Wave of Wearables

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Wave of Wearables

Clinical Management of Patients and the Future of Connected Medicine

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KEYWORDS

• Wearable electronic devices • Biosensors • Diagnostics • Drug delivery • Personalized medicine • Telemedicine • Health monitoring

KEY POINTS

- Technologic advancement in health care continues to drive the expansion of health data. These data are increasingly being collected by devices called wearables.
- Existing literature focusing on wearables describe applications of novel technologies but lack outcomes data. Additional large-scale clinical trials are needed to show whether wearables are able to improve health outcomes or decrease health care costs.
- Efforts to reduce health care costs, increase care quality, and improve clinician efficiency are driving the development and study of wearables in medicine.
- The widespread use of wearables in clinical practice will depend on data integration with the electronic health record and physician workflow.

INTRODUCTION

Modern health care depends on technology across the care continuum. Value-based care incentives are facilitating a further expansion into consumer health. This process has been accompanied by a rapid expansion of health data, and the corresponding development of clinical informatics as a discipline dedicated to organizing, understanding, and using data to improve health care and patient outcomes.[1,2]

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The ubiquity of digital health increases opportunities to capture patient information derived outside the walls of a medical facility. The personal health record (PHR) is one way of integrating health data for individual patients across a multitude of environments.[3]

An increasingly prevalent source of data is the information generated by the subset of consumer technology known as wearable devices.[4] Broadly defined, wearable devices are specialized devices comprising a specialized sensor (or sensors) with a computer at a scale small enough to be worn or carried by individuals. This functionality may include the ability to measure or sense a certain physical parameter, or to provide a certain input or information to the user.[5] Many wearable devices feature the ability to connect wirelessly to other devices, facilitating the transfer and exchange of information and placing these devices in a category of technology known as the Internet of Things (IoT).[6]

This article provides a review of the clinical application, utility, or potential offered by a variety of commercially available wearable devices and technologies across several medical specialties in order to show the current and coming impact of these tools on the practice of medicine. This article excludes devices from the related, but more restricted, collection of medical devices ordered and prescribed under the direction of a clinician, such as a cardiac pacemaker. The latter category, designed for explicit therapeutic purposes, is required to engage in regulatory processes with the US Food and Drug Administration (FDA) in order to arrive to market,[7] whereas regulation for consumer devices offering a broad suite of functionality, both health and non–health related, is not as mature.[8] Although most wearable devices are currently marketed with the intention of being used by the consumer for largely self-directed activities, this article also discusses the use of these technologies in the setting of clinician-patient co-management and use.

USABILITY OF WEARABLE DEVICES

Literature focusing on the clinical impact and management of patients with wearable devices is limited. Peer-reviewed reports of novel applications of individual technologies outnumber clinical trials showing improved patient outcomes. Many investigators predict that the widespread adoption of this technology could lower health care costs through disease prevention and longitudinal care, although cost savings attributed to focused implementation of wearables have not been widely described.[9–12] Levine[13] proposes with several case studies that the technical simplicity, low production costs, and near ubiquity of wearable devices offer a particular potential for improving health in high-poverty and vulnerable populations.

Cross-sectional survey studies of primary care providers suggest they perceive benefits and trust wearable sensors and devices.[14,15] Patients also express openness to incorporating wearable sensors as part of health monitoring protocols, according to similarly constructed survey studies. However, consumers report opposition to wearable devices that are disruptive to daily life, or seen to replace traditional care provided by clinical professionals.[16] Several studies examine the aging geriatric population as a particular group that may benefit from an increased use of wearable technologies for medication management, prevention of falls, and monitoring of chronic disease,[17] although a relative decrease in ability to adopt new technology relative to younger generations has been cited as a potential barrier.[18]

