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A Systematic Review of Wearable Patient Monitoring Systems – Current Challenges and Opportunities for Clinical Adoption

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Abstract The aim of this review is to investigate barriers and challenges of wearable patient monitoring (WPM) solutions adopted by clinicians in acute, as well as in community, care settings. Currently, healthcare providers are coping with ever-growing healthcare challenges including an ageing population, chronic diseases, the cost of hospitalization, and the risk of medical errors. WPM systems are a potential solution for addressing some of these challenges by enabling advanced sensors, wearable technology, and secure and effective communication platforms between the clinicians and patients. A total of 791 articles were screened and 20 were selected for this review. The most common publication venue was conference proceedings (13, 54%). This review only considered recent studies published between 2015 and 2017. The identified studies involved chronic conditions (6, 30%), rehabilitation (7, 35%), cardiovascular diseases (4, 20%),

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falls (2, 10%) and mental health (1, 5%). Most studies focussed on the *system* aspects of WPM solutions including advanced sensors, wireless data collection, communication platform and clinical usability based on a specific area or disease. The current studies are progressing with localized sensor-software integration to solve a specific use-case/health area using non-scalable and 'silo' solutions. There is further work required regarding interoperability and clinical acceptance challenges. The advancement of wearable technology and possibilities of using machine learning and artificial intelligence in healthcare is a concept that has been investigated by many studies. We believe future patient monitoring and medical treatments will build upon efficient and affordable solutions of wearable technology.

Introduction

In recent years, there has been an ever-growing need for a sustainable health system which manages not only acute care (in hospital wards or emergency departments), but also the care of outpatients, especially those with chronic conditions. Worldwide spending on chronic conditions has increased to a point that immediate action is now required. A chronic condition is defined as a health condition that can be managed but often cannot be cured; common examples include heart disease, stroke, cancer, diabetes and arthritis [1]. The number of people with multiple chronic conditions is likely to continue to increase with the ageing of the population. Major contributing factors are unhealthy lifestyles, along with the impact of the economic downturn on mental and physical health [1].

Wearable patient monitoring (WPM) systems are emerging as an effective tool for the prevention, early detection and management of chronic conditions.

Recent estimates for annual expenditure on healthcare in the US are between $US 210.9 billion and $US 306 billion [2]. In the UK, nearly 29% of the total population now lives with a chronic medical condition, and as much as 80% of the healthcare budget is spent on the management of chronic diseases [1, 3].

As wearable sensors, smart textiles and body-worn garments become smaller, cheaper and more consumer-accessible, it is expected that they will be used more extensively across a wide variety of contexts. The expansion of wearable systems for health data collection offers the potential for user engagement and self-management of chronic diseases [4].

The rapid increase in the global adoption of WPM systems has occurred over the last couple of decades. Some of the early foundation research includes; (1) the wearable healthcare system (WEALTHY) project, which investigated the use of fabric integrated sensors to continuously monitor the vital signs of high-risk patients, including those undergoing rehabilitation [5]; (2) an investigation of a custom-developed ubiquitous healthcare (u-health-care) system consisting of custom 802.15.4-capable nodes interfaced with electrocardiogram (ECG) and blood pressure sensors, as well as a basic cell phone device for data display and signal feature extraction [6]; (3) the Human++ project in the Netherlands which developed a body area network consisting of three sensor nodes and a base station [7]; (4) the CodeBlue project developed by researchers at Harvard University [8]; (5) research from the Media Laboratory of the Massachusetts Institute of Technology (MIT) which involved designing LiveNet [9]; (6) the development of the SmartVest, a wearable physiological monitoring system that consists of a vest and a variety of sensors integrated into the garment's fabric to collect several biosignals [10]; (7–9) and three European IST FP6 programs (the MERMOTH, MyHeart and HeartCycle projects), which are recent examples of WPM systems [11–14].

