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Validity, reliability and utility of connected objects as a tool for clinicians

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**UNIVERSITÉ
DE GENÈVE**

FACULTÉ DE MÉDECINE

Clinical Medicine Section
Department of Medicine
Department of Community Health
and Medicine

**" Validity, reliability and utility of
connected objects as a tool for clinicians "**

Thesis submitted to the Faculty of Medicine of
the University of Geneva

for the degree of Privat-Docent

by

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Geneva

2019

Summary

The development of consumer grade connected objects has the potential to change the way we detect and manage health in many diverse domains, such as cardiovascular, respiratory, neurological disease, diabetes, sleep disorders and post-operative care. Some of the most significant advantages that connected objects could provide to the medical field include early diagnosis of diseases and exacerbations, improved patient autonomy and behavior, and remote communication with healthcare providers.

However, comprehensive studies on the validity and reliability of connected objects in medicine are still limited. More importantly, prospective trials exploring their impact on health outcomes are lacking. Nevertheless, connected tools offer low cost, accessibility and availability across a large community of users, allowing collection of big data in free-living settings. Continuous development in technology added to machine learning systems will further improve connected objects performance in medicine.

With the development of this new technology arise new challenges to our society. Regulatory authorities must revise their approach to address digital health. Confidentiality and personal data are increasingly difficult to protect from cybercriminals. On the other hand, insuring patients' privacy without limiting the development of new potential beneficial technologies is challenging.

An opportunity for improvement or a threat to our society, no matter what our opinion on connected objects is, we will have to adapt to them, as they are already everywhere.

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1 Introduction

Technological progress and innovation have transformed modern society in little more than two decades. Widespread use of the internet and more recently, smartphones, have expanded, accelerated global access to information, and increased connectivity between individuals. The broader technology movement, little more than 10 years ago, set in motion a sub-movement, encompassing trackers, consumer grade wearable tools, and sensors, described here as connected objects.¹

Over time, these technological advancements have ushered in more compact products and streamlined designs, facilitating connectivity through handheld objects and wearable activity trackers. The popularity of connected objects has grown substantially as new technologies have become more affordable, accessible, practical, more comfortable and attractive to wear. Wearable technologies integrated into watches, phones, bracelets, and clothing have revolutionized modern life. The connected objects market share has also shown steady growth, within 2014 “96 % made by Fitbit (67 %), Jawbone (18 %) and Nike (11 %)”.² Since 2015, other global tech leaders like Apple, Google, and Samsung have taken notice and entered the market with their own unique activity tracker concepts. Among the latest tools available is the Apple Watch, which entered the market in April 2015. In just two years, the Apple Watch outperformed the competition, and since 2017 has been lead seller of wearable activity trackers.³ The greater market for connected objects is projected to reach USD 42.4 billion by 2023, from USD 11.5 billion in 2018, with continued steady growth from increasing demand, including developments in healthcare digital technologies.⁴

Equipped with a wide variety of sensors, accelerometers, or infrared instruments, connected objects have the capacity to dynamically process the information through embedded software.⁵ Connected objects offer users a record of daily activities, such as the number of steps, walking distance, energy expenditures, sleeping time and activity intensity. When linked to smartphone or computer apps, they provide organized and aggregated data that can be used for personal training, shared on social media, and used to achieve behavioral changes.^{6,7} Hence, connected devices have contributed to a trend known as the Quantified Self movement.⁸ The Quantified Self movement engages users by allowing them to track their personal data using their connected objects.

The evolution of smartphones has brought about increased storage capacity and better connectivity further supporting the use of connected objects to monitor activity continuously and from anywhere in the world.⁹ The Internet of Things (IoT) is a network of interconnected and interactive objects. It was first mentioned by Kevin Ashton, co-founder of the Auto-ID Center at MIT in a presentation he

made to Procter & Gamble in 1999.¹⁰ IoT was later defined by International Telecommunication Union (ITU) as “a global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies”.¹¹

Technological innovation in the healthcare industry has kept pace with that of broader society, opening up new tools and resources for both patients and healthcare professionals. Patients are able to use medical resources on the internet to better understand their symptoms and identify possible diagnosis. Blogs and online virtual medical centers provide forums for patients to discuss their health concerns and experiences with health professionals and other users.^{12,13}

Most recently, technological progress in healthcare has focused on connected objects as measurement, monitoring and detection tools. Connected objects can provide invaluable data for the improvement of healthcare systems. For instance, monitoring systems provide a way for doctors to extend physiological monitoring out of the hospital over longer periods of time, and in free-living environments.¹⁴⁻¹⁶ Connected objects has also recently been the subject of more intense research. Feehan et al. found that between 2011 and 2017, 171 clinical trials have included Fitbit as a measurement tool in research.¹⁷ The research questions focused mainly on number of steps, daily activity and sleeping time, energy expenditure and walking distance as outcomes.

Based on the existing literature, healthcare use of connected objects can be divided into 4 different areas⁵:

- *Activity*: physical activity tracking, self-monitoring and rehabilitation procedures
- *Prediction*: prediction and prevention of future incidents
- *Anomaly detection*: detection of unusual patterns of behavior, provision of necessary alerts
- *Diagnostic support*: clinical observation based on patient condition and alerts, use in healthcare provider assessment and decision-making

Technological advancements have inspired a wealth of new tools for healthcare providers, but they have also provided new opportunities for patients to become more engaged in their own care. The expansion of health information technology and consumer e-health tools and services, such as tele-monitoring platforms and mobile health applications provide new avenues for patients to actively engage with healthcare resources.¹⁸ Some resources also have the capacity to monitor patients remotely for key physiological parameters in a patient’s typical, day-to-day context, outside the parameters of the medical facility.¹⁹

Patients who are well-informed about their health are more inclined to adapt their behavior to mitigate potential health risks.^{20,21} Consequently, engaging patients in their own care is vital to more personalized and improved quality of care. The use of connected objects could be an effective approach such a goal.^{12,13} Furthermore, connected objects have proven beneficial to post-operative care, both by facilitating patient-participation and by supporting continuous monitoring and follow-up after hospital discharge.¹⁹

The integration of these tools in routine care is underway and could greatly contribute to patients care in the future, but further development and testing is still required.^{22,23} One aspect that is still not well understood relates to the validity and reliability of connected objects, which has not yet been sufficiently explored in the scientific literature, especially for commercial and freely available tools. Still, connected objects are becoming increasingly sensitive and precise. As their accuracy is improving, this paradigm may change in the future.²³⁻²⁵

The principle of remote patient monitoring is not new. However, the large variety of consumer grade connected objects in modern society will likely result in a demonstrable impact on health management. The full extent of this impact is not yet known, though it is likely to affect all aspects of diagnosis and patient follow-up. Burgeoning technologies such as connected objects have become an inescapable part of modern life and a significant tool in the healthcare profession. However, potential benefits of connected object use could require shifts in the practices and routines of healthcare providers. How can healthcare professionals embrace these tools and best leverage new technologies to improve the both the medical field and the quality of care?

The aim of this research is to review consumer grade connected objects available for patients, outside of marketed and prescription products, and to question their legitimacy and reliability in the context of patient care and in the medical field.