Electronic health record (EHR) integration of wearable data is clearly advantageous to provider workflow.[19,20] Ryu and colleagues[21] developed a mobile application that received data from a variety of wearable sensors measuring activity and sleep data, and forwarded information into electronic medical record (EMR) platforms that clinicians then used to provide lifestyle and health counseling recommendations to target outcomes related to nutrition and obesity. Weenk and colleagues[22] presented a pilot study featuring wireless remote monitoring wearable devices collecting vital signs for patients in the inpatient setting, with the hypothesis that the continuous monitoring functionality represented an improvement compared with intermittent provider checks, which may contribute to earlier detection of deleterious changes in vital signs. The study focused on the ViSi Mobile (Sotera Wireless, San Diego, CA) and HealthPatch (Vital Connect, San Jose, CA) systems, capable of measuring and recording electrocardiogram (ECG), heart rate, respiratory rate, temperature, blood pressure, and oxygen saturation, and ECG, heart rate, respiratory rate, temperature, fall detection, and activity metrics, respectively. Indicators of patient and nurse acceptance of these monitoring systems were largely favorable. Lack of correlation between data reported by the devices and traditional bedside patient measurements by nurses was reported and attributed to measurement artifact and unreliable connectivity. Joshi and colleagues[23] reviewed a variety of similar patient vital monitoring platforms and provided additional commentary on considerations for the design of future trials.

The emergence of interoperable PHR platforms developed by the same producers of devices with health functionality suggests a trend toward comprehensive ecosystems in which consumer patients have increased accessibility to their personal health information, which preliminary data suggest may improve patient engagement with their health care providers.[24] Work using machine learning to analyze longitudinal data uploaded to EMRs from health care IoT devices has been described.[25] Future work developing and executing large systematic trials testing population health benefits for patients receiving care via increasingly connected health information systems is needed.

Although the study of system-based effects of wearables on health and cost outcomes remains embryonic, the proliferation of individual technologies for niche populations and specialties provides a broad indication of how devices are currently being used by consumers to assess elements of their health and by clinicians to enhance patient management. This article reviews the implementation of wearable devices across various specialties and medical education practices, with an emphasis on those technologies made available direct to consumers.

DIRECT TO CONSUMER

The most common direct-to-consumer wearable device is the smartphone. With an installation base numbering in the billions of devices, smartphones provide one of the most promising platforms for mobile health interventions, and software applications pledging to improve or track metrics of health are common and widely popular. From activity trackers that measure number of steps, calories burned, or hours sitting a day to telemedicine platforms that allow users to engage in video consultations for minor complaints, health-based apps promise easier weight loss, better sleep, and decreased primary care costs. However, a paucity of literature exists examining these claims outside the context of clinical research studies with additional interventions and protocols. It remains unclear whether outcomes or economics are significantly affected by the use of the consumer independent of clinical oversight or management.[26] Firmer evidence exists for using mobile devices as a means of measuring clinical parameters.

Cardiology

Remote monitoring of patient physiology has been a key tool in the management of many cardiac conditions. Portable technology for the recording of the ECG has existed for more than 70 years,[27] and modern Holter monitors are mainstays in the work-up of new-onset syncopal episodes or arrhythmias, although the relative bulk and obtrusiveness of monitoring devices raise concerns for patient satisfaction and compliance.[28] Modern consumer-wearable devices offer an opportunity to capture some of the clinically relevant information with improved form factors and expansive data storage and transmission capabilities.[29]

The accuracy of heart rate monitoring by commercially available wearables has been assessed, with heart rate measurement at a state of rest more reliable than during various modalities of exercise, although in each setting the photoplethysmography that measures the absorption of light during and after pulsations of blood through skin has been found to be uniformly less accurate than traditional electrophysiologic monitoring.[30] Implementation of specialized computer algorithms has been used to identify dysrhythmias. Tison and colleagues[31] described “teaching” a specialized computer “neural network” to identify variances in heart rate among nearly 10,000 patients enrolling in a remote cohort study consistent with the physiology of atrial fibrillation (AF), as measured by Apple Watch photoplethysmography. The Apple Watch heart rate–based detection method was also less sensitive and specific compared with standard 12-lead ECG. This effect is likely not clinically significant when assessing for basic dysrhythmias such as AF, but may lead to missed abnormalities or misdiagnosis of more subtle abnormalities.