The aim of this review is to investigate how current technological barriers and challenges limiting the global clinical adoption of bed-side patient monitoring have been reduced by the use of WPM systems. In addition, this review will highlight opportunities and recommend the best possible approach for the sustainable adoption of WPM in acute care, as well as in community care settings. This continues on from previous literature reviews conducted on WPM systems [6, 15–18].

Methodology

We chose the preferred reporting items for systematic reviews and meta-analyses (PRISMA) as the systematic review methodology [19]. A total of four databases were searched, including PubMed, Scopus, SpringerLink and the IEEE Xplore Digital Library. All databases were searched using keywords "Wearable Systems" and "Hospital Care" or "Wearable Patient Monitoring" or "Wearable Patient Monitoring Systems" or "Wearable Monitoring System" and "Acute Care". Additionally, we searched ClinicalTrials.gov on 3 October 2016 and limited the search to 2015 to 2017, to include ongoing registered clinical trials.

Articles selection and exclusion criteria

One of the authors conducted an initial screening of the retrieved records. Duplicated articles were eliminated and additional records were excluded after reviewing individual titles and abstracts. A second author then reviewed the included studies and evaluated the full-text articles or eligibility. The eligibility criteria for inclusion in the review were:

a. Original articles published as a journal article or in conference proceedings
b. Publication or reporting year (inclusive) 2015 and 2017
c. Wearable technology (a hardware integrated with a software) for patient monitoring solution was the primary subject of this study
d. Targeted towards acute and community care patient monitoring solutions only
e. Written and published in English

We excluded articles that were not considered original research, such as letters to the editor, comments or reviews. Because this review paper focused on WPM systems, we also excluded studies that solely tracked activity, exercise, sports or fitness and health and well-being applications.
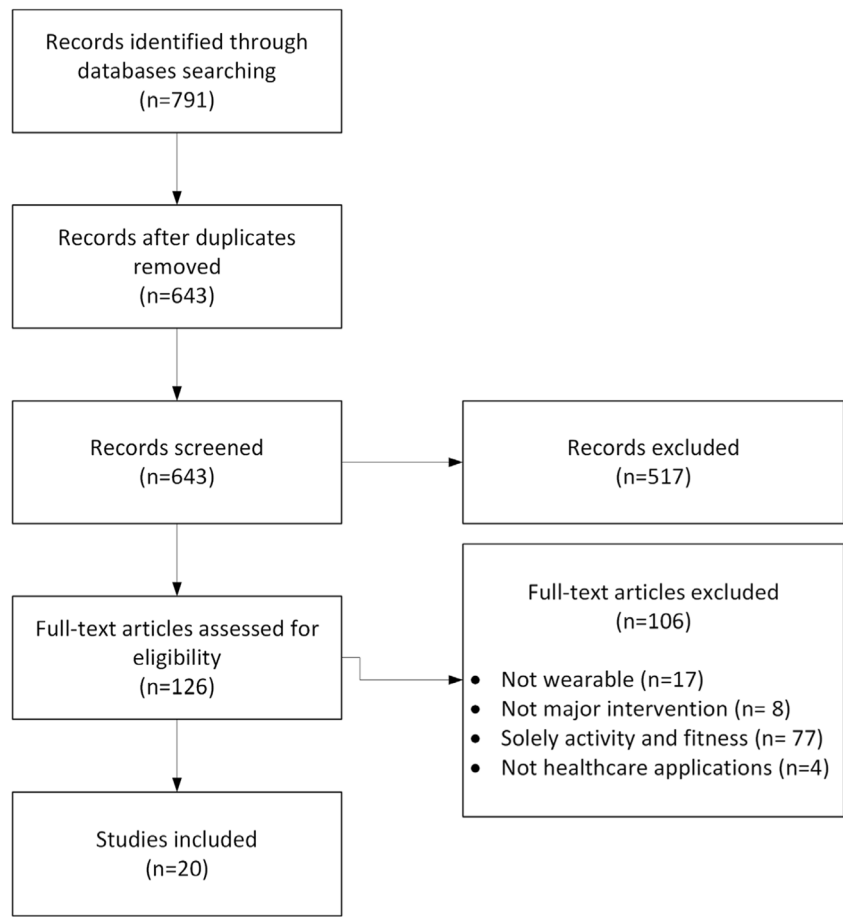
Article search results