2 Connected Objects – Description and type of sensors

The literature review process on the subject of consumer grade connected objects revealed a large diversity of terminology, including but not limited to: *consumer wearable devices, wearable activity trackers, smart wearable sensors, activity trackers, fitness trackers, consumer grade activity trackers, activity monitors, smart medical devices, and wearable health devices*. For the purpose of clarity, *connected objects* will be used in this review as the general, broadly applicable term.

A wide range of connected objects are available in the market, and new wearables are always in development. In principle, connected objects are made up of an accelerometer, a gyroscope, a battery, a wireless connection technology, and a firmware including data management software.²⁶ The most commonly found sensor is the accelerometer, which is used to detect acceleration and indirectly movement, and monitors physical activity.^{24,27} Usually, accelerometer sensors are worn on wrist, ankle, waist, chest, arm or legs. They can also be attached to user clothing. Shoe sensors offer are highly effective in monitoring gait and limping, and can determine foot position and orientation.²⁸ As long as they are connected and worn appropriately by the user, these sensors have the capacity to record motion, speed, acceleration, and step count. In addition, connected objects can compute walking distance, detect posture and estimate energy expenditures.²⁹⁻³¹ Triaxial accelerometers collect acceleration data based on vibrations in a 3D axis plane, which detects and measures movement and posture, such as upright and lying down positions.^{32,33}

Gyroscopes are also commonly found on sensors. A gyroscope is a mechanical device including a spinning rotor that measures rotation and orientation based on the principles of angular motion. These measurements can provide an estimation of the angular velocity.³³

New sensor models have been used to monitor blood oxygen saturation using the optical absorption of hemoglobin proteins to measure pulse and blood oxygen levels. Electrodes are also available to measure the voltage differences generated by the heart and skin conductance.³⁴ These sensors can typically be worn as gloves or rings, as well as necklace, brooches, pins, earrings, and even belt buckles.

Some wearable clothes are for instance able to monitor the heart rate, blood pressure, respiratory rate, body temperature, skin conductance and even record an electrocardiogram (ECG).²⁸ Photoplethysmography technology that detects blood volume change through light absorption is found in latest devices (Apple Watch, Fitbit Charge HR) and offers an important improvement compared to preceding technologies for heart rate determination, and an indirect estimation of energy expenditure.³⁵

3 Validity and Reliability of Connected Objects

Connected objects have been available only for a brief period in recent history. The first connected objects were developed and accessible to consumers in the late 2000s. Research on the validity and reliability of connected objects, in particular in the field of healthcare, is still limited have focused on the accelerometers sensor.²²

Collaboration between Apple and Nike on the Nike and iPod fitness tracking device resulted in the development of a new tracking tool aimed at helping users to exercise more and to maintain or improve their physical fitness. The fitness tracker market expanded further in 2009, with the launch of the first Fitbit attached to a belt, which measured step count using an accelerometer sensor.³⁶ Since then, the number of available connected objects has grown exponentially. Market share from the first quarter sales in 2015 indicated “the top five vendors were Fitbit (34 %), Xiaomi (25 %), Garmin (6 %), Samsung (5 %), and Jawbone (4 %)”. Since 2017, Apple Watch has overtaken the competitor market, including Fitbit.³

Fitbit (Fitbit Inc, San Francisco, CA, USA) has developed several activity trackers, with the first model, the Classic model, introduced in 2009, as a clip-on device to be worn on the chest. New models of clip-on devices became commercially available in 2011 with the introduction of the Ultra, Zip, and One models. In 2013, Fitbit introduced several wristband activity trackers.¹⁷ Fitbit is now one of the most popular commercial wearable activity trackers with more than 63 million devices sold worldwide in the last 10 years and 15 million sold in 2017 alone.³⁷ The trackers have progressively included more and more sensors, and the latest version typically includes a triaxial accelerometer, an altimeter, heart rate monitor and a GPS. Fitbit trackers can be worn, based on the model, at the waist, on the wrist, in a pocket or attached to a bra. The companies developed proprietary firmware with embedded algorithms that provide daily summarized information from data collected from the sensors. The data summary includes steps, distance, physical activity, energy expenditure and sleep time estimation.³⁸

Fitbit wristband connected object has the advantage of offering dependability, durability, and acceptability among users.^{39,40} Although designed as a consumer product to help motivate individuals to be more physically active, Fitbit devices are becoming increasingly popular in field of medical research, and in the healthcare sector, to encourage healthy behaviors and to promote patient–health professional interactions.¹⁷

The Jawbone company, another well-recognized activity tracker enterprise (San Francisco, CA; <https://jawbone.com>), has been developing trackers between 2011 and 2017. Jawbone trackers

contain a triaxial accelerometer and more recently bioelectrical impedance for heart rate, respiration, and skin response, as well as both skin and ambient temperatures. Most Jawbone devices are to be worn at the wrist. Jawbone connected objects offer daily summarized data on step count, distance, physical activity, energy expenditure and sleep.³⁸ In June 2017, the Jawbone company went on liquidation.

Consumers expect high reliability and validity from their Fitbit devices. In the context of healthcare, or when using a Fitbit as a research tool, precision is much more critical. Physicians and researchers cannot rely on uncertain or potentially flawed data to draw important conclusions or make critical therapeutic decisions.^{41,42} The validity (or accuracy) of a connected object refers here to the ability of the device to measure the correct and precise value, whereas reliability (or precision) of the tool refers here as the intra or interdevice consistency of repeated measures.⁴³ Accurate measures are classically defined as a mean absolute percent error within 3% in controlled testing conditions and within 10% in free-living setting.¹⁷ Exploring the validity of trackers is an important matter. Fitbit devices are used more and more frequently in research to measure outcomes and as tools in healthcare decision-making.^{41,42} Feasibility represents how much data was lost or absent, and the relative ease of use based on user feedback. Low feasibility is associated with poor adherence and linked indirectly to poor data quality consequently, it is also an important consideration.³⁸

Studies examining accuracy in controlled settings compare a Fitbit measure against a predefined reference-standard criterion measure, whereas studies conducted in free-living settings compare the Fitbit measure against a predefined research-standard criterion measure.¹⁷ Measurement of accuracy in a controlled setting is not the same as accuracy measurement in a free-living situation. Therefore, the accuracy evaluation must be based on predefined limits, with higher expected levels of accuracy and consistency in controlled settings than in free-living settings.⁴⁴⁻⁴⁷ Connected objects are typically tested in restricted conditions, among non-obese healthy adults in good physical condition. Accuracy levels may vary depending on the demographic and physical condition of the sample group. For instance, measurements from specific characteristic groups, such as obese patients, may yield different results.^{47,48} When assessing validity and reliability of connected objects, the tool should be tested in different contexts, with different populations, with different type of activities, and different intensity levels, as results can differ significantly.^{49,50} Skin pigmentation can affect pulse rate detection emitted from the sensor and introduce bias in heart rate measurement.⁵¹ The validity of photo-emitting sensors should also be tested among groups of individuals with differing degrees of skin pigmentation.