Turakhia and colleagues[32] conducted a prospective study enrolling more than 400,000 patients using the Apple Watch device. In addition to monitoring for heart rate irregularities consistent with AF by way of a specialized pulse-detection algorithm, the study was designed to determine whether notifications from the device resulted in increased follow-up with medical providers and featured a specialized app developed for the Apple Watch that facilitated the enrollment of participants into the study. Once enrolled, patients detected to have multiple episodes of irregular heart rates were given a specialized alert that then engaged a video conference call with a study physician who conducted further history taking and determined whether the patients were eligible for the next step in the study, which entailed patients being mailed a single-channel ambulatory ECG detection device. Additional episodes of potential AF or other arrhythmias detected by both the pulse detection algorithm and ECG device resulted in study physicians recommending patients seek direct care with their primary providers. Findings presented at the American Cardiology Conference in 2019 noted that 0.5% of study participants received app-based notification of pulse irregularity, and that 34% of these patients later using the portable ECG monitor were found to have episodes of AF. Of the patients who were originally informed by the app of arrhythmias, 54% sought follow-up care with non-study medical providers.[33]

In addition to heart rate detection, handheld devices capable of recording ECGs have been described since the 1990s,[34] and several platforms harness the modern smartphones to facilitate ECG procurement, storage, and transmission. The KardiaMobile product line (AliveCor, San Francisco, CA) consists of specialized cases for a variety of smartphones and tablets that contain electrodes capable of obtaining a single-lead ECG.[35] The products have been cleared by the FDA for consumer use to record and monitor for basic dysrhythmias and have been used in studies screening for AF, prolonged corrected QT intervals, and pediatric tachyarrhythmias.[36–39] The arrival of built-in ECG functionality in the Apple Watch Series 4 may further increase the sensitivity of these devices for cardiac rhythm analysis, although, with only 2 electrodes providing a single lead, it is clear that the traditional 12-lead ECG will remain the gold standard of electrophysiologic analysis, at least for now.[40]

Bariatric Medicine

Weight management has been an attractive target for a variety of mobile applications, wearable devices, and digital consumer technologies. Multiple survey studies have shown that overweight and obese patients across different populations are open to the incorporation of activity trackers and smartphone apps into preexisting fitness and diet routines. Wang and colleagues[41] performed a small trial with 69 overweight and obese adults who were given FitBit One activity trackers to monitor daily exercise, with half the group randomized to additionally receive short message service (SMS) text messages promoting exercise via mobile phones. Participants were found to have marginal increases of less than 5 minutes in daily activity with the addition of activity trackers compared with their baseline, and no additional benefit was detected in the SMS group.[41] Jakicic and colleagues[42] conducted a larger randomized clinical trial with 471 subjects between the ages of 18 and 35 years with body mass indexes ranging from 25 to 40 and who were initially assigned specialized diets, exercise plans, and behavioral coaching with group counseling. Six months into the study, subjects gained access to a Web site with further weight loss information, specialized SMS messages, and phone-based counseling sessions. A randomized subset was then additionally given a wearable activity tracker interfacing with a Web-based application that gave feedback on exercise and allowed the logging of caloric intake. The subgroup with the wearable intervention had less weight loss than the comparable nonwearable group. A study by Finkelstein and colleagues[43] combining the use of activity trackers with cash or charitable donation exercise incentives was also unable to show any tangible health benefits from their use. The literature pertaining to the use of activity trackers and mobile applications for weight loss practices suggests that the utility may be optimized when designed to execute a previously constructed evidence-based program.[44]

Endocrinology

The effective management of diabetes mellitus (DM) requires significant effort and attention from patients to track, understand, and act on a vast range of data (ranging from blood glucose levels, to insulin dosing, to complex nutritional information). Competence with, and adherence to, therapeutic regimens has been associated with improved glycemic control. The potential of software and wearables to acquire and organize personal DM information has attracted interest in researchers seeking to enhance the ability of patients and clinicians to actively manage the condition.