Initially, 791 studies were identified through database searching. After excluding duplicated records, 643 records were eligible for screening. There were 517 records that did not meet our inclusion criteria based on the initial screening. A total of 126 studies were included to be evaluated for eligibility. Full-text records were retrieved and reviewed by two authors. After excluding irrelevant studies, 20 articles were selected for final review. The study selection process is depicted in Fig. 1, the subject-wise distribution of the selected articles is shown in Fig. 2 and the complete description of the included studies is shown in Table 1.

The use and opportunities of wearable monitoring systems in healthcare settings

Wearable systems/sensors and medical devices are widely used to measure key health indicators, such as ECG, heart rate, blood pressure, blood oxygen saturation, body temperature, posture

Fig. 1 The study selection process


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Records identified through
databases searching
(n=791)
        ↓
Records after duplicates
removed
(n=643)
        ↓
Records screened          →   Records excluded
(n=643)                        (n=517)
        ↓
Full-text articles assessed for   Full-text articles excluded
eligibility                        (n=106)
(n=126)                      →
                              • Not wearable (n=17)
                              • Not major intervention (n= 8)
                              • Solely activity and fitness (n= 77)
                              • Not healthcare applications (n=4)
        ↓
Studies included
(n=20)
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and physical activities. The wearable systems supported by the advanced information technology and sophisticated sensors have the capability to continuously monitor human physiology and consequently expedite treatments [26]. Typically in a functional healthcare system, technology support is required for conducting standardized clinical tests, to monitor disease progression, to aid in treatment decision making, and to enable access to patient medical records. These instances present an opportunity for adopting wearable solutions and thus creating a more seamless healthcare system experience. Relocating the resources into a laterally distributed healthcare system allows the cost to be shared and involves active patient engagement in long-term disease management [27]. This increases longitudinal–temporal flexibility in the performance of regular examination and treatment procedures, and reduces the work-load needed to maintain continuous supervision. The wearable monitoring and seamless integration of standardized clinical tests provides an example of the potential that WPM systems have for self-management of long-term and multiple conditions in the wider healthcare system [28, 29].

The chronic and progressive nature of many diseases, which often present with symptoms that can vary within a day and over longer periods of time, offers an ideal opportunity for more demand on WPM systems [30]. Wearable monitoring systems/ sensors are being designed to capture a variety of disease data sets, including gait patterns, tremor episodes, activity levels, motion and physiological parameters. These solutions can be built by assembling small, inexpensive, convenient and wearable sensors that can be connected to the Internet via data aggregators such as mobile phones [31]. The information can then be transmitted to the cloud or local server for data processing and sent back to the user via alerts, reminders, warnings or notifications for further actions
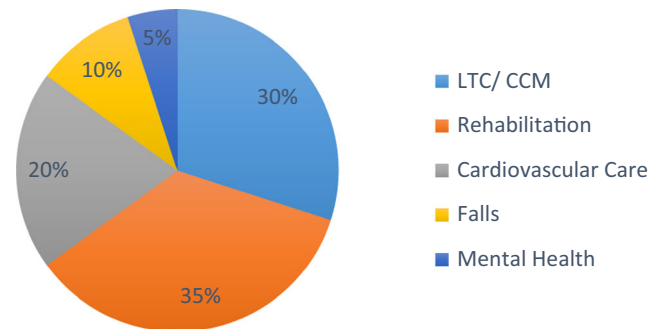

Fig. 2 Subject-wise distribution of the selected articles. LTC/CCM is the long-term conditions/ chronic care management. Number of studies for Long-term conditions (LTC)/chronic care management (CCM) = 6, rehabilitation = 7, cardiovascular care = 4, falls = 2 and mental health = 1 (total n = 20)

