an increase of 1800 steps per day, 40 minutes per day of walking time, and 6 minutes per day of moderate-to-vigorous physical activity. Increases in physical activity were found to occur in all age groups, from children to older adults, and among groups with different levels of baseline health, including healthy participants, as well as those with diabetes, cardiovascular disease, obesity, Alzheimer disease and other conditions.

Activity trackers have also been shown to have positive, although generally smaller, effects in studies with physiological outcomes. The strongest evidence was seen for weight loss, of 0.5 to 1.5 kg over time of use, decrease in waist circumference of around 1.5 cm, decreased body mass index (BMI) of 0.5 kg/m^2, and increased aerobic capacity measured by maximum oxygen consumption (VO_2 max) of 1.7 mL/kg/min.[6] Decreases in systolic blood pressure and heart rate were also found by most studies included in the meta-analyses, but with less consistency and a lesser effect. Studies on effects of activity tracker use on diastolic blood pressure, cholesterol, triglycerides, hemoglobin A1C (A1C), and fasting glucose reported effects that were not statistically significant. Studies on the duration of effects on increasing physical activity showed strong effects maintained over 4 to 6 months, with diminished but still significant effects as far out as 4 years in 1 study. Effects on body composition were less robust or long lasting. Results of studies regarding psychosocial effects and quality of life have been mostly inconclusive.[6–10]

Toward Increasing Real-World Impact

The overall conclusions from RCTs involving usage of activity trackers from several months to several years, are that they are an effective intervention to increase physical activity, regardless of how accurate the measures, with resultant positive effects of weight loss, decreased BMI, and increased VO_2 max, with less effect on other physiologic parameters. Study participants with illnesses appeared to be more motivated by activity tracker interventions overall.[6]

The decrease in effect in promoting activity and in use of the devices in general over time by individuals observed even in the relatively controlled setting of these clinical trials, however, begs the question of what effect these devices have in the real-world setting. Although uptake of commercial products has been robust, abandonment of these devices is common, limiting their potential for lasting effects on personal health and on a population level as evidenced by reports that many devices have failed to achieve sustained user engagement.[11–13] Indeed, research on acceptance and adoption of activity trackers indicates their influence on behavior is mediated by many social, cognitive, and psychological factors, involving unique life priorities, personal circumstances, and personalities, and resulting in outcomes ranging from abandonment to strong acceptance.[11,14,15]

Thus, it has been concluded that these devices are best approached as facilitators and not drivers of behavior change in and of themselves and that their use is not one-size-fits-all. Designs and behavior change elements will continue to need to be further developed and incorporated to optimize the effect of activity trackers in promoting

personal fitness that can have impact on a population level. Features such as goal-based gamification, social support, and customized output should continue to be explored in the context of the goals of the individual. The reviewed literature suggests that wearable activity trackers targeting patients with chronic illness, for example, may be most effective when integrated into programs that recommend a customized regimen and specific levels of physical activities.[11,16,17] In contrast, activity tracking targeting health office workers with sedentary behavior, as another example, may be more effective as a reminder for the user to engage in physical activity at regular intervals. Other potential solutions include alternative forms of data visualization and textual cues and designs that take users' past history into account.[11,18]

SECONDARY PREVENTION: ELECTROCARDIOGRAM DEVICES FOR EARLY DETECTION OF ATRIAL FIBRILLATION, THE MOST COMMON ARRHYTHMIA IN PEOPLE, ESPECIALLY OLDER ADULTS

Early Development

Measurement of the electrical activity of the heart is based on a relatively simple concept involving placement of electrodes on the skin at at least 2 separate points. Beginning with the first ECG machine, which was large enough to fill a room and was built in 1902 by Willem Einthoven, who a had described the wave forms of the heart's electrical activity a decade earlier, the quest to build machines of decreasing size had begun. The first portable ECG machine was developed in 1928 and weighed 20 kg. Subsequent development of transistors and ultimately microchips led to ever increasing portability.

The first wearable ECG device in the form of the Holter monitor was introduced in 1957, allowing continuous readings in ambulatory settings typically over 24 hours as a diagnostic tool. Eventually the wearable ECG would be reduced to the size of a band-aid that could be worn on the chest for up to 14 days. At the same time, devices that could be used for intermittent ECG recordings at home emerged, with AliveCor's Kardia device being one of the earliest entering the consumer market and receiving US Food and Drug Administration (FDA) approval. With the introduction of the Apple Watch and other smartwatches, this technology became truly portable, enabling ECG recordings to be recorded at the wrist by placing a finger on the electrode-containing crown of the watch.