An SMS-based diabetes support platform implemented in a large employer-based health plan in Chicago was associated with study participants reporting an increase in blood glucose monitoring, diabetic foot examinations, and diabetic medication compliance, with a subsequent decrease in hemoglobin A1c (HbA1c) measurements and number and cost of outpatient clinic appointments.[45] A proliferation of mobile applications focusing on diabetes and related concerns have accompanied the exponential increase in smartphone adoption and use, many of which target American Diabetes Association and American Association of Clinical Endocrinologists practice guidelines and standards of care for the management of diabetes.[46] An early randomized pilot study with patients with type II DM found that the use of a cell phone software program providing medication reminders, blood glucose tracking, and instructions for treatment of high or low blood glucose levels was associated with a larger decrease in HbA1c levels compared with the control group.[47] Larger, more recent studies indicate that widespread adoption of evidence-based glycemic control apps may provide similar sustained benefits across the health care ecosystem.[48,49]

DEVICES USED OR MANAGED BY CLINICIANS

In addition to direct-to-consumer technologies, wearable devices offer the potential to change how clinicians practice and manage patients in both the inpatient and outpatient settings. The following discussion focuses on devices used to improve access to consultant opinions, provide alternate procedural functionality, and facilitate organization of clinical and personal health data among several specialties.

Cardiology

In addition to electrophysiology, application of wearable devices in the interventional cardiology space has been described. Duong and colleagues[50] reported on the use of Google Glass as a telemedicine solution for the remote interpretation of coronary angiogram, and Opolski and colleagues[51] developed a virtual reality system displayed on a wearable computer that projected three-dimensional computed tomographic angiography of occluded coronary arteries to assist in percutaneous revascularization.

Dermatology

As with many medical subspecialties, uneven geographic distribution, a limited number of training positions, and an aging population have combined to create a shortage of dermatologists. Telemedicine has been proposed as a solution to rectify access disparities, and wearable devices may assist in facilitating remote care. Studies have described using the hands-free real-time video calling and image capture functionality of Google Glass to allow teleconference with dermatologists in the setting of micrographic surgery and allergy consultations.

Emergency Medicine

The use of wearables by emergency physicians has been well documented. Chai and colleagues[52] described using a version of the Google Glass for emergency department dermatology consultations, and several researchers have identified the portable, compact, and hands-free nature of the technology as being ideal for supporting first responders in disaster situations.[53]

Particular focus has been applied to Google Glass as a platform for teletoxicology evaluations. Chai and colleagues[54] additionally reported a series of 18 toxicology consultations conducted via Google Glass, with nearly 90% of the video calls featuring a high enough image resolution and minimal latency to facilitate clinical decision making. More than half of the consultations resulted in a change in management based on the transmitted information, with 6 patients receiving specific antidotes prescribed from findings obtained via Google Glass–facilitated examination.[54] Skolnik and colleagues[55] performed an expanded prospective observational cohort study with 50 patients that included the transmission of ECG data via Google Glass as well. Respondents found the technology largely reliable to perform remote examinations.

A study by Wu and colleagues[56] examined heads-up displays (HUDs) as a potential facilitator of ultrasonography-guided central venous cannulation by trainees. Real-time ultrasonography imaging displayed by Google Glass allowed participants to place central lines on a task trainer with the superimposed ultrasonography feed in direct vision. Wu and colleagues[56] hypothesized that limiting the need for the traditional turning to and from the ultrasonography machine to the procedure would minimize inadvertent hand movements during the procedure. Although the small sample size of 40 participants across different competence and learning levels did not produce significant results, the procedure was noted to take longer with Google Glass than with the traditional ultrasonography-guided technique.