Table 1 Comparison of the selected wearable monitoring systems

Author and Year	Target Area or Population	Study Aims	Outcomes/Findings	Platform/Type of Sensor Used
Etemadi et al. 2016 [20]	Long-term monitoring; chronic care monitoring	To develop a low-power multi-modal patch for measuring activity using ECG and SCG sensors	The developed patch measured the combined activity, environmental context, and hemodynamics, all on the same hardware, capable of operating for longer than 48 h at a time with continuous recording	Three-channels of SCG; one-lead ECG; the pressure sensor; an average current consumption of less than 2 mA from a 3.7 V coin cell (LIR2450) battery.
Thomas et al. 2016 [21]	Non-invasive continuous BP monitoring	To develop a wrist watch-based BP measurement system using ECG and PPG	The average root mean square error between the measured systolic BP and the calculated systolic BP was between 7.83 to 9.37 mmHg across 11 subjects	A PPG sensor with both infra-red and red LEDs; two differential electrodes; third bias electrode; BioWatch comes with two analog front ends: the TIADS1292 for acquiring ECG signal and the TI AFE4400 for reading PPG
Wu et al. 2015 [22]	Biofeedback system to monitor and learn from physiological signals	To develop a wearable biofeedback system for personalised emotional management using heart rate variability	Real-time HRV biofeedback is significantly effective in cases of negative emotion	A conductive textile material as the electrodes for ECG and breathing activity; a differential separation filter and a common signal conditioning
Xu et al. 2016 [13]	Treatment, in-community rehabilitation and athlete training	To develop a contextual online learning method for activity classification based on data captured by low-cost, body-worn inertial sensors	Real-time learning system and contextual multi-armed bandits approach that enables efficient, personalized activity classification	Context driven activity classification and feedback; a set of sensors with a smart device attached to the user; activity classification module and the context classification module
Sardini et al. 2015 [11]	Posture monitoring and rehabilitation exercises	To develop a wireless wearable T-shirt for posture monitoring during rehabilitation or reinforcement exercises	The wireless wearable sensor produced reliable data compared with the data obtained with the optical system	A copper wire and a separable circuit board; the actuator is a vibration micromotor (Pico Vibe) commercialized by Precision Microdrivers
Spano et al. 2016 [23]	Remote patient monitoring; ECG monitoring	To develop an ECG remote monitoring system that is dedicated to non-technical users in need of long-term health monitoring in residential environments and is integrated in a broader IoT	The researchers developed 1) integrated ECG prototype sensors with record-low energy per effective number of quantized levels; 2) an architecture providing low marginal cost per added sensor/user; and 3) the possibility of seamless integration with other smart home systems through a single IoT infrastructure	The wearable ECG sensor consists of a battery-powered chest belt; two dry plastic electrodes and the electronic printed circuit board. The circuit extracts, filters, amplifies and digitizes the ECG signal, which is then acquired by the microcontroller
Lee et al. 2015 [24]	HRV analysis	To develop a smart ECG patch to measures ECG using three electrodes integrated into the patch, filters the measured signals to minimize noise, performs analog-to-digital conversion, and detects R-peaks	The R-peak detection results obtained with the device exhibited a sensitivity of 99.29%, a positive predictive value of 100.00%, and an error of 0.71%. The device also exhibited less motional noise than conventional ECG recording, being stable up to a walking speed of 5 km/h	The material used for the patch is non-woven fabric with hydrogel and adhesive. An Ag−/AgCl-based electrode array is printed into the patch and protected by an insulation coating
Melillo et al. 2015 [25]	Risk assessment of vascular events and falls in hypertensive patients	To design and develop a flexible, extensible, and transparent, and to provide proactive remote monitoring via data-mining functionalities	The developed system was able to predict a future vascular event within the next 12 months with an accuracy rate of 84% and to identify fallers with an accuracy rate of 72%	The ShareLogs was developed by using the BioHarness Bluetooth Logging System Interface available in the BioHarness Bluetooth Developer Kit provided by Zephyr Technology

[31]. In the future, classification of the data based on population studies will typify disease-specific symptoms and their progression, enabling precise treatment options for clinicians to make informed decisions. The increasing usage of WPM systems will lead to the generation of a huge streams of new data sources, which will ultimately amplify the data-oriented medical knowledge base and, will complement and improve the electronic health record [32].

