Wearable Health Devices: The Unintended Effects of Continuous Health Monitoring

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Over the last decade, personal health devices, typically in the form of wearable devices (wearables) have proliferated. Wearables offer real-time health and fitness feedback that is far more convenient than visits to physicians or trainers (Haghi et al., 2017). Personal health wearables and mobile applications, which are often paired, are portable and serve individuals, usually outside of the formal healthcare system. Most have communication functionality (Fox, 2017). Banaee et al. (2013) conclude that wearables are shifting to specialize in pattern recognition, anomaly detection, context awareness, and personalized models. Since their introduction, wearables have been intended to put "the individual citizen in the center of the healthcare delivery process," which is commonly referred to as patient empowerment (Nykänen, 2008). Besides promoting health ownership, wearables can save time and medical costs. Networked wearables may be less expensive and improve patient and physician access to personalized medical information (Fox, 2017). In general, wearables have and continue to affect the landscape of digital health with respect to preventative medicine, clinical support, monitoring and intervention, data integration, and health education (Amft, 2018).

Industry performance has reflected these perceived benefits. The consumer use of wearables increased from just 9% in 2014 to 33% in 2016, according to a 2016 Accenture study (Francis, 2016). Revenues from wearables related to healthcare and medicine were expected to reach $15 billion worldwide in 2019 (Yussuff, 2014). Gartner, a global information technology company, forecasted that total revenue from all wearable types, including devices not formally associated with healthcare, would reach $41 billion in 2019 (Goasduff, 2019). A 2014 McKinsey study estimated that, by the end of 2020, about 40% of the Internet of Things (IoT)

technology will be health-related. This would represent a $117 billion market, of which wearables would constitute a substantial portion (Bauer et al., 2014). But continuous health monitoring bears complex implications for data privacy, network security, insurance practices, the physician, and the patient (Fox, 2017). Wearable health devices have been integrated in health systems in some cases, but before wearables can achieve widespread adoption, concrete legislation must address privacy, security, and accuracy concerns.

Review of Research

Researchers have studied health wearables. Piwek et al. (2016) found no evidence that wearables improve the health of healthy individuals and contend that they do not yet support reliable patient diagnosis. Cheung et al. (2019) attribute low consumer adoption of wearables to companies' "inadequate knowledge in the adoption intention of users of wearable healthcare technology." Adoption barriers additionally stem from wearables' substantial dependency on communication, which can be constrained by mobile data cost, and the older population's technology awareness and user attitude (Baig et al., 2019). One study found that the two leading reasons for abandoning wearables are limited functionality and lack of inbuilt connectivity (Ericsson ConsumerLab, 2016). Because approximately half of users stop using their wearables within six months of purchase, technology companies have not been able to take advantage of user data, the commodity on which the industry's potential value is based (Canhoto and Arp, 2016).

Although Schukat et al. (2016) contend that large-scale data sharing benefits individuals and researchers, they warn that trust in sensors may leave users' data vulnerable to compromise. Mettler (2016) found that the personnel and systems involved in the treatment of a patient

require cost-intensive data storage and authentication processes, without which data security cannot be guaranteed. Data security vulnerabilities are ubiquitous. One user of Zoom, a cloud computing communications company, discovered a flaw in Zoom's software that "allowed malicious actors to secretly access the cameras of anyone who'd ever used the popular videoconferencing service"; the firm went public weeks later but failed to remedy the flaw for months (Burt, 2019). Banerjee et al. (2017) found that many health data sharing problems could be addressed via regulation: "the greatest potential for industry self-regulation resides with a mixed form of industry rule-making and government oversight."

With blockchain, developers may reduce risk in a decentralized way (Reyna, 2018). Zheng et al. (2018) argued that the application of blockchain could reduce data security risks, simplify data access for research, support data ownership, and improve tracking. Gordon and Catalini (2018) concluded that "as interoperability becomes more patient-centric, there is an opportunity to leverage blockchain technology to facilitate this exchange and give patients greater control over their data", yet there exist realistic challenges that must be addressed as blockchain-related solutions are surveyed.

Patient Care

Patients typically weigh financial costs and time benefits against privacy costs (Blau, 2017). In a French study of patients with chronic conditions, researchers found that most believe wearables could improve their treatment. One patient asserted only wearables can let a physician account for all parameter inputs to diabetes treatment assessment. A group of patients feel symptom and activity monitoring for follow-up purposes would be another benefit –one of which said, "Connected applications and tools will help patients in monitoring their symptoms by

guiding their observations and informing them. This will reassure them, help them to better know themselves and their diseases" (Thran, 2019). Patients also identified risks. One commented: "There are risks or drawbacks if some information is disclosed to social networks, banks, insurance or work. It will be necessary for patients to be educated on that" (Thran, 2019).