Monitoring and measurement is not limited only to one position or sensor. Connected objects may sometimes include several sensors that simultaneously collect different measures on the same user. Furthermore, several tools can monitor the same user from different points on the body, such as the wrist, ankle and thorax. When combining the different collected information on the same variable, validity increases. In a study conducted by Olguín et al. with accelerometers, the validity of the measure increased dramatically with the addition of a second sensor. The addition of a third sensor also yielded a slight improvement to validity, although the difference was not significant.⁵² On the whole, it is understood that the combined information of several sensors can improve overall validity.

Although sensors have the capacity to provide reliable and valid data, the measurement and monitoring is limited by the consistency and frequency of use. Sensors that are not worn consistently may produce flawed or inaccurate results. Data may sometimes be collected from the devices even if the device is not worn. Imprecise information and useless data could introduce bias in the analysis. Confirming skin contact by temperature or heart rate sensors could potentially address these challenges.⁵³

As previously noted, Fitbit and Jawbone are among the first and the most well-known products available on the market. The validity and reliability of Fitbit and Jawbone devices as activity trackers were explored in several publications and summarized by Evenson et al. in a literature review published in 2015.³⁸ The authors analyzed 22 studies published since 2012 and evaluated the validity and reliability for steps, distance, physical activity, energy expenditure and for sleep, as well as feasibility; defined as absent or lost data, and patient feedback. They concluded that 21 of the 22 studies explored the validity of at least one type of activity tracker, and seven studies reported the interdevice reliability of several Fitbit trackers. However, no studies reported intradevice or interdevice reliability of the Jawbone or the intradevice reliability of the Fitbit. Consequently, several research gaps remain in the published scientific data related to these tools.³⁸

Evenson et al. showed the highest levels of validity in measurements of the step count, with less validity in the detection of physical activity and distance traveled. Findings related to energy expenditure and sleep generally showed poor validity results. However, no comparable studies were found for the Jawbone. Several reviewed studies concluded that better documentation on validity and reliability should be provided for new connected objects in the future, including clinical and research settings. In addition, some studies provided suggestions for future improvements, including how tracker validity could be improved in future products.³⁸

In a systematic review of the literature in 2018, Feehan et al. concluded that Fitbit activity trackers were often not enough explored in research “in the manner for which the devices were intended, which is for self-monitoring of physical activity patterns and motivating individuals to achieve their physical activity goals”.¹⁷ Several authors draw similar conclusions with regard to this issue.^{41,42,54,55}

4 Data Management and Machine Learning Systems

Connected objects include an integrated firmware with a software, that is frequently not open-source, nor publicly accessible. Softwares are regularly updated, which can affect validity and reliability, positively or negatively.⁵⁶ Therefore, the component data processing software plays an integral role in the evaluation of validity and reliability in connected objects.²² Consequently, although the software component of the tool plays a vital role in the product function, it is often difficult to control, and may present certain challenges to consistent evaluation of validity and reliability.

Companies tend to limit access to data only through their embedded software, and full raw data is not always freely available for research purposes. Limited data access can hinder reliability testing and further research project development. In the case of Fitbit, data can be extracted using a third-party service provider, such as Fitabase (Small Steps Labs LLC; <https://www.fitabase.com>).⁵⁷ The Fitbit company declared that based on internal studies, they “tuned the accuracy of the Fitbit tracker step counting functionality over hundreds of tests with multiple body types. All Fitbit trackers should be 95–97 % accurate for step counting when worn as recommended”.⁵⁸ This information is however not verifiable, as the company does not provide the exact condition of testing, the inclusion criterion and exact outcome measured, nor have the data been made available to confirm these claims.

Similarly, the Jawbone company indicated that “while variations in user, terrain, and activity conditions can influence specific calculations, testing has shown UP to provide industry-leading accuracy in tracking activity and sleep”.⁵⁹ However, the way in which reliability and validity was defined is not indicated by the company.³⁸ Typically, data collected from sensors are processed through the company proprietary algorithm. In such cases, only the processed data, only a small amount of the available data collected, is actually made available. The firmware filters and selects the exported data, offering summarized values with missing information.⁵²

In the case of the Apple Watch, Apple offers free access to heart rate data through the iPhone Health app and the iPhone Health Export app. Conversely, data concerning energy expenditure is only available after the data has been processed with embedded software that calculates the energy spent through an unknown algorithm.⁶⁰ As a counterexample, the ActiGraph accelerometer

company publishes firmware updates openly in order to give access for research and clinical purposes. Hence, modifications of measurement properties and data treatment from sensors should be clearly understood and integrated when clinical conclusions are drawn from the data.^{61,62}

The embedded algorithm's capacity to adapt progressively to user-specific and personalized parameters is a significant value to the function of the product. This quality is exemplified by machine learning systems, comprised of dynamic software that evolves over time, using data collected from a variety of users.⁶³ The use of machine learning systems also supports the management of large amounts of extracted data. The performance of the associated tools will also improve and evolve simultaneously, offering higher validity and reliability than the original tool. This process of continuous adaptation of the system elevates the quality of the product by providing individualized parameters, and by improving overall validity for all users.⁵² Devices that integrate machine learning systems have the ability over time to recognize individual patterns and to create tailor-made therapy.⁵²

5 Examples of clinical applications of connected objects

5.1 Steps, walking distance and physical activity

In 2015, Evenson et al examined the "validity and reliability of...[Fitbit devices] and their ability to estimate steps, distance, physical activity, energy expenditure, and sleep".³⁸ They concluded that Fitbit devices were moderately associated with reference controlled tool for measures of steps, sleep, and distance, with associations varying from poor to moderate for measures of energy expenditure and time in activity. They also found that Fitbit had a high interdevice reliability for all outcome measures. In addition, the review provided some data for measurement accuracy. However, it did not comprehensively examine device measurement accuracy or study quality.^{41,42}

In 2018, Feehan et al. systematically reviewed 67 published studies exploring the accuracy of Fitbit devices for steps, distance, time in activity, energy expenditure and sleep, in controlled and in free-living settings. They defined accurate measures as those within a 3% margin of error in controlled testing conditions and within a 10% margin of error for a free-living setting.¹⁷ For step count, Fitbit measurements were compared to research-grade accelerometers or pedometers.

In controlled testing conditions, Fitbit comparison of the step count to treadmill results provided accurate measures with an overall tendency for underestimation. The Feehan study also concluded that step count accuracy was dependent on the sensor placement, with better results found when

the device was worn on the chest during normal walk pace, worn on the wrist during jogging activities and worn on the ankle during slow or very slow walking activities.