Most of these technologies involve single lead recordings, which for many ECG uses are inferior to the 12-lead standard in medical settings. However, in both formats–continuous and intermittent recordings—they have been found accurate for detecting atrial fibrillation (AF) in comparison with the conventional 12-lead ECG. AF is an important public health target given that it is the most common arrhythmia, particularly among older adults, and its early detection and treatment are important in preventing strokes.

With the current standard of care for screening for AF being palpation to detect an irregular pulse, the use of mHealth for AF detection in fact predated the development of ECG devices. Heart rate monitoring with devices using photo-plethysmography (PPG), such as the Fitbit, led to AF detection algorithms with high sensitivity and specificity.[19] Given that ECG is the gold standard for detection of AF, the newer wrist worn ECG devices have not unexpectedly shown high sensitivity and specificity. In a meta-analysis, sensitivity of wrist worn ECG devices in individuals known to have AF was 96% overall, with a specificity among individuals in normal sinus rhythm of 98%.[20]

Devices providing continuous recordings have demonstrated even greater sensitivity, allowing detection of AF of shorter duration and lower burden, as measured

as percent of time a person is in AF. In the mSToPS study involving the Zio patch, a continuous ECG device storing recordings over a 2-week period, for example, the longest episode of AF detected in individuals during a total of 2 periods (28 days) of monitoring was less than 5 minutes in 7.2% of participants, 5 minutes to 6 hours in 55%, 6 to 24 hours in 25%, and more than 24 hours in only 13% participants.[21] Numbers were similar in SCREEN-AF, another trial of continuous monitoring.[22]

Although, by definition, AF detected on ECG of any duration is AF, it is not yet clear what the associated risks of stroke with the low-duration/low-burden AF are and what the appropriate management should be (ie, what additional monitoring or what threshold for initiating treatment should be). This is a particularly important question given that treatment of AF for prevention of stroke can also come significant potential harms. Anticoagulant therapy, the primary intervention for stroke prevention, is associated with a substantial risk of bleeding, and pharmacologic, surgical, endovascular (eg, ablation), or combined treatments to control heart rhythm or heart rate can also cause harm. In addition, ECG may detect other abnormalities (either true- or false-positive results) that can lead to further testing and treatments that have further potential for harm.

The 2022 USPSTF recommendation for screening for AF reflects this uncertainty and concern for the benefit-to-harm ratio.[23,24] Noting that it considers opportunistic pulse palpation to be routine or usual care for AF detection, the task force concluded that there was currently insufficient evidence to recommend screening for AF with devices, citing that "the stroke risk associated with subclinical AF, particularly subclinical AF of shorter duration (less than several to 24 hours) or lower burden (amount or percentage of time spent in AF), as might be detected by some screening approaches, is uncertain, and the duration of subclinical AF that might warrant anticoagulant therapy is unclear."[24] Thus, the task force concluded, for the output of these devices to be truly beneficial to users as a screening tool for AF, much greater understanding of the risk of stroke associated with AF detected by these devices and that risk varies with duration and burden of AF as well as the potential benefit anticoagulation therapy among persons with subclinical AF must be demonstrated in subsequent studies.[23,24]

TERTIARY PREVENTION: CONTINUOUS GLUCOSE MONITORS FOR IMPROVED GLYCEMIC CONTROL IN PEOPLE WITH DIABETES

Glycemic control is a cornerstone of diabetes management, with the goal of preventing diabetic complications such as such as retinal, kidney and nerve damage that ultimately can result in blindness, need for dialysis, and limb amputations. Traditional methods of assessing glycemic control have been through daily self-monitoring of blood glucose (SMBG) and tracking of long-term A1C levels. Adherence to the rigid SMBG regimens required to adjust therapy, diet, and activity adequately to delay the onset and slow the progression of diabetic complications, however, is difficult, typically requiring 4 to 10 finger sticks daily. Continuous glucose monitoring (CGM) technology has been heralded as having the potential to revolutionize diabetes care by allowing greater fine-tuning of glycemic control. This is based on the idea that by providing real-time data passively collected by an implanted electrode, CGM enables more timely therapeutic interventions and changes in lifestyle or dietary intake to enhance glycemic control, with accompanying increase in quality of life because of the reduced need for finger sticks.

The basic technology underlying CGM is an enzyme-based electrode, which is inserted transdermally to measure glucose levels in interstitial fluid. Backed by

extensive research and development that started in the early 1960s, the first marketable implantable glucose sensors were introduced in 1999.[25,26] These first sensors, however, proved to have limited clinical utility. They were bulky and unreliable, exhibiting significant drift in sensitivity over the initial FDA-approved 3-day implantation period, and required calibration with finger stick glucose every 6 to 12 hours. These limitations, as well as the fact that readings were not available in real time and had to be downloaded by medical professionals, diminished enthusiasm for these devices early on, and their use was relegated to primarily a supplement to SMBG.[26] In the intervening years, real-time glucose readings viewable by users on their own mobile devices with programmable high and low glucose alerts have become the state-of-the-art. Advances in sensor chemistry, sensor coatings, and improved implantation techniques have also contributed to improved biocompatibility, reducing the foreign body response and allowing extension of device lifespan from 3 days to 14 days. In the mid-2010s, flash glucose monitoring systems entered the market, allowing users to scan the receiver over the sensor to obtain their current glucose value and glucose trends and eliminated the need for repeated calibrations.

