

Reliability of Wearable Fitness Device Data



Reading time:
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Last Modified on 01/05/2024 11:28 am AEST

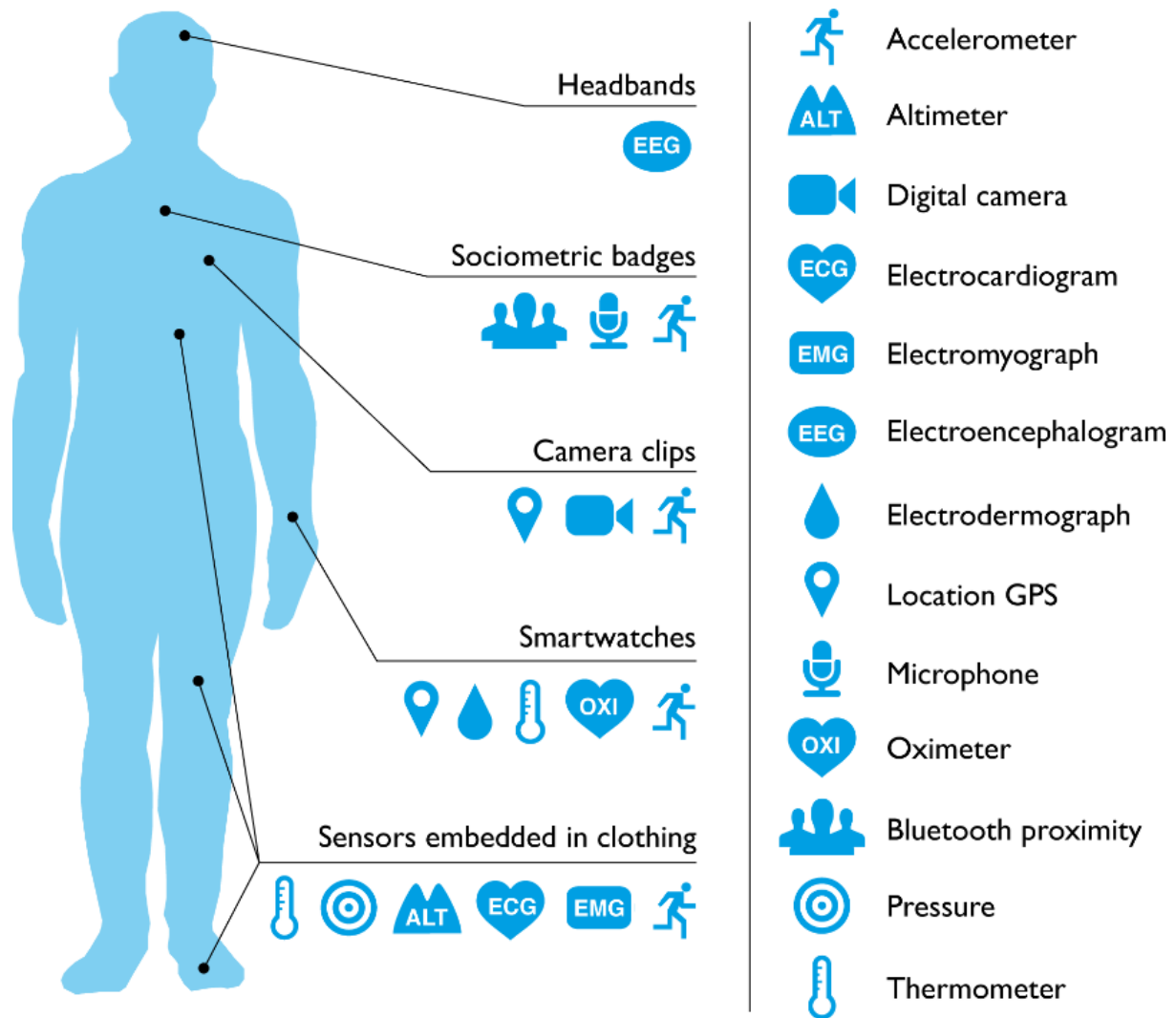
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Over the past few years the Australian wearables market has grown significantly with a whopping compound annual growth rate of 78 per cent between 2014 and 2018 and reaching revenues of \$1 billion, according to a report from industry analysts Frost & Sullivan.¹ A survey conducted by communications agency Ansible also shows that nearly one in five Australians owns a wearable device, with 18% saying they owned devices ranging from fitness trackers to smartwatches.²

With the increased reliance on smartphones and new technologies, people are increasingly trusting data from health and fitness wearable devices such as the FitBit and the Apple Watch. Individuals are also taking a more empowered role in their health and wellbeing and managing their fitness and health more autonomously by measuring, tracking and storing data with these non-invasive and compact devices despite the privacy risks from data collected on insecure devices. But how does this impact the healthcare professional in their practice and are you ready for the wearable revolution?

Data relating to health must always be treated with extra care and accuracy particularly when it reflects the life of a person. Each device has the capability to capture information relating to activity such as heart rate, glucose levels, sleep, nutrition and fitness. This data encapsulates a great deal more on an individual's overall health compared to the information a single blood pressure reading or single blood draw could achieve.

Healthcare professionals are using the data on wearables to create a more robust profile of an individual by examining inclusive trends and correlations.



