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Patient acceptability of wearable vital sign monitoring technologies in the acute care setting: a systematic review

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TITLE

Patient acceptability of wearable vital sign monitoring technologies in the acute care setting: a systematic review

ABSTRACT

Aims and objectives: To examine patient acceptability of wearable vital sign monitoring devices in the acute setting.

Background: Wearable vital sign monitoring devices may improve patient safety, yet hospital patients' acceptability of these devices is largely unreported.

Design: A systematic review.

Methods: Cumulative Index to Nursing and Allied Health Literature Complete, Medline Complete, and Embase were searched, supplemented by reference list hand-searching. Studies were included if they involved adult hospital patients (≥ 18 years), a wearable monitoring device capable of assessing ≥ 1 vital sign, and measured patient acceptability, satisfaction or experience of wearing the device. No date restrictions were enforced. Quality assessments of quantitative and qualitative studies were undertaken using the Downs and Black Checklist for Measuring Study Quality and the Critical Appraisal Skills Programme Qualitative Research Checklist, respectively. Meta-analyses were not possible given data heterogeneity and low research quality. Reporting adhered to the PRISMA guidelines and a PRISMA checklist was completed.

Results: Of the 427 studies screened, seven observational studies met the inclusion criteria. Six studies were of low quality and one was of high quality. In two studies, patient satisfaction was investigated. In the remaining studies, patient experience, patient opinions and experience, patient perceptions and experience, device acceptability, and patient comfort and concerns were investigated. In four studies, patients were mostly accepting of the wearable devices, reporting positive experiences and satisfaction relating to their use. In three studies, findings were mixed.

Conclusion: There is limited high quality research examining patient acceptability of wearable vital sign monitoring devices as an a priori focus in the acute setting. Further understanding of patient perspectives of these devices is required in order to inform their continued use and development.

Relevance to clinical practice: The provision of patient-centred nursing care is contingent on understanding patients' preferences, including their acceptability of technology use.

KEYWORDS

Medical Subject Headings

Nursing Assessment
Patient Participation
Patient Preference
Patient Satisfaction
Wireless Technology
Vital Signs
Wearable Electronic Devices

INTRODUCTION

Wearable vital sign monitoring devices are intended to improve patient safety (Nangalia, Prytherch, & Smith, 2010). The nomenclature used to describe wearable devices is highly variable in the literature. In the acute care context, wearable vital sign monitoring devices may be defined as body-worn technologies that facilitate continuous, real time vital sign monitoring without the need for nurse-to-patient contact or restrictive leads connecting the patient to wall-mounted or free standing equipment (Downey, Brown, Jayne, & Randell, 2018; Jeffs et al., 2016; Nangalia et al., 2010).

Traditionally, few beds on general hospital wards have been equipped with continuous vital sign monitoring equipment and, where available, continuous vital sign monitoring has been reserved for deteriorating patients or those deemed to be at high risk of deteriorating. Most commonly, ward patients have their vital signs measured intermittently at variable intervals by nurses (Considine, Trotter, & Currey, 2016; Hands et al., 2013). For some patients, vital sign assessment may be delayed due to suboptimal care practices, nursing workloads or an unexpected change in the patient's clinical status deeming the previous schedule for intermittent vital sign assessment insufficient (Cardona-Morrell, Hillman, Prgommet, Turner, & Nicholson, 2016; Duffield et al., 2011). Delayed vital sign assessment may delay the recognition of physiological abnormalities, precluding the appropriate management of clinical deterioration and increasing the risk of serious in-hospital adverse events (Mitchell & Van Leuvan, 2008). Given the concerns relating to intermittent vital sign monitoring, continuous monitoring of ward patients using remote technologies has gained momentum as a component of a patient safety system (Downey et al., 2018).

Although there is a substantial body of knowledge evaluating the use of wearable devices in the out-of-hospital setting, less is known about the value and acceptability of wearable vital sign monitoring devices in the acute hospital environment (Baig, Gholamhosseini, & Connolly, 2013; Jeffs et al., 2016). The few studies published to date have focused on the use and acceptability of wearable technologies in

the ward setting and emergency department (ED) including the waiting room, where ongoing vigilance of large numbers of patients is often difficult (Hubner et al., 2015; Pollack, 2009). Hospital patients are different to those in community and residential care settings as they are in a phase of acute illness or surgical recovery. Hospital patients may therefore view the implementation of wearable devices differently, and device compatibility with the provision of nursing and medical care during acute illness may be of particular importance to patients and families.