Some physicians doubt monitoring helps them care for patients (Rosenblum, 2015). These doctors warn that non-contextualized patient data, such as step count, are useless in diagnosis and treatment (Rosenblum, 2015). They note that data patients present from wearables can be very challenging to interpret and may overwhelm office or hospital staff (Brown, 2019). Ida Sim, a primary care physician and director of digital health for general internal medicine at the University of California, San Francisco, also worries about the volume and interpretability of data: "We are struggling at the front end because this data comes in so many different formats—a .pdf file here, a [step tracker] read-out here, a blood glucose app output there … which leads to a lot of cognitive overload for providers" (Sukel, 2019). Sim added that it's important for doctors to discuss with patients what kind of data the wearable will collect, why they want to collect that data, and how that data will be used (Sukel, 2019).

Even if the data is easily digestible and potentially actionable, some doctors fear it may not be accurate. Ripley Hollister, a family medicine specialist and Physicians Foundation board member, expressed his desire for "significantly more large-scale, peer-reviewed studies validating the accuracy of the data before [physicians] start basing care decisions on the data" (Brown, 2019). Hawley Montgomery-Downs, psychology professor and researcher at West Virginia University, concurs that wearable data inaccuracies are troublesome. In application to sleep science, she says that although the devices may be highly accurate in some settings, they may lead to completely false conclusions in other settings. She and her colleagues feel that

physicians should not yet use wearables for diagnosis and treatment not only because they may cause improper treatment, but also because companies should be pushed to improve their products to the highest standard (Eramo, 2017).

But proponent physicians note that any additional data can be valuable. Florence Comite, endocrinologist at Comite Center for Precision Medicine, uses wearable data to better personalize treatment and predict possible complications, as she says, for her team, "wearables are almost like magic." In response to data accuracy concerns, she argues that it is the healthcare provider's responsibility to scrutinize all data, regardless of the source (Eramo, 2017). Other wearable-proponent doctors believe that with wearables, they can monitor outpatients' medical compliance (Loos, 2016). Jacek Urbanek, assistant professor of medicine at Johns Hopkins Medicine, describes that patients can lie when they self-report behavior, but "wearable devices provide accurate data that cuts through bias and guesswork" (McGrail, 2019). Like-minded physicians explain that wearables will allow them to monitor patients' recovery or lifestyle change progress in real time and intervene when necessary (Wicklund, 2016; Wicklund, 2019).

The American Medical Association (AMA), the largest association of physicians in the United States, is "ensuring the physician perspective is represented in the design, implementation and evaluation of new health care technologies" (AMA, 2020). The group recommended that physicians ensure their patients are aware of regulatory status, data privacy, and information flow before considering wearables (Robeznieks, 2019). The AMA founded nonprofit Xcertia to develop mobile health app guidelines to address personal health data privacy and security (Robeznieks, 2018). The 2019 Xcertia guidelines detail six privacy concerns and nine security concerns, specifically directed towards those who develop mobile health apps; wearables fall under this category. The guidelines additionally address app usability, operability, and content.

Xcertia invites public comment before formally solidifying each wave of guidelines, allowing for physicians, patients, and other participants to provide their input (Xcertia, 2019). Meg Barron, AMA digital health strategy vice president, likened the digital health technology landscape to the "wild, wild West," but believes the Xcertia guidelines can improve clarity (Robeznieks, 2019).

The AMA's Digital Health Implementation Playbook is another example of the organization's digital health initiative. Written primarily for healthcare providers, like physicians, the Digital Health Implementation Playbook presents a research-backed strategy for implementing digital health solutions to expedite adoption. The playbook's introduction states, "Digital tools that enable new methods and modalities to improve health care, enable lifestyle change, and create efficiencies are proliferating quickly. Clinical integration of these tools is lacking. We want to change that" (AMA, 2018). The group is excited by digital health technology, like wearables, but recognizes that additional steps are necessary before large-scale implementation is feasible.