Crouter et al. demonstrated that underestimation of step counts at low speeds is a common phenomenon with several research grade pedometers, and not a specific characteristic of connected objects in general.⁶⁴ In free-living settings, the study showed that approximately 50% of the time, Fitbit devices provided relatively accurate measures of steps when worn on the thorax or wrist in healthy adults with no mobility limitations. However, the research showed some evidence of step count overestimation in controlled settings. The number of studies in free living conditions was limited, and showed an underestimation of sedentary time and an overestimation of time spent in activity, as intensity of activity increased.¹⁷ Accuracy was affected by the walking speed, with a tendency to underestimate steps at very low pace or when using a walker, during activities that involve regular interruption. In terms of the time spent in different intensity of activity, compared to research grade accelerometers, Fitbit devices tended to underestimate sedentary time in free-living settings.¹⁷

Evenson et al. found that the validity of the Jawbone steps count was generally high, particularly in controlled settings, compared to the tool measurement to treadmill results.³⁸ The tracker tended to underestimate step count, in particular at low speeds, similarly to the Fitbit. Mammen et al. showed that the placement of the device on the hip improved step count accuracy except for older adults with slower walking speeds.⁶⁵ Takacs et al. assessed the validity and reliability of distance walked with Fitbit, showing that reliability was high, with an overestimation at lower speed and underestimation at higher speed.⁴⁸ Ferguson et al. compared Jawbone connected objects to other accelerometers and showed a large overestimation of moderate to vigorous physical activity with up to 1.5 hours per day in excess, whereas Tully et al. found better agreement with the reference tool.^{66,67}

In 2018, Bourdeaux et al. conducted the first study to determine the validity of connected objects during a gradually increasing cycling exercise test and during a structured resistance exercise.⁶⁸ They found that both heart rate and energy expenditure during exercise had an insufficient validity (defined as a mean absolute percent error of >10%) and concluded that the 8 tested devices (“Apple Watch Series 2 (AWS2), Fitbit Blaze (FB), Fitbit Charge 2 (FC2), Garmin Viviosmart HR (GVHR), TomTomTouch (TT), PolarA360 (PA360), Polar H7 (PH7)”), and were not medical-grade devices and therefore not acceptable for medical use.⁶⁸

Veerabhadrapa et al. showed a high accuracy of the Apple Watch for steps evaluation and did not find any significant differences with genders, age, and Body Mass Index (BMI) groups.⁶⁹

5.2 Energy expenditure

Energy expenditure can be calculated using connected objects based on physical activity time and intensity estimates. For example, the accuracy of connected objects for the estimation of energy expenditure was explored in several studies in controlled settings, comparing the Fitbit tool with a reference standard calorimetry, and reviewed by Feehan et al.^{17,49,70-74} Fitbit devices were worn on the chest or wrist and could estimate energy expenditure during an activity and at rest. Overall, Fitbit tended to overestimate energy expenditure during physical activity and underestimate energy expenditure at rest. Research carried out by Feehan et al. concluded that Fitbit devices were seldom likely to provide accurate measures of energy expenditures.¹⁷ The study also concluded that Fitbit devices were biased in their estimates of energy expenditure depending on the condition of the measure. Results were commonly overestimated when the device was worn on the wrist, or when walking at normal adult speed on flat surfaces. However, when trackers were worn on the thorax or during inclined ambulation or irregular physical activity, the results were often underestimated.

In free-living settings, the accuracy of energy expenditure measurement of Fitbits in healthy adults showed biased results.^{66,73,75} Some studies indicated a tendency towards underestimated energy expenditures by up to 30% compared with research grade tools.^{70,76}

More recently, photoplethysmography has become available on consumer grade products like the Apple Watch. The validity and reliability of these systems for energy expenditure has still not been sufficiently explored and does not seem to achieve more reliable estimations.⁷⁷

5.3 Sleep evaluation

Connected objects are advertised and often used by consumers to evaluate their sleep quantity and quality. However, published data on the accuracy on sleep measurement of common trackers like Fitbit or Jawbone are not available open source. Several authors have addressed this question.^{29,66,78-82} When compared with a classical polysomnography, sleep measurement showed high sensitivity of the trackers. The heightened sensitivity, however, included a tendency to overestimate the total sleep time and sleep efficiency, defined as the number of minutes of sleep divided by the number of minutes in bed, by up to 15%,⁸¹ and underestimation of wake period after sleep onset.^{29,78-80,83}

Feehan et al. reviewed the existing literature in 2018 and explored the question of connected objects accuracy for sleep evaluation. The study concluded overall that there was limited research examining the accuracy of sleep measures in controlled and free-living settings. With regard to the Fitbit tracker, they concluded that the measures of sleep quality and quantity were not accurate compared

with polysomnography. They also concluded that sleep-onset latency (time to initial sleep) and time awake after sleep onset measurement errors varied largely from the reference measurement.¹⁷ However, in free-living settings, when comparing Fitbit tracker to controlled grade accelerometers, they found higher accuracy of the Fitbit tool for time spent in bed and time sleeping in free-living settings.

Mantua et al. tested 4 different connected objects compared to research grade measurement in 2016 and confirmed low reliability of total sleep time, sleep efficiency and did not provide quality data concerning sleep staging, i.e. light versus deep sleep.⁸²

5.4 Cardiopulmonary and vascular monitoring

5.4.1 Cardiac rhythm

Several connected objects have been developed to monitor cardiovascular activity. Most of the connected objects are external and located on the wrist or the chest to accurately monitor cardiac function.²² Some of the smart wearable devices are surgically implemented to achieve higher reliability.²² Data from these devices is uploaded to a smart phone and provides access to the collected data, such as 24h ECG, available for patients and/or their physician. The Advanced Medical Monitor is a cardiovascular-specific device that can simultaneously measure physical activity, blood pressure, oxygen saturation, temperature and ECG.⁸⁴

The Murata sensor is another example of a multi-sensor connected object. The Murata device (*Murata Manufacturing Company*. <http://www.murata.com/>) uses optical absorption of hemoglobin to record heart rate and blood oxygen saturation. It also uses electrodes to obtain a continuous ECG. Based on Murata's collected data, included software provides information on fatigue and exercise-related stress.

An example of another external multi-sensor device is the AliveCor. AliveCor is integrated in a phone case and includes ECG electrodes, which allow recording of patients' cardiac activity, and provide access to the data to healthcare providers.⁸⁵ In the detection of asymptomatic atrial fibrillation, Halcox et al. showed use of the AliveCor device resulted in superior outcomes when compared to standard care.⁸⁵

More recently, photoplethysmography has been made available on consumer grade connected objects which offers higher accuracy in the measurement of heart rate. The validity and reliability of these systems for heart rate monitoring has not yet been sufficiently explored.⁸⁶ Among the available connected objects, Apple Watch seems to offer the highest accuracy in heart rate estimation.⁷⁷

Khushhal et al. conducted a study of 21 male adults tested in a controlled setting, the Apple Watch showed high validity results during walking activities, but less accurate estimates during running.⁶⁹ In 2018, Falter et al. explored the validity of Apple Watch among patients with cardiovascular disease.⁶⁰ They concluded that the Apple Watch heart rate evaluation was highly precise. Koshy et al. confirmed that Smart Watches offer a good accuracy to measure heart rate in sinus rhythm and atrial flutter. However, Smart Watches may underestimate heart rate in atrial fibrillation.⁸⁷

In late 2017, Cardiogram, an App available for several consumer grade connected objects, declared from a study conducted with the University of California, San Francisco, that the Apple Watch can detect atrial fibrillation when associated with an artificial intelligence neural network called DeepHeart.⁸⁸ This information has not been published in a scientific journal nor verified externally.

