# WEARABLE HEALTHCARE TECHNOLOGY – THE REGULATORY PERSPECTIVE

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REVIEW ARTICLE

**Akshay Anand M*,** Venkatesh M P, Pramod Kumar T M

JSS College of Pharmacy, JSS University, S.S. Nagar, Mysuru 570015, Karnataka, India

**Corresponding Author's E-mail: axayanand@gmail.com*

**ABSTRACT**

The world today isn't the one which it was yesterday. With the continuing evolution in technology and technological applications on medical field, innovative products and services have been emerging every day. Wearable gadgets have risen up as revolution in the medical field for patient care. A number of tech giants are pouring into this segment; wearables have already shown an impact on various fields such as communication and navigation; but perhaps the greatest potential lies in healthcare. With this article, an attempt has been made to unlock the potential of wearable healthcare technology and the regulatory aspects imparted on them currently.

**Keywords:** Wearables, Wearable technology, Wearable healthcare gadgets.

## INTRODUCTION

The definition of wearables or wearable gadgets is constantly changing with the evolution of these devices. According to Wikipedia, the definition of wearable technology states that "wearable computers, also known as body-borne computers or wearables are miniature electronic devices that are worn by the bearer under, with or on top of clothing." This definition stresses that wearable technology is especially useful for applications that require more complex computational support.

From a technological standpoint, wearables are self-contained devices with embedded sensors that are worn by the user to detect, diagnose, monitor and communicate the health and performance data of the user. Wearable technology that is regulated as a medical device, instead of being simply a consumer wellness device, can help to revolutionize patient care while driving down healthcare costs.

Across the developed world, healthcare systems face numerous challenges driven by increasing costs, increasing demand due to changing demographics, increasing longevity and greater incidence of chronic conditions and big improvements in addressing complex, previously untreatable conditions. Most healthcare systems are on an economically unsustainable path as healthcare consumes an ever increasing portion of the nation's investment.

Improvements in technology offer the most likely solution to meeting this rising demand at low cost. In the recent past, there has been a lot of activity in the wearable technology space in healthcare, though most current applications are focused on wellness and health tracking. Industry reports estimate that the market will grow to over $5 billion by 2018. In this time, we an increased activity in wearable technology that qualifies as medical devices and gathers data in a way that integrates into the patient's health record are expected. The technology would be user friendly, cost efficient, and will enable providers to offer more tailored care and advice to patients.

### Objectives

The main focus of this article is to compile the current stance of wearable healthcare technology in the world and the regulatory perspective. The objectives of the article include-

- To describe the potentials of wearable healthcare technology.
- To shed light on commercially available wearables in use currently.
- To oversee the challenges wearables offer to the regulatory authorities.

 

## Discussion

Widespread adoption of wearables to monitor the wearer's vital signs and other indicators seems to be the future of healthcare, making it easier for data collections which in turn could reduce health care costs. Many early adopters, patients and clinicians are already using mHealth apps on their smartphones and other devices. According to a report by Robert Wood Johnson Foundation, number of wearables and apps will grow by 25 percent a year. This study also projects that by 2018, 1.7 billion people worldwide will download a health app and use some wearable device. Some experts say we are already in the wearables era and Apple Inc., has taken it to the next step by releasing the 'HealthKit' API (application programming interface) for app developers and 'Health' app in 2014. Stanford university hospital and Duke University have launched trials with diabetics and chronic disease patients using this unique platform to integrate data from applications already used by medical devices such as glucose monitors and blood pressure tracking devices.


**Figure 1: User interface of 'Health' app running on an Apple iPhone 6**

Wearable technology enables constant monitoring and data collection, thus allowing providers to look at data over time and understand patterns of patient behaviour. A deeper understanding of patient behaviour is one of the keys to improving health, especially in managing chronic conditions that are primarily driven by leading an unhealthy lifestyle. (1)

As constant stream of data captured from patients comes, automated tools can quickly highlight any anomalies so that providers can initiate early interventions to prevent the onset of future complications. This improves overall patient health and thereby reduces healthcare costs. Providers can also use the data from wearable devices to identify patients that are fully compliant with their care regimen and show improvements, avoiding the need for unnecessary office visits.

Whereas a diagnosis is mostly based on a patient's account of events and symptoms experienced, wearable technology offers an additional source of information, which will improve providers' ability to diagnose their patients. Such applications are particularly useful when the patient may not be able to directly provide information to the physician, such as with children, the elderly, or those battling mental health issues.

Another valuable functionality is to use wearable technology such as 'Google Glass' or 'Microsoft HoloLens' to provide a heads-up display. For instance, anesthesiologists could use devices like this during surgery to keep track of patients' vitals without taking their eyes off the patient. They can also be used to unobtrusively record patient behaviour in cases where the act of observing changes behaviour, such as in developmentally challenged children who often behave differently at home than in a specialist's clinic.

**Figure 2: Google Glasses (Left) and Microsoft HoloLens (Right)**

**The Regulatory Perspective**

To realize its full potential, wearable technology in healthcare has to cross the boundary from consumer electronics devices to regulated medical devices. Regulated wearable devices can be relied upon to provide accurate data and can potentially be integrated into patient health records.

The regulatory framework that exists for the approval of medical devices while quite robust has proven to be challenging for many start-ups to navigate. As a result, they have chosen the option of providing wellness tracking devices that can be marketed as consumer electronics, rather than as medical devices under the jurisdiction of the U.S. Food and Drug Administration (FDA).