Industry

In general, the wearable health devices industry recognizes that it must improve its products' value propositions to bolster consumer adoption. In a 2016 press release, Angela McIntyre, research director at Gartner, noted that a high number of consumers stop using their wearable devices at an early stage, principally because the devices are not independent enough from smartphones. She added, "The greatest hurdle for fitness tracker and smartwatch providers to overcome is the consumer perception that the devices do not offer a compelling enough value proposition" (Moore 2016). Gartner further reported, in a 2017 press release, that the majority of consumers decided not to buy smartwatches because of small perceived benefit relative to

smartphones, illustrating that the obstacle is significant for the industry. The information technology firm added that artificial intelligence-related capabilities will be critical towards growing wearables' independent value proposition (van der Meulen and Forni, 2017).

Gartner additionally reported that it found the importance of the design of wearables has been overlooked (Moore, 2016). The International Data Corporation (IDC), an information technology, telecommunications, and consumer technology market research firm, reports similarly (IDC, 2020). Jitesh Ubrani, a senior research analyst for the IDC Mobile Device Trackers, echoed Gartner's view on wearable design: "As the technology disappears into the background, hybrid watches and other fashion accessories with fitness tracking are starting to gain traction. This presents an opportunity to sell multiple wearables to a single consumer under the guise of 'fashion'" (Adegeest, 2017).

These concerns and trends have been reflected in wearable technology companies' research and product development. Last year, Fitbit, known primarily for its smartwatches and trackers, made clear its commitment to delivering personal, affordable, and design-focused products. In an early 2019 press release announcing its launch of four new wearables, Fitbit described the technologies' offerings as "essential, easy-to-use features in a sleek, stylish design at a low price for consumers and health plan customers," while emphasizing the value of personalized services (Ralls, 2019). Garmin, a leading smartwatch technology company, released a smartphone application for smartwatch personalization and management in April 2019. Most notably, Garmin made clear that the app and many of its add-on features were free and described the app as "easy and fun" and as something that "lets customers bring personality and customized functionality to their device" (Woodbury, 2019). The firm also helped reveal its

effort to support extensive data analysis to enable more precise personalized insights after it announced a collaboration with health researcher Fitabase in late 2018 (Hysell, 2018).

In February 2020, Johnson & Johnson launched a study in partnership with Apple to help improve health-related outcomes via the Apple Watch and an iPhone app. The health study, which has particular emphasis on reducing the risk of stroke with early detection of atrial fibrillation, is designed for individuals ages 65 and older (Chang and Fishman, 2020). This addresses Baig et al.'s finding that wearables must cater to older populations to increase adoption. The study's use of the iPhone and Apple Watch in tandem also shows that the wearable may not have to be independent from the smartphone; instead, the wearable can gain utility from its relationship with the smartphone.

Insurance

Insurance companies have welcomed wearables because they may induce customers to make healthier choices. Health insurer UnitedHealthcare has offered financial incentives for meeting physical health goals, as tracked by wearables, and recently expanded the list of wearables that can be used by customers. Sam Ho, chief medical officer of UnitedHealthcare, commented, "The enhancements … enable the program to offer companies and their employees more digital health and wellness resources that are personalized, connected and intuitive" (UnitedHealthcare, 2017). Health insurer Humana, which has been offering financial incentives for meeting physical health goals since 2013, recently expanded its partnership with Fitbit to further encourage active behavior (Ralls, 2018). Aetna, a CVS-owned health insurance firm, launched a new insurance plan that personalizes fitness recommendations and rewards each

member for healthy actions through an Apple Watch. Aetna makes clear that privacy and data security are high priorities (McGuire and Slavin, 2019).

Life insurer John Hancock has followed suit, as it began incorporating fitness tracking into plans in 2015. In 2018, the company announced that all of its life insurance policies will come with a fitness tracking platform. Brooks Tingle, president and CEO of John Hancock Insurance, noted that new technology is altering customer expectations: "We have smart phones, smart cars and smart homes. It's time for smart life insurance that meets the changing needs of consumers" (Senior, 2018).

Nevertheless, though the National Association of Insurance Commissioners (NAIC) acknowledges such benefits highlighted by insurance companies, it is cautious about data security, privacy, and accuracy. (NAIC, 2019). The NAIC created the Innovation and Technology (EX) Task Force to facilitate the discussion of and provide guidance on the innovation and technology in the insurance industry. Various other working groups are assigned within the NAIC to monitor big data, speed to market, and artificial intelligence (NAIC, 2020). Shanique Hall (2017), Center for Insurance Policy and Research manager at the NAIC, holds that "privacy, security, and data accuracy concerns must be addressed to protect consumers before the implementation of any large-scale efforts to use wearable device data for insurance purposes." It is evident that although insurance companies are quickly embracing wearable technology, many obstacles remain.