Different wearables and different apps can measure a wide variety of physical activity. 3

Affecting behaviour

The trends so far have been that wearables are usually purchased by individuals who already lead healthy lifestyles and look to the devices to record progress. Wearable manufacturers assert that their devices are all encompassing platforms to improve physical performance and promote positive habits. But do they actually do that? As much of the research is still in its infancy, it is difficult to quantify. However, some studies have shown that older people increased their physical activity with a combination of using a pedometer and a consultation with their GP.

"... recent surveys showed that 32% of users stop wearing these devices after six months, and 50% after one year"⁴. The lack of interest in the devices stems from them being deemed to be too much effort as users adopt this technology as a means to solve a problem.

For those with chronic health conditions, wearable devices can provide some general longitudinal data to assist in monitoring progress while limiting more uncomfortable and expensive options. For example, when diagnosing levels of conditions such as depression, a Smart Watch or FitBit could assist with readings of physical activity and sleep duration. Sleep apnoea can be diagnosed with a device that measures snoring and breathing volume. Some can also measure mild body movement and therefore diagnose symptoms of Parkinson's disease.

But despite all the uses of wearables and enhancements they've contributed to individuals reading their health, the actual use within the clinical population remains limited. "Clinical studies to date that have a closer resemblance to consumer wearables involve (1) pedometers and smartphone apps to tackle a sedentary lifestyle and obesity and (2) home telemonitoring solutions for patients with pulmonary conditions, diabetes, hypertension, and cardiovascular diseases."⁵

Privacy and Reliability

There are a couple of main points to address where the privacy of these devices is concerned:

1. Is the data stored from these devices secure?
2. Is the information and functioning of the devices reliable?

Current literature is not reflective of the potential harm associated with the over-reliance of these automations that “provide a false sense of security or fuel a self-driven misdiagnosis”⁶ As well as that, the manufacturers of these devices promote their benefits and the empirical evidence to demonstrate they perform effectively. A recent study even found that a number of these devices returned varying results when compared to each other with error margins of up to 25%. This is the main reason this data should be treated with some trepidation from a clinical perspective.

Wearers do not own the data saved on these devices; that usually remains the property of the manufacturers. There could be a number of issues with this, not just in terms of security and privacy, but also because wearers only receive a summary report and not a complete record of their results. Some of this information could also be sold on to third party agencies. The biggest issue with these devices and one that cannot be completely alleviated is the possibility of hacking due to the transfer of data between wearables and smartphones. “While the consequences of hacks are reduced for non-invasive wearables, a well-coordinated cyber-attack could lead to patient health data being compromised, lost, or distorted.”⁷

The impact of wearables in healthcare?

The data collected from wearables can provide healthcare practitioners with some extra information that will assist them to tailor care to patients and help patients take ownership of their care.

“For instance, David Rhew, MD, chief medical officer for Samsung, hopes that wearables can help patients move to the highest level of patient activation, Level 4: The Four Levels of Patient Activation

- Level 1: Predisposed to be passive. “My doctor is in charge of my health.”
- Level 2: Building knowledge and confidence. “I could be doing more.”
- Level 3: Taking action. “I’m part of my healthcare team.”
- Level 4: Maintaining behaviours, pushing further. “I’m my own advocate.”⁸

As these devices grow in popularity, regulators are careful not to restrict innovation, but instead form frameworks that will ensure the use of these devices is “validated in the context of their health-oriented value”⁹. The USA Food and Drug Administration and the UK National Health Service have both implemented regulations to manage mobile apps that are classified as “mobile devices”. In Australia, the Therapeutic Goods Administration (TGA) is currently reviewing the Australian regulatory guidelines for medical devices (ARGMD), however, there is some guidance in place.

What is a medical device?

According to the TGA “a medical device is:

1. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
 1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
 2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
 3. investigation, replacement or modification of the anatomy or of a physiological process;
 4. control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.”¹⁰ The regulation and classification of medical devices is based on the level of risk that product represents to the patient or the healthcare practitioner. As medical devices and its software are all relatively new, the current regulations do not adequately capture all under its rules. However, all Software as a Medical Device (SaMD) must appear on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied to the public. Even if the device is of the lowest classification ie has the lowest risk, it must meet the Essential Principles for safety and performance.

So, as the focus of healthcare systems turns to a more preventative based model, wearables can assist with patient care. Clinicians will work closely with data scientists to develop algorithms to quantify various health conditions and risk factors. It is difficult to predict if the popularity of these devices will stand the test of time or if the novelty will wear off eventually, but in the interim as the use of these continues to grow, healthcare practitioners must remain mindful that a greater number of patients may present with the data from these devices. It is the role of the healthcare practitioner to ensure that all clinical information is examined, and it is explained to patients that the data from these devices is not always 100% accurate.

1. [Australian wearables to hit \\$1b Business First Magazine](#)
2. [One in five Australians use wearables: Is your business smartwatch friendly?](#) Dominic Powell. Wed Nov 23, 2016. Smart Company
- 3,4,5,6,8. [The Rise of Consumer Health Wearables: Promises and Barriers](#) Lukasz Piwek, David A Ellis, Sally Andrews, Adam Joinson. Feb 2, 2016
7. [Wearable Medical Devices Give Abundant Data—and Risks](#) Miranda Felde, MHA, CPHRM, Vice President, Patient Safety and Risk Management
- 9,10. [Australian regulatory guidelines for medical devices \(ARGMD\)](#)

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