The intent of wearable vital sign monitoring devices is to enable continuous vital sign monitoring, thus supporting clinicians, namely nurses, to recognise clinical deterioration in real time, and respond to deteriorating patients in a timely manner (Harper et al., 2010; Jeffs et al., 2016; Pollack, 2009). Theoretically, wearable vital sign monitoring devices may also reduce nursing workload, enhance patient mobility (Jeffs et al., 2016; Nangalia et al., 2010), and give rise to economic benefits related to a better distribution of clinical resources and a reduction in errors and adverse events in the ward and ambulatory care setting (Milenković, Otto, & Jovanov, 2006; Nangalia et al., 2010). It is well known that hospitalised patients commonly exhibit physiological antecedents prior to adverse events such as cardiac arrest or unplanned intensive care unit (ICU) admissions (Hillman et al., 2001; Schein, Hazday, Pena, Ruben, & Sprung, 1990). More recent studies also show that many patients have vital sign abnormalities in the 24-hours prior to rapid response system (RRS) activation (Sprogis, Currey, Considine, Baldwin, & Jones, 2017). Further, 3% to 14% of ward patients have one or more abnormal observations at any point in time (Bucknall et al., 2013; Buist, Bernard, Nguyen, Moore, & Anderson, 2004; Shearer et al., 2012; Tirkkonen et al., 2014) and 1.5% to 23% of ED patients experience clinical deterioration that fulfils ED-specific or hospital wide RRS activation criteria at some stage during their ED care (Considine, Jones, Pilcher, & Currey, 2017; Considine, Lucas, & Wunderlich, 2012; Considine, Rawet, & Currey, 2015; Hosking, Considine, & Sands, 2014; Lambe, Currey, & Considine, 2016; Mitchell Scott, Considine, & Botti, 2015). A recent systematic review and meta-analysis has highlighted that continuous vital sign monitoring may result in earlier recognition of clinical deterioration in ward patients when compared to intermittent assessment by nurses (Cardona-Morrell et al., 2016). However, when compared to intermittent monitoring, continuous vital sign monitoring had no significant effect on in-hospital mortality, unanticipated ICU admissions or hospital length of stay (Cardona-Morrell et al., 2016).

To date, wearable devices have largely been used and studied in subacute, residential, outpatient, community or home care settings, often in the context of elderly populations or patients with chronic conditions such as heart failure (Baig et al., 2013; Boyne & Vrijhoef, 2013; Jeffs et al., 2016). In these settings, some wearable devices may have capabilities to measure other parameters in addition to vital signs including location, activity, mobility, blood glucose, and social engagement, and they may also

assist patients to seek help in an emergency (Fraile, Bajo, Corchado, & Abraham, 2010; Kang et al., 2010). Studies examining patient acceptability of the use or idea of out-of-hospital wearable technology report mixed findings. In respect to the home care setting, positive findings relate to maintenance of patient independence with activities of daily living (Fensli et al., 2010), and negative findings relate to fear of technology (Steele, Lo, Secombe, & Wong, 2009), aesthetics (Steele et al., 2009), discomfort, and difficulty manipulating the device (Ehmen et al., 2012).

Patient acceptability is the degree to which a patient deems, in this case, a particular technology, to be appropriate in relation to their needs and preferences (Or & Karsh, 2009). Importantly, technology acceptance is represented in the literature in several ways and may be ascertained through user satisfaction, actual technology use, effective technology use or intention to use the technology (Or & Karsh, 2009). Both patient satisfaction and patient experience determine patient acceptability of innovations such as wearable devices. Patient satisfaction is defined as how contented a patient feels about a particular aspect of care or the degree to which they perceive care has met their expectations (Berkowitz, 2016). Patient satisfaction with care is not necessarily synonymous with quality of care and may be highly subjective. Conversely, patient experience refers to actual events, encounters or interactions the patient is exposed to while in care. The determinants of patient satisfaction and experience are complex and individual (Berkowitz, 2016). A patient's level of satisfaction may determine their overall experience of an aspect of health care (Berkowitz, 2016). Similarly, a patient's day-to-day experiences within the healthcare system may determine their satisfaction (Berkowitz, 2016). Although patient satisfaction and patient experience are often used interchangeably, they are two separate but interrelated concepts.

Although the primary aim of wearable vital sign monitoring devices is to optimise patients' physiological safety, patient acceptability of these devices is an essential consideration related to their implementation (Fensli et al., 2010; Jeffs et al., 2016). Importantly, acceptance is not inferior to physiological safety, as acceptance is central to a patient-centred care approach which is inextricably linked to patient safety. Low patient acceptance is a potential barrier to the success of wearable vital sign monitoring devices; if patients find them uncomfortable and obtrusive, they are less likely to wear them or wear them in the manner in which these devices are designed and this may impact negatively on their health care experience. Understanding patient acceptability of wearable vital sign monitoring devices may enable nurses to more appropriately plan care and identify, understand, and manage both favourable and potentially unfavourable aspects of wearable devices using a collaborative approach. Further, understanding patient acceptability of wearable devices may inform future development and implementation of these devices.

AIMS

The aim of this systematic review was to examine patient acceptability of wearable vital sign monitoring devices through analysis of patient acceptability, satisfaction, and experience, in the acute care setting.

METHODS

A systematic review design was used. Reporting was informed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009). A PRISMA checklist was completed (see Supplementary File 1). The review protocol is registered with PROSPERO, the international prospective register of systematic reviews (No. CRD42017081190).

Studies were considered eligible for inclusion if they:

- Were peer-reviewed;
- Involved adults ≥ 18 years of age;
- Involved hospital patients admitted to a medical or surgical ward or the ED (including the waiting room);
- Involved a wearable monitoring device capable of assessing one or more vital signs (respiratory rate, heart rate, blood pressure, pulse oximetry, temperature) and enabled patient ambulation and;
- Reported patient acceptability, patient satisfaction or patient experience data in relation to a wearable vital sign monitoring device.

Studies were excluded if they involved children only; patients admitted to critical care environments with continuous monitoring (ICU, Coronary Care Unit, High Dependency Unit, perioperative areas); patients admitted to obstetric or maternity units; patients in out-of-hospital settings; or wall-mounted monitors or mobile monitors on stands.

Abstract-only studies, editorials, letters, commentaries, and animal studies were excluded. All studies had to be published in English. No date restrictions were applied.