Endocrinology

Regular self-monitoring of blood glucose levels remains a compliance challenge for clinicians treating diabetic patients, with nonadherence behaviors having complex psychosocial foundations. The need for repeated painful finger sticks with small lancet needles has led to the search for and development of alternate methods to assess glucose levels, and continuous glucose monitors (CGMs) offer such a solution. The prototypical CGM comprises a small sensor placed subcutaneously that measures glucose concentrations in the interstitial fluid. Although the glucose gradient between blood and interstitial fluid ensures a delay before reaching equilibrium that precludes real-time assessment of blood glucose levels for the purpose of prandial insulin bolus dosing, the data related to glucose trends over time have nevertheless contributed to advances in diabetes management, including the development of tools for prediction of hypoglycemic or hyperglycemic episodes. In the Daily Injections and Continuous Glucose Monitoring in Diabetes (DIAMOND) trial, Beck and colleagues[57] found that, in a group of 158 type 1 diabetic patients randomized to either CGM or traditional blood glucose checks for a 24-week period, the CGM group had a significantly greater decrease in HbA1c levels, a finding replicated in related studies. Work continues on novel wearable modalities for glucose sensing, with the popular news media focusing on Google's further development of research surrounding contact lenses that can measure glucose content in tears.[58]

One major challenge with CGM data is that the data sets are significantly larger than those from finger-stick glucometers, and providers have not traditionally had access to this information. Kumar and colleagues[20] described the first successful integration of CGM data in the EHR using a standard consumer interface from Apple, and subsequent studies have confirmed this approach as feasible and patient friendly.[59]

The combination of wearables with traditional medical devices, CGMs have recently been connected to subcutaneous insulin pumps, forming closed-loop systems in which algorithms working with glucose data received from CGMs are used to adjust the continuous delivery of insulin; in effect, functioning as rudimentary artificial pancreases.[60] Garg and colleagues[61] reported a multicenter study with 129 type 1 diabetics treated with a Medtronic-based closed-loop platform (Medtronic, Northridge, CA) for a 3-month period. Although patients still had to enter information related to carbohydrate loads and perform finger sticks to ensure safe bolus dosing, the platform was shown to be safe and effective at maintaining basal glucose levels, and subsequent studies have suggested that such systems may also contribute to improved glycemic control.

The potential benefits provided by this expanding collection of continuous glucose monitors, including novel noninvasive monitors, support apps, PHR integration, insight from population-based informatics, and even closed-loop insulin delivery systems, conjures an exciting future in which the management of this chronic condition becomes less arduous and expensive.

Neurology and Psychiatry

Investigators have suggested a broad array of use cases for quantifying the brain.[62] Patients with epilepsy disorders represent another population with an often difficult to manage chronic condition, with seizure frequency being particularly unpredictable and associated with significant potential morbidity.[63] The biometric data collected by wearables have been examined to determine whether early recognition of seizure activity can be measured. Detection of seizures through measurement of motion by accelerometry as detected by a commercially available smart watch was found to be significantly lacking in accuracy,[64] although algorithms generated from a combination of wearable motion and electrodermal data seem to be promising.[65]

Autism spectrum disorders (ASDs) are characterized in part by difficulties with socialization, including the processing of behavioral cues such as facial expressions. Supplementary visual information has long been recognized as a valuable tool to assist patients with ASDs in navigating intrapersonal interaction.[66] Work by The Autism Glass Project at Stanford Medicine has shown the potential utility of HUDs, including Google Glass, in providing a platform for therapeutic tools, including structured play, real-time visual cues, and monitoring of eye contact.[67] A recently published randomized clinical trial by the same group suggested that autistic patients using these technologies in conjunction with standard applied behavioral analysis treatment subsequently scored higher on certain behavioral indices compared with a control group receiving only the standard-of-care intervention.[68]

HUDs have additionally been evaluated as a telemedicine solution for neurorehabilitation and physical therapy purposes,[69] and interest has focused on using virtual reality systems such as the Oculus Rift as modalities for assisting patients dealing with acute and chronic pain in distracting and refocusing attention.[70]