To date, uptake of the devices has been greatest among patients with type 1 diabetes, but their use among the much larger population of patients with type 2 diabetes is expected to grow rapidly. A 2021 market report estimated that of the 2.4 million CGM users in the United States at that time, up to 70% had type 1 diabetes, and only 3% to 4% of the US type 2 diabetes population was using the devices.[27] With more than 37 million persons with diabetes in the United States, growth in use is expected to increase, particularly as out-of-pocket costs–which can be hundreds of dollars per month–go down and insurance coverage increases.

RCTs comparing glycemic control with CGM versus usual care have been conducted in multiple clinical populations including persons with both type 1 and type 2 diabetes. Meta-analyses of these trials found use of CGM for periods ranging from 12 to 36 weeks was associated with modest reductions in A1C in patients with either type of diabetes, with real-time CGM leading to larger improvements in A1C compared with flash CGM.[28,29] Decreases in A1C levels in CGM versus usual care over the relatively short time periods of the studies were on the order of 0.2% to 0.3% greater for the CGM group.

Improvement in glycemic control as reflected by the decreases in A1C in participants on regimens including adjustable insulin and other therapies involved, at least in part, better fine-tuning of these therapies. However, a relatively large trial published in 2021 focused on CGM use in adults with type 2 diabetes treated only with basal insulin at baseline only and no prandial insulin showed a similar difference in mean change in A1C from baseline between CGM and usual care of −0.4% after 8 months.[30] This occurred without significant changes in amount of insulin or other treatments used, indicating that the effect involved primarily lifestyle changes in response to the glucose readings.

CGM is also providing new measures of glycemic control with the CGM-specific metric of time in range (TIR)—measured as the percent of time continuous readings are in the range of 70 to 180 mg/dL—included American Diabetes Association's recommendations for assessment of glycemic control along with A1C for tertiary prevention.[31] The document cites the association of TIR with risk of microvascular complications and published data suggesting a strong correlation between TIR and A1C as the basis of these recommendations, with a goal of 70% TIR aligning with an A1C of approximately 7%. Direct evidence of CGM's effect on long-term macrovascular outcomes is not as well established.

Continuous Glucose Monitoring in Secondary and Primary Prevention?

The findings for CGM in participants with diabetes have several implications for prevention beyond improved disease management for people with diabetes. By enabling users without diabetes to track the effects of dietary choices and physical activity on glucose levels, including spikes and prolonged periods of elevated glucose that may be triggered differently among individuals, CGM has potential for use in primary prevention of diabetes, especially among those with prediabetes. Earlier diagnosis of prediabetes and diabetes through measures such as TIR are also possible.

Beyond Continuous Glucose Monitoring: Sampling Interstitial and Other Fluids

The potential for wearable technologies involving use of electrodes to measure biochemicals in body fluids extends CGM. Sensors for DNA, for example, are being developed that will allow detection of infectious agents and cancer biomarkers applicable to all levels of preventive medicine.[32] Although the potential is also present for measurement of many other blood chemistries, it remains to be determined whether the accuracy of these methods will ever be sufficient to rival the well-established assays and efficient processes of the current system of laboratory analysis.[33]

OTHER DEVICES FOR USE TO PREVENT DISEASE AND IMPROVE HEALTH

Sleep

Activity trackers are useful not only for measuring activity, but also measuring inactivity, which in extended periods correlates with sleep. Wearing devices during sleep requires a higher level of wearability, leading to the development of rings and patches in attempt to find devices, including smart rings, that are even less obtrusive, than those worn at the wrist. Applications include primary prevention as an indicator for to promote more and better quality sleep, an important lifestyle pillar for health. Studies comparing activity tracker sleep metrics with polysomnograms have found that total sleep time and sleep efficiency are overestimated by these devices, while wake after sleep onset, an important measure of sleep quality, is underestimated.[34,35] Studies on whether availability of these data actually promote better or longer sleep are largely lacking. More sophisticated devices that integrate data including heart rate and use more sensitive motion detectors are now being used to assess time in different stages of sleep.[36] With this technology, the devices could be used in place of the polysomnogram as a diagnostic tool, allowing earlier diagnosis of sleep disorders and even for delivering the intervention. For example, these devices are being investigated for treating insomnia through sleep retraining involving repeated awakenings, as detected by the device, shortly after initiating sleep.[37–40]