Studies were identified by accessing the following databases: Cumulative Index to Nursing and Allied Health Literature (CINAHL) Complete via EbscoHost, Medline Complete via EbscoHost, and Embase. Hand searching and electronic searching of reference lists of all relevant articles was performed to identify eligible articles not located using the search strategy.

Limits were applied to the final line of all searches to maintain consistency. Notably, both CINAHL and Medline databases define adults as aged ≥ 19 years. In order to comply with the inclusion criteria, hand searching was also undertaken to capture studies involving patients aged 18 years. The search terms for each major concept included 'wearable', 'wireless', 'monitor*', 'device*', 'vital sign*', 'health assessment', 'satisf*', 'experience*', and 'accept*'. Medical Subject Headings (MeSH) were also identified for each concept by examining database indices such as 'Monitoring, Ambulatory' and 'Wireless Technology'. A multitude of terms were used to reflect the high variability in wearable device nomenclature. All search terms were reviewed and approved by all members of the research team and a specialist University Librarian. An example of the search string used for Medline Complete is available as an online appendix.

A single reviewer conducted the search (XX - initials redacted for anonymity). The last search was conducted on 30th April 2018. Two independent reviewers screened all titles and abstracts using Rayyan, an online systematic review web application (XX and XXX - initials redacted for anonymity) (Ouzzani et al., 2016). The full texts of all studies classified as potentially eligible were examined to confirm their appropriateness by two reviewers (XX and XXX - initials redacted for anonymity). Inter-rater reliability was calculated using the Kappa Measure of Agreement (McHugh, 2012). Discrepancies were resolved using a consensus process and a third reviewer (XXX - initials redacted for anonymity). Study selection was reported using a PRISMA diagram (Figure 1) (Moher et al., 2009).

Quality assessment of quantitative studies was conducted by two reviewers using the Downs and Black Checklist for Measuring Study Quality (XX and XXX - initials redacted for anonymity) (Downs & Black, 1998). This checklist was selected as it can be used to appraise both randomised and non-randomised (cohort and case-control studies) quantitative work (Downs & Black, 1998). Qualitative studies were assessed by two reviewers using the Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist (XX and XXX - initials redacted for anonymity) (CASP, 2017). This checklist was developed by experts in the field, is commonly used in medical literature, and provides a systematic approach for appraising the quality of qualitative studies specifically (CASP, 2017).

Data were extracted by a single reviewer using Microsoft Excel (Microsoft, 2016). The characteristics of each study were extracted including the author/s; year of publication; country; study design; whether the work was single site or multi-site in nature; the type and capabilities of the wearable device used; the duration the device was worn; the presence of comparators; characteristics of the sample; sample size; specific methods used to evaluate the outcomes; and the relevant major findings. A meta-analysis was not possible due to the heterogeneity of the data from the included studies.

RESULTS

After removal of duplicates, the combined database searches yielded 402 studies. An additional 25 studies were identified from hand searching the reference lists of relevant studies. Title and abstract screening resulted in 22 studies that were potentially suitable for inclusion in this systematic review (Figure 1). Inter-rater reliability at this stage was substantial ($Kappa = 0.786$) (Munoz & Bangdiwala, 1997). Full text screening resulted in the exclusion of a further 15 studies leaving seven studies meeting the inclusion criteria.

Insert Figure 1 near here

The key characteristics of the seven studies included in this review are presented in Table 1. Studies were published between 2009 and 2018. Two studies were conducted in the United States of America (Michaels et al., 2009; Pollack, 2009), three in the United Kingdom (UK) (Downey et al., 2018; Harper et al., 2010; Jeffs et al., 2016), one in Austria (Hubner et al., 2015), and one in Taiwan (Hsiao, Lee, Tien, Feng, & Huang, 2015). One study was conducted at multiple sites within a single UK Trust (Jeffs et al., 2016); the remaining six were single-site studies (Downey et al., 2018; Harper et al., 2010; Hsiao et al., 2015; Hubner et al., 2015; Michaels et al., 2009; Pollack, 2009). Six quantitative studies (Harper et al., 2010; Hsiao et al., 2015; Hubner et al., 2015; Jeffs et al., 2016; Michaels et al., 2009; Pollack, 2009) and one qualitative study (Downey et al., 2018) met the inclusion criteria. All studies were observational in nature, specifically executed as feasibility, pilot or evaluative research (Downey et al., 2018; Harper et al., 2010; Hsiao et al., 2015; Hubner et al., 2015; Jeffs et al., 2016; Michaels et al., 2009; Pollack, 2009).

Insert Table 1 near here

Two studies focused on patient satisfaction in relation to the wearable device (Hsiao et al., 2015; Pollack, 2009). The focus of the remaining five studies was patient experience (Michaels et al., 2009), patient opinions and experience (Hubner et al., 2015), patient perceptions and experience (Downey et al., 2018), patient acceptability (Harper et al., 2010), and patient comfort and concerns which were nested

within the notion of acceptability (Jeffs et al., 2016). Specific areas explored included patient experience or satisfaction related to comfort, mobility, safety, device functioning, inclination to recommend it to others, and the overall level of satisfaction of wearing the device.

In four studies (Hsiao et al., 2015; Hubner et al., 2015; Michaels et al., 2009; Pollack, 2009), a survey approach was used. Of these, three used questionnaires with Likert scales (Hsiao et al., 2015; Hubner et al., 2015; Pollack, 2009), and the other did not provide details of the type of questionnaire used (Michaels et al., 2009). In one study, limited methodological detail was reported and patient comfort appeared to be inferred from the reasons patients gave for removing their wearable monitor (Jeffs et al., 2016). In the qualitative study, semi-structured interviews were used to explore hospital patients' experience of intermittent vital sign monitoring and the use of a continuous remote monitoring device (Downey et al., 2018).