Pain Management

The increasing prevalence of opioid use disorder in the United States is a public health crisis with a significant economic and societal cost in addition to the tens of thousands of lives lost every year. Innovative methods for helping to prospectively monitor patients at particular risk for adverse outcomes are in high demand, and multiple investigators have suggested that wearable devices may be of use in this context. Proof-of-concept work using biosensors similar in size and function to activity trackers that monitor temperature, movement, and electrical activity across the skin have developed physiologic profiles that are consistent with acute opioid use, although implementation of this technology as part of a monitoring or treatment program has, to our knowledge, not been described.[71]

Pulmonology and Sleep Medicine

Many commercially available smartphone applications and wearable devices feature functionality that claims to evaluate metrics of sleep quality. Evaluation by most hardware is accomplished by technology such as accelerometry that detects movement, with the device assessing low-movement periods as being consistent with sleep. Such technology is of limited utility in demarcating complex sleep behaviors or stages of sleep.[72] Software algorithms incorporating additional biometric data, including respiratory and heart rate variations, have been described,[73] and combined with wearable pulse oximetry sensors have been used in smartphone-based platforms to detect episodes of obstructive sleep apnea (OSA).[74] Surrel and colleagues[75] described an IoT OSA monitoring system using a single-lead ECG linked via Bluetooth to a smartphone, allowing continuous monitoring over a period of weeks. Despite advances, wearable sensors have not yet been able to replicate the reliability and granularity of data provided by polysomnography, the gold standard sleep medicine study.[76]

Surgery

HUDs have been widely investigated within the surgical subspecialities as platforms to facilitate remote consultation and assistance between surgeons and for providing enhanced or augmented visualization of relevant operative anatomy.[77] Microsoft's HoloLens has been the focus of proof-of-concept studies in neurologic surgery,[78] vascular surgery,[79] orthopedics,[80] and plastic surgery,[81] whereas Google Glass has been trialed in the pediatric surgery[82] and transplant surgery arenas,[83] among others.[84] The ophthalmology literature has reported on the use of modified HUDs as an alternate method of fundoscopy, providing a mobile and economical alternative to conventional hardware.[85] Virtual reality has long been recognized as a way to acquire task-based proficiency,[86] and work has continued to focus on the utility of HUDs displaying augmented or virtual reality environments as educational tools for surgical trainees.[87] In addition to facilitating direct learning, HUDs such as Google Glass have also been used by educators for the evaluation of trainees in simulation-based encounters.[88,89]

SUMMARY

The rapid proliferation of consumer-wearable devices, smartphone applications, and ancillary technology such as virtual and augmented reality form a key and increasingly important opportunity for modern health care. The potential of these tools to encourage engagement with clinicians, facilitate chronic disease management, and collect vast amounts of health data has long been touted, and the prospect of a future health care IoT ecosystem delivering personalized, high-quality care while decreasing cost burdens is a common vision. Especially promising are the synergies between wearables and other emerging technologies, such as artificial intelligence. The vast amounts of data collected by consumer devices may be particularly useful when analyzed by complex algorithms that may allow enhanced pattern recognition and clinical decision support, which is an increasingly important consideration in the setting of improved functionality. If wearable devices are to be relied on to provide early warning of disorder, it is attendant that appropriate information is conveyed to the patient to allow an escalation of care. Similar information may be provided in advance to clinicians to allow quicker triage and assignation of resources. To date, clinical decision support implications in the setting of wearable devices have not been widely studied.

Although there is no shortage of interesting clinical applications of these technologies, there remains a dearth of high-quality literature showing significant benefit to outcomes or other clinical metrics. The clearest advantages of these devices to date may lie in their ability to facilitate telemedicine applications to assist with significant geographic and socioeconomic disparities in access to care. Despite these caveats, with ever-increasing functionality, an increasing blurring of the lines between traditional implanted medical devices and wearables, and synergy with emerging informatics technologies, wearables promise to remain an area of active and exciting research and development.

DISCLOSURE

The authors have nothing to disclose.

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