Popular Interest Groups

The Center for Digital Democracy (CDD) calls for "meaningful, effective, and enforceable safeguards" to regulate wearables. The organization points to the inevitable

evolution of wearable systems to employ algorithmic classification systems, which could ultimately lead to profiling and discrimination. The CDD added that "While claiming to give consumers tools for controlling their own personal data, many of the actual practices are often described in such vague, complex, or highly technical language" (Montgomery et al., 2017). In 2018, 34 civils rights, consumer, and privacy groups released Public Interest Privacy Legislation Principles to encourage and guide legislation to protect consumer privacy rights. The document asserts that "Existing enforcement mechanisms fail to hold data processors accountable and provide little-to-no relief for privacy violations" (Access Humboldt et al., 2018).

Interest groups have called upon Congress to protect data privacy rights. The American Civil Liberties Union (ACLU) (2019), in a letter to the Senate, asked the body investigate the effects of gene patenting, an issue analogous to health data privacy. Also in a letter to Congress, large technology companies urged lawmakers to "act and ensure that consumers are not faced with confusion about their rights and protections" so that the companies can strengthen consumer trust (Stephenson et al., 2019). Root motivations may differ between the two groups, but they both hope Congress makes consumer protections clearer.

Relevant Legislation

The United States Food and Drug Administration (FDA) has identified the potential of digital health technology and is actively addressing the digital health technology landscape. The FDA's Center for Devices and Radiological Health developed the Digital Health Innovation Action Plan to put "patients at the forefront of our vision—we are driven by timely patient access to high-quality, safe and effective medical technology," the plan says. It gives guidance related to the 21st Century Cures Act and discusses a new approach to digital health technology

regulation (FDA, 2017). The 21st Century Cures Act, which became law in late 2016, takes a series of steps towards softening regulation of medical products, while directing the FDA to provide updated oversight guidance for medical products (H.R.34, 2016).

As one follow-up measure, the FDA released a guidance document, General Wellness: Policy for Low-Risk Devices, in 2016 and an updated version in 2019. The most recent version most notably provides the FDA's interpretation as to which technologies are formally considered medical devices, in accordance with the modified definition described by 21st Century Cures Act (FDA, 2019). The Principal Deputy Commissioner of the FDA released a statement about the guidance, clarifying that "certain digital health technologies – such as mobile apps that are intended only for maintaining or encouraging a healthy lifestyle – generally fall outside the scope of the FDA's regulation. Such technologies tend to pose a low risk to patients, but can provide great value to consumers and the healthcare system" (Abernethy, 2019). This response fails to address how risk is assessed, giving little regulatory clarity to consumers, physicians, and other participants.

The United States Federal Trade Commission (FTC) created a guidance tool for mobile health app and technology developers, in cooperation with the Office of National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), and the FDA (Mayfield and Han, 2016). The tool helps direct developers towards relevant legislation that may govern their technologies (FTC, 2020). Lucia C. Savage, chief privacy officer of the ONC, commented that "as Americans become increasingly engaged in managing their health through diverse health IT products, this tool will provide product developers with access to the critical information and consistent guidance they need in order to innovate" (Han and Mayfield, 2016). The FTC also released a set of best practices for legal compliance (FTC, 2016).

The Health Insurance Portability and Accountability Act, published by the U.S. Department of Health and Human Services, released both the Privacy Rule and the Security Rule, in 2002 and 2003 respectively (HHS, 2002; HHS, 2003). The Privacy Rule aims to "maintain strong protections for the privacy of individually identifiable health information" (HHS, 2002). The complementary Security Rule seeks to improve "the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information" (HHS, 2003). Attorney Anna Spencer explained that HIPAA cannot be applied when the user and technology company are the only two parties involved when the user collects data via a wearable. Otherwise, there is ambiguity, unless a HIPAA covered business is involved, she contends. Jeremy Meisinger, another attorney, also believes HIPAA's relationship with wearables is uncertain, and companies should keep that in mind (Snell, 2017).

Conclusion

Wearable health devices require additional research and scrutiny to ensure their safety and efficiency. Assessment and recommendations from users, physicians, and organized interest groups must inform formal legislation and regulation by legislators to guide the industry and insurers. The quickly improving capabilities of wearables is certainly promising for the healthcare space, and strict, multipartisan efforts can only help accelerate this growth.

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