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The Wearable Revolution: Opportunities and Risks

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As the spread of COVID-19 continues, so does exploration into the use of wearable technologies and applications to help detect and track signs and symptoms of the virus and promote public health. As a direct response to the pandemic, Google's Verily "is developing a small, body-worn temperature patch that transmits data to a phone application to provide timely notification of fever and support earlier diagnosis and treatment of a viral infection like the flu or coronavirus."[1] Wearable technology is also expected to play a role in telemedicine after the pandemic as it allows practitioners to closely monitor a patient's health outside of the office as a means to augment traditional medical care.

Wearables are electronic devices worn on the body that have the ability to track patient data such as heart rate, blood pressure, body temperature, blood oxygen saturation, and blood glucose levels. Many can also track activity level, like counting the number of steps walked.

A 2018 Deloitte survey of U.S. healthcare consumers showed that the number of individuals tracking their health data via wearables had more than doubled since 2013. Moreover, 60% of respondents were willing to share wearable-generated protected health information with their physician to improve their health.[2] The medical wearable marketplace is expected to expand from $6 billion in 2017 to $14.1 billion by 2022.[3] According to Pew Research, wearable and embedded health tracking devices will be ubiquitous by 2025.[4]

The reported benefits to patients include supporting healthy behaviors, improving outcomes, identifying potential health problems early, decreasing hospital admissions, and reducing healthcare costs. The capacity for improved health can be a compelling reason for clinicians to access health data on a patient's device. As an example, step count data could help indicate whether a patient's antidepressant medication is working, according to Joseph C. Kvedar, MD, vice president of Connected Health at Boston-based Partners HealthCare. "The more you walk, the more evidence you're not depressed," he says. "So by tracking activity level, you can look in and see how well they're responding to their medicine."[5]

There have been no reported lawsuits involving wearables, but many experts predict it's only a matter of time before losses emerge. Consider the following areas of potential liability when using remote monitoring devices:

Type of Wearable. It is important to distinguish medical-grade devices, which are approved by the Food and Drug Administration (FDA), from consumer-grade wearables. Medical-grade wearables are subject to FDA approval if their purpose is to help with diagnosis or treatment. On the other hand, consumer-grade wearables are used primarily as a motivational tool for patients. As a general rule, because medical-grade devices undergo rigorous testing, they are likely to be more accurate and reliable than consumer-grade devices.

It is also important to consider whether the patient initiates the tracking or the physician prescribes it.[5] If the devices are used as part of care management, having a mechanism to route the data directly to a patient's electronic medical record with an alert for the care team to review is advisable.

Interoperability with Electronic Medical Record. Receiving, analyzing, and following up on wearable data can be a daunting task for practices. If your organization is not prepared to interact with this technology, it can lead to claims for failure to monitor, failure to detect, or missed diagnosis. Secure and reliable transmission of data using vendor platforms that integrate data transmission and alert systems into workflows and the patient's medical record is key.

For example, if an organization is managing patients with congestive heart failure to prevent acute events, wireless scales and blood pressure cuffs must be connected to the system and accompanied by continuous data monitoring and response. Designating a qualified healthcare professional and a process to monitor and quickly respond to the incoming data is recommended. Educate the healthcare team on "alert fatigue," which leads staff to ignore or override an overwhelming number of incoming alerts.

Patient Selection. Not all patients are appropriate candidates for remote monitoring. Several factors should be considered, including how motivated patients are to manage their health as well as their ability to understand and use the technology.

Patient Education. Once patients are identified as appropriate candidates, educating them on the technology is crucial. Patients should know how to use and maintain the device, when and how often to transmit the data, what to do if the device malfunctions, and how the healthcare team will handle alerts.

Informed Consent/Setting Expectations. Prior to the initiation of monitoring, discuss expectations regarding roles and responsibilities. It is imperative that patients understand that although the healthcare team is monitoring their data, if they feel sick or are having a medical emergency, they should call 911 or go to the nearest emergency room. Include a written agreement outlining expectations, roles, and responsibilities regarding wearables in the patient's chart. In addition, obtain informed consent for using the technology and thoroughly document it in the medical record.

Data Breaches and Cybersecurity Risks. Wearables transmit patient data; therefore, the risk for a data breach exists. Properly encrypted data transmission is essential to comply with the Health Insurance Portability and Accountability Act (HIPAA). The FDA has also provided guidance on cybersecurity risks for medical devices. Accordingly, providers who use medical devices should not rely on manufacturers to ensure security and must safeguard patient information within their own network.

Education on Devices and Contract Review. It is important to stay abreast of the most current information regarding wearables, including approved uses and any FDA alerts or recalls. Additionally, engaging legal counsel to review contracts with medical device vendors is recommended.

Insurance Coverage. Although wearables use has benefits, do not ignore the liability risks. Contacting your agent and insurer to discuss coverage needs arising from the use of wearables, such as bodily injury and cyber and technology errors and omissions coverage, is advisable.

Integrating wearables use into healthcare can potentially improve quality of life and reduce healthcare costs. Successful implementation of wearable health technology requires careful planning. Understanding the opportunities and risks related to wearables will help us to embrace patient care in an emerging digital revolution.

For more information on remote patient monitoring, refer to the American Medical Association's Digital Health Implementation Playbook.

We hope you found this RisKey helpful. If you have questions or would like further resources on this

topic, please contact your Coverys Risk Management Consultant.

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