Sample sizes in the included studies ranged from 12 to 226 patients. In five studies, purposive sampling methods were used (Downey et al., 2018; Hsiao et al., 2015; Hubner et al., 2015; Jeffs et al., 2016; Pollack, 2009). Convenience sampling was used in one study (Harper et al., 2010). The sampling method in the final study was not provided but convenience sampling was likely given the absence of inclusion or exclusion criteria (Michaels et al., 2009). In all studies, different types of wearable vital sign monitoring devices with varying capabilities were used.

In the seven studies included in this review, data were collected from a total of 682 patients. Three studies included ED patients (Hsiao et al., 2015; Hubner et al., 2015; Pollack, 2009). The first study involved patients presenting with chest pain and a diagnosis of acute coronary syndrome (Hsiao et al., 2015). The second study involved patients in the ED waiting room deemed to be at risk of cardiovascular or respiratory deterioration (Hubner et al., 2015). The third study involved patients in the main ED or waiting room who did not otherwise require conventional continuous monitoring and were not imminently deteriorating (Pollack, 2009). The other four studies involved general-medical ward patients (Harper et al., 2010), surgical ward patients (Downey et al., 2018, Michaels et al., 2009), and ward patients recently discharged from an ICU (Jeffs et al., 2016). Patients' primary diagnoses were reported in three studies. Of these, the first study involved patients with chest pain and associated symptoms such as dizziness or dyspnoea (Hsiao et al., 2015). In the second study, the most common reasons for presenting to the ED were chest pain and hypertension (Hubner et al., 2015). In the third study of medical patients, the most common conditions were 'chronic heart, chest and kidney disease' (Harper et al., 2010, p. 95).

The mean age of participants included 64 years (Harper et al., 2010), 57 years (Michaels et al., 2009), and 55 years (Hubner et al., 2015). In two studies, only the individual ages of patients were

reported (Downey et al., 2018; Hsiao et al., 2015), so median patient ages of 54 years (IQR: 48, 65) (Hsiao et al., 2015), and 73 years (IQR: 59, 78) (Downey et al., 2018) were calculated from these data for the purposes of this review. Adult patients were included in two studies but their ages were not reported (Jeffs et al., 2016; Pollack, 2009). The gender of participants was reported in four studies, and the proportion of female patients ranged from 21% (Jeffs et al., 2016) to 95% (Harper et al., 2010).

All studies involved different wearable vital sign devices with varying capabilities as outlined in Table 1. The major characteristics of the device design included: a small body-worn clip-on device (Harper et al., 2010), a textile vest and chest belt (Hsiao et al., 2015), wireless measurement pods (Hubner et al., 2015), a 3-lead wireless transmitter (Michaels et al., 2009), a portable monitor fitted into a holder placed around the neck or arm (Jeffs et al., 2016), a one-lead ambulatory electrocardiograph (ECG) device (Pollack, 2009), and a wireless patch worn on the chest (Downey et al., 2018). In one study, the monitor holder had to be redesigned after being trialled on four patients who reported overly tight halter garments (Jeffs et al., 2016). All devices measured ECG, heart rate, or pulse at a minimum.

Major findings of each study are presented in Table 1. In studies that focused on patient satisfaction with wearable vital sign monitoring devices, the majority of patients reported being very satisfied with the device (Hsiao et al., 2015; Pollack, 2009). In studies of patient experience and opinions, the majority of patients reported that they felt safer, would recommend the device to other patients, and had confidence in the way in which the device worked (Hubner et al., 2015; Michaels et al., 2009). In the qualitative study that focused on patient perceptions and experiences of intermittent vital sign monitoring compared to the use of a continuous monitoring patch, findings were mixed (Downey et al., 2018). Most patients found the monitoring patch to be very comfortable to wear, reported that they felt safer, and recognised its likely value, particularly in monitoring ward patients overnight (Downey et al., 2018). However, some patients in that study also expressed concerns that the use of the monitoring patch might replace nursing interactions, and that the technology may not be reliable (Downey et al., 2018). A proportion of patients ($n = 27$; 12%) in one study (Hubner et al., 2015) found the device to be uncomfortable to wear. In the study investigating acceptability, most patients forgot they were wearing the device (insinuating that the device was comfortable to wear), but results did not explicitly include data related to device comfort (Harper et al., 2010). When device comfort and concerns were investigated (Jeffs et al., 2016), 32% ($n = 61$) of patients found the wearable monitors uncomfortable and irritating to wear resulting in monitor removal. Only 43% ($n = 83$) of patients kept the monitors in place until discharge, until the end of the 14-day study period or until removal was required to facilitate other monitoring, procedures or admission to the ICU (Jeffs et al., 2016). Jeffs et al. (2016) also found that about half of the patients (52.4%) approached refused participation. Similar to findings reported by

Downey et al. (2018), potential participants in the study by Jeffs et al. were also concerned that monitor use might lead to the demise of nursing practice. Further, some patients approached had concerns about the aesthetics of the monitors and what they may represent in relation to illness severity (Jeffs et al., 2016).