There appears to be three major wearable sensor modalities with applications in healthcare. Firstly, *biopotential-specific sensor units*, such as ECG, electromyography (EMG) and electroencephalography (EEG) sensors. Secondly, *motion sensor units*, such as accelerometers and gyroscopes. Finally, *environmental sensor units* such as video cameras, vital signs monitors (such as heart rate, pulse rate and temperature) and pressure sensors [33]. WPM systems have the potential to change the way healthcare is currently being managed. Moreover, healthcare information exchange will make it easier for any service provider to access the relevant information and provide better and informed point-of-care solutions [12].

Apart from the advancement in technology, many WPM systems still face the most common challenge of signal quality [34, 35] and particularly for one of the common issue (use-case) of ECG monitoring, electrodes drying out. In addressing the issue of electrodes drying out, a textile integrated active electrode as opposed to a commercial wet Ag/AgCl electrode has been developed and tested with the signal integrity during a five-cycle washing test [36].

Barriers to the clinical adoption of WPM systems

The next generation of WPM systems is likely to improve the quality of human life by assuring high comfort while increasing the intelligent use of limited resources. Further improvements in textile sensors design, signal quality, miniaturization and data acquisition techniques are required to fulfil these expectations. Figure 3 shows the overview model of WPM systems and lists four key areas which are currently limiting the wider clinical adoption of wearable technology. The following sections elaborate the issues pertaining to these four key areas.

Sensors and signals

The number of biosensors used in current WPM systems is generally large and requires specific on-body placement or body postures in order to provide reliable measurements [37]. One of the technical barriers when using WPM systems is the obstruction of feature extraction from the signal due to motion artefacts. This is due to body movement or respiration and needs to be resolved [38]. A study by Etemadi et al. [20] utilized advanced signal processing to collect accurate and reliable seismocardiography (SCG). To increase the quality and accuracy of the SCG, linear filtering, detecting the R-wave peak timings from the ECG, and using these timings as a fiduciary for ensemble averaging the SCG were implemented. In a similar study that investigated biofeedback training for emotion management and patient monitoring [22], the signals collected were unreliable and disturbed by a variety of noises. Most body-worn applications report that the system's accuracy is hampered by noises such as: electromagnetic interference of power line, poor quality of contact between the electrode and the skin, baseline wander caused by respiration, electrosurgical instruments and movement of the patient's body. Most of these noises cannot be filtered out completely over the hardware-processing unit due to the processing limitations. Therefore, it is necessary to filter out these noises as much as possible in the software platform. The researchers from this study adopted the Butterworth Notch Filter (BNF) and finite impulse response (FIR) band-pass filter to eliminate power line interference and baseline wander, and a novel multi-scale mathematical morphology (3 M) filter to reduce the impact of the non-linear noises caused by poor electrode contact and motion artefacts. Another study used a wireless wearable T-shirt to monitored the patient's posture during rehabilitation exercise [11]. The researchers manually sewed an enamelled copper wire of 1 mm diameter to a T-shirt and constituted the sensor (about 9 cm long and 2.5 cm wide with a total length of 50 cm). The copper wire was stitched with a zigzag pattern on the back and the chest, thus allowing the lengthening of the T-shirt and sensor in the sagittal plane. The study achieved good outcome in a small setting, but the impedance value of the sensor changed due to the different factors such as the relaxation of the T-shirt or skin conductivity variation. The T-shirt with the sewn copper wire was washed (expecting a relaxation) after it was used, but no variation was observed [11].