5.4.2 Connected object in hypertension

The European guidelines on cardiovascular disease prevention recommend regular blood pressure measurement in order to prevent coronary heart disease and stroke.⁸⁹ Adherence to this recommendation is low and only few patients regularly follow up on their blood pressure. Connected objects could play a determinant role in this regard, allowing regular home-based blood pressure monitoring, and improving quality of care among patients suffering from hypertension.⁹⁰

Hsu et al.⁹¹ developed a blood pressure measurement technique based on pulse wave velocity using two microelectromechanical sensors placed in two adjacent points of the body (wrist and neck). More recently Woo et al.⁹² built an experimental watch prototype which uses a pressure sensor close to the radial artery to estimate an absolute blood pressure without any discomfort. Blood pressure and ECG can also be monitored continuously by integrating a photoplethysmographic sensor and an ECG sensor in the same smart wearable device.⁹³

Even though blood pressure is probably the most important vital parameter to follow closely to improve health outcome, validity and outcome study on impact of these tools on hypertension is still missing.

5.4.3 Chronic heart disease and connected objects

Cardiac failure is a severe chronic disease with high morbidity and mortality characterized by multiple relapsing exacerbations.⁹⁴ Patients' outcome can be improved by careful vital parameters monitoring. Connected object using multiple sensors including blood pressure measurement, weight

scale, activity monitoring with Smart Phones could help detect early signs of worsening cardiac failure, propose faster intervention, avoid excessive consultation and improve quality of care.⁹⁴

Cook et al. have studied functional recovery in the elderly after cardiac surgery using accelerometers to assess mobility after cardiac surgery and they showed a correlation between early stage steps walked, and length of stay and dismissal disposition.²⁵

5.5 Connected Objects in Respiratory Medicine

Respiration rate is an essential vital parameter affected by most severe health situation. Early signs of cardiovascular, respiratory or metabolic exacerbations have an impact on it, and respiratory rate is a good predictor of sudden cardiac arrest.⁹⁵

Respiratory rate can be determined using connected objects using very different technologies and from different sources, including contact and non-contact sensors, well summarized by Al-Khalidi et al. review.⁹⁶ Multimodal sensor connected objects are able to record respiratory rate continuously at the same time as oxygen saturation, and detect respiratory events like coughing. The microwave reflectometric vital signal sensing systems is able to detect weak microwaves that irradiate from the patient's body without direct contact and is an attractive, comfortable solution.⁹⁷

An example concerns chronic obstructive pulmonary disease (COPD) patients who suffer from relapsing exacerbations, for which early detection and intervention would be beneficial. Wu et al. demonstrated with a cohort study that using smart watches with audio, heart rate and physical activity information continuously collected among COPD was feasible.⁹⁸ A preliminary study of 30 COPD patients monitored at home with wearables has demonstrated the high validity and sensitivity of detection of patients' exacerbation.⁹⁹ A randomized trial using sensors and vibrating inclinators showed an impact on sedentary time among COPD patients using teaching protocols associated with connected objects among participants.¹⁰⁰

Sleep apnea is a common and underdiagnosed disease with severe morbidity. Simple, inexpensive and reliable tool to detect sleep apnea would help sleep apnea early detection and treatment, and avoid complications including car accidents. However, for the time being, only medical grade devices have been considered as accurate enough to set up the diagnosis.¹⁰¹ As previously stated, Cardiogram, the App available for several consumer grade connected objects declared that the Apple Watch can detect atrial fibrillation and sleep apnea when associated with DeepHeart.⁸⁸

5.6 Connected objects in Neurology

In 2009 Kuo et al. measured steps and distance walked, and estimated gait among children with cerebral palsy (CP) using two wearable sensors, one placed on the lower back and another placed superior to the right ankle.¹⁰² They showed some of the tested sensors were providing very accurate and reliable data to monitor gait in this population, whereas other sensors were not reliable or accurate. Another study conducted in 2011 using inertial sensors that provided auditory and visual feedback demonstrated a rehabilitative approach to sensors. This study demonstrated that patients with CP related gait disorders had a 21% residual short-term improvement in walking speed and 8% increase in stride length with visual feedback, as well as an average short-term improvement of 25% in walking speed and 13% in stride length for auditory feedback. The results were compared to matched controls, which did not show a measurable change in gait.¹⁰³

In epilepsy, early detection and seizure monitoring is an important matter. Accelerometer sensors can also be used to monitor seizure activity in patients, as shown by a study conducted at Stanford University Medical Center. The authors used a wristwatch device, the SmartWatch, to detect seven out of eight total seizures and healthcare providers were directly informed of the events.¹⁰⁴ Early contact with healthcare providers could allow quick intervention, hence reducing risk of serious injury.

Among stroke patients, the follow-up of physical activity in free-living condition is of interest, as reaching recommended exercise levels could help maintain the patient at home. Accelerometers have been shown as a reliable tool to monitor physical activity among stroke patients.¹⁰⁵ Rand et al., monitored 40 stroke patients for 3 consecutive days and on a 6-minute walk and found that the data collected from the devices was reliable, showing low physical activity with approximately 60% of the patients not reaching the recommended daily activity levels. This could increase healthcare providers access to patient feedback and help improve patient behaviors.

In Alzheimer's disease, early detection could help address early intervention. Specific motion abnormalities related to temporal dysfunction can be detected among patient's suffering from early sign of Alzheimer's disease, as shown by a team from Rostock University using axis accelerometer sensors on the ankles compared to a matched healthy control cohort.¹⁰⁶ The built algorithm was able to detect Alzheimer's among patients 90% of the time, which is more than the conventional Cohen-Mansfield Agitation Inventory clinical test.

Parkinson disease, which affects mainly motion at early and late stage of the disease, is naturally a good target for early detection and follow up using accelerometer sensors in free-living settings.

Weiss et al. evaluated the ability of connected objects to recognize motion patterns specific to Parkinson disease and assess their mobility.¹⁰⁷ Healthy adults and patients with Parkinson disease had sensor placed on their waist during short walks. Gait variability and average stride times were explored using frequency analysis in free-living setting. The author concluded that estimated stride-to-stride is an objective, easily calculated marker of gait variability for Parkinson disease monitoring using ankle accelerometer sensors.

5.7 Connected Objects in Rehabilitation

The ability of connected objects to monitor daily physical activity in free-living settings makes them incredibly well-suited to rehabilitative care. Connected objects can provide both patients and their care providers with detailed and objective information related to the recovery progression process, and embedded software can include warnings, and educational content. Furthermore, feedback mechanisms can provide patients with suggestions to improve their level of activity and behaviors.

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Connected object have been used in different settings, including cardiovascular and pulmonary rehabilitation with positive results on outcomes.^{25,109} In respiratory rehabilitation, some researchers consider wearable sensors to be an integral component of care for severe lung disease.

Accelerometers, in particular have the potential to drive patients to increase their overall level of physical activity.^{100,109} Connected objects can measure the adherence to the intervention of patients following a pulmonary rehabilitation program to promote physical activity and exercise after program completion. Although most of the research has been devoted to sensors involving rehabilitative therapies, sensors as diagnostic tools for prevention and early detection are gaining in popularity.