Ten items from the Downs and Black Checklist (1998) were deemed non-applicable to the included quantitative studies as these studies were observational cross-sectional studies with single patient groups. The quality score denominator was therefore adjusted from 27 to 17. Quality scores for the quantitative studies are reported in Table 1. Quality appraisal outcomes for the qualitative study are presented in Table 2. The methodological quality of the quantitative studies was very low to low; four studies scored 6/17 (Harper et al., 2010; Hubner et al., 2015; Jeffs et al., 2016; Pollack, 2009), one scored 2/17 (Hsiao et al., 2015), and one scored 1/17 (Michaels et al., 2009). The methodological quality of the qualitative study was high (Downey et al., 2018). Overall, the major limitations of the studies included unclear aims; a lack of randomisation; failure to address adverse consequences that may have arisen as a result of the wearable devices introduced; minimal reporting of patient compliance with the study devices; lack of detail regarding validity and timing of surveys; unclear outcomes; and failure to report consideration of potential bias and the nature of the researcher and participant relationship.

Insert Table 2 near here

DISCUSSION

The aim of this systematic review was to examine patient acceptability of wearable vital sign monitoring devices in the acute care setting. Specifically, we sought to examine patient acceptability, satisfaction or experience. The use of wearable vital sign monitoring devices is receiving increased interest in acute health care. Theoretically, wearable vital sign monitoring devices may enhance patient safety by improving the timely recognition of patient deterioration (Nangalia et al., 2010); however, little is known about how patients in ward or ED environments perceive their use. It is important to understand patient acceptability of wearable vital sign monitoring devices in order to inform device design and implementation in hospital patients.

Results of the studies included in this systematic review were variable. In four studies that predominantly used surveys, patients mostly reported positive experiences wearing vital sign monitoring devices or felt satisfied in relation to the devices and their intended purpose (Harper et al., 2010; Hsiao et

al., 2015; Michaels et al., 2009; Pollack, 2009). Conversely, in three studies the findings were mixed, as some patients found the devices physically uncomfortable (Hubner et al., 2015; Jeffs et al., 2016), had concerns about the devices reducing engagement with nurses, or were apprehensive about the reliability of the technology (Downey et al., 2018). Jeffs et al. (2016) report that many patients found the wearable monitors used in their study burdensome even when modifications to the monitor holders were made. In that study, the monitor holder had to be changed from a chest band to one that could be worn around the neck or on the arm because it was too tight and interfered with care (Jeffs et al., 2016). Further, potential participants also worried that the wearable monitors could reduce interactions with nurses and were concerned about the aesthetics of the monitors (Jeffs et al., 2016).

The overall quality of the studies included in this systematic review was low, limiting the generalisability of the research findings. All studies were observational in nature, and six studies examined the use of wearable vital sign monitoring devices in single patient groups. In one study, patient acceptability of wearable vital sign monitoring devices was compared with other vital sign monitoring methods (Hsiao et al., 2015). In another study, it was reported that the researchers aimed to compare the experiences of patients monitored using intermittent and continuous vital sign monitoring using a wireless patch to the experiences of patients monitored using intermittent methods only. However, the demographic data from that study shows that all patients interviewed wore the monitoring patch (Downey et al., 2018). Thus, while these patients were equipped to comment on both intermittent and patch monitoring methods, they experienced both concurrently, potentially influencing their comments about each method (Downey et al., 2018). Some of these patients may have previously experienced intermittent vital sign monitoring alone, although this was not reported (Downey et al., 2018).

In the included quantitative studies, frequently the aims were unclear and patient perspectives were not the primary focus of the study, but results and discussion regarding this phenomenon were reported. Thus, at times, it was not apparent that patient acceptability, satisfaction or experience data were collected until the results of each study were reviewed. Most studies had small samples, and all used non-probability sampling techniques. Although all studies involved different wearable vital sign monitoring devices which had the same essential purpose, the devices differed in relation to their physical size, materials, the way in which they were worn, and their exact vital sign measuring capability. The varied device designs may have, in part, contributed to the varied patient acceptability results in ways that are not fully understood. Most studies did not report patient compliance with wearing the devices or whether there were particular efforts to monitor patient compliance. The integrity of device application and the duration of monitoring was either variable or unclear.

Many of the study measures were also poorly described; the degree to which study findings can be compared is therefore unclear. In three studies (Hsiao et al., 2015; Hubner et al., 2015; Pollack, 2009), surveys with Likert scales were used; however, the validity and reliability of the survey instruments and item details were not reported. This method of data collection may also be a source of bias as closed-style questioning (such as Likert scale items) may be more likely to yield positive responses (Marcinowicz, Borzuchowska, & Grebowski, 2002). Therefore, survey methodology may have contributed to the largely positive perceptions reported in four of the studies reviewed (Harper et al., 2010; Hsiao et al., 2015; Michaels et al., 2009; Pollack, 2009). In one study (Jeffs et al., 2016), there were reports that several patients had unfavourable views regarding the monitors evaluated. Although the outcome measures for this study were unclear, the authors report that a researcher interacted with the patient to assess their level of comfort or their reason for removal of the monitoring device, if applicable (Jeffs et al., 2016). It is not known whether a specific tool was used, questions were open or closed, or whether patient responses were documented by the patient or researcher. In the qualitative study, semi-structured interviews, enabled patients to share both positive and negative perceptions and experiences in relation to a wireless monitoring patch (Downey et al., 2018). Future research related to wearable vital sign monitoring devices should ensure that patients are afforded appropriate opportunity to voice their views, both positive and negative, about these devices and that methods and measures used to capture patient perspectives are clearly reported.