Connectivity

One of the most common issues with wearable systems is the delay in providing results and generating alerts due to data loss, buffering, network communication, monitoring or processing [21, 39, 40]. These systems were developed for specific setup and care settings in order to assist patients' specific need. WPM systems using 3G/4G data suffer connectivity issues due to the remote network, low signal strength in remote places, low battery life time, low transmission speed, thus resulting in delay or low quality data for periods of short time [39, 41]. To address these issues, a cross-layer framework has been developed based on unequal resource allocation to support secure wireless wearable data encryption and transmission [42]. The low battery life issue occurs due to continued connectivity of device/sensor with the Bluetooth, WiFi or 3G/4G networks [43–45]. Moreover, if the power supply is

not an issue then the mobility of the device may become problematic, especially for older adults.

A portable ECG monitoring device developed by Lee et al. [44] can easily measure the ECG by connecting the measuring module to a patch with a minimized electrode array using a snap button. The measuring module is small (38 mm wide, 38 mm long, and 7 mm thick). The weight of the module including the battery is 10 g. The study reported that an ECG signal was collated using a commercial device that was similar to the conventional Holter monitor. The study reported that even with the wires firmly fixed, the ECG signal quality was often disturbed, as the wires moved depending on the subject's body movements. According to another study, the ratio of motion peaks to normal peaks was estimated as being about 10% when the ECG was taken from a freely moving patient using the Holter monitor [43]. For this reason, ECGs obtained using Holter monitors are limited, and algorithms used to eliminate noise from the data have been actively developed. As important as it is to detect and exclude generated noise from the analysis, it is even more important to reduce the occurrence of noise itself in the first instance, and this is a common issue with almost all sensor-based WPM systems [44, 46]. Table 1 summaries the selected wearable systems.

In real-time scenarios, wearable data transmission often requires some data processing and therefore network delays. Some systems produced good results when tested offline but reported delay when tested in real-time [39]. Prakash et al. [47] demonstrated an efficient connectivity and communication framework in a real-time wireless hospital sensor network, which could be adopted for acute care settings.

Data processing, integration and clinical decision support

Machine learning and artificial intelligence techniques have the potential to transform healthcare services by improving diagnostics and predictive modelling. The utilisation of these techniques in healthcare is still emerging, as it requires considerable analysis to provide reliable results that clinicians would actually use. The raw data collected from wearable sensors would provide a data source that did not exist before. These data would undergo further analysis to be transformed into meaningful and actionable information. This process would be supported by real-time machine learning processing techniques. Advanced signal processing algorithms for faster processing, low power consumption, low cost, and less complexity have been applied to healthcare settings. However, such algorithms are often tested by simulation or under fixed conditions. Implementation of these algorithms in the wearable monitoring in an acute care environment led to poor results due to significant processing time and delay. A medical grade remote monitoring system with a reliability exceeding 99% has been developed, but a 2.4 s initial buffering delay, as well as a small processing and network delay were reported [48].

The current concern with the deployment of expert systems in healthcare is accuracy and reliability. To achieve higher accuracy in decision support, a complete data set must be employed for different stages of training, testing and validating of expert systems. Currently, the majority of existing clinical decision support models contain medical knowledge of a specific or pre-defined task and therefore can analyse the collected data from individual patients or from a small data sets only. Thus, highlighting the issue of scalability and wider integration is a challenge for future research and development. Moreover, machine-learning approaches can be used to analyse the streaming of real-time clinical data and map it to known/existing condition(s). The current state of wearable monitoring systems can be further enhanced with the integration of such techniques into the hardware or in the cloud computing platforms for real-time processing.