Harmful Environmental Exposures

Measurement of personal exposures to environmental hazards has been another early area of mHealth, beginning with the wearing of badges to measure exposure to radiation among laboratory workers and others with potential exposures. Although these devices did not provide real-time readings, the data were actionable for primary prevention, indicating the need to limit and avoid exposures according to health guidelines. Similarly, wearable devices involving silicone wristbands combined with high throughput chemical analysis platforms capable of detecting harmful chemical exposures, including pollutants and even infectious agents, are now being developed.[41–43] The challenge with these technologies to date for quantitative exposure assessment mostly lies with the inherent complexity in calibrating them.[41]

Other Technologies on the Horizon for Health-Related Decision-Making

Devices designed to provide data for health-related decision making are also providing novel types of data not previously used in medicine, including preventive medicine. These include vocal biomarkers, including acoustic sensors for detection of cough and a smartphone-based device for detection of tonic-clonic seizures, which, combined with AI, has the ability to predict their occurrence.[33]

As reviewed by Xu and colleagues, advances are also being made in how and where sensors can be placed. Development of softer, skin-interfacing materials and continued progress in miniaturization allow placement of devices on fingernails, earlobes, and in the nose, to measure blood oxygenation and heart rate.[33] Other devices are being developed for measurement of substances in sweat and tears, including sensors in contact lenses.[33]

INTEGRATION OF MULTIPLE DEVICES/MODALITIES FOR HEALTH CARE MANAGEMENT AND PREVENTION IN PEOPLE AND POPULATIONS

While this article described the use of individual types of devices, integration of the data streams from multiple sensors representing multiple modalities holds even more promise. For example, wearable devices are part of the expansive vision of the hospital-at-home concept, wherein multiple sensors deliver data to remote patient monitoring platforms that, aided by machine learning algorithms, can guide treatment decisions by health care professionals in real time. Although the concept received a boost in interest during the coronavirus disease 2019 (COVID-19) pandemic and has been studied for use in various conditions, a recent meta-analysis reported that the use of wearables was not as common as expected in the approaches with studies published to date.[44]

Integration of multiple modalities from mHealth devices is also a concept with potential at the personal primary prevention level. One of the earliest examples of successfully using a person's "physiome" as measured by heart rate, skin temperature, blood oxygen levels, and physical activity and integrated with AI algorithms was reported by Li and colleagues in 2017,[45] demonstrating the ability to detect a Lyme disease infection before overt signs and symptoms were present. The signal prompted the individual to seek medical care and resulted in earlier diagnosis and application of effective treatment than would have been likely without the sensor data.

At the population level, aggregating multiple signals from multiple modalities from multiple people has provided a new vision of precision public health for detection of epidemics among other uses.[46–48]

Meeting Challenges in the Future

For these visions of improved personal and public health through mHealth to be realized, challenges must be addressed, including the transforming or translating of the available data to meaningful behavior changes for individuals and populations. But new technologies are also likely to incorporate solutions to this in the form of digital health coaches. Given the current state of AI, It is not hard to envision a Siri- or Alexa-style coach who is able to integrate personal health data flowing from myriad devices, prioritize actionable data, determine the most healthful responses, and interact in a personable way, answering questions like "What's the most important thing I should do for my health today?" or "How's my heart doing?" as easily as these digital assistants answer questions like "Who won the last Super Bowl?"

Another challenge that has grown along with the availability of these data is the problem of maintaining privacy, which is particularly important for health-related

data. Studies have shown this to be a concern of participants in studies of biometric monitoring devices.[49] A recent article by the National Academy of Medicine underscored these concerns, arguing that transparency and consent for consumers and patients regarding data sharing, agency, and privacy within and across platforms and stakeholders must be simplified and standardized and that "privacy and security risks with big data and AI require special attention."[50]

SUMMARY

mHealth has long been available in some form, starting with activity trackers dating from the Renaissance. Modern technology has resulted in an ever-increasing number of wearable devices that can generate various health-related data. Some of the most mature of these devices to date have been successfully utilized in primary, secondary, and tertiary prevention and combinations thereof. From the examples of wearable activity trackers, ECG monitors, and CGM, the potential effects on health and the need for future research to identify and address the challenges—including the need for incorporating effective behavior change interventions, successfully integrating data from multiple sensors, and determining the long-term health effects of their use—are clear.

In the meantime, clinical use of these devices to date has been most prominent in tertiary prevention hospital-at-home settings designed to allow remote monitoring and treatment. Increased use of mHealth in combination with telemedicine can be expected as ease of use and connectivity to health systems increase, enabling further collaboration between health care providers and patients in optimizing care, including preventive care at all levels.

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