There were limitations in the way data were presented in some studies that raise questions of reporting bias. Jeffs et al. (2016) report results related to patient comfort embedded in other data that described reasons for monitor removal. Although it is unclear, it appears that patient reports of discomfort or irritation from the monitor, or feelings of being overwhelmed resulting in monitor removal were used as proxies to measure patient comfort in relation to the monitors. It is therefore possible that some of the findings of this study appear negative because the authors sought reasons for monitor removal rather than patient feedback concerning reasons for continued use of the monitors (Jeffs et al., 2016). Further, there are broad statements emphasising negative patient perceptions of the monitors. For example, many patients found the devices burdensome; however, these statements are not supported by published data (Jeffs et al., 2016). The data show 43% of patients kept the monitors in place until they had to be removed or until the study period was over (Jeffs et al., 2016). In another 11% of patients, the monitors were removed for unspecified reasons (Jeffs et al., 2016). Similarly, Michaels et al. (2009) report the proportion of patients who had a positive experience with wearable devices but results from the remaining patients that may have been negative or neutral were not published.

The findings of this systematic review raise a number of issues regarding the acceptability of wearable vital sign monitoring devices by adult patients in acute care settings. There are limitations in both the quantity and quality of research, thus limiting our knowledge of the patient perspective of new technologies. Further, the variability in the study designs, devices tested, and findings make it difficult to draw meaningful conclusions. Nonetheless, it is unlikely that any single wearable vital sign monitoring device will be appropriate for every patient. This notion is supported by Rogers' Diffusion of Innovations Theory (Rogers, 1983) which can be used to understand acceptance of new technology and the way in which technology use may proliferate among populations (Xiaojun, Ping, Jun, Spil, & Ton, 2015). Rogers (1983) asserts that four main elements impact on acceptability and therefore the success of new technologies: 1) the nature of the communication around the technology, 2) the characteristics of the technology itself, 3) the characteristics of those who will use the technology, and 4) the social system within which the technology will be used (Xiaojun et al., 2015). Therefore, user characteristics, population, and context are likely to determine the degree to which wearable vital sign monitoring devices succeed and are used in acute care settings. Specifically, the patient's primary diagnosis, stage of hospitalisation, and their level of acuity may be key influences on device acceptance, satisfaction or experience.

Patients included in the studies of this systematic review were from various clinical areas and backgrounds. Most of the negative results in this systematic review were from the study by Jeffs et al. (2016) that involved ward patients recently discharged from an ICU. Although it is unclear, some patients in that study, particularly those with experience of previous hospitalisation during which wearable devices were not used, may have viewed wearable monitors as new 'experimental' technology. Patients may have viewed the monitors as non-essential and something additional to their usual care that they could discard if desired. Further, patients from an ICU could reasonably be expected to have more complex care requirements; however, patient acuity at ICU discharge is not reported in this study (Jeffs et al., 2016). The presence of pain, wounds or other therapeutic devices such as surgical drain tubes may have influenced overall patient comfort and the compatibility of the wearable devices with the patients' care requirements. However, these details were not reported. In an ICU setting, many invasive and non-invasive devices are used and patients have little control over their use. It is possible that a significant proportion of patients in the Jeffs et al. study removed their wearable monitors because they had more control to do so once discharged from the ICU. Jeffs et al. also report that many potential participants had concerns that the monitors would decrease nursing contact time and that nurses may be replaced, therefore refusing participation. It is possible that these patients experienced the documented phenomenon of transfer or relocation anxiety related to their transition from the ICU to the ward environment (Coyle, 2001) that drove their concern about less nursing contact. This concern about the transition from the ICU

to the ward may have influenced participation rates and some of the other negative views voiced by participants in this study.

Studies involving ED patients, medical ward patients, and postsurgical patients as participants tended to report more positive findings (Harper et al., 2010; Hsiao et al., 2015; Michaels et al., 2009). It is possible that ED patients may have viewed wearable vital sign monitoring devices positively as they had made the decision that they needed prompt medical attention so monitoring was a welcome intervention. Patients in the ED may have considered the devices as key to their initial management and associated them with safety in a context of uncertainty or anxiety. As many as 78% of patients presenting to the ED report that pain is their chief complaint (Cordell et al., 2002; Todd et al., 2007). Thus, it is possible that ED patients may have been distracted by symptoms such as pain and were therefore less concerned about the presence of a device.

There are a number of limitations that should be considered when interpreting the findings of this systematic review. Only seven studies met the systematic review inclusion criteria highlighting a significant gap in the research literature. The implementation of wearable vital sign monitoring devices is emerging in acute hospital in-patient settings and the research to date has focused on feasibility and accuracy of vital sign measurement. At this point in time, the patient voice is largely absent from the literature. None of the wearable devices evaluated in the studies included in this review were explicitly described by the authors as being 'under development'. However, minor device modifications were reported in one study (Jeffs et al., 2016) to improve its tolerance by patients and some devices received unfavourable reports from the perspective of patients. It is therefore possible that further modifications were made to some devices prior to continued use and further research, and/or that some devices are no longer available in the form in which they were studied. It is important to acknowledge that technological developments occur rapidly and are constantly changing and that some of the wearable devices referred to in this review may be rapidly superseded. Therefore, results concerning their level of acceptability should be interpreted conservatively. Nonetheless, the patient perspectives in this review provide essential information to inform ongoing wearable device development and the nursing care of hospital patients with wearable devices insitu.