One of the bottlenecks to consider for third generation of pervasive sensing platforms is to achieve rapid and scalable processing for large datasets. From a software point-of-view, processing big data is usually linked with programming paradigms [49]. Several open-source frameworks such as Hadoop [50] are being used to setup distributed database environments via a scalable architecture. This provides a basis for further usage via other tools (such as Cascading, Pig, Hive) [50] that enable developing applications to process vast amounts of data (by the order of terabytes) on commodity clusters. However, when combined with continuous streams of pervasive heath monitoring, this also requires capacities for iterative and low-latency computations, which depends on sophisticated models of data caching and in-memory computation. Thus, other frameworks such as Storm and Spark have been created to fulfil this gap [50].

Rich clinical decision support could be achieved by using the insights gained by taking a machine-learning approach to data collected via wearable sensors and/or wireless medical devices [51]. A cloud-based clinical decision support system embedded with machine learning techniques could include: drug-drug allergies, individualised drug dosing, clinical risk scores/ scales and gaps in care – alerts, reminders, warnings and notifications [52–54].

Patient engagement and interaction

We believe that one of the core advantages of WPM systems is the patient's (user's) self-engagement with the treatment – which is often missing. There is a shift in wider thinking of WPM systems as 'only data collectors' to viewing them as being self-engaging and motivating systems which allow rich interactions between patients and clinicians [55–57]. Due to WPM systems being traditionally regarded as data collectors only, the majority of wearable systems lack user-engagement and user-interaction aspects. The wearable systems are often focused on providing real-time health data to clinicians for
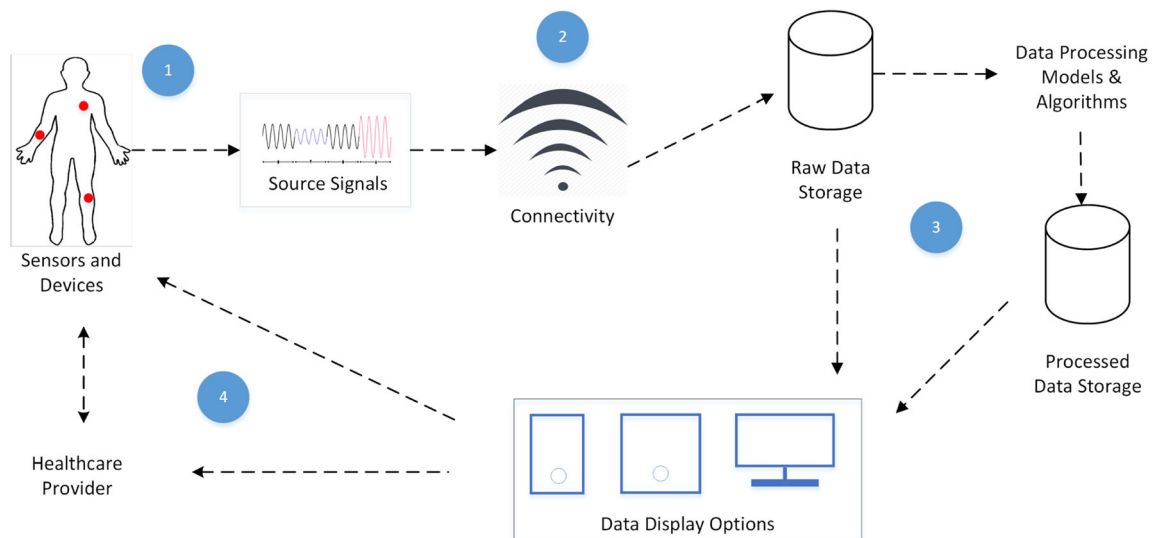
Fig. 3 Overview model of WPM systems

timely treatment and actions, but are missing user-acceptance and engagement. User-engagement and user-interaction are some of the key uptake factors among consumers (non-clinical care settings) for wearable technologies [58–60].