The connected object allows self-monitoring, enabling users to strive towards and track progress of specific physical activity goals. Connection to the broader community of activity trackers can allow users to benchmark their progress against the activity levels of others, which can in turn motivate wearers to exercise more and reach more challenging goals.^{7,110}

Accelerated rehabilitation after surgery, or enhanced recovery after surgery (ERAS) initially introduced by Kehlet¹¹¹ could be an opportune context for the use of connected objects, which would allow heightened healthcare provider– patient interaction after early discharge from the hospital.^{25,112-114}

5.8 Connected Objects for Glucose Level Monitoring

Global diabetes rates have been steadily increasing for the last 30 years, with an estimated 1.6 million directly related deaths and 2.2 million attributable deaths due to hyperglycemia, based on World Health Organization data.¹¹⁵

An adapted diet, and regular physical activity are critical to diabetes management and a reduction in the associated risks. Self-monitoring tools could improve patient autonomy by providing simple and convenient monitoring options, encouraging patients to better manage associated risk factors and related outcomes.¹¹⁶

Technologies to measure glucose levels have rapidly evolved in recent years, becoming increasingly sophisticated, streamlined, and compact. Non-invasive glucose monitoring tools, in particular, are very useful for diabetes patients. The connected object developed by Solianis Monitoring AG is a multi-sensor with several electrodes that collect glucose levels, temperature, and humidity levels.¹¹⁷ New non-invasive sensors are continuously in development, and tech giants are exploring new ways to measure sugar levels more efficiently and to improve the diabetic quality of life. Google and Novartis, for example, collaborated to create a connected ocular lens that could measure tear glucose levels.^{118,119} This project, however, is not likely to be feasible for the time being for technical reason.¹²⁰

Kovatchev et al. explored the feasibility of a portable pancreas system in patients with type I diabetes using a monitoring device with an insulin pump, controlled by a software algorithm coupled with a smartphone.¹²¹ Diabetic patients were monitored during a 42-hour period as outpatients with equivalent glycemic control as with a laptop configuration. The system allowed greater autonomy, an improved quality of life, while also offering the healthcare provider a remote connection to their patients.

Recent progress in smartphone applications and wearable sensors will bring a new dimension to diabetes care and personalized medicine.¹²²

6 Discussion and perspectives

From the first consumer grade trackers to newest sophisticated multi-sensor devices with dynamic machine learning software, connected object development has been booming in the last decade. Quality research must keep pace with these sudden developments. The reliability and validity of the data provided by new tools must be tested by comparing them to reference tools. However, given their recent development, available research on their validity and reliability is limited, in particular for the latest devices. Independent research is of critical importance to ensure objective, unbiased study of future developments in connected objects.

Validation of tools must be done in different settings (in controlled and in free-living settings), among different populations (i.e. older, obese populations) and in different conditions (position of the tool, intensity and diversity of activity). Most research available on connected objects has been done in controlled environments. There is a need for additional studies carried out in uncontrolled conditions, during typical daily activities of connected object users. Consequently, conclusions of research work on connected objects may not be broadly comparable or relatable to all settings and populations. In the validation of connected objects for sleep evaluation, for example, performance of the object improves over time, as it learns from a network of connected users. Testing the device in a lab, during one single night, would underestimate the performance of an adaptive tool.²⁹

6.1 Impact of machine learning and AI

Fitbit wristband connected objects are consistently recognized by users as dependable, durable, and acceptable. More broadly, users are commonly attracted by the low cost, accessibility and widespread availability of connected objects. In addition, extensive use of these tools provides an opportunity to collect data from a diverse network of users in their free living settings. Large data centers can support new algorithms and improvements to the software processing the data through machine learning and AI systems. As a result, the software will be able to adapt to the users, and offer superior personalized data processing. Recent developments in AI technology, including the DeepMind approach from Google, have the ability to detect new patterns from big data mining and help to dramatically improve tool performance.¹²³

Connected objects include embedded machine learning systems to manage large amounts of data. The elimination of human intervention presents several advantages. Automation reduces costs and improves validity and reliability. However, smart devices that include software to access and process the data can introduce bias, which must be accounted for. For research purposes and clinical decision making processes, unknown and inaccessible raw data can be challenging, and requires regular

retesting. Firmware can correct bugs and improve measurement properties, as well as how variables are built from the data. These changes may not be visible by the user, researcher or clinician. ⁵⁸

If a machine learning system is continuously learning from a network of connected users worldwide, the validity of the tool as a whole is dynamic and will likely improve over time. Consequently, even shortly after publication, research findings on validity and reliability may no longer reflect the real performance of the tool, due to the machine's learning progression.

6.2 The benefits of connected objects in medicine

The number of research papers on the use and benefit of connected objects in medicine is increasing fast, exploring each of the domains described by Banaee et al.⁵ : activity and rehabilitation, prediction of disease development or exacerbation, detection of anomaly or unusual patterns of behavior, and diagnosis and therapeutic decision support.

Chronic disease represents one of the greatest healthcare challenges of our modern society.¹²⁴ Connected objects could benefit patients suffering from chronic disease. The potential for early detection of disease could trigger specific responses and prevention measures for at-risk populations. Early detection of exacerbations could prompt alerts and specific targeted actions. New unknown signs of disease could be discovered through sensor and machine learning processes. Treatments could be adapted more precisely and customized to the patient, based on specific key parameters. Finally, automated software included in smartphones could offer rapid management protocols and help to adapt the treatment of patients without the direct intervention of healthcare providers. Connected objects could also yield cost savings for patients and insurance providers, both by encouraging healthy behaviors and through the recommendations of early intervention. Early intervention is often more efficient and less expensive than a late hospital treatment, potentially eliminating the need for hospitalization. Reducing the need of healthcare provider intervention by automated protocol also supports cost reductions.

In addition, therapeutic approaches can be influenced by the use of connected objects. For example, early detection of medication related side effects could trigger adjustment of treatment dose/schedule to better meet the needs of the patient, based on his characteristics and parameters. Furthermore, the detection of low compliance to treatment is helpful in understanding therapeutic failures and could support healthcare providers in developing more effective measures, such as reminders or educational resources. Based on continuous learning processes from large data sets, optimization of the therapy, or novel therapy/protocols could be developed.

In order to assess the impact of connected objects on healthcare related outcomes, large, well-conducted prospective randomized trials should be carried out. This research has yet to be completed.²⁹ For now, scientific literature is sparse and large gaps exist between existing proof of efficacy and the existing tools. The speed of development of electronic and connected tools presents additional challenges. As soon as a trial is finalized for a given connected object and new technologies are likely to have emerged, diminishing the relevance of the completed research. Consequently, a thorough and up-to-date evaluation of connected objects is a near impossibility.

Similarly, the fast development of new and more performant tools competing with existing tools induces rapid obsolescence. Hence, life expectancy of connected tools is by essence short and companies developing these tools are at risk of early bankruptcy, like the Jawbone company that went into liquidation after only a few year of development. Given the time needed to obtain research data on patients' outcome and the short lifespan of connected tools, at the time the data will be available, the tool might not be any more available probably already overtaken by a new and more performant tool.