This systematic review was limited to studies published in English. We appreciate there may have been studies published in languages other than English that may have been relevant to our research questions; however, the location and translation of studies published in other languages was beyond the scope of this review. Although meta-analyses were unable to be performed, we utilised robust review methods, consistent with standardised requirements in the literature (Higgins & Green, 2011; Moher et al., 2009). There was variation in the nomenclature related to wearable devices; however, our search

terms were carefully chosen with the assistance of an information specialist librarian and informed by the published literature. Our overall search strategy was thorough and well designed, unrestricted by date limits, and underwent peer review from experts in nursing research and information synthesis. Two reviewers independently selected the studies for inclusion and conducted quality assessments.

CONCLUSION

The available research related to patient acceptability of wearable vital sign monitoring devices is limited and of low quality. Although generalisation of the results of this systematic review is not possible, variability in the results suggests that patients have complex needs and different preferences regarding wearable vital sign monitoring devices. Adequately powered multi-site randomised controlled trials and further well-designed qualitative studies are needed to ascertain robust data regarding patient acceptability, patient satisfaction or patient experience of a range of wearable vital sign monitoring technologies.

RELEVANCE TO CLINICAL PRACTICE

Wearable vital sign monitoring devices are a rapidly emerging technology in acute health care and are promoted as a component of a patient safety system. However, in order for wearable devices to have value, they must be worn as intended and be effectively integrated into nursing care provision. It is imperative that patient perspectives of these devices are better understood in order to maximise patient safety through the provision of patient-centred nursing care.

CONFLICT OF INTEREST

There are no conflicts of interest to declare.

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ETHICAL APPROVAL

Ethical approval was not required. In this systematic review, we synthesised and appraised previously published studies. There was no participant recruitment.

SUPPORTING INFORMATION

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An appendix containing the search string used for Medline Complete can be found in the online version of this article.

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SUMMARY BOX / IMPACT STATEMENT

What does this paper contribute to the wider global clinical community?

- The use of wearable vital sign monitoring devices is increasing in the acute care setting. However, there is a dearth of high quality research examining hospital patients' acceptability, satisfaction or experience of wearable vital sign monitoring technologies.
- Reported patient perceptions of wearable vital sign monitoring devices are mixed, suggesting patients may have complex needs and preferences in relation to monitoring technologies.
- Further multi-site research with an a priori focus on patient acceptability of wearable vital sign monitoring technologies in the acute care setting is needed in order to inform their continued use and further development. The provision of patient-centred nursing care is contingent on understanding patients' values and preferences, including their acceptability of technology use.

Table 1: Study Characteristics of Studies Included in the Systematic Review

Author, Date, Country	Quality score	Outcome/s reported	Study design	Method of data collection	Type of monitoring device	Duration of monitoring	Sample	Major findings
Downey et al., 2018, England	NA	Patient perceptions and patient experience	Observational study (evaluation)	Semi-structured interviews	<ul style="list-style-type: none"> • SensiumVitals patch • Wireless patch worn on the chest • Data are transmitted to a mobile device that alerts the nurse when there are abnormal values • Capability: Continuously measures heart rate, respiratory rate, temperature 	<ul style="list-style-type: none"> • 1 – 15 days 	<ul style="list-style-type: none"> • Patients admitted to two surgical wards (n = 12) 	<p>MIXED</p> <ul style="list-style-type: none"> • Some patients were concerned that the use of the monitoring patch would replace nursing interactions • Some patients felt that the patch would be particularly valuable overnight • 10/12 patients found the patch very comfortable to wear • 11/12 patients said they felt safer wearing the patch and recognised that it may help nurses who were perceived to be very busy • Several patients had concerns about the

								reliability of the technology
Harper et al., 2010, Ireland	6/17	Patient acceptability	Observational study (evaluation)	Not specified	<ul style="list-style-type: none"> • Vitalsens VS100 patient monitor by Intelsens Ltd. • Reusable, miniaturised clip-on body worn device • Paired with a web based tool (Canberra), allows patient data to be viewed via a web browser • Capability: ECG (10 seconds of data), heart rate (30 minutely), skin temperature (30 minutely) 	<ul style="list-style-type: none"> • > 7 days (n = 6) • > 10 days (n = 3) • Unspecified duration of monitoring for the remaining patients 	<ul style="list-style-type: none"> • Patients admitted to a designated 4-bed bay on a general-medical ward (n = 20) • 19/20 patients were female 	<p>POSITIVE</p> <ul style="list-style-type: none"> • Limited detail – the authors report that “the majority of patients quickly forgot they were wearing the system” (Harper et al., 2010, p. 97)
Hsiao et al., 2015, Taiwan	2/17	Patient satisfaction	Observational study (feasibility and accuracy)	Survey: 3-item questionnaire with 5-point Likert scale scoring (1 = Very bad, 5 = Great)	<ul style="list-style-type: none"> • 3-part original system: 1) Bluetooth heart rate monitor and smart textile, 2) tablet or smart phone and 3) physician’s computer • Wearable vest and chest belt • Capability: ECG/heart rate • Conventional ECG 	<ul style="list-style-type: none"> • Unclear 	<ul style="list-style-type: none"> • ED patients with ACS presenting with chest pain (n = 31) 	<p>POSITIVE</p> <ul style="list-style-type: none"> • 93.5% rated ‘interference to body movement’ as at least ‘very good’ ($\bar{x} = 4$) • 80.6% rated ‘degree of wearing comfort’ as at least ‘very good’ ($\bar{x} = 4.2$) • 80.6% rated

monitoring appeared to be used concurrently in order to validate the system although it is unclear whether both monitoring techniques were used for the duration of the study

