Wearables in a Pandemic: What Are They Good For?

Brinnae Bent, Jessilyn Dunn

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Brinnae Bent[1] MSc; Jessilyn Dunn[1] PhD

[1]Duke University Durham US

Corresponding Author:
Jessilyn Dunn PhD
Duke University
2424 Erwin Road
Durham
US

Abstract

Recently, companies including Apple, Fitbit, and Garmin released new wearable blood oxygenation (SpO2) measurement technologies. While the release of these technologies has great potential for generating health-related information, it is important to acknowledge repercussions of consumer-targeted biometric monitoring technologies (consumer BioMeTs) that in practice are often used for medical decision-making. BioMeTs span both general wellness products and medical devices, and consumer BioMeTs intended for general wellness are not required to undergo a standardized and transparent evaluation process to ensure their quality and accuracy. A combination of the product functionality, marketing, and the circumstances of the global pandemic have inevitably led to the use of consumer BioMeTs that report health-related measurements to drive medical decision-making. We urge consumer BioMeT manufacturers to go beyond the bare minimum requirements described in FDA guidance when releasing information on wellness devices, and we also explore new methods and incentive systems that may result in a clearer public understanding of consumer BioMeT performance and intended use.

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Wearables in a Pandemic: What Are They Good For?

Brinnae Bent[1], MS, Jessilyn P. Dunn[1,2*], PhD

[1]Department of Biomedical Engineering, Duke University, Durham, North Carolina

[2]Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, North Carolina

*Corresponding author

Corresponding author address: 2424 Erwin Road, Durham, NC 27705

Corresponding author phone: 919-668-9798

Corresponding author email: jessilyn.dunn@duke.edu

Abstract

Recently, companies including Apple, Fitbit, and Garmin released new wearable blood oxygenation (SpO_2) measurement technologies. While the release of these technologies has great potential for generating health-related information, it is important to acknowledge repercussions of consumer-targeted biometric monitoring technologies (consumer BioMeTs) that in practice are often used for medical decision-making. BioMeTs are connected digital medicine products that process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function. These BioMeTs span both general wellness products and medical devices, and consumer BioMeTs intended for general wellness are not required to undergo a standardized and transparent evaluation process to ensure their quality and accuracy. A combination of the product functionality, marketing, and the circumstances of the global SARS-CoV-2 pandemic have inevitably led to the use of consumer BioMeTs that report health-related measurements to drive medical decision-making. We urge consumer BioMeT manufacturers to go beyond the bare minimum requirements described in FDA guidance when releasing information on wellness BioMeTs, and we also explore new methods and incentive systems that may result in a clearer public understanding of consumer BioMeT performance and intended use.

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Recently, several big tech companies released novel health functionalities such as the blood oxygenation (SpO_2) measurement capability. In September 2020, Apple released the Apple Watch 6, which is the first Apple wearable with SpO_2 monitoring capabilities. This comes on the heels of the Fitbit software update in January 2020 that included SpO_2 monitoring in existing

wearables and Garmin's August 2018 release of the Vivosmart 4, one of the earliest consumer wearable BioMeTs to perform SpO_2 monitoring at the wrist with the reported intent for fitness measurements at elevation. As of today, consumer-targeted biometric monitoring technologies (consumer BioMeTs) that are intended for general wellness purposes[1] do not require medical device regulatory oversight and instead fall under oversight by the Federal Trade Commission Act which prohibits unfair and deceptive acts or practices in commerce[2]. Accordingly, the majority of consumer BioMeT manufacturers do not report publicly on the performance of their sensor technologies. With the backdrop of the SARS-CoV-2 pandemic, wearables and other connected sensors that are marketed as consumer wellness BioMeTs are in practice being used for health decision making[3-6]. For example, during the recent Apple Watch 6 release event, this new SpO_2 functionality was referred to multiple times by company executives as a "health sensor" and mentioned in the context of SARS-CoV-2 detection and for studies on asthma, heart failure, and influenza[7-9]. Transparency about consumer BioMeT performance is desperately needed to avoid misinterpretation of data or improper use, which will ultimately undermine public perception and trust in these products. We propose three recommendations (Table 1): first, to include the intended use of the product for consumers, patients, medical practitioners, and researchers, rather than stating what they are *not* intended to be used for (i.e. medical decision-making). Second, consumer BioMeT companies should make it clear how the data should be interpreted and move qualifying statements that the products are not intended for health purposes from the fine print to the headlines. Lastly, we advocate for clarity surrounding performance of consumer BioMeT to increase trustworthiness of measurements from these products (Figure).