6.3 Quantified self: patient's empowerment through self-care

Quantified self is a term used to describe self-tracking, using parameters from connected objects to better understand our own health.¹⁹ In the healthcare context, the Quantified Self movement can encourage patients to be proactive and engaged in their own health, often promoting improved healthy behaviors.¹⁹ Self-efficacy is defined as "the individual's capacity to produce desired effects."¹²⁵ Using connected objects, individuals can improve self-efficacy through the use of apps that inspire and encourage activity. Devices can be now linked to Smartphone Apps which both track user activities, as well as recommend additional activities, and advise on healthy behaviors.¹²⁶

Fox S et al. carried out a web survey in 2012 that showed that close to 20% of participants have used some form of technology to track their health data. One third of those surveyed responded that activity trackers have influenced the way they treat a medical condition.¹²⁷ When integrated into care for chronic diseases, connected objects may help patients and their care providers to more actively manage health and well-being.²³ Better habits can support better health outcomes. In order to achieve behavioral changes, however, collecting data from connected objects is not enough.¹²⁸ To introduce sustainable behavioral changes and to become more physically active, it is important to get the appropriate education to do so. Well-informed patients are generally more proactive and likely to adopt new, more healthy behaviors, resulting in improvements to both health and well-being.¹²⁹

The Quantified Self movement and self-empowerment are further supported by the IoT. Through multiple channels of information, sensors, connected objects, and associated feedback and learning tools, the IoT has the potential to enhance self-efficacy. Helping patients to proactively engage in their own healthcare would not only promote healthy behaviors, but could also potentially lower the costs associated with disease management.

Limitation of behavioral changes through Quantified Self Model has been underlined by several authors.^{130,131} A key factor that impacts negatively the expected behavioral changes is the user's adherence to the tool itself. A recent survey showed that only 21% of users of a Google Play® tracker had used it for more than 2 weeks.¹³² Interaction between computer and human are not yet well understood as little is known about people reactions and what influences their decision.¹³³ Hyper-personal systems that include patient's needs and preferences will probably improve this interaction.¹³³ A study on behavioral changes on physical activity found that the adoption rate of the tool was only 7% among those who had no defined plan about exercising. It went up to 50% contemplation or preparation.¹³²

6.4 Institutional impacts on the use of connected objects

Connected tools offer hospitals a medium for staying connected with their patients. With ERAS program, post-surgical health outcomes have been improved through the use of evidence-based medical protocols. These tools have helped to reduce the amount of time spend in unnecessary therapy and allowed for shorter medical stays. Early hospital discharge can present certain risks in cases where a patient is not prepared to adapt to new situations. Use of connected objects after hospital discharge could ensure ongoing contact with the discharge service, as well as offering educational materials and/or tools to the patient. Similarly, the use of connected objects for fragile, post-surgical patients could reduce complications by keeping an open link and line of communication between the patient and healthcare provider, even after the patient has been discharged from the facility. In addition, reliable connected objects measuring vital parameters could help to identify patients with early exacerbation, or help to detect signs indicating that early discharge may not be appropriate. The use of connected objects for purposes such as those discussed above could further reduce the average length of hospital stay, reduce costs, and improve the quality of care.

In addition, digital health can help insurance companies to improve the care of their insured patients and to reduce costs. By encouraging early detection, behavioral change, and self-learning measures, connected objects benefit insurance providers by reducing overall risks and potentially lowering expenses from claims. However, the way in which insurance companies use the personal data of

their patients must not be taken lightly. Without guidelines or regulations, there is a risk that certain insurance providers could stratify patient risk, select patients based on risk, and hinder access to insurance coverage for higher risk groups. The confidentiality of patients must be protected in order to ensure that personal data is not misused in a way that could impact high risk individuals or exclude patients from insurance coverage.

Similarly, large companies may offer their employees connected objects to evaluate alertness and physical fitness in order to reduce work-related health hazards, as well as to measure performance. In certain fields, such as aviation, performance evaluation could help avoid catastrophic accidents. Nonetheless, confidentiality risks and potential risks for the exclusion of workers do exist.

6.5 Risks and limitations of connected objects in medicine

Recent developments in the functionality and use of connected objects are overwhelming, fueled by tech giants and new market opportunities. The strict rules and regulations applied to medical grade devices have until recently not been applicable to consumer grade devices and connected objects. However, the U.S. Food and Drug Administration (FDA) approval, or similar CE approval, is required for the use of any digital tool to be used for “diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”¹³⁴

There are some risks that producers of connected objects or digital tools could circumvent the control of regulatory authorities. The responsibility for medical decisions based on consumer grade connected objects data must be also clarified. One could argue that a consumer grade connected object with high validity and reliability and with demonstrated positive impact on health outcomes in the medical literature should be considered as a medical grade device. Connected objects are more cost effective, and accessible to more users. Furthermore, the use of learning machine processing big data from streamlining connected objects will continuously improve accuracy over time. Therefore, given the rapid pace of development and advancement over time, consumer grade tools could conceivably outperform some medical grade devices with regard to certain metrics. For this reason, the FDA has developed and published in 2017 the “Digital Health Innovation Action Plan” to revise its approach to digital health, and to offer patients access to “high-quality, safe and effective digital health products”.¹³⁴ The focus will also be also on tools which present a “higher risk to patients, while choosing not to enforce compliance for lower risk mobile apps.”¹³⁴

The aim of these new technologies is to increase patient autonomy and create a collaborative relationship between healthcare providers and patients. However, falsely reassuring information from a device could interfere with a patient’s usual inclination to consult with their physician.

Conversely, excessive and inaccurate alerts from a connected object could trigger rapid, useless and costly medical consultations and induce excessive stress to patients. These risks could be reduced through patient education on the limitations of these technologies.²² Hence, healthcare providers should inform their patients on the risks of excessive trust and over interpretation of conclusions drawn from connected objects and digital health.

The success of connected objects depends largely on acceptance from patients and healthcare providers. There is probably no “one size fits all solution”, and matching the right technology to the right patient or clinician goal is necessary to convince users and healthcare providers of value and benefits of use.^{135,136} To facilitate use for patients, connected objects should be easy to wear and to operate, and should not interfere with daily activities. In practice, the device should complement and not replace healthcare provider care.¹³⁶ Connected object users have the option of engaging with social networks which can promote a sense of community and shared experiences. The efficacy of social networks may depend highly on the preferences of an individual user. Some independent-minded users may reject the interdependence associated with connected object social networks. Older, more isolated users, on the other hand, could potentially benefit from additional means of connection and social interaction.¹³⁷

Privacy, confidentiality, and data ownership are urgent priorities due to the modern challenges related to cybersecurity. The risks and benefits of data collection must be carefully weighed in order to ensure the security of patient personal data without hindering the progress of new technologies.¹³⁵ Government regulatory offices must carefully consider these aspects prior to the approval of any digital tools for medical use. Patients must receive clear information and provide their written consent for the collection and/or use of personal data, for a specified, limited period of time. If the same or other personal data is to be used in the future, new consent agreements must be arranged. Total anonymity is nearly impossible when collecting data on mobility.¹³⁸

Although they are commonly less expensive than medical grade tools, connected objects can be expensive, particularly the newly available watches. Codes for reimbursement of connected objects by health insurance will need to be discussed given their growing utilization in medicine.^{22,26}

6.6 Other limitations

The literature on activity trackers is rapidly expanding. It is possible that, despite my best efforts, key publications were not included in this review.