‘comparison with ECG of hospital’ as at least ‘very good’ ($\bar{x} = 3.8$)

Hubner et al., 2015, Austria	6/17	Patient opinions and experiences	Observational study (feasibility)	Survey: 17-item questionnaire with Likert scale scoring. Survey was administered when the patient was transferred to a different department or discharged from hospital	<ul style="list-style-type: none"> Philips IntelliVue Guardian Solution, in conjunction with a cableless monitoring device - IntelliVue cableless measurement pods Capability: Pulse oximetry (15 minutely), pulse (15 minutely), respiratory rate (15 minutely), non-invasive BP measurement (30 minutely) 	<ul style="list-style-type: none"> Median duration of monitoring = 178 hours 	<ul style="list-style-type: none"> ED patients located in the waiting room (n = 226) Patients triaged as ESI 2 or 3 Patients considered to be at risk of cardiovascular and/or respiratory deterioration Alert and able to provide consent 	<p>MIXED</p> <ul style="list-style-type: none"> 86% of patients strongly agreed that they felt safe and well taken care of while wearing the device 86% of patients felt that the device ‘worked well’ 12% of patients complained the device was uncomfortable
Jeffs et al., 2016, England	6/17	Patient acceptability (comfort and	Observational study (feasibility)	Minimal detail provided. A researcher	<ul style="list-style-type: none"> Hidalgo EQ02 Sensor Electronics Module Portable wearable monitor 	<ul style="list-style-type: none"> Variable - 14 days or until discharged 	<ul style="list-style-type: none"> Patients discharged from ICU in the 	<p>MIXED</p> <ul style="list-style-type: none"> 31.8% of patients removed the device due

concerns)

visited the patients and assessed comfort in relation to the device

fitted into holder positioned around the neck or arm

- Capability: two-lead ECG, respiratory rate, SpO₂, skin temperature sensor (also accelerometer functionality)

- Monitors were removed earlier if requested by the patient
- 15 patients wore the monitors for the total duration

preceding 24 hours (n= 192)

- to discomfort/irritation
- 5.2% of patients felt too unwell to wear it/the patient removed it because they were confused
- 4.7% felt overwhelmed
- 32.3% kept the monitor in place for the specified period
- 25% requested removal of the monitor within one day
- Many potential participants were concerned that the research might result in the demise of nursing†
- Despite modifications made to the monitors, patients found the monitors burdensome†

Michaels et al., 2009, United States

1/17

Patient experience

Observational study (pilot)

Survey: unknown format.

- 3-lead device
- Multi-parameter wireless transmitter in conjunction

- 24 hours
- Unclear if all patients were

- Patients admitted to postsurgical units (n = 27)

POSITIVE

- 91% of patients indicated they felt safer

of America

Administered
after removal of
the system

with a centralised
monitoring system

- Capability: ECG/heart rate, respiration rate, pulse oximetry, non-invasive BP (hourly)

monitored for
total duration

wearing the device

- 87% of patients indicated they would recommend the device to other patients
- Technology can positively influence the patients' post-operative experience

Pollack,
2009, United
States of
America

6/17

Patient
satisfaction

Observational
study
(feasibility)

Survey:
questionnaire
with 5-point
Likert scale
scoring (1 = not
satisfied, 5 =
very satisfied).
Survey was
administered
when the device
was removed

- NetGuard Automated Clinician Alert System
- Ambulatory, one-lead ECG device that provides alarms and provides data when triggered by specified rate and rhythm deviations
- No continuous visual monitoring capability
- Capability: ECG/heart rate monitoring only, no pulse rate

• Variable –
patients were
monitored until
they left the ED,
until they
required
conventional
monitoring or if
the patient
wanted the
device to be
removed

- ED patients (n = 174)
- Located in the main department or waiting room
- Exclusions: patients already monitored by telemetry, triaged to urgent care area, expected to stay less than 1 hour, concern for ED elopement, patient refusal

POSITIVE

- 'Good' satisfaction with the device
- All measures were rated as above 4 (very satisfied)
- Overall satisfaction – median = 4.55

Note. BP = blood pressure; ECG = electrocardiograph; ED = emergency department; ACS = acute coronary syndrome; ESI = emergency severity index; SpO₂ = peripheral oxygen saturation; ICU = Intensive Care Unit.

† These results were reported in the discussion section of this paper. No corresponding data are reported.

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Table 2: Quality Appraisal Outcomes of the Qualitative Study

Quality assessment question	Downey et al., 2018
Was there a clear statement of the aims of the research?	Yes
Is a qualitative methodology appropriate?	Yes
Was the research design appropriate to address the aims of the research?	Yes
Was the recruitment strategy appropriate to the aims of the research?	Yes
Was the data collected in a way that addressed the research issue?	Yes
Has the relationship between researcher and participants been considered?	No
Have ethical issues been taken into consideration?	Can't tell
Was the data analysis sufficiently rigorous?	Can't tell
Is there a clear statement of findings?	Yes
How valuable is the research?	Yes

Note. Quality appraisal was conducted using the Critical Appraisal Skills Programme (CASP) Qualitative Research Checklist (CASP, 2017).

Figure 1: PRISMA diagram adapted from Moher et al. (2009)

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Title:

Patient acceptability of wearable vital sign monitoring technologies in the acute care setting: A systematic review.

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