An advanced WPM system named Hexoskin™ [61] (ClinicalTrials.gov Identifier: NCT02591758) with a vest and embedded sensors is being developed. It provides the user with seamless and fully integrated information regarding heart rate, breathing rate, minute ventilation, heart rate maximum, resting heart rate, heart rate recovery, maximal oxygen uptake and cadence. It uses textile-integrated sensors for activity, respiration and heart rate and intelligently makes use of the three-cardiac dry and textile electrodes. The cardiac sensors for ECG uses 1 channel, 256 Hz, heart rate 30–220 beats/min, 1 Hz with QRS event detection, RR intervals and heart rate variability analysis. For breathing monitoring, the system uses two channels, 128 Hz; breathing rate 3–80 breaths per minute, 1 Hz; tidal volume (last inspiration) 80–10,000 mL, 1 Hz; minute ventilation (inductance plethysmography) 2–150 L/min, 1 Hz and inspiration and expiration events: 8 ms resolution. Hexoskin™ provides users with real-time and remote monitoring via secure Bluetooth connected mobile app (iOS and Android), a web dashboard, up to 14 h of battery life (rechargeable), free data storage in cloud and secure access anytime [61, 62]. Hexoskin™ allows users to download the raw data in machine readable format, as well as provide users with raw, processed / meaningful data. The access to the application programming interfaces (APIs) and raw data in machine-readable format enables the healthcare professionals and researchers to explore the data for wearable solutions healthcare benefits.

BP = blood pressure; ECG = electrocardiogram; IoT = Internet-of-Things; HRV = heart rate variability; PPG = photoplethysmogram; SCG = seismocardiogram.

Discussion and conclusion

Most research in WPM systems has focused on applications related to older adults (aged more than 60 years), as opposed to younger adults. A study by Bergmann and McGregor reported that 93% of patients in an elderly care facility accepted a proposed WPM system, because of its low invasiveness and its non-interference with their normal daily life activities [63]. However, Bergmann and McGregor's overall quality of individual studies was relatively low, with small participant numbers, limited details of methodology and a restricted reporting of research processes [63].

In this paper, we reviewed 20 wearable monitoring systems by selecting papers published from 2015 to 2017 in order to evaluate their technological advancements and their employment of advanced sensors and data collection techniques. We studied the design concepts of wearable wireless WPM systems, identified key specifications and parameters such as sensors and signals, data processing, integration, signal quality and user-engagement and user-interaction that require attention. In addition, we have highlighted the potential of deployment of such technologies in the clinical environment [54, 64].

With the ever growing use of WPM systems, end-user acceptability is becoming an important aspect of the design of such systems. The acceptance of any system in the healthcare domain depends on user-awareness, as well as clinician and patient acceptance. Moreover, this review indicates the heavy dependency of wearable monitoring systems on communication technology and some studies have reported cost problems when using mobile data (3G/4G) for data communication for longer time and multiple data collection. Data connectivity is one of the main drawbacks of deployed WPM systems where patients are 'constrained' within fixed spaces fitted with monitoring devices with small Bluetooth range [34, 35, 45, 56, 65].

A marked change in healthcare delivery is occurring which has been made possible by the technological revolution in WPM systems, the Internet of Things (IoT), and the potential of employing machine learning and artificial intelligence. The treatment of many medical conditions are guaranteed to benefit from the use of wearable technology [41].

Validation of clinical and scientific findings is an important task to take on in this new context. The determination of repeatability and reliability of the new assessment tools based on wearable technologies and the IoT remains challenging. Likewise, the extent to which these new methods of diagnosing and treating will replace or complement the existing assessment and therapeutic tools is wide open to experimentation and debate in the global healthcare community [40, 45].

In conclusion, the advancement of wearable technology and possibilities of using machine learning and artificial intelligence in healthcare is a concept that has been investigated by many studies. We believe future patient monitoring and medical treatments will build upon efficient and affordable solutions of wearable technology.

Compliance with ethical standards

Conflict of interest   Authors declare no conflict of interest.

Ethical approval   This article does not contain any studies with human participants performed by any of the authors.

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