Regulatory Standards for the Safety and Efficacy of Wearable Medical Technologies

Team Never Generic
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Wearables in the Healthcare Landscape

Trend shifting towards patients independently managing their own health using consumer products.
Wearables in the Healthcare Landscape

Role in patients with chronic conditions

● "Predictive preventative diagnosis"
● User-safety gray area
  ○ False sense of security
  ○ Over-reliance & misdiagnosis
● Lack of standardized reliability and validity
  ○ Stanford HEART Trial (Apple)
  ○ JAMA Dermatology Review
Researchers urge caution on wearable health devices

Date: February 3, 2016
Source: Lancaster University
Summary: Wearable devices to monitor health are not always reliable or secure according to researchers.

Wearable Tech is Here to Stay with the Future Healthcare Industry

By Stefanie Cruclis - 4 June 2018

The Apple Watch 4 is an iffy atrial fibrillation detector in those under age 55

By DANIEL YAZDI / JANUARY 8, 2019

Beware the hype over the Apple Watch heart app. The device could do more harm than good

By LARRY CHUSTEN / MARCH 15, 2019
Definitions

“Wearable medical technologies”

Externally worn and portable devices that operate on software connected to sensor systems intended to measure and track health data.
Devices in Development

Examples:

Apple Watch APIs

FitBit

Smartwatch SmartMonitor

Samsung Galaxy Gear Watch
Device Classifications

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No to mild risk to patient</td>
<td>Thermometers, bedpans, stethoscopes</td>
</tr>
<tr>
<td>2</td>
<td>Moderate to high risk to patient</td>
<td>Powered wheelchairs, Apple Watch Series 4, pregnancy test kits</td>
</tr>
<tr>
<td>3</td>
<td>High risk to patient</td>
<td>Pacemakers, breast implants</td>
</tr>
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De Novo and 510(K)

De Novo - Classification process for new medical devices to get approved using risk based strategy.

510(K) Pathway- Approval process for medical devices that are substantially equivalent to an approved device already on the market.
The “Pre-Cert” Program

- Digital Health Software Pre-certification Program ("Pre-Cert")

- SaMD - “Software intended to be used for medical purposes that perform these purposes without being part of a hardware medical device”
Our Proposal

A recommendation and proposal for guidelines addressing the emergence of health-based technologies regarding issues surrounding safety and efficacy.
After De Novo is granted, an FDA verification mark shall be given to a Class 2 medical device provided it meets high-quality clinical standards based on sufficient clinical trial data demonstrating accuracy and precision in results.

- Patient assurance
- Company incentive
- Digital Health Software Precertification Program
False positives and negatives from class II wearable devices with diagnostic and monitoring implications shall be reported to the Manufacturer and User Facility Device Experience (MAUDE) database by patients, healthcare providers, or the manufacturer.

- Manufacturer improvement
- FDA investigation for false-negatives and malfunctions causing significant patient harm.
Recommendation 3

Alongside a formally written privacy statement, it is recommended that the medical device manufacturer should have a user-friendly informed consent tutorial to be included in the interface of the medical device or another supported device

- The FDA can incentivize it by using the verification mark per Recommendation 1.
Closing Remarks

With these recommendations, we hope that the FDA can be prepared for the imminent release of many wearable medical technologies in the future.
Thank You!

- Dr. James Polli
- Dr. Marisa Cruz
- Ms. Roxane Modares
- CERSI and the FDA
Questions?
References