7 Conclusion

Despite having only recently been made available to the consumer market, connected objects have already become overwhelming. Thanks to the continuous technological improvement, they collect more and more parameters from their users. Using these data in medicine could have the ability to change the way we recognize and manage disease prevention, follow-up and treatment in many different areas such as cardiovascular, respiratory, neurological, diabetes, sleep, and post-operative care medicine.

As shown, one of the key benefit that could be expected from connect objects in medicine is early detection of diseases and exacerbations. In addition, improving patient autonomy and behavior, as well as enhance remote communication between healthcare providers and patient are of particular interest.

However, quality research data on the validity and reliability of connected object in medicine is still limited. One of the main reasons is the highly changing and complex nature of connected objects and their embedded/associated software, as they are continuously evolving, and it is nearly impossible to estimate their reliability at the same rhythm of their evolution or their self-improvement. For the same reason, prospective interventional studies exploring connected objects on health outcomes are lacking.

Nevertheless, connected objects offer the advantage of low costs, accessibility and availability for a large community of users, so that large amounts of data can be collected in free living environments. The continuous evolution of technology added to machine learning systems will further improve the performance of connected objects in medicine.

Behavioral changes associated with the Quantified Self has been one of the highest hope for health improvement in the future. However, only few studied have shown a clear impact on behavioral changes yet. Moreover, behavioral changes might not last long as the users are not consistent and tend to give up the use of the connected object shortly over time.

With the future and continuous development of new technologies, our society faces new challenges and regulators need to review their approach to digital health. Confidentiality and personal data are becoming increasingly difficult to protect from cybercriminals. On the other hand, it is difficult to ensure patient privacy without limiting the development of potentially useful new technologies.

An opportunity for improvement or a threat to our society, regardless of our views on connected objects, we must be prepared: they are already everywhere.

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Table 1 - Main research studies on connected tools

Research publication	Study design	Connected object	Conclusion/comment
Steps, walking distance and physical activity			
Evenson et al. 2015 ³⁸	Review	Fitbit	Moderate association with reference tools
Feehan et al. 2018 ¹⁷	Review	Fitbit	Underestimation at low speed
Crouter et al. 2005 ⁶⁴	Original	Several devices	Underestimation at low speed
Mammen et al. 2012 ⁶⁵	Original	Fitbit	Improved by hip placement
Takacs et al. 2014 ⁴⁸	Original	Fitbit	Over/under estimation at low/high speed
Ferguson et al. 2015 ⁶⁶	Original	Several devices	Overestimation of vigorous activity
Tully et al. 2014 ⁶⁷	Original	Fitbit	Good agreement with the reference tool
Boudreaux et al. 2018 ⁶⁸	Original	Several devices	Insufficient validity
Veerabhadrapa et al. 2018 ⁶⁹	Original	Apple Watch	High accuracy
Energy expenditure			
Feehan et al. 2018 ¹⁷	Review	Fitbit	Over/under estimation during physical activity/at rest
Ferguson et al. 2015 ⁶⁶	Original	Several devices	Biased results
Chowdhury et al. 2017 ⁷⁰	Original	Several devices	Biased results
Hargens et al. 2017 ⁷⁶	Original	Several devices	Underestimation
Murakami et al. 2016 ⁷³	Original	Several devices	Biased results
Brooke et al. 2017 ⁷⁵	Original	Several devices	Acceptable
Shcherbina et al. 2017 ⁷⁷	Original	Several devices	Biased results
Sleep evaluation			
Feehan et al. 2018 ¹⁷	Review	Fitbit	Not accurate
Montgomery-Downs 2012 ²⁹	Original	Fitbit	Not accurate
Meltzer et al. 2015 ⁷⁸	Original	Fitbit	Not accurate
de Zambotti et al. 2015 ⁸⁰	Original	Jawbone	Acceptable
de Zambotti et al. 2015 ⁷⁹	Original	Jawbone	Acceptable
Mantua et al. 2016 ⁸²	Original	Several devices	Not accurate
Cardiac rhythm			
Appelboom et al. 2014 ⁵²	Review	Several devices	Good accuracy
Lukowicz P et al. 2002 ⁸⁴	Original	AMON	
Halcox et al. 2017 ⁸⁵	Original	AliveCor	Superior outcomes compared to standard care
Parak et al. 2014 ⁸⁶	Original	Several devices	Not yet been sufficiently explored
Shcherbina et al. 2017 ⁷⁷	Original	Apple Watch	High accuracy for heart rate

Veerabhadrapa et al. 2018 ⁶⁹	Original	Apple Watch	High validity during walking, lower validity during running
Falter et al. 2018 ⁶⁰	Original	Apple Watch	High accuracy for heart rate
Koshy et al. 2018 ⁸⁷	Original	Several devices	Good accuracy heart rate, underestimate in atrial fibrillation
Chronic heart disease			
Cook et al. 2013 ²⁵	Original		Good functional recovery accuracy after cardiac surgery
Respiratory disease			
Colantonio et al. 2015 ⁹⁹	Original	Several devices	High validity to detect COPD exacerbation
Orme et al. 2018 ¹⁰⁰	Randomized	Vibrating inclinorator	Impact on sedentary time among COPD patients
Ko et al. 2015 ¹⁰¹	Review	Several devices	Not accurate enough to detect sleep apnea
Steele et al. 2003 ¹⁰⁹	Review	Several devices	Good to monitor physical activity of chronic pulmonary disease
Neurology			
Kuo et al. 2009 ¹⁰²	Original	2 wearable sensors	Very accurate to monitor gait in children with cerebral palsy
Baram Y et al. 2012 ¹⁰³	Original	2 wearable sensors	Gait improvement in patients with cerebral palsy
Lockman et al. 2011 ¹⁰⁴	Original	SmartWatch	Early detection of epilepsy
Rand et al. 2009 ¹⁰⁵	Original	Actical	Good to monitor physical activity among stroke patients
Kirste et al. 2014 ¹⁰⁶	Original	Accelerometric sensors	Good detection of Alzheimer's
Weiss et al. 2011 ¹⁰⁷	Original	Accelerometric sensors	Good detection of gait variability in Parkinson disease
Rehabilitation			
Aziz et al. 2011 ¹¹³	Original	Activity sensor	Good postoperative recovery monitoring at home
Aziz et al. 2007 ¹¹²	Original	Activity sensor	Good postoperative recovery monitoring at home
Abeles et al. 2017 ¹¹⁴	Review	Several devices	Good postoperative recovery monitoring at home
Diabetes			
Kovatchev et al. 2013 ¹²¹	Original	Diabetes Assistant	Good glycemic control when coupled to a smartphone
Rao et al. 2010 ¹²²	Review	Several tools	Good glycemic self-control