Fortunately, this trend is changing. The FDA has announced smart regulation with more oversight directed to technology that represents high risk to patients and scaling back from the traditional approach (Class I, Class II, Class III). Another promising development is the advent of large players into the market who are promising to provide somewhat open platforms for wearable technology. Samsung, for example, introduced its 'SAMI' health platform in late May 2014 to enable interoperability between wearable devices. (2)

As mentioned earlier in the article, Apple's 'HealthKit' product announcement is an effort to position Apple as a platform for enabling wearable health applications. Other large players have similar ambitions of introducing open platforms for wearable health technology. Such platforms can have far-reaching consequences for the future direction of the wearable technology industry. In fact, such platforms can provide some structure to the market and move technology vendors from selling specific point solutions, to easily integrated solutions that rely on common architecture and platforms. Common platforms will also encourage further innovation by reducing market uncertainty for new entrants. Using common platforms will also reduce the cost of regulatory compliance as only individual sensors will need to be FDA certified, rather than the entire solution.

Wearables along with being used as a personal fitness, sleep tracker can be a potential solution to in-house monitoring and many other challenges faced during clinical trials. One important such problem faced in various studies involves a connecting number of surface electrodes to the participant/patient to collect data, which may be intimidating and may affect their natural responses. But the use of wearables which makes little or no difference will help record data measures as naturally as possible. As the potential applications are almost limitless, investors and industries are currently very active making the market buoyant at the moment.

As wearable technologies evolve to be clinically-focused, FDA is rightly concerned about the potential problems caused to consumers, more importantly focused on the security of these medical devices. FDA released its latest guidelines 'Steps to strengthen cyber security of medical devices' in October 2014. Key recommendations in the guidelines were focused on data security to be considered from the initial stages of product design, and not added on as a patch. Specific concerns include malware, data corruption and unauthorized dissemination of patient information and password leaks.

The FDA regulates medical devices which are classified based on their intended use, most fitness apps and current wearables don't fall under its jurisdiction, but clinically focused mHealth apps and devices will. The FDA intends to exercise enforcement discretion for the majority of mobile apps that meet the definition of device. FDA has cracked down on a small number of mobile medical apps and medical device companies which make medical claims, but did not seek regulatory approval in recent years. To avoid liability, developers typically include disclaimers in their terms of use. But these are often buried, stating 'Warning: The instrument, although accurate, is not actual medical equipment. Consult your physician' but most users tend to ignore such information from the app's description.

A study by the New England Centre for Investigative Reporting in 2012 revealed that of 1,500 health apps it evaluated, 20 percent claimed to treat or cure medical problems, but

 

only a small percentage of them had been clinically tested or approved. Although Regulatory authorities across the globe are trying to enforce strict regulations to avoid such applications and devices to be marketed. To truly make this technology the future of healthcare, wearable technology in healthcare has to cross the boundary from consumer electronics devices to regulated medical devices, Companies need be more proactive in self reporting and help the user make an informed decision. (3)

**Current Stance of FDA**

The FDA has said in a draft guidance – 'General Wellness: Policy for Low Risk Devices' issued in January 2015 that it does not intend to regulate general wellness products, which include an array of consumer-oriented wearables like Fitbit's exercise trackers. (4, 5)

No longer does the mere mention of a disease in promotional materials of a general wellness product mean that FDA may regulate it, states FDA. It has chosen to draw a very common sense line that avoids regulating products that help people manage common chronic diseases. Those are incredibly important extensions of FDA's policy of enforcement discretion.

In a related and concurrently released draft guidance on the classification pathway for new accessory types, the FDA strongly hints that new medical device accessories can apply for less stringent regulation and approval pathway so that they are more loosely regulated than their parent device. The guideline states that classifying an accessory in the same class as its parent device is appropriate when the accessory, when used as intended, meets the criteria for placement in that class. However, some accessories can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class.

This guidance applies to wide array of devices, not just wearables. The FDA defines a medical device accessory as a device intended to support, supplement, and/or augment the performance of one or more parent devices. Specific examples given include rechargeable batteries, a new balloon catheter used to insert an already approved trans-catheter heart valve, and a new guidewire intended for use with a previously approved device.

The FDA encourages industries to utilize the de novo approval process, designed to accommodate low-to-moderate-risk devices that do not have a 'substantially equivalent' predecessor on the market. The guidance explained the process by which a manufacturer can file a de novo application for a new medical device accessory. FDA also states smartphones and computer monitors that display information will not automatically be considered medical device accessories. (6)

Approval of a medical device accessory under the de novo pathway means that it poses a low to moderate risk and is subject to Class I or Class II requirements. It also means subsequent candidates deemed substantially equivalent to the accessory can apply for approval under the less stringent pathway.

## CONCLUSION

Wearables are a rapidly evolving product segment. Wearable technology offers much promise to improve the delivery of healthcare for both patients and care providers, especially with the advent of regulated, wearable medical devices. We are on the cusp of rapid innovation being brought about by large players that are offering standard platforms for wearable technology. This will reduce the cost of regulatory compliance and propel the industry to the more stable ground of wearables as regulated medical devices instead of merely consumer electronics devices. It is high time that regulators, developers and healthcare providers embrace the potential of these new technologies to improve the delivery of care to patients.

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## CONFLICTS OF INTEREST

The author declares that there are no conflicts of interest.

 

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