Table 1.
Recommendations

1.	Include the use of the product for consumers, patients, medical practitioners, and researchers rather than saying what they are *not* intended to be used for.
2.	Clarify how data should be interpreted by moving qualifying statements that the products are not intended for health purposes from fine print to the headlines.
3.	Clarify performance of consumer BioMeTs to increase trustworthiness of measurements from these products.

With the SARS-CoV-2 pandemic, the desire to use consumer BioMeTs to monitor potential symptoms of infection is understandable because monitoring for signs of infection at home may reduce anxiety and increase one's confidence in their healthy or sick status. The danger, however, is that many people are improperly using consumer BioMeTs to monitor for signs of illness, relying too heavily on data that does not have a sufficient evidence base, including without any oversight by medical professionals[10,11]. Adding to the confusion, it has become increasingly common for a single product to have differentially regulated features. For example, the Apple Watch received FDA clearance for detecting irregular heart rhythm using their electrocardiogram sensor, but the other sensors on the Apple Watch, including optical heart rate, are unregulated[12]. It can be challenging for consumers to understand which sensors are regulated (since, in this example, heart rate is monitored with two different sensors, only one of which is regulated by the FDA). This can be addressed through our first recommendation to change the status quo from manufacturers listing what the product is *not* intended for in the fine print to instead clearly stating the product's intended use and specifying the general wellness category from the FDA guidance document list[13]. For example, Garmin has set clear targets for use - for evaluating fitness at altitude for mountain climbers, hikers, and runners. Other consumer

BioMeT manufacturers have been less transparent about the target use case for their product, resulting in confusion on intended use for consumers, patients, clinicians, and researchers.

Users of BioMeTs should understand their intended purpose, limitations, and adhere to instructions for wear to ensure that measurements are interpreted correctly while minding the roles of noise, error, and biological variability. To support this, information should be provided in an easy to find and easy to digest format. Recently, researchers at Elektra Labs and the Digital Medicine Society proposed the use of a 'connected sensor label', similar to a nutrition facts label, which reports objective measures of a BioMeT's validation, usability, utility, security, and data governance components[6]. To support transparent validation, the group also developed the V3 Framework as a systematic assessment tool for BioMeT performance[14], and, very recently, published evaluation criteria for BioMeTs used for vital sign monitoring during SARS-CoV-2 [15]. Perhaps the most integral component of V3 is reporting results in a standardized and transparent manner[6,14,16-18]. These protocols and reports of findings are 'key tools for documenting scientific evidence needed to draw inferences on whether a technology is fit-for-purpose for the intended use and context of use'[14].

Table 2.
Scenarios to support and incentivize open evaluation and reporting of consumer BioMeT performance.

Scenarios (non-exclusive)	**Incentives**
Manufacturers of consumer BioMeTs release results already collected through internal product testing	• Consumer demand • Cultivate trust • Differentiate from competitors
Independent third parties (research laboratories, consumer groups, professional societies) evaluate and	• Impartial research • Expands fit-for-purpose use

publish against reference standards	• Publication/exposure • Potential funding by extension of Cures Act
New regulatory definitions through the FDA Digital Health Center of Excellence	• Innovate regulatory approaches • Provide efficient and least burdensome oversight

We can envision several possible scenarios to support and incentivize such open evaluation and reporting of consumer BioMeT performance (Table 2). Manufacturers of consumer BioMeTs are incentivized by consumer demand and can benefit from releasing results already collected through internal product testing to build trust in their products and differentiate from competitors. Independent third parties, including research laboratories, consumer groups, and/or professional societies, could also evaluate and publish accuracy and quality of measurements against reference standards. This work could be funded as an extension of the Cures Act[19] to support translation of these products into practice. While these practices are not intended to fall under FDA oversight, there is a possibility that they could be done in alignment with the goals of the new FDA Digital Health Center of Excellence which is to innovate regulatory approaches to provide efficient and least burdensome oversight while meeting the FDA standards for safe and effective products[20]. Transparency on the performance and intended use of consumer BioMeTs will cultivate trust and encourage their expanding fit-for-purpose use.

Contributors

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Declaration of interests

The authors declare no competing interests.

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Supplementary Files

Figures

We recommend a consumer BioMeT transparency label that would accompany all product marketing materials, packaging, and mobile applications. Transparency on the performance and intended use of consumer BioMeTs will cultivate trust and encourage their expanding fit-for-purpose use.